RADAR FIELD MEMOS

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: *List

August 21, 2002

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo #019: RADAR Operations Manual Version 4: August 2002

Over the past year several operational changes have been made in the RADAR Study. This memo will highlight the most significant revisions that have been made to the RADAR Operations Manual. Please see the descriptions of modifications that have been made to the manual chapters below.

Chapter 2. Donor Enrollment and Blood Product Management

- 10ml lavender top (EDTA) vacutainer tube (preferred);
- 2.6: Revised section to further explain the sources and conditions of which to obtain the donor blood specimen;
- 2.7: Blood mobiles are prohibited from pre-labeling blood collection bags for RADAR.
- 2.8: Documentation of reconciliation step taken to ensure all specimens have a corresponding ; and informed consent.
- 2.9: A new section added to generally address processing of donor repository sample specimens.

Chapter 3. Hospital Transfusion Service

- 3.2: The transfusion service should track all RADAR units transfused to enrolled and non-enrollable recipients, and units with other dispositions;
- 3.3: Added a detailed description of sources used to obtain pre-transfusion samples; and
- 3.4: All pre-transfusion samples must be transported to the blood center for processing and freezing within one week of collection. Non-consenting pre-transfusion samples should be discarded.

Chapter 4. Recipient Enrollment

- 4.1 Specified inclusion and exclusion criteria:
  Inclusion Criteria:
  - 18-85 years
  - High anticipated rate of 6-month post-surgical survival
  - Component immune system
  - Received at least one RADAR unit

Exclusion Criteria:

- ❖ <18years or >85 years
- ❖ Language barrier
- ❖ Residents of states or foreign countries long distances from location
- ❖ Organ transplant patients
- ❖ Dialysis patients

Patients with history of intravenous drug use, HIV infection, or allogenic blood transfusion will not be excluded from the study.

- Box 4B Steps 7, 8, and 9 should be conducted to determine if patients are currently enrolled;
- 4.5.3 A post-transfusion sample should be obtained if a pre-transfusion sample is not collected or available;
- 4.6 Hospitals should follow the same procedures for pre-surgery or post-surgery enrollment;
- 4.7.1 Recipients without pre-transfusion or post-transfusion samples will be de-enrolled; and
- 4.9 Multiple Transfusion Events:
  - ❖ Clarified definition of multiple transfusion events
  - ❖ Revised instructions for re-setting the follow-up visit
  - ❖ Specified information needed to identify currently enrolled recipients
  - ❖ Stated no action will be taken if recipients receive non-RADAR units within 5 months of enrollment

Chapter 5. Follow-up Visit

- 5.1 The 6-month designation refers to the 6-month follow-up eligibility interval not the date of the follow-up visit. While it is desirable for the follow-up visit to occur as close to 6 months as possible, the visit may occur up to 12 months after enrollment. Thus, the "6-month" designation for study materials and activities has been removed to clarify this issue.
- 5.2 Decisions to continue following recipients beyond 12 month is at the discretion of the blood center and MCC.

Chapter 6. Follow-up Testing

- 6.2 Interim notification may occur if there are delays in testing.
- 6.3 Source documents should be sent to the MCC via fax; and
- 6.4.1 Provided additional detail on how to report HBV and HCV test results. Separated Screening and Confirmatory Results sections for HbsAg, Anti-HBs, HCV, and HCV.

Chapter 7. De-enrolling Study Participants

- Clarified three reasons for de-enrolling study participants

Chapter 8. Sample Processing and Storage at the Blood Center

- Modifications and additions were made to this chapter in Sections 8.3, 8.8.1, and Box 8C to provided instructions for processing inadequate volumes.

Chapter 9. Shipping Samples

- Changes made to Chapter 9 were completed July 15, 2002 and a new chapter was distributed. Field Memo #18 delineated revisions that have been implemented.

RTS

- Part Two: How to Enter Recipient Information
  Added instructions on how to search for prior admissions by a recipient; and
- Part Four: How to Enter Pre-Transfusion Information
  Transfusion information entered during earlier admissions cannot change.

The RADAR Operations Manual Version 4: August 2002 has been enclosed. If you have any further questions regarding this issue, please contact Sheba Hakiza by phone at (301) 610-4865 or by email at shebahakiza@westat.com.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (3)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (10)
Dr. Higgins
Ms. Hutching (12)
Dr. Kleinman
Dr. LeParc
Dr. Luban
Ms. Moore (7)
Dr. Murphy
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Mr. Rey (4)
Dr. Smith
Dr. Triulzi
Dr. Zuck

Radar Field Memo Index

Field Memo #	Title	Date
1	RADAR Data QC Reports	07/14/00
2	Revision to RADAR Operations Manual, February 2000 Version (previously distributed as *Field Memo #1: Revision to RADAR Operations Manual, February 2000 Version*)	09/06/00
3	RADAR 6-Month Follow-Up Testing Procedures	11/02/00
4	RADAR Operations Manual Version 3 Replacement Pages	03/29/01
5	Revised RADAR HBV/HCV Test Results Form	06/07/01
6	RADAR Reports	06/15/01
7	RADAR Recipient 6-Month Test Results Tracking Report	08/22/01
8	Biorepository Review of Shipper's Declaration of Dangerous Goods	11/12/01
9	RTS Update and 6-Month Follow-up Reports	11/14/01
10	Blood Center Shipping Containers for Special Testing Shipments	11/13/01
11	Collection of Pre- and Post-Transfusion Recipient Samples	11/28/01
12	Turn-Around-Times for Testing of Recipient Index Sample	11/28/01
13	Revised 6-Month Follow-up Reports 3, 4, and 5	04/01/02
14	RTS Modifications: Previous Transfusion History and Administrative Recipient Contact Information Report	04/24/02
15	6-Month Follow-up Recipient Information Recording	04/24/02
16	New Linking Report "Donation Blood IDs in RTS but no in SIS"	06/13/02
17	New RADAR Study Protocol	07/10/02
18	Revised RADAR Operations Manual Chapter 9	07/15/02
19	RADAR Operations Manual Version 4	08/14/02

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: List*

July 14, 2000

FROM: Coordinating Center

SUBJECT: Field Memo #1: RADAR Data QC Reports

Attached please find reports for your blood center that were run on data received as of June 8, 2000. The purpose of these reports is to ensure that we are capturing all of the data points that are required for each enrolled participant in order to meet the research objectives of the study. Some of the reports list missing demographic information, missing transfusion information, problems with linking the recipient's transfused unit WBN to a WBN in the SIS, etc.

Data reports will be generated on a monthly basis. In instances where problems are not resolved prior to the next monthly data delivery it is likely that you will see the same problems on the next month's reports. Each center has been sent reports that will aid in identifying and resolving specific problems with the RADAR data collected within a given month at that center. You will be receiving additional reports within the next week that will bring you current to the most recent data delivery (June data).

Please remember, updates and edits made to recipients that are not labeled as "COMPLETED" should be executed on the hospital RTS. Conversely, any edits or updates made to recipients who are listed as "COMPLETED" must be made on the blood center administrative RTS. Any efforts to resolve these issues prior to delivering your July data is greatly appreciated.

- Coordinating Center Contact for this field memo is Ade Adebayo, 301-517-4108, or adebaya@westat.com.

*Nass
Campbell
Hutching
Guiltinan
Chandler

TABLE OF CONTENTS

TABLE OF CONTENTS

Chapter			Page
1	STUDY OVERVIEW		1-1
	1.1	Background	1-1
	1.2	Participating Blood Centers and Hospitals	1-3
	1.3	Computer Systems	1-4
	1.4	Schedule	1-4
2	DONOR ENROLLMENT AND BLOOD PRODUCT MANAGEMENT		2-1
	2.1	Target Number of Blood Units and Donors	2-1
	2.2	Selection of Participating Blood Mobiles	2-1
	2.3	Blood Mobile Study Supplies	2-2
	2.4	Eligible Donors	2-3
	2.5	Obtaining Donor Informed Consent	2-3
	2.6	Collection of Donor Repository Sample Specimen	2-4
	2.7	Tagging Donor Blood Units	2-5
	2.8	Entering Donor Informed Consents into the SIS at the Blood Center	2-5
	2.9	Processing of Donor Repository Sample Specimen	2-6
	2.10	Donor Blood Product Management	2-6
3	HOSPITAL TRANSFUSION SERVICE		3-1
	3.1	Introduction	3-1
	3.2	Maintaining the Physical Inventory of RADAR Repository Blood Units	3-1
	3.3	Obtaining the Pre-transfusion Blood Sample from Surgical Patients	3-3
	3.4	Sending Pre-Transfusion Sample Specimens to the Blood Center for Processing	3-4
4	RECIPIENT ENROLLMENT		4-1
	4.1	Recipient Eligibility and Enrollment Criteria	4-1
	4.2	Tracking of Recipients who Receive RADAR Repository Designated Units	4-2
	4.3	Supplies Needed for Recruiting Recipients	4-4
	4.4	Recipient Study Identification Labels	4-4
	4.4.1	Consenting Recipient Study Identification Labels	4-4
	4.4.2	Non-Consenting Recipient Study Identification Labels	4-7

TABLE OF CONTENTS (continued)

Chapter			Page
	4.5	Study Recruiter Enrollment Preparatory Work	4-7
	4.5.1	Identifying Eligible Recipients	4-7
	4.5.2	Verification that RADAR units were transfused	4-9
	4.5.3	Indications for Collecting a Post-Transfusion/ Enrollment Phlebotomy	4-9
	4.6	Enrolling Recipients and Obtaining Consent	4-10
	4.6.1	Recording Enrollment Information in the RTS	4-12
	4.6.2	Drawing a Post-Transfusion/Enrollment Sample	4-14
	4.6.3	Recipient Information Brochure	4-14
	4.7	Sending Pre-Transfusion and Post-Transfusion/Enrollment Blood Samples from the Hospital to the Blood Center	4-15
	4.7.1	Retrieving and Shipping Samples	4-15
	4.7.2	Applying the Study ID Label to the Pre-Transfusion Sample Tube or Specimen	4-18
	4.8	Closing Out Recipients Using the Hospital RTS	4-18
	4.9	Multiple Transfusion Events	4-18
5		FOLLOW-UP VISIT	5-1
	5.1	Overview	5-1
	5.2	Procedures for Contacting the Recipient to Make the Appointment	5-2
	5.3	Supplies Needed for the Follow-up Appointment	5-3
	5.4	Follow-up (6M) Phlebotomy	5-4
	5.5	Administering the 6-Month Follow-up Questionnaire and General Interviewing Techniques	5-5
	5.5.1	Types of Questions	5-6
	5.5.2	Asking the Questions	5-7
	5.5.3	Probing	5-8
	5.5.4	Kinds of Probes	5-9
	5.5.5	The Don't Know (DK) Response	5-10
	5.5.6	Recording Answers and Editing Responses	5-10
	5.5.7	The Provider Roster	5-12
	5.5.8	Preparing the Questionnaire Booklet Prior to Conducting the Interview	5-13
	5.5.9	Question by Question (Q x Q's) Specifications for Administering the Questionnaire	5-13

TABLE OF CONTENTS (continued)

Chapter			Page
	5.6	Tracking Recipient Close-outs and Completion of the Follow-up Visits	5-30
	5.7	Shipment of Completed Questionnaires to the MCC	5-31
6		TESTING, REPORTING, AND NOTIFICATION OF RECIPIENT FOLLOW-UP SAMPLES	6-1
	6.1	Testing of Recipient Follow-up (6M) Samples	6-1
	6.2	Follow-up Sample Screening Assay Result	6-3
		6.2.1 Non-Reactive Screening Results on the Follow-up Sample	6-3
		6.2.2 Repeatedly Reactive Screening Results on the Follow-up Sample	6-3
	6.3	Notification of MCC by Blood Center of Reactive Follow-up Screening Results	6-4
	6.4	Reporting of the Follow-up Supplemental/Confirmatory Results	6-5
		6.4.1 Forms for Reporting RADAR Recipient Test Results for HBV and HCV (Exhibit L)	6-6
		6.4.2 Forms for Reporting RADAR Recipient Test Results for HIV and HTLV (See Exhibits M and N)	6-8
		6.4.3 Instructions for the completion of the RADAR Recipient 6-Month Test Results Tracking Report (See Exhibit O)	6-8
	6.5	Notification of Blood Center and Recipient of Results of Reactive Follow-up Sample and Subsequent Index Sample Testing	6-9
		6.5.1 Routine Transfusion Transmitted Infection (TTI) Result Notification of RADAR Study Enrollees	6-10
		6.5.2 Study Testing Directives	6-11
7		DE-ENROLLING STUDY PARTICIPANTS	7-1
8		SAMPLE PROCESSING AND STORAGE AT THE BLOOD CENTER	8-1
	8.1	Overview	8-1
	8.2	Laboratory Supplies	8-1
	8.3	Sample Volume Requirements	8-2
	8.4	Aliquot Volume Adjustment	8-3
	8.5	RADAR Repository labeling system	8-4

TABLE OF CONTENTS (continued)

Chapter				Page
		8.5.1	Freezer Rack Labels	8-4
		8.5.2	Box Labels	8-5
		8.5.3	Aliquot Tube Lab ID Labels	8-6
		8.5.4	Application of a Label to a Tube	8-7
	8.6		Processing Donor Repository Samples	8-7
		8.6.1	Setting Up For Donor Repository Sample Processing	8-7
		8.6.2	Instructions for Processing Donor Repository Specimens	8-11
	8.7		Processing of Recipient Repository Samples	8-14
		8.7.1	Entering Recipient Consents Into the SIS	8-14
		8.7.2	Setting Up For Recipient Repository Sample Processing	8-16
		8.7.3	Procedure for Temporary Storage of the Designated NAT Tube From the 6-Month Follow-up Visit	8-17
		8.7.4	Step-by-Step Procedures for Processing and Accessioning Recipient Samples	8-18
	8.8		Processing of Pre-transfusion Samples Sent to Blood Centers Prior to Recipient Enrollment	8-20
		8.8.1	Setting Up for Processing	8-20
		8.8.2	Step-by-Step Procedures for Processing Pre-transfusion Samples Prior to Receiving Recipient Consent	8-21
		8.8.3	Retrieval of Specimens From the Holding Area Corresponding to Enrolled Recipients	8-22
9			SHIPPING DONOR AND RECIPIENT SAMPLES TO THE CENTRAL REPOSITORY	9-1
	9.1		Overview of Shipment to the Central Repository (BTRL)	9-1
	9.2		Shipping Supplies	9-2
	9.3		Instructions for Shipping Recipient Samples	9-2
		9.3.1	Instructions for Completing the Recipient Shipping Form	9-3
	9.4		Instructions for Shipping Donor Samples	9-4
		9.4.1	Box Maps	9-7
		9.4.2	Reboxing Donor Repository Tubes	9-7
		9.4.3	Instructions for Completing Donor Shipping Forms	9-8

TABLE OF CONTENTS (continued)

Chapter			Page
10	RADAR TRACKING SYSTEMS DATA TRANSFERS		10-1
	10.1	Overview	10-1
	10.2	RTS Daily Data Backup	10-1
	10.3	Routine Data Transfer Between the Blood Center and Hospital	10-3
	10.4	Data Delivery to the MCC	10-3

List of Boxes

Box		Page
2A	RADAR donor recruitment supplies	2-2
2B	Enrolling a donor in the RADAR Repository	2-4
2C	Entering donor informed consents into the SIS	2-6
3A	Utilization and Dispensation of RADAR Repository blood units by the hospital Transfusion Service	3-2
3B	Method 1: Hospitals utilizing the cardiac perfusionist	3-3
3C	Method 2: Hospitals obtaining the pre-transfusion sample during the pre-admission workup	3-4
3D	Method 3: Hospitals utilizing the type and crossmatch specimen	3-4
4A	RADAR recruitment supplies	4-4
4B	Patient Log Form: Identifying recipients eligible for enrollment	4-8
4C	Medical chart review	4-9
4D	Supplies needed for an enrollment visit	4-10
4E	Procedures for enrolling a recipient	4-11
4F	Required enrollment information to be entered in the RTS during the visit at the patient's bedside	4-12
4G	Required enrollment information to be entered in the RTS after the patient enrolls (not at bedside)	4-13

TABLE OF CONTENTS (continued)

List of Boxes (continued)

Box		Page
4H	Required information to be entered in the RTS for eligible recipients not enrolled in the study	4-13
4I	Procedures for obtaining a post-transfusion/enrollment blood sample	4-14
4J	Shipment of pre-transfusion and cross-match blood samples to the blood center after recipient enrollment	4-16
4K	Shipment of pre-transfusion blood samples to the blood center before recipient enrollment	4-17
5A	Follow-up visit supplies	5-3
5B	Blood sample collection by study recruiter at follow-up visit	5-5
5C	Rules for asking questions	5-7
5D	Probing methods	5-9
5E	Recording open-ended questions	5-11
5F	Steps in preparing the questionnaire	5-13
5G	RTS recipient close-out codes	5-31
7A	Procedures for de-enrolling a study participant	7-1
8A	Laboratory supply list	8-1
8B	Optimal sample aliquot volumes for storage in the RADAR Repository	8-3
8C	Processing donor repository specimens	8-11
8D	Entering recipient consent into the SIS	8-15
8E	Processing recipient 6-month NAT samples	8-17
8F	Processing recipient repository samples	8-18
8G	Processing and storage of pre-transfusion samples before recipient consent and enrollment	8-21

TABLE OF CONTENTS (continued)

List of Boxes (continued)

Box		Page
8H	Accessioning recipient pre-transfusion samples from consenting recipients into the SIS after retrieval from the holding area	8-23
9A	Supplies needed when shipping samples to BTRL	9-2
9B	Instructions for Shipping Recipient Repository Samples	9-3
9C	Instructions for Pulling and Reboxing Donor Samples	9-9

List of Figures

Figure		
1	Summary and overview of the RADAR Repository	1-2
2	Project schedule	1-5
3	RADAR Recipient Tracking Flowchart	4-3
4	Recipient ID labels	4-5
5	Applying a label to a vacutainer tube	4-19
6	RADAR Recipient Testing and Notification Timeline and Flowchart	6-2
7	Applying a repository label to a bar code labeled vacutainer tube	8-9
8	Applying a label to a cryotube	8-10
9A	Box Map Diagram – Example	9-5
9B	Storage Box Diagram	9-6
10	Data flow between computer systems	10-2

STUDY OVERVIEW CHAPTER 1

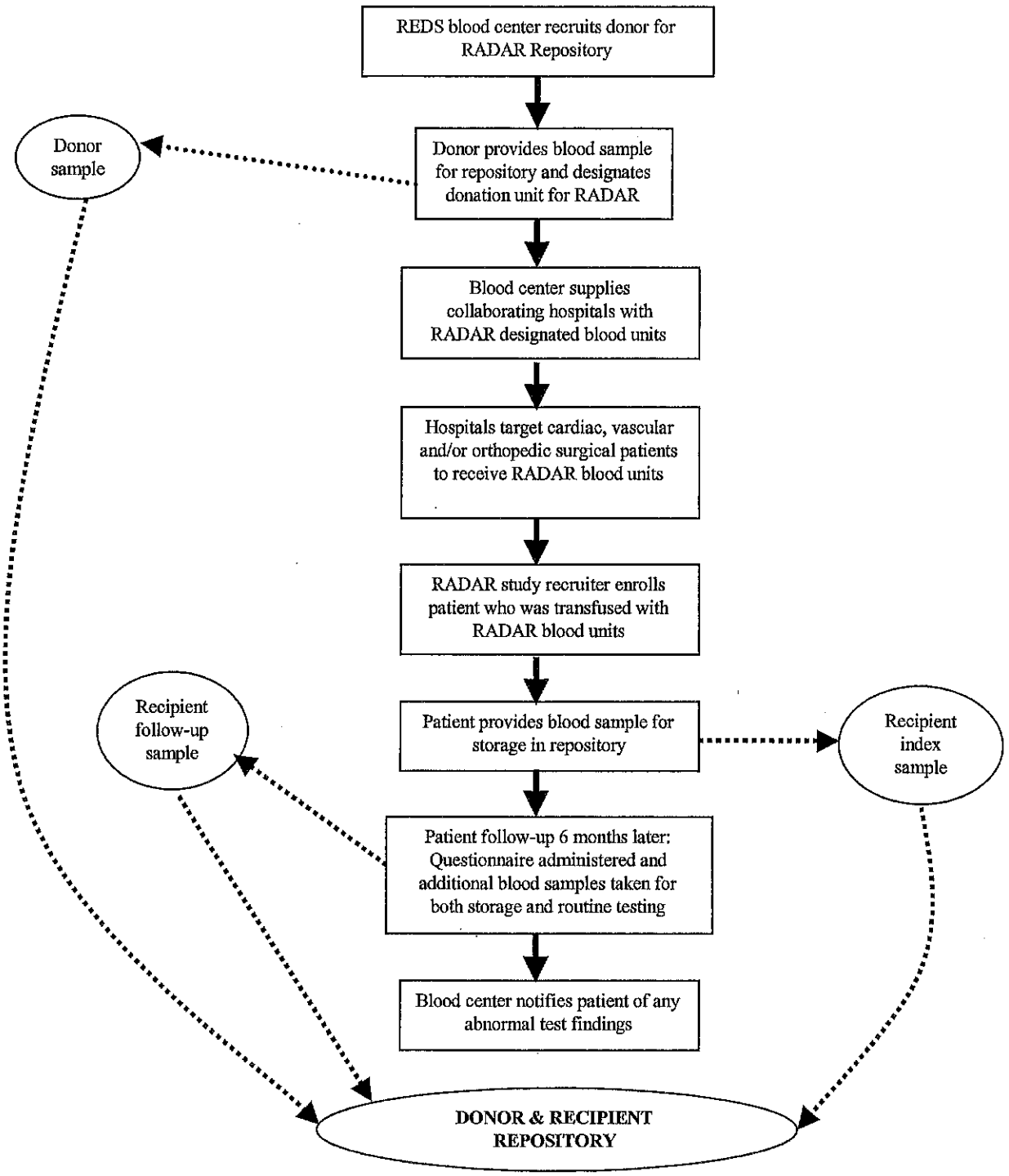
1. STUDY OVERVIEW

1.1 Background

The Retrovirus Epidemiology Donor Study (REDS), funded by the National Heart, Lung, and Blood Institute, has provided a framework for questions of critical importance to the safety of the nation's blood supply. REDS has focused on issues of infection in blood donors, particularly with regard to issues related to retroviruses and other transfusion transmitted infectious agents. Since the recognition in the mid-1980's that the human immunodeficiency virus (HIV) could be transmitted by transfusion, there has been a high level of concern that other newly emerging or newly discovered infectious agents may also prove to be transmitted by blood transfusion. In the past several years, governmental and public health organizations have enunciated strong positions regarding the need to rapidly and effectively detect the transfusion-transmission of new agents. There have been several agents recently identified that have sparked such concern; these include Hepatitis G virus (HGV), human herpes virus 8 (HHV-8), and the possible retroviral agent of idiopathic CD4+ t-lymphocytopenia (ICL), subsequently shown to have an etiology that was not infectious. Based on these examples, it is likely that future agents will be discovered that will elicit similar concern.

The REDS Allogeneic Donor and Recipient (RADAR) Repository will be a resource that can be rapidly accessed to determine whether a newly discovered agent is likely to be transmitted by transfusion. Collaborating blood centers will designate a portion of their collections for distribution to hospitals participating in the RADAR Repository. Blood samples from the donors of these designated units will be placed in the RADAR Repository. The participating hospitals, in turn, will target their cardiac and/or orthopedic surgical patients to receive the designated RADAR units. Upon patient (recipient) enrollment, a pre-transfusion blood sample will be retrieved (and/or an enrollment sample may also be collected) for the RADAR Repository. Six months subsequent to enrollment, the patient will complete a follow-up visit involving the completion of a brief questionnaire and phlebotomy. The blood sample collected at this visit will be tested for routine viral markers. The blood samples from both the donor at the blood center and the recipient at the hospital will then become part of the linked donor-recipient repository, RADAR. A randomly selected portion of donor samples that do not subsequently become linked to an enrolled recipient will be saved as part of the RADAR Repository, enabling tests for other purposes, such as determining the prevalence of a new agent. Figure 1 provides an overview of this

Figure 1. Summary and overview of the RADAR Repository



process. This operations manual provides full details concerning donor and recipient enrollment, the 6-month recipient follow-up visit, the processing and shipping of repository samples, and other study activities.

1.2 Participating Blood Centers and Hospitals

The RADAR Repository is a cooperative effort that depends on the collaboration of the REDS blood centers, participating hospitals, the Medical Coordinating Center (MCC), and the central repository storage facility. The five REDS blood centers and the hospitals with which they are working in association are:

- American Red Cross (ARC) Blood Services of Greater Chesapeake and Potomac Region, collaborating with Johns Hopkins University Hospital;
- American Red Cross (ARC) Blood Services of Southeastern Michigan Region, collaborating with St. John Hospital;
- American Red Cross (ARC) Blood Services of Southern California Region, collaborating with Good Samaritan Hospital and Little Company of Mary Hospital;
- Blood Centers of the Pacific-Irwin (BCP), collaborating with University of California-San Francisco Medical Center; and
- Oklahoma Blood Institute (OBI), collaborating with Integris Baptist Medical Center.

The Centers for Disease Control and Prevention (CDC) has funded the following non-REDS blood center and collaborating hospital to recruit blood donors and surgical patients for the RADAR Repository:

- Institute of Transfusion Medicine, collaborating with Allegheny General Hospital; and
- Florida Blood Services, collaborating with St. Joseph's and the University Community Hospital.

Westat is serving as the MCC for the RADAR Repository, and is responsible for protocol implementation and monitoring, as well as data management, processing, and storage. BBI-Biotech Research Laboratories, Inc. (BTRL) is serving as the central storage facility for the repository specimens.

1.3 Computer Systems

The MCC will provide each RADAR Repository site with two computerized tracking and enrollment systems to be utilized for the RADAR Repository. These systems described below will run on hardware provided by the MCC, which includes one desktop administrative blood center computer with accompanying printer and one laptop computer for use at the hospital.

Sample Inventory System (SIS)

The RADAR Repository Sample Inventory System (SIS), housed in each blood center laboratory, is designed to track the processing, storage, and shipment of both donor and recipient blood samples collected for the RADAR Repository. A detailed guide, The RADAR Sample Inventory System User's Guide, providing instructions for the SIS can be found at the back of this manual.

Recipient Tracking System (RTS)

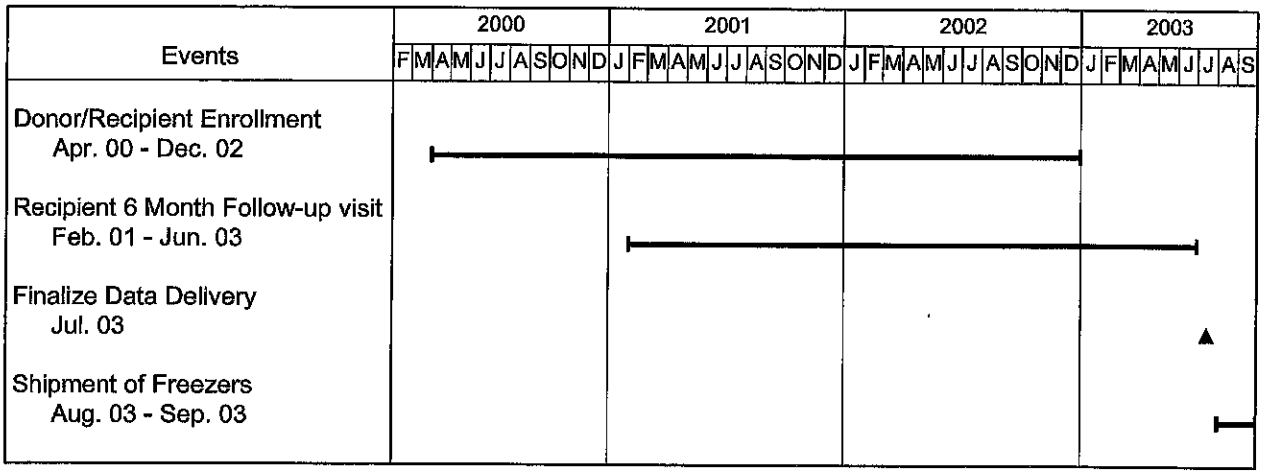
The MCC will provide each hospital-based study recruiter with a laptop computer loaded with the Recipient Tracking System (RTS) software. The RTS software has also been loaded onto the REDS administrative computer which should be located at each participating blood center. The RTS allows the study recruiter at the hospital to enroll recipients and the RADAR staff at the blood center to track and follow-up with recipients, as well as make edits to the database, as needed. The Recipient Tracking System User's Guide, which provides detailed instructions on operating this system, can be found later in this manual. Additionally, hospital computer inventory systems already in place in the Transfusion Services should allow the study recruiter and transfusion service staff ways to monitor the inventory of RADAR units at each hospital.

1.4 Schedule

Study enrollment of both donors and recipients will occur for a period of three years. Recipient follow-up visits will continue for 6-12 months after the conclusion of the 3-year enrollment

period, until all enrolled recipients have been worked and closed out. Figure 2 projects the timeline to be adhered to for study enrollment, recipient follow-up, and study analysis.

Figure 2. Project schedule



WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: List* September 6, 2000

FROM: Cathy Cranston

SUBJECT: Field Memo #2: Revision to RADAR Operations Manual, February 2000 Version (Previously distributed as Field Memo #1: Revision to RADAR Operations Manual, February 2000 Version)

In light of several procedural changes in the shipment of RADAR donor and recipient samples to BTRL, Chapter 8 of the February 2000 Version of the RADAR Operations Manual has been revised. Enclosed are replacement pages and all older version so f this chapter should be discarded. A brief summary of the major changes is below. Please consult the revised Chapter 8 and its accompanying exhibits for more detailed explanation and direction.

- **Shipping Schedules**
  Because of the sheer volume of samples that will be shipped to the Repository, BTRL has requested that the MCC devise a fixed shipping schedule. This will ensure that proper personnel are available during times of high volume shipments, more efficient inventorying of samples, quicker resolution of problems, and appropriate allocation of shipping resources.

  Each center will be assigned a unique shipping schedule, however, an overview of the entire schedule is available as Exhibit L. Please note that this schedule is firm and all centers should ship to BTRL only on their assigned dates. If problems arise with meeting schedule dates, the MCC should be contacted immediately to arrange a suitable resolution.

- **Shipping Form**
  To accommodate the changes in the shipment of both recipient and donor boxes, the shipping form has been revised. Although the majority of the form content remains the same, it now contains tow "sections."

  For shipments of donor boxes, the entire form should be completed and faxed to Westat, BTRL, and NHLBI at the time of shipment. This procedure remains unchanged.

  For shipments of recipient boxes, Section II of the form should be completed on a quarterly basis on the 5th of the month, as described in the shipping schedule. The form should then be faxed to Westat only. From this the MCC will generate a box contents list that will be returned to the blood center for inclusion with the shipment. On the assigned shipment date, Section I of the same form should be completed and faxed to Westat, BTRL, and NHLBI.

- **Shipping Recipient Boxes**
  During the first scheduled shipment of recipient samples (August 2000), the MCC encountered some problems with the method of identifying full recipient boxes for shipment. The revised procedure is more blood center driven and leaves the identification of "full" recipient boxes to the discretion of individual centers.

- **Reboxing Linked and Randomly Selected Unlinked Donor Samples**
  Previous chapters of the RADAR Operations Manual have described a reboxing procedure that involves the reboxing of linked and randomly selected unlinked donor samples into two separate boxes, one for infectious donors and one for non-infectious donors. Upon further study of the IATA shipping regulations of infectious substances, the procedure has been revised to involve reboxing into only one box.

  As originally planned, the MCC will continue to provide box maps that indicate both the position and aliquot number of the tubes to be pulled. However, there will no longer be a distinction between infectious and non-infectious samples on the map. Labels indicating the RADAR center ID, shipping date, and "Box # __ of __" will be distributed to each center ad must be placed on the top and bottom halves of each <u>new</u> donor box.

- **Storage of Unlinked Donor Samples**
  Because of the nature of the donor sampling process, there is a potential, although rare, that the remaining unlinked samples in the alternate freezers may need to be accessed to locate samples from transfused fresh frozen plasma units or de-enrollees. This should be kept in mind when organizing these original boxes in your -40°C freezers or other designated alternate freezers after sampling.

- **Shipping to BTRL**
  <u>All</u> shipments leaving the blood centers will now be shipped on dry ice according to the latest International Air Transport Association (IATA) Dangerous Goods Regulations for shipping infectious substances. Centers should continue to request the infectious shipping containers from Amanda Murray at BTRL.

Coordinating Center contact for this field memo: Cathy Cranston (301-517-8044) or Debbie Todd (301-738-8315).

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. Chandler (7)
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Orton
Dr. Ownby
Dr. Sacher
Dr. Smith
Dr. Triulzi
Dr. Viele
Dr. Williams
Ms. Yuen
Dr. Zuck

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: *List November 2, 2000

FROM: Cathy Cranston

SUBJECT: RADAR Field Memo # 3: RADAR 6-Month Follow-Up Testing Procedures

Introduction

Each blood center is responsible for arranging viral marker screening for HIV-ab, HTLV, HCV, HBsAg, and Anti-HBc on each recipient's 6-month follow-up blood sample. Additionally, the blood center is responsible for arranging appropriate confirmatory (or supplemental) testing on any sample which is repeat reactive for one or more markers. Screening and confirmatory results must be routinely reported to the MCC for all recipients undergoing testing. The MCC also requires that source documents be furnished for all test results regardless of result, as described in the following sections. Due to the sensitive nature of testing and notification, guidelines must be adhered to in order to ensure expedient and accurate delivery of test results to all parties involved.

Overview of testing algorithm and information flow:

The blood center will be responsible for designating an appropriate REDS Research staff person to notify recipients of their test results. This person may either be at the hospital or at the blood center. In the case of reactive 6-month samples, no notification should occur until both sets of results are received (6-month sample confirmatory and all index sample results).

If a 6-month follow-up screening result is returned with all non- reactive screening results, notification of the recipient is up to the discretion of the designated REDS Research staff person, but should be dealt with in a timely manner. Steps 5 and 6 must be completed as described above. Although non-reactive results do not require the completion of any test result forms, source documents must still be provided.

If a 6-month follow-up screening result is reactive:

1. Cathy Cranston or Debbie Todd must be notified **immediately** by e-mail using the RADAR MCC Notification Form (see Field Memo Exhibit A – details for use on pg. 2) and then again by follow-up phone call. Test results forms (see Field Memo Exhibits B1-B3 – details for use on pg. 2) do not need to be completed at this time.

2. Upon notification of a reactive 6-month follow-up result, the MCC will have the recipient's index sample aliquoted and moved from BTRL to the Central Laboratory, NTL/NCTL, for screening. Meanwhile, confirmatory testing will continue on the reactive 6-month sample.

3. If the index sample is found to be reactive, the aliquot at the Central Laboratory will receive appropriate confirmatory testing. All results on the index sample (i.e. reactive/non-reactive, confirmatory negative/positive/indeterminate) will be reported directly to the MCC. The MCC will complete all necessary test results forms and disseminate test results to the blood center.

4. Using the RTS data, which is delivered to the MCC by the 5th of every month, the MCC will generate the RADAR Recipient 6-Month Test Results Tracking Report (see Field Memo Exhibit C – details for use on pg. 3). This report lists all recipients who were scheduled for a 6-month follow-up visit the previous month. The form will be distributed within 1 week to each blood center. The information on the form should be verified and completed within the following two weeks and returned to the MCC with all accompanying documentation (i.e. test results forms and source documents).

Instructions for the completion of the RADAR MCC Notification Form (Exhibit A)

This form is intended to notify the MCC that a recipient's 6-month follow-up sample was returned with a repeat reactive screening result, and that their index sample must be aliquoted and moved to the Central Laboratory for testing. Blood centers should not wait on receipt of confirmatory results before faxing this form to Westat. This fax must be sent as soon as a reactive result is identified at the blood center, and must be followed up with a phone call to either Cathy Cranston or Debbie Todd at the MCC to confirm receipt. Centers must provide the recipient ID, the date of the 6-month follow-up draw, name of the blood center, and the testing BUI number. The testing BUI number is the label on the aliquot used for testing. This will allow the MCC to distinguish between different draws from the same recipient. Because the information on this form is vital to the movement and testing of the recipient's index sample, all fields must be completed.

Instructions for the completion of the RADAR Recipient Test Results Forms (Exhibits B1-B3)

These forms are to be completed for all recipients with reactive 6-month follow-up test results. These forms have been designed to follow current blood center testing algorithms and are similar to those test results forms currently being completed for REDS confirmatory data. A recipient may be reactive for more than one marker and in such a case, a form must be completed for each reactive marker. Instructions for each form are below.

Exhibit B1 – RADAR Recipient Test Results for HBV and HCV

- Blood centers should complete this form for all repeat reactive 6-month HBV (Anti-HBc, HBsAg) and/or HCV test results.
- In the first section, centers must provide the recipient ID, blood center name, 6-month draw date, and the testing BUI number.
- Centers must then check off whether these results are for a 6-month follow-up sample, an index sample, or a follow-up redraw sample. Blood centers will be completing these forms mainly for routine 6-month follow-up draws, however, there may be occasion when a sample is QNS, or a vial is lost or broken and the 6-month follow-up sample must be redrawn. If this is the case, the "Follow-up Redraw" box should be checked. The index sample box will be for MCC use only.
- The next section contains a series of check boxes indicating for which marker the recipient is reactive. Check the appropriate box. If the recipient is reactive for more than one of these markers, all corresponding sections must be completed. Centers need only complete the section corresponding to the marker for which the recipient is reactive.

- Section 1, Anti-HBc
  Check "Reactive" box if sample is reactive. This section does not need to be completed if the sample is Anti-HBc non-reactive.

- Section 2, HBsAg
  Screening Results - Fill in the optical density (OD) and cut-off values for any sample that is repeat reactive for HBsAg. If both Ortho and Abbott tests are used, complete both boxes. If only one is used, complete the information in the corresponding box and check the "Not Done" box of the other.

  Confirmatory Results –In the spaces provided, fill in the test name and manufacturer, as well as the neutralization percentage of the sample. Check the appropriate final interpretation box (Pos, Neg, or IND). If a confirmatory test was not done, be sure to check the "Not Done" box and circle the reason why. For ARC centers, this might be because the first EIA was positive but the second EIA was negative. For OBI this might be because the sample was Anti-HBc Positive.

- Section 3, HCV
  Screening Results - Check the "Reactive" box if sample is reactive. This section does not need to be completed if the sample is HCV non-reactive.

  Confirmatory Results – In the spaces provided, fill in the test name and manufacturer. Circle the intensity of each band. If a band is not present, circle 0. Check the appropriate final interpretation box (Pos, Neg, or IND).

Exhibits B2 and B3 – RADAR Recipient Test Results for HIV and HTLV

- Blood centers should complete these forms for all repeat reactive 6-month HIV or HTLV test results.
- As with the Test Results for HBV and HCV form, source documents must accompany completed forms. Blood centers are to provide the recipient ID, blood center name, date of 6-month draw, and the testing BUI number.
- Again, the type of sample must be identified by checking the appropriate box (6-month follow-up, index, or follow-up redraw).
- The format of the remainder of these forms is the same as those currently in use for REDS confirmatory data. Please refer to REDS field memo #'s 90 and 91, which accompanied those forms for detailed instruction on their completion.

Instructions for the completion of the RADAR Recipient 6-Month Test Results Tracking Report (Exhibit C)

This report lists the recipient ID, draw status, and date of every recipient scheduled for a 6-month follow-up visit during the previous month. The MCC will generate this report monthly using RTS data received from blood centers on the 5th of every month. Once received, the MCC will generate and distribute the report within 1 week. Blood centers should complete the form as follows.

- Fill in the testing BUI number for each recipient listed in the spaces provided.
- Circle the 6-month screening test result of each recipient listed (circle 1 if sample is reactive, circle 2 if sample is non-reactive). Reactive results will already be circled when you receive this form.
- Verify the draw status and test results of all recipients.
- For any recipient with reactive results, complete RADAR Test Results form(s) for that specific viral marker.
- Attach all source documents, including those for recipients who are NR on all screening tests.
- Forward completed forms and all source documents to Westat.

If any reactive result is not pre-circled, Westat must be notified **immediately** to ensure that testing of an index sample was not overlooked. If the draw status of a recipient is incorrect, please write in the correct information. Forward the completed form and all accompanying documentation to Westat within two weeks of its receipt at the blood center.

Further instruction will follow regarding any upcoming decisions concerning NAT testing and redraws on indeterminate or ambiguous testing results. Any comments or questions should be directed to Cathy Cranston.

Coordinating Center contact for this field memo: Cathy Cranston (301-517-8044) or Debbie Todd (301-738-8315).

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. Chandler (7)
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Orton
Dr. Ownby
Dr. Sacher
Dr. Smith
Dr. Triulzi
Dr. Viele
Dr. Williams
Ms. Yuen
Dr. Zuck

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: *List March 29, 2001

FROM: Donna Smith

SUBJECT: RADAR Field Memo # 4 : RADAR Operations Manual Version 3 Replacement Pages

Introduction

This memo reviews the major revisions and procedural modifications made to the RADAR Operations Manual, Version 3. Minor revisions such as formatting issues or correcting typographical errors have also been addressed. Instruction cards and blood center directives have been laminated for your convenience. Replacement pages for the revised RADAR Operations Manual are attached to this memo. Please discard the appropriate pages currently in your Operations Manual and replace them with the enclosed pages. Note that revision dates are included at the top of each page. Revised Recipient 6-Month Follow-up Questionnaires are enclosed with this shipment for those whose names appear in italics at the end of this memo. Please discard the obsolete questionnaires and replace them with the revised questionnaires upon receipt.

Chapter 4: Recipient Enrollment

- **Section 4.9, page 4-17: Multiple Transfusion Events**

  When an enrolled recipient experiences a multiple transfusion event within 5 months of enrolling in the study, the 6-month follow-up date should be reset to reflect the most recent transfusion discharge date. Retrieve the recipient's latest pre-transfusion or crossmatch sample according to the RADAR Operations Manual, Version 3, Section 4.9. In lieu of using a pre-transfusion blood sample (PR) label, all multiple transfusion event samples should be labeled as research blood sample 1 (R1). Update the RTS per standard operating procedures.

Chapter 5: 6-Month Follow-up Visit

- **Recipient 6-Month Follow-up Questionnaire**

  The Recipient 6-Month Follow-up Questionnaire has been modified in Sections D and E. The question by question (Q x Q's) specifications for administering the Questionnaire have been revised to reflect the following modifications:

- **Section D., pages 5-24 and 5-25: Hepatitis**

  Code 96 has been removed from Question #14, OTHER (PLEASE SPECIFY). If the recipient reports having a type of hepatitis not listed, record the recipient's responses exactly as reported next to "OTHER (PLEASE SPECIFY)".

- **Section E, page 30 and 31: Recipient Health History**

  Since all references to obtaining recipient medical records have been removed from the RADAR Operations Manual Version 3 revisions, Box D from Section E of the Recipient 6-Month Follow-up Questionnaire has been eliminated. In Section E, Question 21, (GO TO BOX D) and (SKIP TO BOX D) have been replaced with (THE END).

  The corresponding Q x Q's instructions are as follows:

  - Question 21: If the recipient answers "NO" or "NOT SURE", read the response, located at the end of the questionnaire, thanking the recipient for his/her time.
  - Question 21a.: If the recipient answers "NO", read the response, thanking the recipient for his/her time.
  - Question 21d.: Upon completion of the questionnaire, read the response, thanking the recipient for his/her time.

- **Section 5.6, page 5-32: Medical Record Release Form**

  Recipient medical records consent will not be collected at the time of completion of the 6-month follow-up visit. This decision was made during the February 28, 2001 conference call concerning the necessity of collecting the recipient's consent for release of medical records at the time of completion of the 6-month follow-up visit, (depending on the questionnaire responses given by the recipient). Until such time medical records are required, all references to medical records have been removed from the RADAR Operations Manual Version 3 revisions.

- **Section 5.6, pages 5-32 and 5-33: Tracking Recipient Close-outs and Completion of the 6-Month Follow-up Visits**

  Box 5G, RTS recipient close-out codes, has been revised to include a description of Successful Complete and Partial Complete.

  - Successful Complete: All components (questionnaire and repository sample) of 6-month follow-up visit were completed.
  - Partial Complete: Either questionnaire or repository sample for the 6-month follow-up visit could be completed. If this code is used, utilize the RTS comments section to explain further.

Chapter 8: Sample Processing and Storage at the Blood Center

- **Section 8.7.2, page 8-13: Setting Up for Recipient Repository Sample Processing**

  Section 8.7.2 further details labeling requirements for repository sample processing.

Coordinating Center contact for this field memo: Donna Smith (240) 453-2774.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. Chandler (7)
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Orton
Dr. Ownby
Dr. Sacher
Dr. Smith
Dr. Triulzi
Dr. Viele
Dr. Williams
Ms. Yuen
Dr. Zuck

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: List* June 7, 2001

FROM: Cathy Cranston

SUBJECT: RADAR Field Memo #5: Revised RADAR HBV/HCV Test Results Form

This field memo outlines the revisions made to the RADAR HBV/HCV Test Result Form, found as Exhibit M in the RADAR Operations Manual V. 3. The new, hard copy version of the form (version date 06/01/01) is enclosed with this memo and the electronic version will be sent via email attachment. All forms with a version date of 02/01/01 should be discarded and replaced. Instructions for electronic completion of this and other RADAR Test Results forms can be found in the RADAR Operations Manual V. 3 section 6.4. Blood centers should complete this form for all repeat reactive 6-month HBV (anti-HBc, HBsAg) and/or HCV test results. Forms for reporting Index testing results will continue to be completed by the MCC as well as the OBI staff due to their unique testing algorithm. Use of the new form should begin immediately. Specific instructions for the completion of the revised form are found below.

- The top portion of the form containing the check boxes for type of sample, recipient ID, draw date, blood center, and WBN remains the same.
- The section containing a series of check boxes to indicate for which marker the recipient is reactive has been removed. Centers must now complete all sections of the form.
- "Non-Reactive" and "Not Done" check boxes have been added to each section of the form. Please be sure to check "Non-Reactive" for any Non-Reactive HBV or HCV results on each recipient. "Not Done" boxes should be checked for any confirmatory tests following "Non-Reactive" screening results.
- A section has been added for anti-HBs results. This field is currently applicable only to OBI or for a specific pattern of test results, and all other centers should check the "Not Done" box when completing the form.

Please distribute copies of Exhibit M (version date 06/01/01) so that all V.3 Operations Manuals are correctly updated. Also, please be sure to delete and replace both versions of the from from the diskettes that were included with the Operatons Manual V. 3. If you have any further questions regarding completion of this form or any others, please contact Cathy Cranston by email at cranstc@westat.com or by phone at (301)517-8044.

*
Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. Chandler (7)
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Orton
Dr. Ownby
Dr. Sacher
Dr. Smith
Dr. Triulzi
Dr. Viele
Dr. Williams
Ms. Yuen
Dr. Zuck

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List * June 15, 2001

FROM: Cathy Cranston

SUBJECT: RADAR Field Memo #6: RADAR Reports

This field memo outlines the general purpose of each of the RADAR reports that are distributed by the MCC. These reports have been developed to aid in monthly data cleaning efforts. Because the accuracy of all reports relies on the data we receive, it is extremely important that the MCC not only receive data on time, but that the blood centers cooperate in the ongoing effort to collect the most complete and accurate data possible. On a monthly basis, the following reports will be sent to each blood center:

1. Recipient 6-Month Follow-Up Tracking Report

Purpose: To collect 6-Month follow-up sample test results.

This report is generated using the RTS data. Recipients will appear on this report whenever a new 6-month record is created in the RTS with a draw date entered into the "draw date" field of the RTS. These reports should not only be completed for testing information, but also reviewed for accuracy of draw date and draw status information.

2. Recipients Overdue for Follow-Up Report

Purpose: To help blood centers with managing any backlog of returning recipients.

The Recipients Overdue for Follow-up Report will include the recipient's ID number, admission and discharge dates, and the originally anticipated 6-month follow-up date. In summary, recipients will appear on this list if:

- The recipient has not been seen at the 8-month mark after his/her discharge date.
- The RTS indicates that the recipient was seen, but a valid draw date for the 6-month follow-up was not entered.

3. Linking/Logics Reports

Purpose: To ensure that data collected on each recipient within the previous month is complete and accurate.

- The *linking* reports are used for resolving problems matching a recipient's transfused unit's WBN with the corresponding donor WBN in the SIS and/or donation data.
- The *logic* reports aid in collecting missing data and cleaning data inconsistencies.

Please see Attatchment A for help with specific fields on reports. If a particular problem is not correctable, a note should be made on the report and faxed back to Cathy Cranston at the MCC. Please keep in mind that these reports are generated on a monthly basis using the RTS back-up from the previous month. Due to this lag time between data entry at the blood center and receipt at the MCC, there may be times when problems have been corrected at the blood center but still appear on new reports. Updates and edits to the blood center data should be made within the month they are received.

Periodically (every 6 months), the MCC will send out cumulative linking/logic reports to reflect any outstanding problems. If the blood centers have handled fixing data problems on a monthly basis, these lists should be rather short. Please note, problems that were previously found to be uncorrectable by the blood center will continue to appear on these cumulative reports due to the way the programs check the data. These previously addressed problems can be ignored.

4. **Recipient Index Sample Tracking Report** (OBI only)

Purpose: A mechanism to collect data for each newly enrolled recipient's Index test results.

The report is generated using the monthly RTS backup. Each time a new recipient record is created in the RTS and a valid draw date is entered, that recipient will appear on the report, regardless of what month they were enrolled. If there is an error on this report, please correct it both on the report and in the RTS.

If you have any further questions regarding completion of this form or any others, please contact Cathy Cranston by email at cranstc@westat.com or by phone at (301)517-8044.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. Chandler (7)
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Orton
Dr. Ownby
Dr. Sacher
Dr. Smith
Dr. Triulzi
Dr. Viele
Dr. Williams
Ms. Yuen
Dr. Zuck

Attachment A

Linking Reports

1 Blood Unit (WBN) Discrepancy Report: WBN in SIS does not match WBN in Donation Data

- Whole blood numbers listed on this report have been documented in the SIS as a RADAR unit but are not recorded in the monthly donation data. If the donation is eligible, the donation record should be forwarded to Westat.
- If a whole blood number appears on this report and the donation is NOT eligible, the recipient receiving this unit should be de-enrolled, unless he/she has received other RADAR units.

2 Blood Unit (WBN) Discrepancy Report: WBN in RTS does not match WBN in SIS

- A unit appears on this report because a non-RADAR unit is mistakenly entered as a RADAR unit; or
- It is possible that the error was made when entering data into the SIS. Currently, the blood centers cannot edit WBNs in the SIS, thus these errors should be noted on the report and returned to Steve Schweinfurth at the MCC, who will then create an edit file for the SIS.

Logic Reports

1 Enrolled Recipients: Pre/Post Transfusion Sample Check (RTS)

"No Sample" box

- All information located in Pre/Post Transfusion screen missing including sample, type, draw date, source code, and/or phlebotomy code.

"Incomplete Information" box

- Some information has been entered but not all.
- If all information has been entered, check data for logical inconsistencies.

2 Enrolled Recipients: General Information Check (RTS)

Missing or Inconsistent Dates

- If indicated that any date information is missing, enter missing data.
- A check may appear in a date field even if a date is entered into this field. In this case, check that the dates given are logical based on other information given. For example, if Admission Date is checked, verify that the Admission Date is prior to the Transfusion or Discharge Dates.

Missing Transfused Units

- Verify that the number of RADAR units entered is consistent with the number of RADAR units listed as transfused.
- Verify that the number of non-RADAR units entered is consistent with the total number of units listed as transfused.

Attachment A

Missing Completed Status

- "Completed Status" must be selected on the lap-top after the patient has been discharged and all enrollment information has been entered. The recipient's enrollment information must be recorded in the RTS as "completed" before a 6M appointment can be scheduled.

3 Other Information (RTS)

- If a Recipient has been "completed," all edits must be made on the Administrative computer.
- If a Recipient has not been "completed," edits must be made on the laptop.

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* August 22 2001

FROM: RADAR Operations Staff

SUBJECT: RADAR Field Memo #7: RADAR Recipient 6-Month Test Results Tracking Report

It has come to the attention of the Medical Coordinating Center (MCC) that some blood centers are recording recipient draw status results on the Recipient 6- Month Test Results Tracking Reports using study status codes instead of phlebotomy codes. Therefore, the MCC has made the following modifications to improve the accuracy of draw status recording.

1. To avoid any coding discrepancies, the "Draw Status" and the "Draw Date" column titles have changed to "Phlebotomy Code" and "Visit Date" repectively. These directly correlate to the fields on the RTS Screen, Six- Month Follow-up.

2. The 6-Month Test Results Tracking Report will only list phlebotomy codes "Successful Draw" and "Partial Draw".

3. Blood centers will be required to complete any missing data on the 6-Month Test Result Tracking Report. Missing phlebotomy status should be recorded in the phlebotomy code column using the following phlebotomy codes:

   - Unsuccessful Draw
   - Patient Refusal
   - Medical Refusal
   - Other Reason

The modified report is included with this memo. Should you have any questions, please contact Cori Keckler by email at corikeckler@westat.com or by phone at (240) 314-2322. Thank you for your coorperation.

*

Dr. Busch	**Ms. Hutching (10)**	Dr. Ownby
Ms. Campbell (5)	Dr. Kleinman	**Mr. Rey (4)**
Dr. Chamberland	**Dr. LeParc (4)**	Dr. Sacher
Ms. Chandler (7)	Dr. Luban	Dr. Smith
Ms. D'Andrea (2)	**Dr. Murphy (4)**	Dr. Triulzi
Dr. Garratty	Dr. Nemo	Dr. Viele
Dr. Gilcher	**Dr. Nass (6)**	Ms. Yuen
Ms. Guiltinan (7)	Dr. Operskalski	Ms. Yuen
Dr. Higgins	Dr. Orton	Dr. Zuck

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* November 12, 2001

FROM: REDS Coordinating Center Staff

SUBJECT: REDS Field Memo # 98
and
RADAR Field Memo # 8 :
Biorepository Review of Shipper's Declaration of Dangerous Goods

Biorepository Review of Shipper's Declaration of Dangerous Goods

This field memo is to inform you about a new shipping procedure that should be implemented immediately for any REDS or RADAR sample shipment. Currently, when each blood center fills out a Shipper's Declaration for Dangerous Goods, it is not reviewed by anyone outside the center. Although most of the time, this paperwork is done correctly, we have had a number of instances where it is not and the shipments have had to be returned. In order to avoid this problem in the future and at the suggestion of the BTRL, please fax your Shipper's Declaration to BTRL for review the day before your shipment is sent. This will allow for paperwork to be double-checked so errors could be found and corrected before there are undue consequences. BTRL will then let you know if they detect any problems.
Thank you for your cooperation.

Coordinating Center contact for this field memo: Debbie Todd

Debbie Todd
Phone: (301) 738-8315
Fax: (301) 517-4079
Email: DeborahTodd@westat.com

Dr. Alter
Dr. Barbosa
Ms. Baxter (2)
Dr. Busch
Ms. Campbell (6)
Dr. Chamberland
Ms. D'Andrea (4)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc
Dr. Luban (2)
Ms. Moore (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Orton
Dr. Ownby
Mr. Rey (5)
Ms. Schechterly (2)
Dr. Smith
Dr. Triulzi

Westat Staff

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* November 14, 2001

FROM: Sheba Hakiza

SUBJECT: RADAR Field Memo #9: RTS Update and 6-Month Follow-up Reports

I. New Option for RTS 6-Month Follow-up Visit Field

As requested by the blood centers during the September 5th RADAR Repository Meeting, a new 6-Month Follow-up Status code of "Pending" has been created in the RTS. Centers can now classify recipients who have been scheduled for a 6-month follow-up visit, but have not yet returned. In addition, two new Phlebotomy Codes have been added to the phlebotomy options in the RTS. Recipients who refuse all testing or partial testing can be entered as "Refused Testing" or "Partial Testing", respectfully.

An update RTS diskette is included with this memo. To install please follow the instructions that are provided with the diskette. This installation should be completed by November 30, 2001. Once the installation is completed you should begin to use the new options, as they will be reflected in the next set of recipient 6-Month Follow-up Reports.

Any difficulties experienced with this RTS load or any other hardware/software problems should be brought to the immediate attention of the MCC. The MCC should always be the point of contact for these issues.

II. RADAR 6-Month Follow-up Reports

Five new RADAR Recipient 6-Month Follow-up Reports will be distributed by the MCC. These reports have been developed to provide a monthly update of 6-month follow-up activity by blood centers. The accuracy of all reports relies on the data we receive, thus it is extremely important that the MCC not only receive data on time, but that the blood centers cooperate in the ongoing effort to collect the most complete and accurate data possible.

On a monthly basis, the following reports will be sent to each blood center:

A. RADAR Report 1: 6-Month Follow-up Status for Eligible Recipients

Purpose: To report the number of recipients eligible for 6-month follow-up by their 6-month follow-up status.

This report is used to document the total number of recipients eligible for 6-month follow-up. The report shows the disposition of recipients eligible for 6-month follow-up by study status. For each blood center, the total number of "Not Worked", "Returned", "Refused", "Lost to Follow-up", or "Missing" recipients are reported. It further classifies "Returned" recipients by closeout codes

"Successful Complete" or "Partial Complete". The report also categorizes the number of recipients Lost to Follow-up by their appropriate closeout codes.

A. RADAR Report 2: Status of Recipients At or Past 6-Month Follow-up Eligibility Interval
Purpose: To report the status of recipients at or past their 6-month follow-up eligibility interval.

This report summarizes the number of recipients that have "Returned" or "Remain to be Worked"during or past their 6-month follow-up interval. Report 2 shows each blood center's follow-up activity from the beginning of the 6-month follow-up to the end of the eligibility interval. The report shows the number of recipients that are still "Remaining to be Worked" past the 6-month eligibility interval. It also reports the number of recipients included in "Other Closeouts" and those with "Missing Study Status" during or past their 6-month follow-up eligibility interval.

B. RADAR Report 3: 6-Month Follow-up Status
Purpose: To provide a graphical disposition of the status of recipients eligible for a 6-month follow-up visit per month.

This report is a bar graph that shows the study status of recipients eligible for a 6-month follow-up visit. Each bar reports the disposition of recipients by status for a given month.

C. RADAR Report 4: 6-Month Follow-up Eligibility Interval
Purpose: To provide a graphical disposition of eligible recipients during 6-month follow-up eligibility intervals.

This report shows the distribution of eligible recipients for each 6-month follow-up eligibility interval. The graph reports the study status of recipients during their 6-month eligibility interval. In subsequent monthly reports, the status of recipients may change during the 6-month interval, but the number of recipients eligible will remain constant. For example, a recipient that was "Not Worked" at the beginning of the 6-month interval may have a study status of "Returned" by the end of the interval. This report will illustrate on-going recipient follow-up activity by blood centers during the eligibility interval.

D. RADAR Report 5: Past 6-Month Follow-up Eligibility Interval
Purpose: To report the status of recipients past their 6-month follow-up eligibility interval.

This report is a graphical representation of the study status and follow-up activities of recipients past their 6-month follow-up eligibility interval. Similar to Report 4, the study status of recipients may change.

If you have any further questions regarding these reports, please contact Sheba Hakiza by e-mail at shebahakiza@westat.com or by phone at (301) 610-4865.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. Chandler (7)
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Orton
Dr. Ownby
Dr. Sacher
Dr. Smith

Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Dr. Triulzi
Dr. Viele
Dr. Williams
Ms. Yuen
Dr. Zuck

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* November 28, 2001

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo # 10:
Blood Center Shipping Containers for Special Testing Shipments

This memo is in response to the increasing number of RADAR Recipient samples being shipped from the blood centers to alternate laboratories for special testing purposes. To ensure that each center has the appropriate materials available for sending a frozen infectious RADAR Recipient sample to a testing facility, we've attached a list of supplies and contact information to purchase a small quantity of shippers.

We recommend purchasing the STP 310 made by SAF-T-PAK. This shipper is the most suitable for the purposes of RADAR and is inexpensive. We suggest that each blood center order a package of four shippers, which will cost $100.50. The price quote is for the government (NHLBI) rate. These packages contain everything you need including labels and a cover piece to be placed over the biohazard labels for return of an empty container to your site; additional labels and parts may be purchased separately at a later date.

Supply and Ordering Information:

Vendor: SAF-T-PAK
Phone: 1-800-814-7484
Website: www.saftpak.com

PRICING SCHEDULE
GSA - USA -- Freight not included

Product	Price
INFECTIOUS SHIPPER	
STP 310 New Refrigerated Shipper Bndl/4 (recommended)	**100.50**
STP 310SP New Refrigerated Shipper Each	38.64
STP 311 Outer Box Bndl/10	34.51
STP 303 Mailing Flap Bndl/10	8.53
STP 610 Saf-T-Rap Bubble 20/Bag	23.00
STP 710 Combination bag 50/case	90.03
ABSORBENT STRIPS	
STP 150 Absorbent (50 mL) 2X250B	31.83
STP 151 Absorbent (100 mL) 250B	24.68
STP 152 Absorbent (250 mL) 250Bg	59.67
LABELS AND FORMS	
STP 800 Shipper's Decs Pkg/15	66.27
STP 801 Dangerous Goods Forms 500/bdl	70.29
STP 802 Class 6 Infect Labels 10XPk12	40.89

STP 803 Class 9 Hazard Lbl 10XPk12	40.89
STP 804 Dry Ice Label 10XPk12	61.28
STP 809 UN2814 Inf.Sub. Labels 10x12pkg	51.31

**** All prices are subject to change without notice. Revised June 15, 2000**

***** Expedited Delivery will be at an additional charge**

If you have any questions, please contact Debbie Todd:
Phone: (301) 738-8315
Fax: (301) 517-4079
DeborahTodd@westat.com

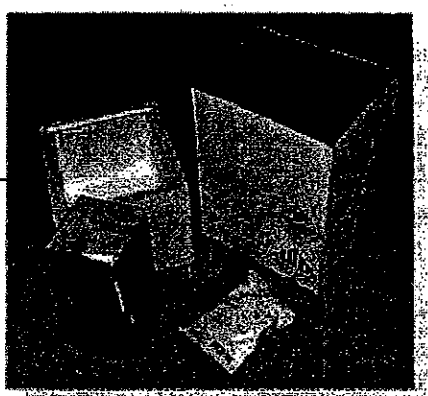
*

Dr. Alter
Dr. Barbosa
Ms. Baxter (2)
Dr. Busch
Ms. Campbell (6)
Dr. Chamberland
Ms. D'Andrea (4)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc
Dr. Luban (2)
Ms. Moore (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Orton
Dr. Ownby
Mr. Rey (5)
Ms. Schechterly (2)
Dr. Smith
Dr.Triulzi

STP 310

Revolutionary Infectious Substance Packaging

The STP 310 meets the requirements outlined in IATA Packing Instruction 602 for safely shipping infectious substances. The STP 310 also meets the requirements for IATA Packing Instruction 650 for shipping large volumes of diagnostic specimens (up to 4 Liters)



Holds more

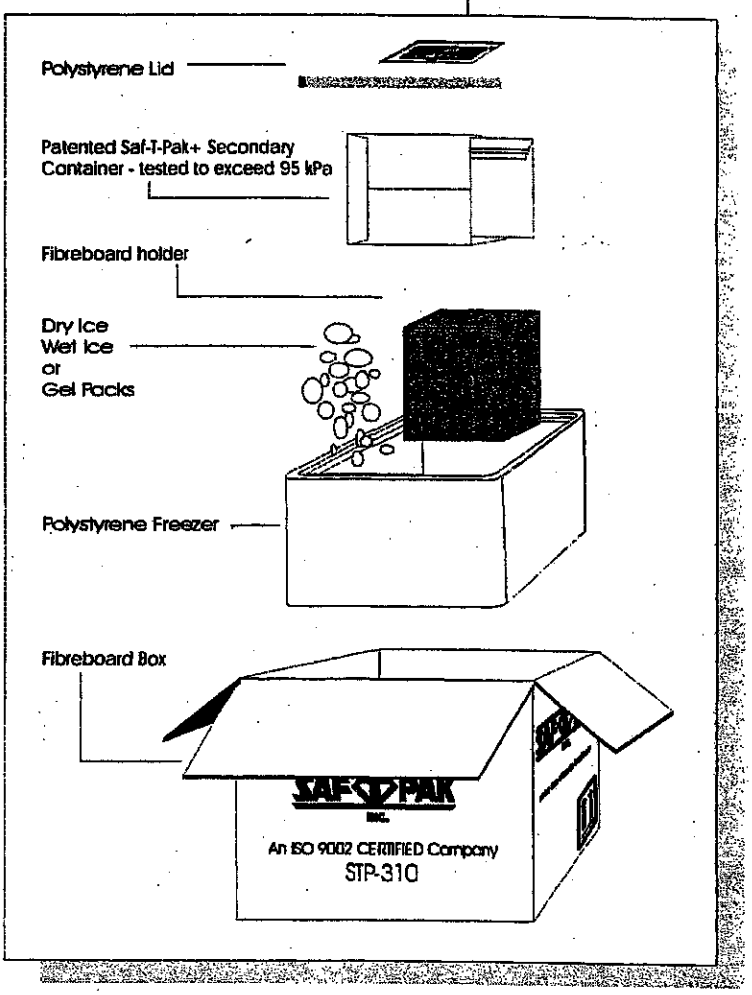
243 - 2 mL tubes
2 x 500 mL Blood bags
32 x 10 mL Evacuated Blood Collection tubes
many other configurations approved call for listing

Costs less

Costs from 50% to 90% Less per specimen than conventional Packaging

Accepting Orders for December Delivery

Disclaimer:
This package meets the test criteria outlined in federal regulations for the safe transport of infectious substances if used as directed. Shipper must use the package system as directed to ensure compliance.
Manufacturer/Agent/Distributor will not be liable if the package system is altered or not used according to these instructions.
Federal regulations require that before shipping dangerous goods, the Shipper must be conversant and comply with applicable shipping regulations.

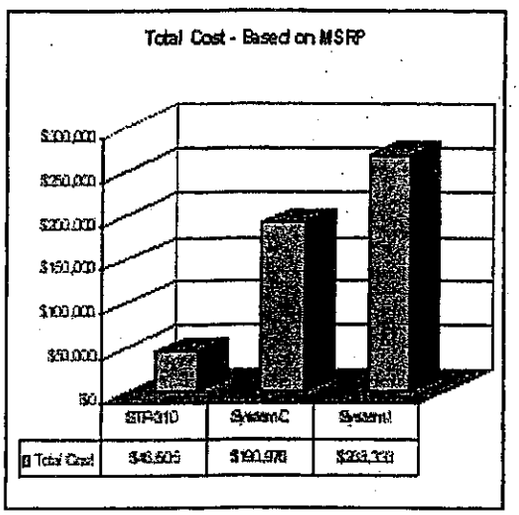


SAF-T-PAK®
INC.
10807-184 Street
Edmonton Alberta
Canada,
T5S-5T1
Tel: (780) 486-0211
1 800 814-7484
Fax: (780) 486-0235
http://www.saftpak.com

Printed in Canada

STP-310 Revolutionary packaging for Infectious substances

- Reduces costs by up to 90%
- Reduces labor by up to 80%
- Environmentally friendly
- Easy to use
- Keeps specimens frozen for up to 72 hours
- Meets Packing Instruction 602, and 904



- Calculate your savings, compare STP310 to what you are using now.
- Order this product online
- Instruction Manual - Contains a list of capacities and specifications
- Product Flyer - Contains illustrations and details
- Video of a VAN and 9 passengers parked on inner containers from STP-310

As a new, low-cost, simple to use Infectious Substance package, the STP 310 uses the patented Saf-T-Pak+ technology. This package is full certified to meet ICAO/IATA/49-CFR/TDG/CGSB making it legal for use in the air. The STP 310 consists of a rugged outer box constructed of Stackor high performance liner board. A lightweight Expanded Polystyrene (EPS) insulated package for transporting specimens which must be kept frozen or refrigerated. Suitable for dry ice, Package contains all of the necessary hazard labels and instructions. Two Saf-T-Pak+ soft secondary containers and 2 x 250 ml absorbent strip. This package will hold up to 243 x 2ml cryovials.

STP-310 #  times

IATA Changes for 2001

The International Air Transport Association "Dangerous Goods Regulations, 42nd Edition" came into effect January 1, 2001. This well presented and user-friendly manual serves as a "bible" for those who ship and handle dangerous goods by air. Each year changes recommended by airlines, shippers, and biosafety workers worldwide are reviewed by an international panel of experts. Additions, deletions, and changes are made with the end goal of further protecting all involved with handling Dangerous Goods. This new edition offers just a few changes for the shippers of Class 6.2, Infectious Substances

The Definition of Dangerous Goods (1.0) has been slightly modified again and the word "however" has been moved. This is simply a rewording and the definition itself does not change.

Another addition and change of which shippers should be aware comes under State and Operator Variations 2.9.

FX 12 (Federal Express) states that "Effective 1 June 2001 FedEx Express will only accept Shipper's Declarations that are typewritten or computer generated. Handwritten forms will no longer be accepted." This variation affects everyone that ships Dangerous Goods.

Of great interest to shippers of Class 6.2 Infectious Substance is the change made to Special Provision A 81 which comes into effect July 1, 2001

"A 81 The quantity limit shown in column J does not apply to body fluids known to contain or suspected of containing infectious substances provided they are not in Risk Group 4, when in primaries not exceeding 1000mL, and in outer packagings not exceeding 4L. The quantity limits shown in column J and L do not apply to body parts, organs or whole bodies known to contain or suspected of containing infectious substances. These materials must be packed in accordance with packing instruction 602 so as to present no hazard to persons or animals during transport. This special provision does not apply to infectious substances carried in the mail."

Briefly, A 81 has been expanded to include all body fluids and the size of primary increased from 500mL to 1000ml. The total volume per package remains at 4L.

Packages suitable for use with special provision A81

STP-350 Bulk infectious substance shipper (capacity 4 L) http://www.saftpak.com/Products.htm#STP 350
STP-100 Infectious substance shipper(Capacity 500 mL) http://www.saftpak.com/Products.htm#STP 100
STP-110 Infectious substance shipper (Capacity 1500 mL) http://www.saftpak.com/Products.htm - STP 110
STP-310 Insulated infectious substance shipper (Capacity 3 L) http://www.saftpak.com/Products.htm#STP 310

Having handy access to the IATA DGR is an absolute essential for shipping compliance. Every shipping department should have their own copy. Call IATA at 800-716-6326 to order.

Or order online at http://www.saftpak.com/cdorder.htm

Here are some handy web sites

The International Air Transport Association

Emergency response for a spill of Infectious Substances, how do you handle it?

http://www.saftpak.com

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* November 28, 2001

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo # 11:
Collection of Pre- and Post-Transfusion Recipient Samples

This Field Memo is in response to data presented at the RADAR Steering Committee Meeting on September 5, 2001. This data exhibited that many blood centers were not storing adequate recipient sample volumes in the repository, which was impeding protocol driven testing of these recipients' samples.

Recipient 6-month samples that are found to be reactive for viral marker screening trigger the testing of the recipient sample collected at enrollment, i.e. the index sample. It has been found with all too frequent regularity that the enrollment or index samples collected have volumes that are inadequate for testing of one or more viral markers eliminate the concern of transfusion transmission that may arise in cases where the 6-month follow-up sample is reactive. This can cause great anxiety on the part of the recipient if we are unable to complete testing and demonstrate the same results from a sample collected prior to their transfusion as those that were detected at the 6-month follow-up visit. This is seen most frequently with centers that are only collecting the residual volume from a type and cross match sample at enrollment. In response to this, centers that have been collecting only this residual volume type of sample should now collect a sample post-transfusion. Both the pre-transfusion and post-transfusion samples must be placed into the repository to ensure adequate volume for both testing and long-term storage.

This action should take effect immediately. If there are problems with a blood center's ability to collect this post-transfusion sample please inform Debbie Todd at Westat by telephone (301)738-8315 or e-mail deborahtodd@westat.com.

*

Dr. Alter
Dr. Barbosa
Ms. Baxter (2)
Dr. Busch
Ms. Campbell (6)
Dr. Chamberland
Ms. D'Andrea (4)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc
Dr. Luban (2)
Ms. Moore (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Orton
Dr. Ownby
Mr. Rey (5)
Ms. Schechterly (2)
Dr. Smith
Dr. Triulzi

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: List* November 28, 2001

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo # 12:
Turn-Around-Times for Testing of Recipient Index Samples

This Field Memo is in response to a request from the RADAR Steering Committee Meeting on September 5, 2001 to provide average RADAR Recipient testing turn-around times (TAT). This information is intended to aid in evaluation of the study's ability to perform necessary recipient index sample testing as rapidly, as well as better enable the sites to counsel the recipients on when they can expect their test results. Below is a list of the average time it has been taken to get final on the recipient index samples by viral marker.

Viral Marker	**Average # of Calendar Days**
Anti-HBc	9.5 *
Anti-HCV	17
Anti-HIV-1	14 **
Anti-HTLV	45-60

* final results for HBV can take longer if HBsAg testing is required
** can take up to 21 days

In the next few months we anticipate some modification to this timeline as the testing facility, American Red Cross National Confirmatory Testing Laboratory (NCTL), will be moving from Maryland and will be consolidating testing in North Carolina. Additionally, supplemental testing for HTLV antibody will be modified due to the test kit for Western blot being discontinued by the manufacturer.

If there are any questions please contact Debbie Todd at Westat by telephone (301) 738-8315 or e-mail deborahtodd@westat.com.

*

Dr. Alter
Dr. Barbosa
Ms. Baxter (2)
Dr. Busch
Ms. Campbell (6)
Dr. Chamberland
Ms. D'Andrea (4)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc
Dr. Luban (2)
Ms. Moore (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Orton
Dr. Ownby
Mr. Rey (5)
Ms. Schechterly (2)
Dr. Smith
Dr. Triulzi

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: List* April 1, 2002

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo #013: Revised 6-Month Follow-up Reports 3, 4, and 5

The RADAR Recipient 6-Month Follow-up Reports 3, 4, and 5 are generated monthly to provide a graphical representation of each center's 6-month follow-up activity. The reports are purposefully designed to describe the status of eligible recipients during the different periods of the 6-month follow-up eligibility interval.

On November 14, 2001, RADAR field memo #009 and five new RADAR Recipient 6-Month Follow-up Reports were sent by the MCC to RADAR centers. Since November, monthly distribution of Reports 3, 4, and 5 has been halted while implementing programming modifications necessary to produce more accurate reports and to ensure that all reports are serving their desired functions.

A summary of revised 6-Month Follow-up Reports 3, 4, and 5 has been provided below. Please note that the number of eligible recipients for follow-up may change from the beginning of the 6-month follow-up interval (Report 3) to the end of the 6-month follow-up interval (Reports 4) due to de-enrollment or multiple transfusion events.

RADAR Report 3: Recipient Status at the Beginning of 6-Month Follow-up Eligibility Interval

Report 3 has been modified to only report the status of eligible recipients at the end of the first month of the 6-month follow-up eligibility interval. This report provides a "snap shot" of the status of eligible recipients at the end of the first month of the 6-month follow-up eligibility interval (i.e., at month 7). Therefore, the status of eligible recipients will not change in subsequent monthly reports.

RADAR Report 4: Recipient Status at the End of the 6-Month Follow-up Eligibility Interval

Report 4 is designed to provide a graphical disposition of the status of eligible recipients at the end of the 6-month follow-up eligibility interval. The graph reports the blood centers' follow-up activity at the end of the 6-month follow-up eligibility interval. The revised Report 4 only includes recipients who have reached the end of their 6-month follow-up eligibility interval (i.e., at the end of month 12). Similar to Report 3, the status of recipients will not change in subsequent reports.

RADAR Report 5: Recipient Status In or Past the 6-Month Follow-up Eligibility Interval

Report 5 is a cumulative report that represents the status of recipients during or past their 6-month follow-up eligibility interval (from month 7 through 12 and beyond). This report captures the current study status of recipients while they are in or after the 6-month follow-up eligibility interval has ended. Unlike Reports 3 and 4, the status of eligible recipients may change in subsequent months.

The MCC will continue to routinely send centers RADAR Recipient 6-Month Follow-up Reports 1 and 2 every month. If centers would also like to receive RADAR 6-Month Follow-up Reports 3, 4, and 5 on a monthly basis, please contact the MCC.

If you have any further questions regarding these reports, please contact Sheba Hakiza by e-mail at shebahakiza@westat.com or by phone at (301) 610-4865.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Ms. Moore (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Dr. Rey
Dr. Smith
Dr. Triulzi
Dr. Zuck

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* May 9, 2002

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo #014: RTS Modifications: Previous Transfusion History and Administrative Recipient Contact Information Report

Modifications have been made to the Previous Transfusion History section and the Administrative Recipient Contact Information Report of the Recipient Tracking System (RTS) to ensure that accurate information is being recorded and the system is operating efficiently.

Previous Transfusion History

Prior to the system's modifications, the information in the Previous Transfusion History could be changed at any time during the study. The modification has restricted changes to the Previous Transfusion History based on multiple admissions. If a recipient has a single admission, the recipient information in the Previous Transfusion History may be updated to correct the data at any time during the study. Since the data in the Previous Transfusion History, reflects transfusions prior to enrollment in RADAR, it is not necessary to return to the transfusion history for recipients with multiple admissions. Therefore, in cases where recipients have more than one admission this section will be locked. Centers will not be able to change the recipient information in the Previous Transfusion History for recipients with multiple admissions.

Administrative Recipient Contact Information Report

Additional RTS system modifications have been made to enable centers to efficiently generate Administrative Recipient Contact Information Reports. If the centers want to generate a Recipient Contact Information Report for an individual recipient, this can be completed by entering the requested Recipient ID and highlighting the type of information desired for the reports. The system is modified to only print the information of the recipient requested. Please note that another modification will be implemented in the near future to enable centers to generate Recipient Contact Information Reports for more than one recipient at the same time, using the consent date range. Thus, a report including recipient contact information of all recipients consented within a specified time period would be printed.

If you have any further questions regarding these modifications, please contact Sheba Hakiza by e-mail at shebahakiza@westat.com or by phone at (301) 610-4865.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (3)
Dr. Luban
Ms. Moore (7)
Dr. Murphy
Dr. Nass (10)

Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (10)
Dr. Higgins
Ms. Hutching (12)
Dr. Kleinman
Dr. LeParc
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Mr. Rey (4)
Dr. Smith
Dr. Triulzi
Dr. Zuck

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: List* May 9, 2002

FROM: RADAR Medical Coordinating Center

SUBJECT: RADAR Field Memo #015: 6-Month Follow-up Recipient Information Recording

The purpose of this field memo is to clarify that 6-month follow-up information obtained about recipients who actively refuse to participate or who are Lost To Follow-up (LTF: Too Ill, Passive Refusal, Deceased, Moved, and Not Locatable) should only be entered in the comments box of the Six-Month Follow-up section of the RTS. The date when a recipient passively or actively refuses to complete their 6-month follow-up visit, or the date at which centers learned that a recipient was "Deceased", "Too Ill", "Not Locatable", or had "Moved" should not be recorded as the "Visit Date". In Summary, the "Visit Date" entry should only include the date a recipient completes their 6-month follow-up visit.

If you have any further questions regarding this issue, please contact Sheba Hakiza by e-mail at shebahakiza@westat.com or by phone at (301) 610-4865.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (2)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (7)
Dr. Higgins
Ms. Hutching (10)
Dr. Kleinman
Dr. LeParc (4)
Dr. Luban
Ms. Moore (7)
Dr. Murphy (4)
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Dr. Rey
Dr. Smith
Dr. Triulzi
Dr. Zuck

WESTAT
An Employee-Owned Research Corporation

MEMORANDUM

TO: List* June 13, 2002

FROM: Sheba Hakiza

SUBJECT: RADAR Field Memo #16: New Linking Report "Donation Blood IDs in RTS but no in SIS"

As explained in RADAR Field Memo #6, the linking reports are used for resolving problems matching a recipient's transfused unit's WBN with the corresponding donor WBN in the SIS and/or donation data. The new linking report will be used to identify discrepancies found in the RTS and SIS. If donor WBN in the RTS does not match donor WBN in the SIS, the recipient ID and Blood ID will appear on the new report.

If you have any further questions regarding this issue, please contact Sheba Hakiza by e-mail at shebahakiza@westat.com or by phone at (301) 610-4865.

*List
Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (3)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (10)
Dr. Higgins
Ms. Hutching (12)
Dr. Kleinman
Dr. LeParc
Dr. Luban
Ms. Moore (7)
Dr. Murphy
Dr. Nass (10)
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Mr. Rey (4)
Dr. Smith
Dr. Triulzi
Dr. Zuck

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: *List

July 10, 2002

FROM: RADAR Medical Coordinating Center

SUBJECT: Field Memo # 17: New RADAR Study Protocol

Over the past few months the RADAR Protocol and Operations Manual have been reviewed for consistency and accuracy. Based on the discussions during the March Steering Committee Meeting, it was agreed that since the documents serve different purposes, operational details found in the Manual should not be presented in the Protocol. Similarly, the scientific rationale and background information of the repository in the Protocol should be excluded from the Manual.

As a result of the committee's discussions, several points of interest required clarification. They have been incorporated into the revised RADAR Protocol. Please refer to the list below, which details significant changes that have been made.

Section 7: Recipient Enrollment

1. Eligible Subjects – Clarification of inclusion and exclusion criteria
2. Informed Consent – Collection of multiple transfusion event interim data
3. Sample Collection – Descriptions of pre-transfusion and post-transfusion samples
4. Multiple Transfusion Events
   a. New section added
   b. Recipient consent form updated
5. 6-Month Follow-up
   a. Removed "6-Month" title and re-named "follow-up visit
   b. Follow-up may continue after 12 months

The revised RADAR Protocol is included with this memo. If you have any further questions regarding this issue, please contact Sheba Hakiza by e-mail at shebahakiza@westat.com or by phone at (301) 610-4865.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (3)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (10)
Dr. Higgins
Dr. Luban
Ms. Moore (7)
Dr. Murphy
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Mr. Rey (4)

Ms. Hutching (12)
Dr. Kleinman
Dr. LeParc
Dr. Smith
Dr. Triulzi
Dr. Zuck

WESTAT

An Employee-Owned Research Corporation

MEMORANDUM

TO: *List July 15, 2002

FROM: RADAR Medical Coordinating Center

SUBJECT: Field Memo # 18: Revised RADAR Operations Manual Chapter 9

For more rapid inventory and easier access to specific sample types, the shipping chapter of the RADAR Operations Manual has been revised and updated to reflect modifications in the procedure for shipments of RADAR donor repository samples. This field memo is to familiarize you with some of the changes found in section 9.4 that are more fully delineated in this document.

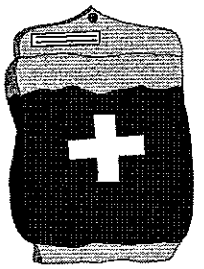
- Donor repository samples will now be separated into two types:
  1) donations that are linked to a RADAR Recipient designated as linked donors or "LD" and
  2) donations that have not been transfused into a recipient but are being sampled to be placed into a contemporary donor repository and are designated by "UD" for unlinked donor.
- Two lists will be sent to the centers every six months and will be color-coded to allow for an easier visual separation of the types.
- This process will be implemented in July 2002 beginning with Donor Shipping Wave 5.

The revised RADAR Operations Manual Chapter 9 is included with this memo. If you have any further questions regarding this issue, please contact either Debbie Todd by e-mail at deborahtodd@westat.com or phone at (301) 738-8315 or Kasia Wachowicz by e-mail at kasiawachowicz@westat.com or by phone at 240-314-2322.

*

Dr. Busch
Ms. Campbell (5)
Dr. Chamberland
Ms. D'Andrea (3)
Dr. Garratty
Dr. Gilcher
Ms. Guiltinan (10)
Dr. Higgins
Ms. Hutching (12)
Dr. Kleinman
Dr. LeParc
Dr. Luban
Ms. Moore (7)
Dr. Murphy
Dr. Nass (6)
Dr. Nemo
Dr. Operskalski
Dr. Ownby
Mr. Rey (4)
Dr. Smith
Dr. Triulzi
Dr. Zuck

DONOR ENROLLEMENT CHAPTER 2



2. DONOR ENROLLMENT AND BLOOD PRODUCT MANAGEMENT

2.1 Target Number of Blood Units and Donors

The number of patients (recipients) eligible to receive RADAR designated units at the hospital actually drives the number of donors that the blood centers need to enroll in the RADAR Repository. The RADAR Repository protocol calls for enrolling approximately 30 transfusion patients (recipients) per month and it is assumed that each eligible patient will require an average of four blood units per transfusion per operation. Historically, blood centers have anticipated needing to collect 5-10 times the number of donation units relative to the number of eligible recipients at the hospitals in order to provide the hospitals with both an adequate volume of blood and an adequate distribution of ABO/Rh types for recipients. Based on these assumptions, each blood center should initially plan to collect approximately 800-1200 units of blood on a monthly basis from consenting donors to supply the hospital's needs for the RADAR Repository. Once the study is operational, the blood centers should adjust the number of RADAR blood units collected based upon the actual needs of the hospital.

2.2 Selection of Participating Blood Mobiles

Blood centers should schedule weekly collections for the RADAR Repository with the following three goals in mind:

1. To meet the needs of the transfusion and clinical services at the hospital(s) participating in the RADAR Repository;

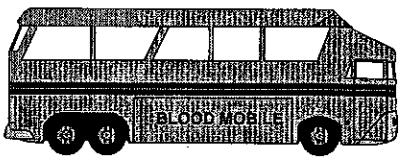
2. To meet the RADAR Repository donor enrollment targets set for each blood center, discussed above in Section 2.1; and

3. To ensure that RADAR Repository specimen collection is relatively randomized throughout the study in order to minimize bias towards any particular ethnic, age, or donor group.

For these reasons, the majority of blood centers have chosen to use mobile collection sites. The MCC will not specify the blood center mobile sites (or fixed sites) from which to recruit donors and collect RADAR Repository specimens. Instead, it is each blood center's responsibility to select sites that will best represent their overall donor population over the course of the study. To achieve this, one

particular mobile may be routinely designated for the RADAR Repository if it collects from different geographically and demographically diverse catchment areas. Alternatively, different mobile units and/or fixed sites may need to be designated weekly for the RADAR Repository in order to collect a representative sample of that blood center's donor population. Throughout this manual, the MCC will refer to operations on "mobile" sites, although fixed sites should follow similar procedures. Again, each blood center may choose which method will best meet this goal. The MCC will routinely compare demographic and other donation data of RADAR Repository donors with the overall monthly donation data collected on donors for REDS to ensure that this goal is being met.

2.3 Blood Mobile Study Supplies



Blood centers are responsible for supplying their RADAR-designated mobile(s) with the items listed in this section. Blood centers should not try to estimate on a given day how many of the donors presenting to make a donation may decide to enroll in the RADAR Repository. Instead, blood centers should anticipate enrolling 100% of all donors presenting to the site and ensure that the designated mobile is amply supplied. Procedures for using each of the supplies listed in Box 2A below are detailed further in the sections indicated.

Box 2A
RADAR donor recruitment supplies

For each donor to be recruited for the RADAR Repository, the following supplies are needed:

- ✓ Two informed consent documents - one form to be signed by the donor for the blood center to retain and one copy for the consenting donor to keep for his/her records (see Section 2.5).
- ✓ One (1) 7 or 10-ml (preferred) lavender-top (EDTA) vacutainer tube – *only for blood centers collecting an extra tube of blood for the RADAR Repository* (see Section 2.6).
- ✓ Three extra whole blood number/blood unit ID (WBN) bar code labels to be placed on each of the two signed informed consent documents and on the extra tube of blood if drawn (see Section 2.6).
- ✓ One brightly colored "tag" to the flag blood unit as originating from a consenting RADAR donor (see Section 2.7).

2.4 Eligible Donors

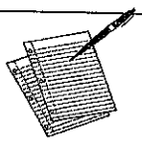
All potential donors making an allogeneic whole blood donation (and possibly including platelet pheresis donors in the future) at the designated RADAR Repository mobile collection site should be considered eligible for the RADAR Repository if they are 18 years of age or older. Donors under 18 years of age, and donors making a directed or autologous donation should ***not*** be asked to participate in the RADAR Repository at the time of their donation. Repository samples collected from eligible donors consenting to be in the study should remain in the repository for long-term storage, regardless of whether (1) the actual donation unit is later found to be reactive or positive; or (2) the donor utilizes a confidential unit exclusion method after donating. Either circumstance would dictate the destruction of the unit, however, the repository sample should be saved. Any donor who enrolls but for whatever reason does not have a sample available for storage in the repository is not eligible. The blood center is responsible for taking appropriate measures to inform the donor of their ineligibility and as necessary, inform the MCC of any de-enrollment (see Chapter 7).

2.5 Obtaining Donor Informed Consent

Each blood center must have a signed IRB-approved informed consent on file for every donor participating in the RADAR Repository. A template of an approved donor consent form can be found in Exhibit A. A separate informed consent must be completed for each donor's RADAR donation (i.e., each time the donor donates over the three year study period), regardless of whether or not a donor has previously consented to be in the RADAR Repository study, as directed in Box 2B below.

Box 2B

Enrolling a donor in the RADAR Repository



The following steps should be followed when enrolling donors for the RADAR Repository:

1. Invite each sequential eligible donor presenting to the mobile to participate in the study. Give him/her an informed consent at the time he/she is screened for eligibility and the blood donor registration form (DRF) is signed.

2. Give each donor enough time to read, ask questions about, and sign the informed consent.

3. Ensure that each donor willing to participate prints his/her name on the form, signs the form, and dates it with the correct date.

4. Arrange for a witness to sign the informed consent just under the study participant's signature.

5. Place a bar code WBN label corresponding to the donor's blood unit on the signed informed consent on the first page, upper right-hand corner.

6. Place a WBN label on the donor's copy of the informed consent, and give the form to each consenting donor to retain for his/her records.

7. Forward all signed and labeled informed consents collected on the mobile to the blood center at the end of the day for reconciliation with the donation specimens to be processed and utilized for the repository.

2.6 Collection of Donor Repository Sample Specimen

There are three sources from which a donor blood specimen may be obtained for the RADAR Repository, i.e. depending upon the individual blood center's logistics:

1. Drawing a separate 7 or 10-ml (preferred) lavender top (EDTA) whole blood tube at the time of donation only from consenting donors;

2. Accessing the serology retention tube after it is released from quarantine so that current limits on the total amount of blood drawn are not exceeded; or

3. Utilizing the residual nucleic acid testing (NAT) tube to obtain the repository specimen.

From the time of collection to the time of processing, all blood specimens should be stored and transported at room temperature. For blood centers obtaining the donor sample specimen from a separate 7 or 10-ml (preferred) lavender top (EDTA) vacutainer tube, this sample should be drawn after the donation unit of whole blood has been collected, and after the tubes required for routine testing by the blood center are collected. This tube should be labeled with the same WBN barcode-readable label as assigned to the donor's blood unit and set aside in a separate rack designated for RADAR specimens only. This rack must be delivered to the blood center RADAR laboratory by the end of each day.

2.7 Tagging Donor Blood Units

The blood centers are responsible for supplying the mobiles with an easily distinguishable and unique label that can be placed on the blood collection bags to identify or "tag" those units designated for the RADAR Repository inventory. Ultimately, blood centers must ensure that the only units identified with the unique RADAR tags are from donors who consented to participate in the study. An additional consideration when developing tagging procedures is any future leukodepletion requirements which would decrease the probability that donor blood would be delivered to the participating hospital in the actual donation bag.

2.8 Entering Donor Informed Consents into the SIS at the Blood Center

A reconciliation step will occur at each blood center laboratory. This step will ensure that all specimens designated for the RADAR Repository have a corresponding signed informed consent. Instructions for entering donor informed consents into the Sample Inventory System (SIS) are described in Box 2C. (Instructions on using the SIS can be found at the end of this manual.)

Box 2C

☛ Entering donor informed consents into the SIS

1. First, manually count the number of signed informed consents to be entered into the SIS and record this number. This step is important for later reconciliation with the number of forms actually entered into the system.

2. Wand all WBN bar code labels on the consent documents into the SIS. Regardless of whether some or all specimen tubes are available at that time, *it is essential to wand in the informed consents before wanding in the actual specimen tubes.*

3. Generate a SIS printout listing all WBNs wanded in that day from consenting donors. Ensure that the number of forms entered into the SIS matches the number of forms manually counted.

4. Resolve any discrepancies before proceeding further with sample retrieval or processing (see Chapter 8). The SIS will only accept repository specimen tubes from donors with an informed consent already recorded in the system.

2.9 Processing of Donor Repository Sample Specimen

After reconciling each donor's consent with specimens, a laboratory technician at the REDS blood center will prepare frozen whole blood and plasma samples for the repository within 48 hours of unit collection. At specified intervals, processed samples will be shipped from each REDS center to a centralized repository facility for long-term storage. Red blood cell units (and, when possible other blood components) from these targeted donors will be maintained in a separate inventory and shipped to the participating hospitals. Detailed instructions for sample processing and shipping samples to the central repository facility are described in detail in Chapters 8 and 9, respectively.

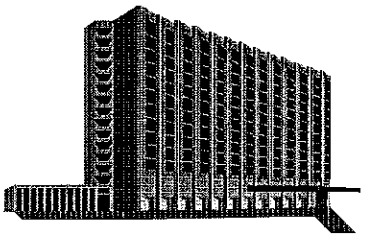
2.10 Donor Blood Product Management

Each blood center will be responsible for supplying collaborating hospitals with the necessary blood units to meet the needs of the Transfusion Services. The blood centers should maintain a separate inventory of tagged RADAR Repository blood units during routine blood center quarantine and process this blood in accordance with blood center Standard Operating Procedures. Orders to participating

hospitals should be filled with these specially tagged RADAR components and be supplemented, as needed, from general stock.

HOSPITAL TRANSFUSION SERVICES CHAPTER 3

3. HOSPITAL TRANSFUSION SERVICE



3.1 Introduction

Active involvement by each of the participating hospitals' Transfusion Services is integral to the accurate dispensation and inventory management of the tagged RADAR Repository components. It is the responsibility of the blood centers to ensure that the goals and requirements of the RADAR Repository are familiar to the appropriate hospital personnel, and that procedures are well established within participating hospitals to monitor the utilization of RADAR Repository blood units.

A cooperative effort of the hospital and blood center staff is necessary to meet the objectives of the hospital's involvement in the RADAR Repository. A RADAR study recruiter will work at each of the collaborating hospitals and in parallel with the Transfusion Service to monitor the use of the RADAR Repository blood units. As directed by the nurse managers on the ward, the study recruiter will contact post-surgical patients at an appropriate time for study enrollment, usually two to three days post-operative. This movement of the RADAR study recruiter within the hospital necessitates the need for familiarity between the recruiter and hospital personnel working in multiple departments.

At each hospital, the Transfusion Service is responsible for: (1) maintaining the inventory and utilizing; RADAR Repository blood units; (2) providing a source for the pre-transfusion recipients' samples; and (3) providing the study recruiter access to the Transfusion Service computer system. This chapter outlines each of the tasks for which the Transfusion Services are responsible.

3.2 Maintaining the Physical Inventory of RADAR Repository Blood Units

The transfusion service at each hospital will maintain an account of the units transfused to the enrolled recipients, units that were transfused to eligible but non-enrollable recipients, and units with other dispositions. The incoming components from the blood center will be clearly tagged as designated for the RADAR Repository. Blood units entered into the Transfusion Service computer will need to be flagged in the system as a RADAR study unit. Depending on the capabilities of the hospital computer

interface, either a unique blood product code may be developed, a "comment" field may be utilized, or a prefix or suffix may be added to the WBN, for example.

When the Transfusion Service checks the surgery schedule on a daily basis, it should direct RADAR units for cardiac, vascular, and orthopedic surgical procedures. Units leaving the transfusion department should be logged out of the computer inventory according to hospital standard operating procedures (SOPs). Box 3A summarizes each step that the Transfusion Service must follow to accurately inventory available RADAR units and direct these units to the appropriate patients at the hospital.

Box 3A

☛ Utilization and Dispensation of RADAR Repository blood units by the hospital Transfusion Service

1. Inventory incoming components from the blood center and separate tagged RADAR Repository units from other units.
2. Enter the WBNs of RADAR units into the Transfusion Service computer and ensure that the units are identified as such in the system according to the method in place at the hospital.
3. Process RADAR units according to Transfusion Service SOPs.
4. If possible, physically segregate tagged RADAR Repository units in refrigerator.
5. Check the surgery schedule daily to identify cardiac, vascular and/or orthopedic patients.
6. Select RADAR units for these patients (supplementing with units from general inventory as necessary).
7. Record outgoing RADAR Repository WBNs in the Transfusion Service computer.
8. Provide study recruiter access to the Transfusion Service computer system to monitor the use of tagged RADAR Repository blood units.
9. Return any RADAR Repository tagged components nearing outdate to general inventory.

3.3 Obtaining the Pre-transfusion Blood Sample from Surgical Patients

The Transfusion Service routinely secures a pre-transfusion blood sample from all patients scheduled for surgery. Based on the specifications of the participating hospital's admissions consent form and other policies, the following three options are available to obtain the required pre-transfusion blood sample for cardiac, vascular, and/or orthopedic surgery patients. They include utilizing the cardiac perfusionist, a sample obtained during pre-admission work-up, or the type and crossmatch sample. Standing orders may be given for the cardiac perfusionist to obtain a separate whole blood tube from all eligible patients during their pre-admission workup. A portion of the type and cross-match specimen obtained from each patient from the participating clinical service may be saved and used as the pre-transfusion repository sample. Utilization of the residual sera from the type and crossmatch tubes requires a minimum of 1.0-ml serum or plasma.

Each blood center should make arrangements with their collaborating hospital to have the Transfusion Service obtain the pre-transfusion blood sample by the best method available at that hospital. A summary describing the steps involved for collecting the pre-transfusion blood sample via each of the three methods is described below, in Boxes 3B through 3D.

Box 3B

☛ Method 1: Hospitals utilizing the cardiac perfusionist

1. Standing orders should be given for all cardiac, vascular and/or orthopedic surgery patients to have a pre-transfusion blood sample drawn on the day of surgery.
2. Obtain the blood sample as the patient is readied for surgery.
3. Use one (1) 7-ml or 10-ml (preferred) lavender top (EDTA) vacutainer tube.
4. Label the tube with the patient's name, medical record number, and date of draw.
5. Collect the blood sample according to SOPs.
6. Return the blood sample to the Transfusion Service for storage at room temperature in a specially designated RADAR Repository rack.

Box 3C

☛ Method 2: Hospitals obtaining the pre-transfusion sample during the pre-admission workup

1. Standing orders should be given for all cardiac, vascular and/or orthopedic surgery patients to have a pre-transfusion blood sample obtained during the patient's pre-admission work-up.
2. Use one (1) 7-ml or 10-ml (preferred) lavender top (EDTA) vacutainer tube.
3. Label the tube with the patient's name, medical record number, and date of draw.
4. Collect the blood sample according to standard phlebotomy procedures.
5. Return the blood sample to the Transfusion Service for storage at room temperature in a specially designated RADAR Repository rack.

Box 3D

☛ Method 3: Hospitals utilizing the type and crossmatch specimen

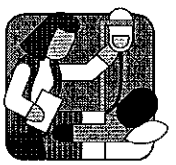
1. Store the residual type and crossmatch specimen routinely collected from each patient designated to undergo cardiac, vascular or orthopedic surgery at 4°C in the Transfusion Service according to hospital SOPs.

3.4 Sending Pre-Transfusion Sample Specimens to the Blood Center for Processing

The study recruiter is responsible for retrieving, and in most cases, re-labeling the pre-transfusion blood samples with the appropriate Recipient Study ID label described in the next chapter. All pre-transfusion samples must be transported from the hospital to the blood center for processing and freezing within one week of collection. In the event, that the pre-transfusion sample is not sent to the blood center within the specified one-week time period, the sample should be discarded. Pre-transfusion blood samples obtained from patients who do not consent to the study will also be discarded. Chapter 4 provides full details on the retrieval of specimens from the Transfusion Service and shipment to the blood center for processing.

RECIPIENT ENROLLMENT CHAPTER 4

4. RECIPIENT ENROLLMENT



4.1 Recipient Eligibility and Enrollment Criteria

To meet the goals of the RADAR Repository protocol, each blood center should try to enroll approximately 30 transfusion recipients per month at each participating hospital. Eligible recipients should be between the ages of 18 and 85; be from patient groups with a high anticipated rate of 6-month post-surgical survival; a high rate of allogeneic blood use; and have competent immune systems such that their antibody responses to infectious agents would be anticipated to occur normally. The primary groups that best fit these parameters are surgical and non-surgical cardiac patients, vascular patients, and/or orthopedic surgery patients. Additionally, these surgery patients should have received at least one RADAR repository designated blood product during their transfusion, and be able to provide a blood sample for enrollment in the study.

Patients younger than 18 years of age, older than 85 years of age, and patients with a language barrier will not be enrolled. Patients who reside in states or foreign countries that are long distances from the location at which the surgery occurs will be excluded due to unavailability for an in-person follow-up visit. Patients who are undergoing an organ transplant, or who are immediately post-transplant as indicated by their medical diagnosis, are ineligible for enrollment due to the likelihood of significant immunosuppression. Dialysis patients are also ineligible due to confounding effects of possible of exposure to an emerging infectious agent in the dialysis unit.

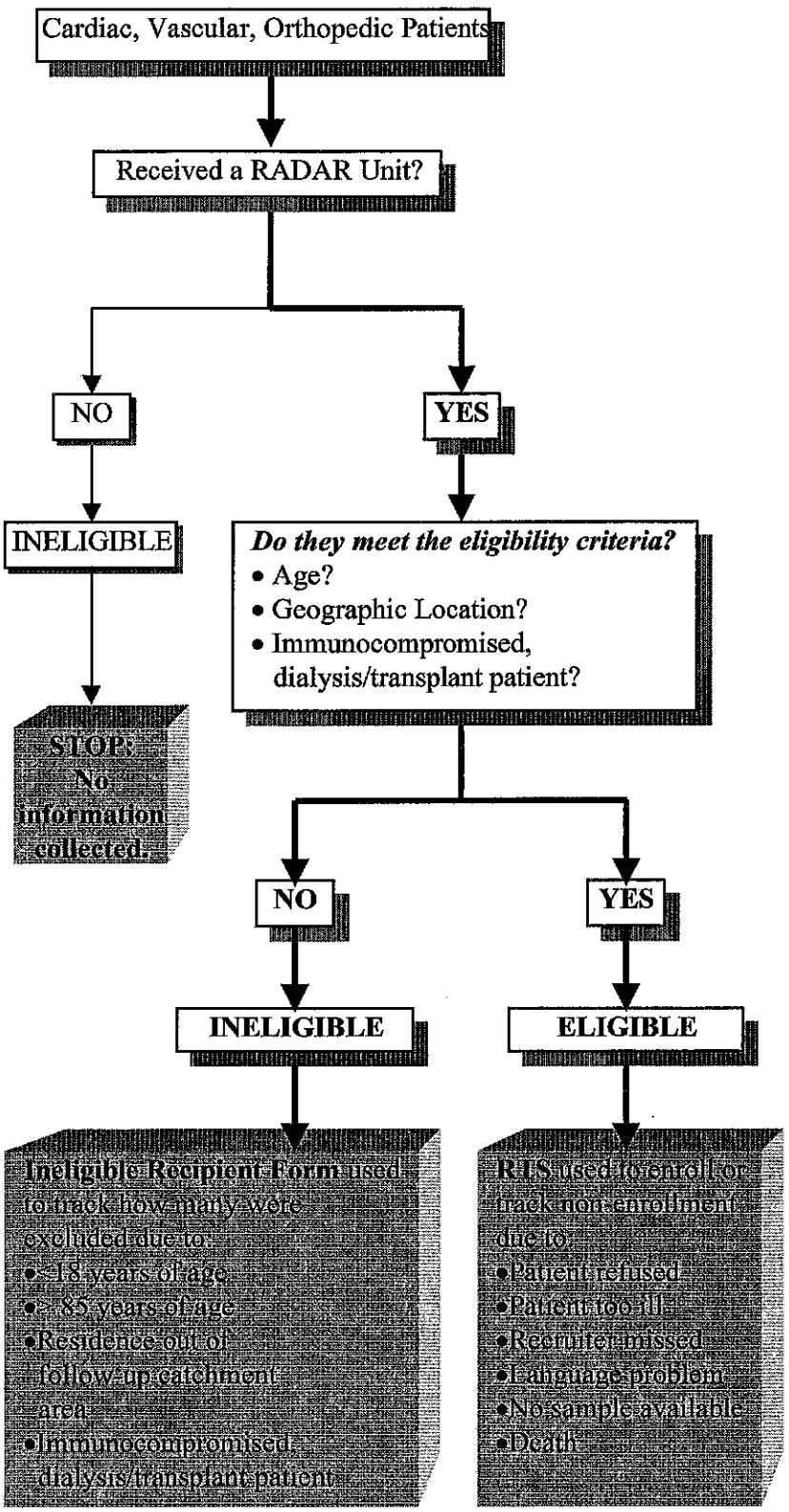
The study does not routinely obtain information about a history of injection drug use or HIV infection from prospective enrollees; therefore, in order to avoid enrollment bias, individuals who voluntarily provide these histories will not be excluded from the study. At the time of enrollment, prospective enrollees will be asked about their history of allogeneic blood transfusion in the prior six months but will not be excluded from the study due to a prior transfusion history.

4.2 Tracking of Recipients who Receive RADAR Repository Designated Units

Figure 3, the RADAR recipient tracking flowchart, provides a visual representation on how to determine whether a recipient is eligible, and indicates how to track all eligible recipients. As indicated, the RTS will track all eligible recipients who refuse to enroll or who are not enrolled because they are too ill, the recruiter missed enrolling him/her, no sample was available for storage in the repository, there was a language barrier, or the recipient died before the recruiter was able to enroll him/her.

The RADAR Monthly Report for Ineligible Recipients on the other hand (see Exhibit B) will track cardiac, vascular, and/or orthopedic patients who received a RADAR designated unit, however, do not meet the criteria regarding age and geographic location of residence, or are known to have immunocompromising conditions. According to the instructions, the report should be completed and faxed to the MCC on the 5th of each month, or the first business day thereafter.

Figure 3. RADAR Recipient Tracking Flowchart



4.3 Supplies Needed for Recruiting Recipients

Box 4A lists supplies that each study recruiter will need at the hospital in order to recruit eligible recipients of RADAR units. Use of all supplies is discussed in detail later in this chapter.

Box 4A
RADAR recruitment supplies

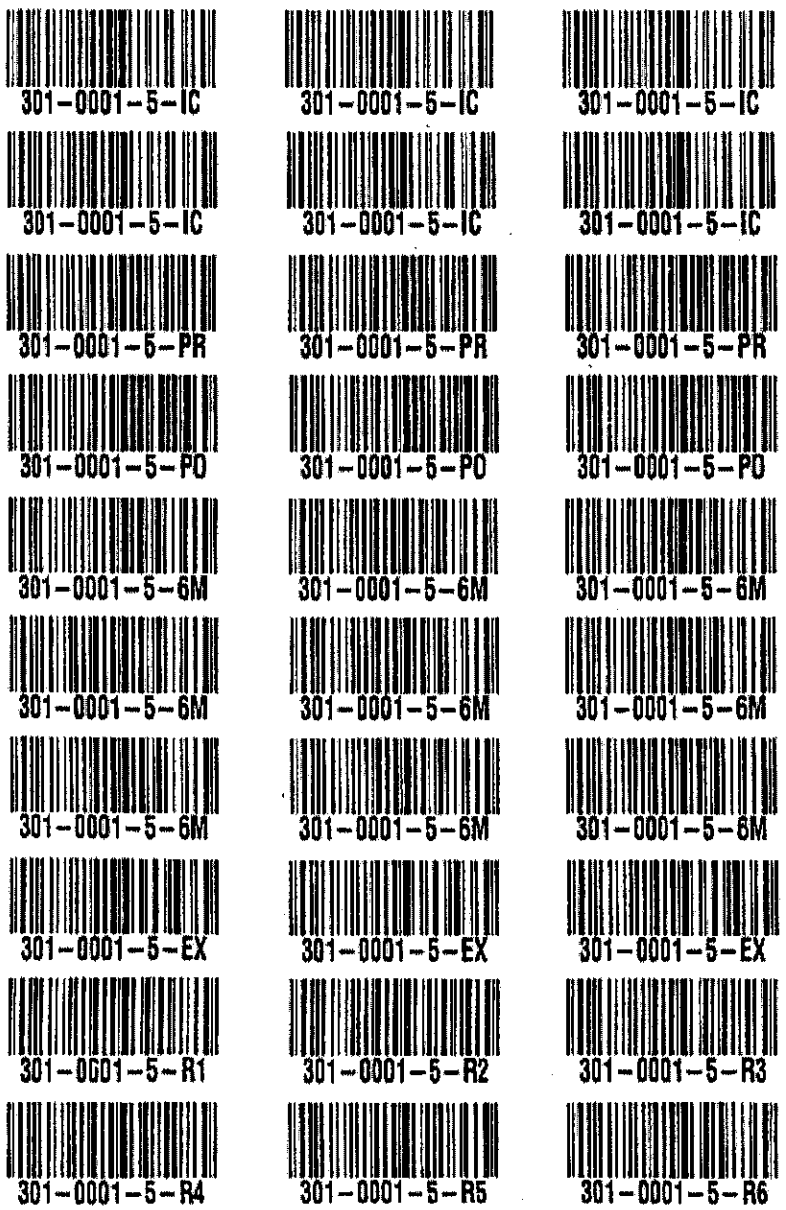
- ✓ Patient Log Forms- template provided by the MCC. See Exhibit C.
- ✓ Recipient Consent Forms- use the blood center IRB-approved form. See Exhibit D.
- ✓ Recipient Study ID labels- provided by the MCC. See Figure 4.
- ✓ Recipient Brochures- provided by the MCC. See Exhibit E.
- ✓ Phlebotomy Supplies- provided by blood center/ hospital.
- ✓ Laptop Computer with Recipient Tracking System- provided by the MCC.
- ✓ Race/Ethnicity Card- provided by the MCC. See Exhibit F.

4.4 Recipient Study Identification Labels

4.4.1 Consenting Recipient Study Identification Labels

The MCC will provide Recipient (patient) Study Identification labels to the blood centers for use by the study recruiters and Transfusion Service personnel. As seen in Figure 4, each label is printed with a bar code and eye-readable ID so that enrolled recipients can easily be accessed and tracked using the RTS and SIS. One sheet of Recipient Study ID labels should be utilized for each enrolled recipient over the course of the study. Enough labels are provided for the recipient's informed consents, pre-transfusion blood sample, post-transfusion/enrollment blood sample (if necessary), the follow-up blood samples, and questionnaire. Additional labels are provided for blood samples that may be drawn for future research purposes.

Figure 4. Recipient Study ID labels



Each blood center must keep track of these sets of labels assigned to each recipient at the time of enrollment. A separate folder may be compiled for each enrolled recipient to hold the assigned set of Recipient Study ID labels, the consent form, and additional study materials such as the Provider Roster (see Chapter 5). These Recipient Study ID labels are essential for the proper accessioning of all study materials into the two computerized tracking systems and must not be lost or mis-assigned to another recipient.

The format for the Recipient Study Identification labels is "AAB-CCCC-D-EE", where:

AAB = Blood Center/Hospital format

AA = Blood Center	10 = ARC – Chesapeake 20 = ARC – Southeastern Michigan 30 = ARC – Southern California 40 = Blood Centers of the Pacific 50 = Oklahoma Blood Institute 60 = Institute for Transfusion Medicine 70 = Florida Blood Services
B = Hospital	1 = Johns Hopkins University Hospital 1 = St. John Hospital 1 = Good Samaritan Hospital 2 = Little Company of Mary Hospital 1 = UCSF Medical Center 1 = Integris Baptist Medical Center 1 = Allegheny General Hospital 1 = St. Joseph's Hospital 2 = University Community Hospital
CCCC = Sequential identification number	0001 – 9999
D = Check digit	0 – 9
EE = Label type	IC = informed consent PR = pre-transfusion blood sample PO = post-transfusion/enrollment blood sample 6M = follow-up visit R1 = research blood sample 1 R2 = research blood sample 2 R3 = research blood sample 3 R4 = research blood sample 4 R5 = research blood sample 5 R6 = research blood sample 6

Examples of Recipient Study ID Labels

201-0054-5-PR indicates that the blood sample was:

- Collected by ARC-Southeastern Michigan at St. John Hospital;
- Recipient identification (ID) number 0054;
- Check digit 5; and
- Pre-transfusion blood sample

302-0125-2-IC indicates that the informed consent was:

- Collected by ARC Southern California at Little Company of Mary Hospital;
- Recipient identification (ID) number 0125;
- Check-digit 2; and
- Informed consent.

4.4.2 Non-Consenting Recipient Study Identification Labels

In addition to the Recipient Study ID labels described in Section 4.4.1, the MCC will provide labels to be used for all eligible recipients who do not enroll in the RADAR Repository because he/she refuses to participate, is too ill, the recruiter missed enrolling, no sample was available for storage in the repository, there was a language barrier, or the recipient died before the recruiter was able to enroll him/her. These labels will have the suffix -NC and allow all RADAR units transfused to eligible recipients to be tracked (counted) whether or not the recipient enrolls in the study. Recipients assigned this type of label should be recorded in the RTS as described in Box 4H.

4.5 Study Recruiter Enrollment Preparatory Work

4.5.1 Identifying Eligible Recipients

Before approaching recipients to enroll in the study, several preparatory steps must be completed by the study recruiter. The study recruiter should identify cardiac, vascular and/or orthopedic surgical patients, investigate the distribution of RADAR units to these patients using the Transfusion Service computer, and perform a medical chart review to verify the use of the RADAR unit(s), as well as review other eligibility criteria. On a daily basis, the study recruiter should check the surgery schedule to identify patients scheduled for cardiac, vascular and/or orthopedic surgery and record these patients'

names and medical identification numbers on the Patient Log Form (see Exhibit C). Using the Transfusion Service computer, the study recruiter should investigate the utilization of RADAR Repository units and thus identify patients eligible for RADAR Repository enrollment. Box 4B describes these preparatory steps in more detail.

Box 4B

☛ Patient Log Form: Identifying recipients eligible for enrollment

Each day the study recruiter should:

1. Review the surgery schedule to identify persons scheduled for cardiac, vascular or orthopedic surgery.

2. Begin a new RADAR Patient Log Form listing each identified cardiac, vascular or orthopedic surgical patient.

For each patient listed on the Patient Log Form:

3. Record the name of the patient and the medical record identification number on the Patient Log Form.

4. Using the Transfusion Service computer to look up each of the patients, document in the appropriate column on the Patient Log Form the WBNs of all units checked out of the Transfusion Service for a particular patient.

5. Investigate which of the WBNs listed on the Patient Log Form were RADAR units. A Transfusion Service flagging method (e.g., the product code, the prefix or suffix code, or the comment field) should indicate in the Transfusion Service computer which of the units reserved for the patient were RADAR units.

6. Place a ✓ mark next to each RADAR designated WBN.

7. Using the hospital laptop, computer conduct a recipient search in the RTS to find out if the recipient was previously enrolled in the study. The search can be conducted by entering the patient's name and birthdate or social security number.

8. If the patient is presently enrolled in RADAR, see instructions in 4.9.

9. If the patient is not presently enrolled in the study, continue following the study enrollment SOPs.

4.5.2 Verification that RADAR units were transfused

Prior to approaching a patient for enrollment, the study recruiter must verify that a transfusion using RADAR units actually took place for each patient listed on the Patient Log Form. Depending on the capabilities of the hospital, this may be done using the Transfusion Service computer, but most likely will require a review of the patient's medical chart. Review of the medical chart (see Box 4C) will also reveal whether or not the patient meets other eligibility criteria.

Box 4C
☛ Medical chart review

1. For patients listed on the Patient Log Form as having received RADAR units, confirm that the surgery and transfusion took place by reviewing each patient's hospital chart. Look for the WBN label placed onto the perfusion report that corresponds to the blood unit utilized during surgery.

2. Verify that the patient meets other eligibility requirements (see Section 4.1). If so, check the box marked "Eligible" on the Patient Log Form.

4.5.3 Indications for Collecting a Post-Transfusion/Enrollment Phlebotomy

As described in Section 3.3, the Transfusion Service should obtain a pre-transfusion blood sample by the best method available at the hospital. However, a post-transfusion sample should be obtained in any instance where a pre-transfusion sample is not obtained or not available. Before approaching an eligible recipient for enrollment, the study recruiter should confirm that a pre-transfusion blood sample was drawn and/or confirm the availability of a crossmatch specimen for use in the RADAR Repository. Verify the draw date of the located sample and record this date on the Patient Log Form. This date should reveal that the sample is no older than one week at the time enrollment is being attempted. At hospitals utilizing the crossmatch specimen for use in the study, an enrollment sample (post-transfusion sample) may need to be drawn to replace a crossmatch specimen that had to be utilized for additional hospital tests, making the crossmatch specimen unavailable for use in the RADAR study.

4.6 Enrolling Recipients and Obtaining Consent

After verifying the eligibility of all patients listed on the Patient Log Form and checking on the availability of a pre-transfusion sample specimen, the study recruiter should collect the enrollment supplies listed in Box 4D, approach eligible recipients, and invite them to enroll in the RADAR Repository. The study recruiter should attempt to enroll all eligible recipients of RADAR units. Hospitals enrolling patients prior to surgery should follow the same procedures, varying only the timing of when the procedures take place.

Box 4D
☛ Supplies needed for an enrollment visit

Gather the following supplies prior to entering a patient's room to enroll him/her:

- ✓ Three (3) blank recipient consent form documents
- ✓ One (1) new sheet of Recipient Study ID labels (each recipient should receive a unique set)
- ✓ Roll of non-consenting labels
- ✓ Patient Log Form on which the patient is listed
- ✓ Laptop computer with RTS
- ✓ One (1) 7-ml or 10-ml (preferred) lavender top (EDTA) vacutainer tube and routine phlebotomy supplies (if needed as described in Section 4.5.3)
- ✓ Recipient Information Brochure

For every recipient consenting to participate in the RADAR Repository, each blood center must have a signed IRB-approved informed consent on file. A template of the ARC-IRB approved recipient informed consent can be found in Exhibit D. Procedures for obtaining consent are summarized in Box 4E.

Box 4E

☛ Procedures for enrolling a recipient

1. Approach eligible patients after they transfer out of the intensive care unit, or within two to three days post-operative. Recruiters may seek the opinion of the nurse manager should there be any doubt concerning the patients ability to be approached for study recruitment.

2. Meet the patient face to face to explain the study, invite him/her to participate in the study, and administer the informed consent.

3. Give each patient ample time to read, ask questions about, and sign the informed consent.

A. ***<u>For recipients who agree to be in the study:</u>***

1. Witness the signing of each informed consent.

2. Place the patient's pre-printed consent Recipient Study ID label (suffix IC) in the upper right-hand corner of each consent form. Additionally, place one of these labels with the IC suffix on the Patient Log Form in the "Consent Status" box corresponding to the patient's name.

3. Enter bedside enrollment information into the RTS as directed in Box 4F.

4. If needed (as described in Section 4.5), obtain patient enrollment/post-transfusion blood sample as described in Box 4I on page 4-14.

5. Place one signed informed consent in the patient's hospital chart, retain one signed copy for storage at the blood center (or other designated area), and give one signed copy to the patient for his/her records.

6. Give the patient a RADAR Repository Information Brochure.

B. ***<u>For recipients who do NOT agree to be in the study:</u>***

1. Remove a Non-Consenting Identification label from the roll (suffix -NC) and place it on the Patient Log Form in the "Consent Status" box corresponding to the patient's name.

2. Enter non-consenting patient information into the RTS as directed in Box 4H.

4.6.1 Recording Enrollment Information in the RTS

During the enrollment visit, the study nurse will utilize the RTS to obtain and record all necessary enrollment information from consenting patients. Box 4F lists items that should be entered at the patient's bedside with his/her input. Box 4G lists items to enter after the enrollment visit is completed (not at bedside), and Box 4H lists information to enter in the RTS for non-consenting patients.

Box 4F

Required enrollment information to be entered in the RTS during the visit at the patient's bedside

For recipients who agreed to be in the study, record:

1. Recipient Study ID from the pre-printed label located on the Patient Log Form.
2. Recipient's name, home address, home telephone number, work (or alternate) telephone number, race/ethnicity (use the Race/Ethnicity card as an aid, see Exhibit F), and the date the informed consent was obtained.
3. Supplemental contact information. This should include the names, addresses, and telephone numbers of two individuals, if possible, who would always know the current location of the recipient.
4. Information relative to organizations to which the recipient belongs, if possible (again, for tracking purposes later).
5. Transfusion history in the 6 months prior to study enrollment.
6. Recipient's primary physician's and/or other physician's name, address, and telephone number.

Box 4G

☛ Required enrollment information to be entered in the RTS after the patient enrolls (not at bedside)

Subsequent to the enrollment visit the following information needs to be entered into the RTS by the study recruiter:

1. Date of transfusion.
2. Total number of units transfused, and of those, the number that are RADAR units.
3. WBNs of all RADAR blood units received by the patient on the specified transfusion date.
4. Draw date of the pre-transfusion blood sample, and post-transfusion blood sample (if necessary).
5. Date the pre- and post-transfusion sample(s) was/were shipped to the blood center.
6. Hospital discharge date and additional transfusion event information (if necessary) as described in Section 4.9.

Box 4H

☛ Required information to be entered in the RTS for eligible recipients not enrolled in the study:

For eligible recipients who do NOT enroll in the study, record:

1. Recipient Study ID (-NC suffix).
2. Type of surgery.
3. Date of surgery.
4. Reason patient did not/was not enrolled.

4.6.2 Drawing a Post-Transfusion/Enrollment Sample

In cases where it is necessary to draw a post-transfusion/enrollment sample, as described in Section 4.5.3, follow the instructions in Box 4I subsequent to obtaining consent from the recipient.

Box 4I

☞ Procedures for obtaining a post-transfusion/enrollment blood sample

1. Obtain the blood sample from the enrolled (consenting) recipient at the completion of the enrollment visit.
2. Use one (1) 7-ml or 10-ml (preferred) lavender top (EDTA) vacutainer tube.
3. Label the tube with the patient's pre-printed post-transfusion Recipient Study ID label (suffix -PO).
4. Collect the blood sample according to standard phlebotomy procedures and return to the Transfusion Service for shipment to the blood center.

4.6.3 Recipient Information Brochure

At the conclusion of the enrollment study visit, each enrolled recipient should be given a RADAR information brochure (Exhibit E), along with one of the signed informed consent documents. The information brochure explains the significance of the RADAR Repository, who is eligible to participate, what study participation involves, how the results will be utilized, and provides a phone number for the recipient to call if they have additional questions. While similar information is provided in the consent form, the brochure is meant to be a less formidable document for easy reference after the recipient leaves the hospital. It also reminds recipients to notify the blood center if contact information changes.

4.7 Sending Pre-Transfusion and Post-Transfusion/Enrollment Blood Samples from the Hospital to the Blood Center

4.7.1 Retrieving and Shipping Samples

Once a recipient has been enrolled, the study recruiter is responsible for retrieving, relabeling, and shipping the pre-transfusion blood samples or as the case may be, post-transfusion/enrollment samples, to the blood center from the Transfusion Service as soon as possible. Regardless of the method used to obtain the pre-transfusion samples (see Chapter 3), samples are only viable for RADAR Repository processing up to one week from the time of draw, limiting the flexibility for when the samples must leave the hospital and be processed by the blood center. Any sample older than one week from the date of draw should be discarded.

Pre-transfusion samples collected in a separate lavender top (EDTA) vacutainer tube may be sent to the blood center for processing either before or after patients enroll in the study, depending on the SOPs in place at the individual hospital. The time when pre-transfusion samples are shipped to the blood center (e.g. before or after study enrollment), however, will dictate the steps to be negotiated by the study recruiter for preparing and shipping samples to the blood center. Intuitively, all post-transfusion/enrollment samples will be shipped after patients enroll in the study. One of the following two methods should be adopted by each hospital for retrieving, labeling, and sending blood samples from the Transfusion Service to the blood center. Recipients without a pre-transfusion or post-transfusion sample should be de-enrolled from the study.

Box 4J describes procedures to be followed when RADAR Repository samples are sent to the blood center after recipient enrollment, whereas, Box 4K describes procedures to be followed when RADAR Repository samples are sent to the blood center before recipient enrollment.

Box 4J

☛ Shipment of pre-transfusion and cross-match blood samples to the blood center after recipient enrollment

On a daily basis, the study recruiter should:

1. Retrieve from the Transfusion Service, all pre-transfusion or crossmatch blood samples collected from enrolled recipients listed on the Patient Log Form that can be released according to hospital SOPs.

2. Relabel the tubes with the corresponding pre-printed pre-transfusion Recipient Study ID label (suffix -PR). See Section 4.7.2 (Figure 5) for instructions on applying the label.

3. Additionally, retrieve any corresponding post-transfusion/enrollment samples. These tubes should already be labeled with the corresponding post-transfusion Study ID label (suffix -PO). Skip this step if not applicable.

4. Record on the Patient Log Form when the samples were shipped to the blood center.

5. Make a copy of this particular Patient Log Form.

6. Ship samples to the blood center for processing along with the original Patient Log Form (i.e., the one with original bar code labels on it).

7. Notify the Transfusion Service of which samples from non-consenting recipients may be discarded according to hospital SOPs.

Box 4K

Shipment of pre-transfusion blood samples to the blood center before recipient enrollment

On a daily basis, the study recruiter should:

1. Complete a RADAR Patient Log Form following Steps 1 through 3 as described in Box 4B.
2. Collect all pre-transfusion or cross-match blood samples stored in the Transfusion Service for each patient listed on the RADAR Patient Log Form.
3. Ensure that each sample is labeled with the patient's name, medical record number, and date of draw.
4. Record on the Patient Log Form the date these samples are being shipped to the blood center. No information found on the Patient Log Form should be entered into the RTS until after a recipient enrolls.
5. Make a copy of the Patient Log Form. Ship these pre-transfusion blood samples to the blood center for processing along with a copy of the Patient Log Form, listing all enclosed samples and the date of their shipment.
6. At the end of the day, identify which of the patients on the Patient Log Form received RADAR Repository designated blood units. Record all whole blood numbers on the Patient Log Form, identifying those units designated for RADAR.
7. Continue with enrollment procedures as described in Section 4.6.
8. Upon completing the enrollment procedures, make a copy of the Patient Log Form and deliver the original Form to the blood center. The Patient Log Form should be used by the blood center laboratory to reconcile which recipient samples in the holding area are from consenting recipients (as indicated by the "Consent Status" column).
9. The pre-transfusion tubes held at the blood center will have to be relabeled with the pre-transfusion Recipient Study ID label (suffix -PR) before the tubes from consenting recipients can be accessioned into the repository.

4.7.2 Applying the Study ID Label to the Pre-Transfusion Sample Tube or Specimen

As described above, the study recruiter is responsible for retrieving, shipping, and in some cases, relabeling the pre-transfusion blood samples. When relabeling the pre-transfusion blood tube, hold the tube and label vertically, wrapping the label around the tube so that the printed Recipient Study ID is

to the right of the bar code. Neither the bar code nor the printed identifying information should be covered. See Figure 5 on the following page for a visual representation of tube labeling procedures.

4.8 Closing Out Recipients Using the Hospital RTS

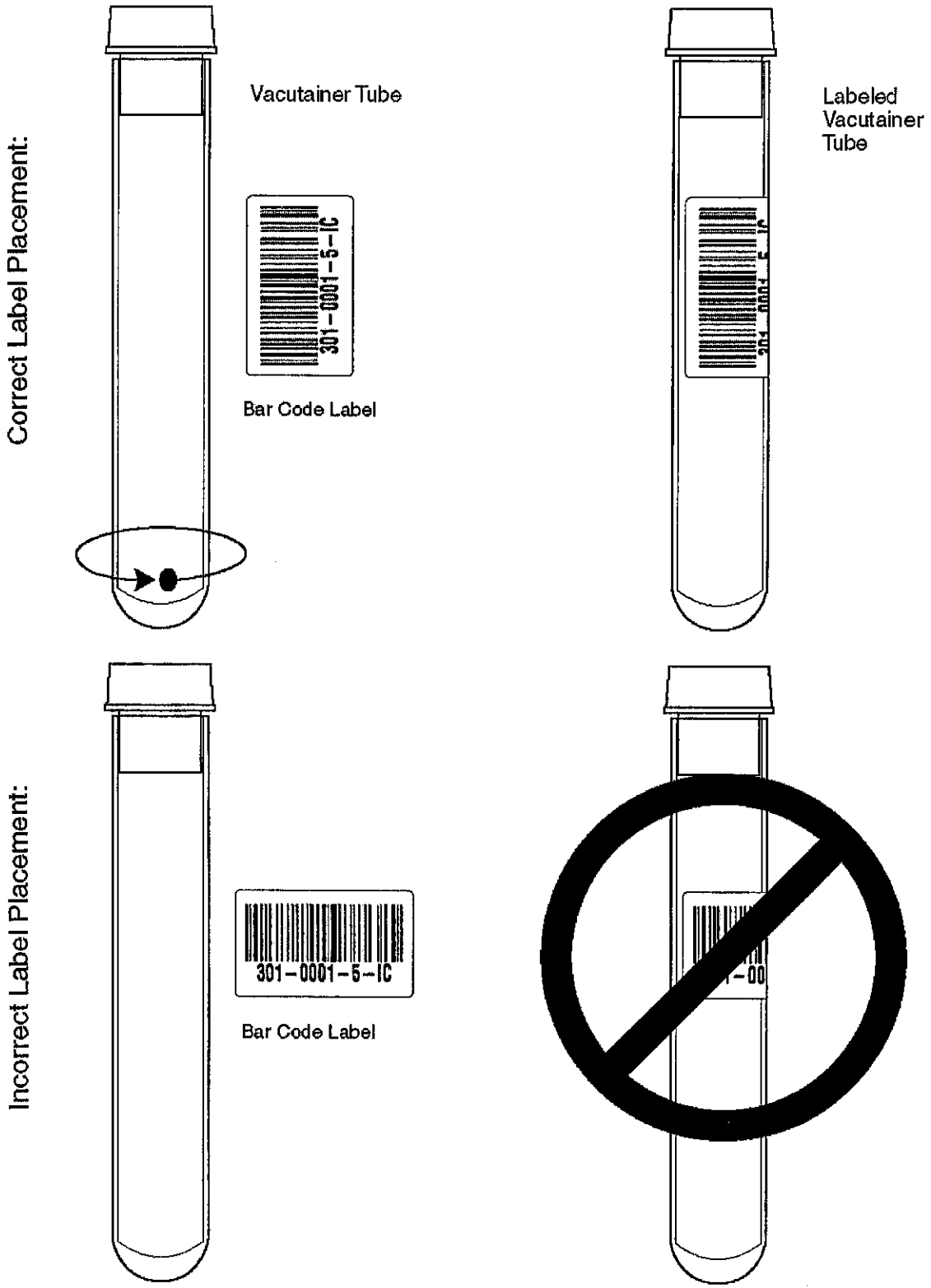
It is imperative that the study recruiter close out the recipient on the laptop RTS once all hospital enrollment activities are completed and documented in the system. Completion of activities includes obtaining all contact information, transfusion history, WBNs of RADAR transfused units, dates pre-transfusion samples are sent to the blood center, and the patient discharge date. Once this is done, the study recruiter should activate the close out by selecting the close out button on the Recipient Information screen. Detailed information about using this function in the RTS can be found later in this manual.

4.9 Multiple Transfusion Events

The possibility exists that an enrolled recipient could require additional surgery at the same RADAR hospital and consequently, could receive additional tagged RADAR Repository blood units. For the purposes of this study, all transfusions occurring during any given hospitalization are defined as one "transfusion event" (regardless of the number of actual transfusion episodes that may have occurred during that hospitalization). In contrast, recipients who subsequent to enrollment and hospital discharge, receive additional RADAR units at the same hospital prior to their follow-up study visit, will be considered to have a "multiple transfusion event". When an enrolled recipient experiences a multiple transfusion event, in which he/she receives at least one RADAR Repository blood unit within five months of enrolling in the study, the follow-up visit date should be reset to reflect the most recent transfusion discharge date.

Recipients are considered to have completed the study once the follow-up visit has been conducted. When possible, recipients with multiple transfusion events will have their follow-up study visit rescheduled to occur 6 months after their most recent transfusion event. Recipients should only be enrolled into the study one time.

Figure 5. Applying a label to a vacutainer tube



The RTS can identify a recipient already enrolled in the study when the recruiter enters either the recipient's name and date of birth or social security number in the Recipient Search window. In the event the recruiter attempts to enroll a presently enrolled recipient, the RTS will alert the recruiter that the patient was previously enrolled in the study and advised of the recipient's study status. In response to this prompt from the RTS, the study recruiter should not reconsent the patient, but instead, depending on the circumstance, do one of four things.

1. If the enrolled recipient is experiencing a "multiple transfusion event" in which he/she receives at least one RADAR Repository blood unit, meaning that they have received another transfusion at the collaborating RADAR hospital as an in-patient or an out-patient, within 5 months of enrolling in the study, document in the Patient Log Form "Consent Status" column that the recipient was previously enrolled. Next, retrieve the recipient's unique set of Recipient Study ID labels previously assigned to the recipient at enrollment. Update the RTS, recording the current transfusion information, the WBNs of RADAR units, and hospital discharge date. As shown later in this manual, the RTS will prompt for the necessary information.

2. All RADAR transfusions after the 6-month period, and prior to the follow-up visit, should be recorded in the RTS, however, the date of the follow-up visit should not be reset.

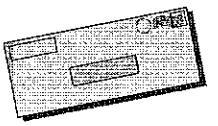
3. If a recipient experiences a "multiple transfusion event" within 5 months of enrolling in the study, but does not receive at least one RADAR Repository blood unit, no further action is required. If the enrolled recipient is actually experiencing a hospitalization requiring a transfusion at the collaborating RADAR hospital between 6 and 12 months from the time of enrollment, then this is the opportunity to arrange for the recipient to complete his/her follow-up visit. The study recruiter should follow the procedures for conducting the follow-up study visit found in Chapter 5.

4. If the enrolled recipient is experiencing a hospitalization requiring a transfusion at the collaborating RADAR hospital subsequent to the 12 month close out period, then regardless if the recipient completed, refused, or is past their follow-up visit window, no further action is required of the recruiter.

6 MONTHS FOLLOW-UP VISIT

CHAPTER 5

5. FOLLOW-UP VISIT



5.1 Overview

All recipients enrolled in the RADAR Repository study are to have a second study visit six months following their surgery and transfusion with RADAR designated units. The "6-month" designation found in study materials and documents will generally be referred to as the "follow-up" (visit, sample, label, etc). While it is desirable for the follow-up visit to occur as close to 6 months as possible, the visit may occur up to 12 months following enrollment. Any study materials and documents including 6-month (-6M) prefixes or suffixes designate the recipient's 6-month eligibility interval. The follow-up visit includes a blood draw and completion of a brief questionnaire. Each blood center is responsible for recontacting the recipient to schedule the appointment, as well as conducting the visit and following the procedures for collecting and delivering data as described here and in Chapter 6. Depending on staffing at each site, either the study recruiter who enrolled the patient at the hospital or other RADAR blood center study staff may conduct the follow-up visit.

From the time that the follow-up visit should take place, blood centers will have a 6-month grace period in which to carry out the follow-up visit. There will be instances when the follow-up visit will be reset to take place later than the anticipated 6-month interval. As described in Section 4.9, the follow-up visit will be reset by the RTS for enrolled recipients who undergo multiple transfusion events at the RADAR study hospital between Months 1 and 5 following their enrollment visit. A decision whether to continue attempting to schedule a follow-up visit with a recipient not having a follow-up completed by the end of twelfth month will be made on a case by case basis jointly by the blood center and Coordinating Center. The RTS loaded on the administrative computer at the blood centers has the capability to alert staff one month in advance (Month 5) of the need to schedule recipient follow-up appointments. Reports may be generated utilizing the RTS to list the recipients' follow-up windows (see the section on using the RTS at the back of this manual). While the RTS provides direction on which recipients need to be appointed a follow-up visit, each blood center is responsible for determining the method best suited for contacting each recipient for this visit (e.g., letter, phone call).

5.2 Procedures for Contacting the Recipient to Make the Appointment

On a regular basis as directed by the RTS, the blood center should contact recipients by phone or generate letters to notify recipients by mail that it is time for their follow-up visit. If letters are sent, they should include a change of address request on the envelope. Letters returned from the postal service with new information should be updated in the RTS. Every attempt should be made to contact the patient for the follow-up visit including the use of the supplemental contact information collected by the study recruiter at the enrollment visit, and other standard tracing methods. When trying to contact or trace a recipient, care should always be taken not to compromise the confidentiality of the recipient or to imply that the recipient has a health problem.

Because the second visit is essential to the success of RADAR, blood centers and study recruiters are urged to make this appointment at a location most convenient to the patient. Suggested locations include the blood center, a private physician's office, the hospital where the surgery was conducted, or the recipient's home. When scheduling appointment times on specific days of the week, the blood center should keep in mind the logistics of ensuring that the phlebotomy specimens obtained can be delivered as soon as possible to the blood center laboratory for processing.

An additional consideration when scheduling the follow-up visit is to try to avoid a two-week period following immunizations, such as an annual influenza vaccine, as these can frequently cause false reactive screening assays. It may be well worth the time to ask the recipient about recent immunizations both prior to scheduling the appointment and immediately before blood is drawn during the follow-up visit.

If a recipient has moved out of the geographical range of the study but is still willing to participate, a questionnaire may be administered over the phone. The blood center may arrange for the phlebotomy specimen to be drawn at a remote site such as at the recipient's physician's office. The specimen should be returned to the blood center by next-day mail following IATA infectious or diagnostic mailing regulations, as appropriate.

If, after contact/discussion, a recipient declines to continue in the study, there are several approaches, which can be effective in having him/her to reconsider. Successful handling of refusals often depends on the resourcefulness of the person making the contact. Just as one subject differs from another, the reasons for refusal are many and varied. Most recipients will not refuse outright, but may express

hesitancy, reservation, or some initial hostility. In order to help the recipient overcome these reactions, he/she should be reassured of the confidential nature of the study, and the importance of the research. It is also important to assure the subject that his/her participation is voluntary, and that failure to participate or to discontinue participation at any time will not result in any penalty. If a particular staff member is not getting anywhere with a particularly hesitant recipient, the conversation should be ended before receiving a definitive "no" from the recipient. Sometimes another staff member talking to the recipient on a different day may be able to establish better rapport. Try to always "leave the door open" so someone else can try again at a later time.

In further attempts to gain cooperation, one of the most important things to remember is to listen carefully to concerns raised by the recipient, and be prepared to offer options. For example, if the main concern is lack of time, offer the recipient different options for completing the follow-up visit. If the concern is confidentiality, review the main points in the consent form dealing with this issue.

5.3 Supplies Needed for the Follow-up Appointment

The supplies listed in Box 5A are needed to complete each follow-up study visit, and should be collected and prepared prior to meeting with the recipient.

Box 5A
☛ Follow-up visit supplies

- ✓ (2) 7-ml vacutainer tubes; red top or lavender top (EDTA) for blood center testing – *provided by blood center.*
- ✓ (1) 7-ml lavender top (EDTA) vacutainer tube for NAT - *provided by blood center.*
- ✓ (1) 10-ml lavender top (EDTA) vacutainer tube - *provided by blood center.*
- ✓ Other phlebotomy supplies – *provided by blood center.*
- ✓ Questionnaire booklet – *provided by MCC.*
- ✓ Provider Roster Card – *provided by MCC. See Exhibit G.*
- ✓ Blue or black ink pen – *provided by blood center.*
- ✓ Recipient's unique label set with follow-up study ID labels (suffix -6M) –*provided by MCC.*
- ✓ Printout of recipient enrollment information from the RTS – *generated by blood center.*

5.4 Follow-up (-6M) Phlebotomy

The follow-up phlebotomy draw should be performed prior to administering the questionnaire. Performing the visit activities in this order is strongly advised that since the phlebotomy specimen for the RADAR Repository is essential for future study of linked donor-recipient pairs. If the recipient is short on time, at least the blood sample will have been collected, and the questionnaire can be administered as soon as possible at a later date. Ask the recipient about recent immunizations before blood is drawn. Try to avoid a two-week period following immunizations such as an annual influenza vaccine, as these can frequently cause false reactive screening assays. If this is unavoidable, please ensure that a note is made on the 6-month follow-up screen of the RTS should there be a question in the future.

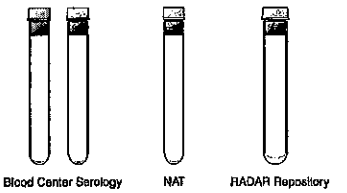
The follow-up phlebotomy consists of drawing the following blood samples: 1) two 7-ml vacuum tubes either red or lavender depending on the testing requirements at your blood center, for infectious disease marker testing, 2) one 7-ml lavender top (EDTA) tube for temporary storage for potential NAT testing and 3) one 10-ml lavender top (EDTA) tube for long-term storage in the repository. Box 5B describes the procedures to follow when collecting the follow-up blood samples.

These sample tubes should be processed as soon as possible after the draw at the blood center laboratory according to procedures found in Chapter 8. They may be temporarily stored at ~25 °C (room temperature) until processed. In addition to a RADAR Repository sample for long-term storage, two 7-ml vacutainer tubes should be drawn for the following tests: HIV-1/2 Ab, HCV Ab, HBsAg, anti-HBc and HTLV-I/II Ab and one 7-ml lavender top (EDTA) tube should be drawn for NAT testing. NAT testing will not be required on all recipient samples and should only be performed as directed in Chapter 6. The 7-ml lavender top (EDTA) tube drawn for NAT testing should be processed and held frozen until the initial testing is completed on the follow-up sample. Once follow-up testing is complete and it is found that no NAT testing is indicated, this temporarily stored sample should be destroyed by the blood center.

Box 5B

☛ Blood sample collection by study recruiter at follow-up visit

Supplies needed:



✓ Two (2) 7-ml lavender top (EDTA) or red top tubes for blood center serology.

✓ One (1) 7-ml lavender top (EDTA) tube for NAT at BCP.

✓ One (1) 10-ml lavender top (EDTA) tube for repository specimen.

✓ Four (4) follow-up sample identification labels (suffix -6M). See Figure 4.

Instructions:

✓ Label the blood tubes with the recipient's corresponding follow-up sample RADAR Repository study ID pre-printed labels (suffix -6M).

✓ Obtain blood samples by normal phlebotomy procedures.

✓ Send all extra -6M labels with the vacuum tubes to the processing site to be used on NAT cryovials.

✓ Transport blood samples to the blood center at ~ 25°C (room temperature) but not frozen for processing, storage, and testing, as soon as possible after completing the follow-up visit.

5.5 Administering the 6-Month Follow-up Questionnaire and General Interviewing Techniques

The purpose of the 6-month follow-up questionnaire is to ascertain if the recipient has had any additional hospitalizations, surgeries, blood transfusions, or symptoms of illness since their enrollment or baseline blood transfusion which may be indicative of a transfusion-transmitted infection (TTI). This section describes general interviewing techniques, and specific procedures for administering the questionnaire.

5.5.1 Types of Questions

In the 6-month follow-up questionnaire the following types of questions are encountered.

- PRE-CODED QUESTIONS: A pre-coded, or closed-ended, question is one in which the answer choices are listed in a coded manner with the question. The simplest form of a pre-coded question requires a "yes/no" answer, while other pre-coded questions may offer several possible answers. An example is shown below:

  5. Have you had any surgeries or operations since your discharge date?

  YES 1
  NO 2

- OPEN-ENDED QUESTIONS: Open-ended questions are those which are followed by a blank space, and which do not list possible answers. An example is shown below.

  6. What kind of surgeries or operations have you had? _____

- DEPENDENT QUESTIONS: Dependent questions can be pre-coded or open-ended. Dependent questions are those which are asked of only some of the recipients. The determination of who is to be asked the question is "dependent" upon the answer to a previous question. The questionnaire will instruct the interviewer using "skip" instructions when a question is to be omitted based on a previous response. An example is:

  5. Have you had any surgeries or operations since _ _/ _ _/ _ _ (DISCHARGE DATE)?

  YES ..... 1 → How many different surgeries or operations have you had?
  NO 2

  In this example, the question asking how many surgeries should only be answered if the answer to the first question was "YES"; otherwise, the instructions are to skip to Q9, if the response was "NO".

5.5.2 Asking the Questions

The interviewer should follow the rules in Box 5C when asking questions during the interview:

Box 5C
☛ Rules for asking questions

✓ Always remain neutral: The interviewer must be careful that nothing in words or manner implies surprise, approval or disapproval of the recipient's answers. It is especially important to remain neutral when probing a recipient's answer for clarification.

✓ Ask all questions in the order presented in the questionnaire: If the subject is talking freely, the interviewer may feel that the subject has already answered some of the questions before being asked them. If the subject becomes a little annoyed and says, "I just told you that," the interviewer can always say something like:

"I have to make sure that I had your full answer to that," or

"You may have already told me this, but let me ask the question to be sure I have the correct answer."

✓ Ask all questions exactly as worded: In general, do not change the wording of any questions. Emphasize only those words that are underlined or specified in the Question-by-Question Specifications. Read everything in a natural, even-toned manner. In order for data collected to be comparable, there must be no doubt that each recipient heard exactly the same question before answering. Sometimes, recipients will ask the interviewer to define words in a question or explain some part of a question. For questions in the 6-month follow-up questionnaire, there are no questions, which you can help explain better. Simply encourage the subject to answer as best he/she can. The interviewer should not attempt to interpret the question or the answer categories for the recipient.

✓ Only questions, phrases, and responses in lower case should be read to the recipient. Answers that are in UPPER CASE should not be read.

5.5.3 Probing

Probing is the technique used by the interviewer to obtain more information when necessary. The interviewer should probe when a recipient's answer is not meaningful or does not adequately answer a question. Probing motivates recipients to clarify or explain their answers. Secondly, probing focuses the subject's answer so that irrelevant and unnecessary information can be eliminated. It is very important to always use neutral probes. That is, the interviewer should never imply to the recipient that a specific answer is expected or that he/she is dissatisfied with an answer. Remember that the reason for probing is to motivate the recipient to respond more fully or to focus an answer, without introducing bias. The potential for bias is great in the use of probes. Below are some examples of answers that require probing.

Question: When were you first seen for this condition?
Answer: It was sometime this past summer.
or Answer: After I felt better from my heart surgery.

The best way to probe these answers is to ask the recipient for the *DATE* that they were first seen for this condition.

Many recipients will answer a pre-coded question in the exact words of one of the answer categories (usually not read to the recipient). Sometimes, however, the answer will not be given in the exact words of the answer categories. In this case, the recipient's answer needs to be probed. Sometimes the best probe for a pre-coded question is simply to repeat the original question with special emphasis on the important points. For instance, in the following example, the interviewer would probe for the type of hepatitis a recipient had.

Interviewer: What type of hepatitis did a doctor or medical person tell you that you had?
Respondent: Well, it wasn't hepatitis C, luckily.
Interviewer: So, what *type* of hepatitis were you told that you had?
Respondent: Oh, it was hepatitis A.

In the case of open-ended questions, probing techniques will need to be used more often since the initial answers given by a subject may not be as specific, clear and complete as desired.

5.5.4 Kinds of Probes

Box 5D below describes several neutral probes that can be used to stimulate a fuller, clearer response.

Box 5D
Probing methods

- AN EXPRESSION OF INTEREST AND UNDERSTANDING. By saying such things as "uh-huh" or "I see" or "yes," the interviewer indicates that the response has been heard and that more is expected.

- AN EXPECTANT PAUSE. The simplest way to convey to a recipient that it is known that he/she has begun to answer the question, but has more to say, is to be silent. The pause allows the recipient time to gather his or her thoughts.

- REPEAT THE QUESTION. When the recipient does not seem to understand the question, misinterprets it, seems unable to decide, or strays from the subject, it is often useful for the interviewer to repeat the question. Many recipients, when hearing the question for the second time, realize what kind of answer is needed.

- REPEATING THE SUBJECT'S REPLY. Simply repeating the recipient's response is often an excellent probe. Hearing the response just given often stimulates the recipient to respond further.

- A NEUTRAL QUESTION OR COMMENT. Neutral questions or comments are often used to obtain clearer and fuller responses. The following are some suggestions for probing questions that may help the interviewer explore many types of insufficient answers:

  PROBES TO CLARIFY:

  "What do you mean exactly?"
  "What do you mean by ...?"
  "Could you please explain that a little? I don't think I quite understand."
  "Could you be more specific about that?"
  "Tell me about that. What/who/how/why ...?"

  PROBES FOR RELEVANCE:

  "I see. Well, let me ask you again ... (REPEAT EXACT QUESTION)."

5.5.5 The Don't Know (DK) Response

The "I don't know" answer can mean a number of things. For instance,

- The recipient doesn't understand the question and says DK to avoid saying he/she doesn't understand;
- The recipient is thinking the question over, and says DK to fill the silence and give himself/herself time to think;
- He/She may be trying to avoid responding because he/she feels uninformed, or is afraid of giving a wrong answer; or
- He/She may really not know or really may have no opinion on the question.

The interviewer should try to decide which of the above may be the case. A "don't know" reply should not be automatically accepted. If the interviewer waits, the recipient will usually think of something further to say. Silence and waiting are frequently the best probes for a "don't know." The interviewer may also find that other useful probes are: "Just give me your best estimate," or "Just do the best you can". If the interviewer feels the recipient has said "don't know" out of fear of admitting ignorance, he/she should be reassuring to the recipient by saying "There's really no right answer to this question -- we're just interested in what you have to say." If asking about a specific date the interviewer can work with the recipient to obtain his/her best estimate. Although the recipient may not remember exactly what the date or amount was, most are willing to give their best approximation. Always try at least once to obtain a reply to a "don't know" response, before accepting it as the final answer. Do not, however, insist on an answer if the subject really does not know.

5.5.6 Recording Answers and Editing Responses

The interviewer should use a blue or black ink pen to administer the questionnaire. Other color inks interfere with data entry at the MCC, and pencils should not be used to discourage erasing.

Pre-coded questions are easy to record. Ordinarily the answers are clearly shown in the interviewer booklets and are designated by a different code number. The usual way to indicate answers given is to circle the appropriate code at the end of the dashed line next to the text. Do not circle the actual text. Sometimes a pre-coded question includes an "OTHER" response choice. In addition to

circling the corresponding code, often the interviewer is asked to specify the actual answer in the space provided. This is indicated by the phrase (OTHER SPECIFY).

If it is necessary to change a code, be sure to indicate the reason. If the recipient changes his/her mind after the interviewer has already circled one code, the wrong code should be crossed out with a single slash line with a note next to it in parentheses (R.E.) to indicate "Respondent Error". Never try to erase or use white-out. If the wrong code is circled by mistake by the interviewer, it should be crossed out and noted (M.E.) indicating "My error -- or interviewer error".

Zero filling techniques should be used when boxes appear for a number or date. In this case, all boxes (spaces) for that answer must be filled. "Zero fill" the empty boxes starting from the left. For example, if the subject said that he/she had 5 transfusions and the answer space has two boxes (NO. OF TIMES |__|__|), "05" would be recorded.

The key to recording open-ended questions is to write everything relevant the subject says in exactly his/her own words. A few suggestions are discussed below in Box 5E.

Box 5E
☛ Recording open-ended questions

- Do not correct or summarize what recipient says; record his/her response exactly as stated.
- Be sure to include pronouns the recipient used (e.g., he, she, it, they). Without them the meaning of the answer is frequently not as clear as thought.
- Use the white space around the page, and margins if needed, when recording. Be sure to mark the answers with the question number if the narrative comments are on a different part of the questionnaire (e.g., the bottom of the page).
- Interviewers should give their own remarks when feeling that something a recipient said needs explanation. It is important to put interviewer remarks in parentheses ( ) so the MCC does not confuse interviewer explanations with a subject's answer.

5.5.7 The Provider Roster

The individual administering the questionnaire should have a Provider Roster card (see Exhibit G) available during the interview. The roster should be used in conjunction with the questionnaire to document the list of providers reported during the interview (e.g., name, address, and telephone number). When a provider has been documented on the roster, this entry is assigned a unique number that will always refer to this provider throughout the questionnaire. The roster should remain at the blood center when completed.

For example, at the time that it is first necessary for the interviewer to document a provider reported by the recipient, the interviewer should assign ROSTER # 01 to this provider in the appropriate place on the roster card. In the box corresponding to # 01 on the roster card, the interviewer should document the relevant provider information. On the questionnaire, the interviewer should record "01" in the space for ROSTER #, for the provider reported in that particular question. In the event that the recipient reports this provider again during the administration of the questionnaire, the interviewer can simply record provider "01" in the space provided for ROSTER # in that question, and move on to the next question in the series. Later during the interview, if the recipient reports on a provider not already recorded on the roster card, the interviewer should assign the next roster number (e.g., 02, 03, etc). The information about each additional provider should be recorded on the roster card, and the unique number should be recorded on the questionnaire. When the questionnaire is completed for that particular recipient, the name of each provider should only be listed once on the roster card, and should always be referred to by the unique roster number assigned to the provider (i.e., 01-10).

5.5.8 Preparing the Questionnaire Booklet Prior to Conducting the Interview

Prior to meeting the recipient, the interviewer should perform the steps discussed in Box 5F.

Box 5F
☛ Steps in preparing the questionnaire

1. Place one of the follow-up study ID labels (suffix -6M) in the upper right hand corner of the questionnaire booklet, and another follow-up (-6M) study ID label in the upper right hand corner of the Provide Roster card. If the recipient's unique study ID labels are not available for any reason, transcribe the recipient's study ID from the RTS printout.

2. Transcribe the discharge date from the RTS printout to the cover and all shaded areas in the questionnaire booklet designated for that recipient. Shaded areas can be found on every page of the questionnaire, and usually are part of the lead questions or introduction text.

5.5.9 Question by Question (Q x Q's) Specifications for Administering the Questionnaire

The following pages provide specific Q x Q's for the 6-month follow-up questionnaire. Interviewing techniques discussed above in Section 5.5 should be utilized while administering the instrument.

Recipient Study ID: *Please place label here or write in the Study ID# below.*

Study ID Label

|__|__|__|-|__|__|__|__|-|__|-|6|M|

Study ID#

RADAR Repository
Recipient 6-Month Follow-up Questionnaire

Study recruiter, please enter:

Hospital name

_____

Discharge Date

|__|__|-|__|__|-|__|__|__|__|
MO DAY YEAR

Date of Follow-up Interview

|__|__|-|__|__|-|__|__|__|__|
MO DAY YEAR

Interviewer Initials

|__|__|__|

COVER PAGE

Prior to starting the interview, affix one of the recipient's follow-up (-6M) study ID labels in the upper right-hand corner box. If a label is unavailable, copy the Recipient Study ID number as it appears on the printout from the RTS.

In the bottom right-hand corner, enter the name of the hospital where the recipient enrolled in the study. The discharge date should be obtained from the printout generated by the RTS and recorded on the questionnaire cover page. These two items should be entered on the questionnaire prior to meeting with the recipient. Finally, enter the date of the interview and your interviewer initials starting from the left, at the actual start of the interview with the recipient.

A. SUBSEQUENT HOSPITALIZATIONS

BOX A

As you may recall, you are eligible to participate in this study because you received a blood transfusion at <HOSPITAL NAME>. During our first study visit with you around that time, you signed an informed consent document and answered some questions for us. As we explained then, we planned to follow-up with you approximately six months later. Now that we are here for your follow-up visit, I'd like to ask you some questions about your health since your discharge from the hospital. Please answer each question as best you can, and keep in mind that at this time we are interested only in things that may have happened **after** you were discharged from <HOSPITAL NAME> on [redacted] (DISCHARGE DATE). Your answers to these questions will be kept strictly confidential.

1. At any time since [redacted] (DISCHARGE DATE), have you stayed overnight again as a patient in a hospital?

YES ..... 1 → How many different times have you stayed overnight as a patient in a hospital since [redacted] (DISCHARGE DATE)? |__|__|
OF TIMES

NO ..... 2 (SKIP TO BOX B)

2. What was the main reason for your hospital stay(s)?	3. On what date were you admitted for this hospital stay?	4. At which hospital did you stay?
a. First stay? _____ _____ _____ →	a. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	a. |__|__| ROSTER # (GO TO 2b)
b. Second stay? _____ _____ _____ →	b. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	b. |__|__| ROSTER # (GO TO 2c)
c. Third stay? _____ _____ _____ →	c. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	c. |__|__| ROSTER # (GO TO 2d)
d. Fourth stay? _____ _____ _____ →	d. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	d. |__|__| ROSTER # (GO TO BOX B)

SECTION A. SUBSEQUENT HOSPITALIZATIONS

BOX A The introduction printed at the top of Page 1 should always be read to the recipient prior to beginning the interview. This narration informs the recipient about the types of questions that will be asked during the interview, and reassures him/her about the confidential nature of the answers provided. Verbally state the <HOSPITAL NAME> using the same Hospital Name provided on the front cover of the questionnaire.

1. This question is designed to determine whether or not the recipient has stayed overnight again as a patient in a hospital since their study enrollment. Code the recipient's response "YES" or "NO".

If the recipient answers "NO", skip to BOX B, Page 2.

If the respondent answers **"YES"** to Q1, follow the arrow to the dependent question to inquire how many times the recipient has stayed overnight in a hospital since their study enrollment. It is important to emphasize the phrase "since the (DISCHARGE DATE)" when asking the question. Fill in the number of times in the space provided. Continue with Q2-4, making sure to ascertain information about the same number of hospitalizations as reported in Q1.

2a-d. The purpose of this question is to gather information concerning the reason for subsequent hospitalizations reported in Q1. Read the question and record the recipient's response regarding their first subsequent hospitalization in the first box provided. Follow the arrow across the row to Q3.

3a-d. Read the question and record the month, day, and year of the first hospitalization. If the recipient is unsure of the exact date, probe for at least month and year. If the date given is after the discharge date, follow the arrow across to Q4.

If recipients provide dates that precede their discharge date, remind them that we are only interested in hospitalizations that occurred after their study enrollment discharge date. If a recipient's only stays are prior to the discharge date, the interviewer should re-probe Q1, and make appropriate edits.

4a-d. This question asks for the name of the hospital where the recipient stayed. Read the question and obtain the name of the hospital. Assign the first hospital reported in Q4a. as ROSTER # 01, etc. Make sure to record the hospital name, address, and telephone number on the Provider Roster page utilizing the space corresponding to the roster number recorded.

B. SURGERIES OR OPERATIONS

BOX B

Now I would like to ask you some questions about surgeries or operations you may have had since being discharged from <HOSPITAL NAME> on [redacted] (DISCHARGE DATE). Please report on surgeries you had either as an inpatient or outpatient at a hospital or other medical facility. Be sure to include any surgeries you may have just informed me about that occurred during an overnight hospital stay. I apologize if you have to repeat any information from the previous question.

5. Have you had any surgeries or operations since [redacted] (DISCHARGE DATE)?

YES ..... 1 ⟶ How many different surgeries or operations have you had? |__|__|
SURGERIES

NO ..... 2 (SKIP TO Q9)

6. What kind of surgeries or operations have you had?	7. On what date did you have this surgery or operation?	8. Where did you have this surgery or operation?
a. _____ _____ _____ →	a. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	a. |__|__| ROSTER # (GO TO 6b)
b. _____ _____ _____ →	b. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	b. |__|__| ROSTER # (GO TO 6c)
c. _____ _____ _____ →	c. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	c. |__|__| ROSTER # (GO TO 6d)
d. _____ _____ _____ →	d. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	d. |__|__| ROSTER # (GO TO 6e)
e. _____ _____ _____ →	e. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	e. |__|__| ROSTER # (GO TO 6f)
f. _____ _____ _____ →	f. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	f. |__|__| ROSTER # (GO TO Q9)

SECTION B. SURGERIES OR OPERATIONS

Section B is a series of questions to ascertain information concerning additional surgeries or operations that the recipient may have had since the discharge date.

BOX B Read the narration to the recipient. Some recipients may have told you about surgeries in the previous section when questioned about hospitalizations. Even if the information reported is redundant, record these surgeries again in Q5-8.

5. This question asks if the recipient has had any additional surgeries or operations since his/her discharge date. These may have been either as an inpatient or outpatient (same day surgery). It is important to emphasize the phrase "since the (DISCHARGE DATE)" when asking the question. Code the recipient's response "YES" or "NO".

If the recipient answers "NO", skip to Q9, Page 3.

If the recipient answers "**YES**" to Q5, follow the arrow across to the dependent question "How many different surgeries or operations have you had?" Record the number of surgeries or operations in the box provided. Continue with Q6–8, making sure to ascertain information about the same number of surgeries/operations as reported in Q5.

6a-f. The recipient is to report about specific information regarding the kind(s) of surgeries or operations. Read the question and record the recipient's response regarding his/her surgery or operation in the box provided. Follow the arrow across to Q7.

7a-f. Read the question and record the month, day, and year of the surgery reported in 6. If the recipient is unsure of the exact date, try to probe for at least month and year. If the date given is after the discharge date, follow the arrow across to Q8.

If recipients provide dates that precede their discharge date, remind them that we are only interested in surgeries or operations that occurred after their study enrollment discharge date. If a recipient's only stays are prior to the discharge date, the interviewer should re-probe Q5, and make appropriate edits.

8a-f. Q8 asks for the location where this surgery or operation was performed. Read the question and obtain the name of the hospital or provider. Assign the next available roster number, if the hospital or provider has not been recorded previously. Remember to fill out relevant provider information, if not already recorded, on the Provider Roster page.

C. TRANSFUSIONS

9. At any time since [redacted] (DISCHARGE DATE) have you received a transfusion of blood or blood products?

YES ..... 1 → How many different times have you received one or more blood transfusions? |__|__| # TIMES
NO ..... 2 } (SKIP to Q14)
NOT SURE. 3 }

10. What was the main reason for this blood transfusion?	11. Was this a transfusion of your own blood, someone else's blood, or both your own blood and someone else's blood?	12. What was the date of this transfusion?	13. Where did you receive this transfusion?
a. First time? _____ _____ _____ _____ →	a. OWN BLOOD ..... 1 SOMEONE ELSE'S ..... 2 BOTH OWN AND SOMEONE ELSE'S..... 3 DK..... 8 →	a. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	a. |__|__| ROSTER # (GO TO 10b)
b. Second time? _____ _____ _____ _____ →	b. OWN BLOOD ..... 1 SOMEONE ELSE'S ..... 2 BOTH OWN AND SOMEONE ELSE'S..... 3 DK..... 8 →	b. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	b. |__|__| ROSTER # (GO TO 10c)
c. Third time? _____ _____ _____ _____ →	c. OWN BLOOD ..... 1 SOMEONE ELSE'S ..... 2 BOTH OWN AND SOMEONE ELSE'S..... 3 DK..... 8 →	c. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	c. |__|__| ROSTER # (GO TO 10d)
d. Fourth time? _____ _____ _____ _____ →	d. OWN BLOOD ..... 1 SOMEONE ELSE'S ..... 2 BOTH OWN AND SOMEONE ELSE'S..... 3 DK..... 8 →	d. |__|__| - |__|__| - |__|__|__|__| MO DAY YEAR →	d. |__|__| ROSTER # (GO TO Q14)

SECTION C. TRANSFUSIONS

9. Q9 asks if the recipient received a transfusion of blood or blood products since his/her discharge date. Code the recipient's response "YES", "NO", or "NOT SURE." Probe the reason for a "NOT SURE" answer, and write it in the margin, if one is given.

If the recipient answers "NO" or "NOT SURE," skip to Q14, Page 4.

If the recipient answers **"YES"** to Q9, follow the arrow across to the dependent question "How many different times have you received one or more blood transfusions?" Record the number of times in the space provided. Continue with Q10 through 13, making sure to ascertain information about the same number of transfusions as reported in Q9.

10a-d. This questions asks for the main reason for the blood transfusion. Record the reason for the transfusion in the box provided, and follow the arrow across to Q11.

11a-d. Ask Q11 exactly as written for each time the recipient was transfused. Code the recipient's response, using Code 8 if the recipient doesn't know. Follow the arrow across to Q12.

12a-d. Record the date of the transfusion. If the recipient is unsure of the exact date, try to probe for at least month and year. If the date given is after the discharge date, following the arrow across to Q13.

If recipients provide dates that precede their discharge date, remind them that we are only interested in transfusions that occurred after their study enrollment discharge date. If a recipient's only transfusion events are prior to the discharge date, the interviewer should re-probe Q9, and make appropriate edits.

13a-d. Q13 asks for the location where the blood transfusion occurred. Assign this location the next available roster number, if the location has not been recorded previously. Remember to fill out relevant provider information, as needed, on the roster page.

D. HEPATITIS

14. Since [redacted] (DISCHARGE DATE), has a doctor or other medical person told you that you had hepatitis?

YES .....1 ⟶ What type of hepatitis was this?
NO .....2 (SKIP TO BOX C)

HEPATITIS A.....01
HEPATITIS B.....02
HEPATITIS C 03
OTHER (PLEASE SPECIFY) _____
NOT SURE.....98

15. When were you told that you had hepatitis?

|__|__|-|__|__|-|__|__|__|__|
MO DAY YEAR

CONTINUE WITH BOX C ON NEXT PAGE

SECTION D. HEPATITIS

This section of the questionnaire inquires if the recipient has been given the diagnosis of hepatitis since the discharge date.

14. This question asks if a doctor or other medical person has told the recipient that they had hepatitis. Code the recipient's response "YES" or "NO."

If the recipient answers "NO", skip to BOX C, Page 5.

If the recipient answers **"YES"**, follow the arrow across to the dependent question, "What type of hepatitis was this?" ***Do <u>not</u> read*** the response categories. Circle the number corresponding to the type of hepatitis reported. If the recipient reports having a type of hepatitis not listed, write in the recipient's response exactly as reported next to "OTHER (PLEASE SPECIFY)."

15. Record the date when the recipient was told about hepatitis in the space provided. If the recipient is unsure of the exact date, try to probe for at least month and year. Probe and make appropriate edits if the date told precedes the enrollment discharge date.

E. RECIPIENT HEALTH HISTORY

BOX C

The following questions ask about conditions you may have had since [redacted] (DISCHARGE DATE). Please note that we are only interested in conditions for which you saw a doctor or sought other medical treatment.

16. At any time since [redacted] (DISCHARGE DATE), have you had:	17. Did you see a doctor or other medical person for this?	18. What did the doctor or medical person say that you had?	19. When were you first seen for this condition?	20. Who did you see for this condition?
a. An unexplained fever above 100°F? YES..... 1 → NO..... 2 (GO TO 16b)	a. YES.... 1 → NO..... 2 (GO TO 16b)	a. _____ → DIAGNOSIS/CAUSE DK.....998	a. |__|__|-|__|__|__|__| MO YEAR →	a. |__|__|_| ROSTER # (GO TO 16b)
b. Drenching night sweats? YES..... 1 → NO..... 2 (GO TO 16c)	b. YES.... 1 → NO..... 2 (GO TO 16c)	b. _____ → DIAGNOSIS/CAUSE DK.....998	b. |__|__|-|__|__|__|__| MO YEAR →	b. |__|__|_| ROSTER # (GO TO 16c)
c. A severe headache in the back of your head? YES..... 1 → NO..... 2 (GO TO 16d)	c. YES.... 1 → NO..... 2 (GO TO 16d)	c. _____ → DIAGNOSIS/CAUSE DK.....998	c. |__|__|-|__|__|__|__| MO YEAR →	c. |__|__|_| ROSTER # (GO TO 16d)
d. A stiff neck, not caused by exercise or injury? YES..... 1 → NO..... 2 (GO TO 16e)	d. YES.... 1 → NO..... 2 (GO TO 16e)	d. _____ → DIAGNOSIS/CAUSE DK.....998	d. |__|__|-|__|__|__|__| MO YEAR →	d. |__|__|_| ROSTER # (GO TO 16e)
e. Sore muscles or joints, not caused by exercise, arthritis, or injury? YES..... 1 → NO..... 2 (GO TO 16f)	e. YES.... 1 → NO..... 2 (GO TO 16f)	e. _____ → DIAGNOSIS/CAUSE DK.....998	e. |__|__|-|__|__|__|__| MO YEAR →	e. |__|__|_| ROSTER # (GO TO 16f)
f. A new rash on your trunk, head, neck, or face that did not itch? YES..... 1 → NO..... 2 (GO TO 16g)	f. YES.... 1 → NO..... 2 (GO TO 16g)	f. _____ → DIAGNOSIS/CAUSE DK.....998	f. |__|__|-|__|__|__|__| MO YEAR →	f. |__|__|_| ROSTER # (GO TO 16g)
g. Feeling nauseous or sick to your stomach for more than 24 hrs.? YES..... 1 → NO..... 2 (GO TO 16h)	g. YES.... 1 → NO..... 2 (GO TO 16h)	g. _____ → DIAGNOSIS/CAUSE DK.....998	g. |__|__|-|__|__|__|__| MO YEAR →	g. |__|__|_| ROSTER # (GO TO 16h)

SECTION E. RECIPIENT HEALTH HISTORY

This section contains a series of grids asking about different physical conditions sometimes indicative of a transfusion-transmitted infection. It is important to read each condition/symptom listed in Q16 exactly as written. Do not attempt to define any of the terms listed or try to make a diagnosis based on the description of symptoms given by the recipient. If a recipient does not recognize a particular term, assume that the recipient has not had the condition.

BOX C Read Box C emphasizing the phrase "for which you saw a doctor or sought other medical treatment.

16a-g. Ask Q16a-g exactly as written, repeating the lead question at least once every 2-3 questions. It is important to emphasize the phrase "since the (DISCHARGE DATE)" when asking the question.

If the recipient answers **"YES"** to any symptom in Q16a-g, follow the arrow across and ask Q17.

If the recipient answers **"NO"**, go directly to the next symptom in 16.

17a-g. Responses to this question should include visits to a nurse, nurse practitioner, and physician's assistant, etc. Code **"YES"** if the recipient ever saw a doctor or other medical person because of these symptoms and follow the arrow across to ask Q18-20 before asking about the next symptom.

If the recipient answers **"NO"**, go directly to the next symptom in 16.

18a-g. Enter the diagnosis given by the provider. We would prefer a diagnosis, but if the recipient does not know a specific diagnosis, probe for a general cause of the condition, as given by the doctor. Enter as much information as necessary in the line provided. Additional margin space may be used, noting the question to which the margin notes belong. Write "don't know" ***in quotes*** on the diagnosis line if the recipient states that the physician was unable to give a diagnosis or cause for the symptom. Use code 998 if the physician gave a diagnosis or cause, but the recipient does not know or remember it. Follow the arrow across to Q19.

19a-g. Ask for the date the recipient was first seen for the condition. Enter the month and year reported. If the date given is after the discharge date, follow the arrow across to Q20.

If recipients provide a month and year prior to their discharge date, remind them that we are only interested in conditions since the discharge date. Make appropriate edits to Q16-18 if it is ascertained that the condition was prior to the discharge date.

20a-g. Record the roster number of the physician or other medical person, remembering to fill out relevant provider information, as needed, on the roster page.

16. At any time since [redacted] (DISCHARGE DATE), have you had:	17. Did you see a doctor or other medical person for this?	18. What did the doctor or medical person say that you had?	19. When were you first seen for this condition?	20. Who did you see for this condition?
h. Vomiting lasting more than 24 hrs.? YES..... 1 → NO..... 2 (GO TO 16i)	h. YES .... 1 → NO..... 2 (GO TO 16i)	h. _____ → DIAGNOSIS/CAUSE DK.....998	h. __|__|-|__|__|__|__| → MO YEAR	h. __|__| ROSTER # (GO TO 16i)
i. Diarrhea lasting more than 24 hrs.? YES..... 1 → NO..... 2 (GO TO 16j)	i. YES .... 1 → NO..... 2 (GO TO 16j)	i. _____ → DIAGNOSIS/CAUSE DK.....998	i. __|__|-|__|__|__|__| → MO YEAR	i. __|__| ROSTER # (GO TO 16j)
j. Unexplained severe fatigue lasting more than 24 hrs.? YES..... 1 → NO..... 2 (GO TO 16k)	j. YES .... 1 → NO..... 2 (GO TO 16k)	j. _____ → DIAGNOSIS/CAUSE DK.....998	j. __|__|-|__|__|__|__| → MO YEAR	j. __|__| ROSTER # (GO TO 16k)
k. Light hurting your eyes? YES..... 1 → NO..... 2 (GO TO 16l)	k. YES .... 1 → NO..... 2 (GO TO 16l)	k. _____ → DIAGNOSIS/CAUSE DK.....998	k. __|__|-|__|__|__|__| → MO YEAR	k. __|__| ROSTER # (GO TO 16l)
l. Swollen or painful glands or lymph nodes anywhere in your body? YES..... 1 → NO..... 2 (GO TO 16m)	l. YES .... 1 → NO..... 2 (GO TO 16m)	l. _____ → DIAGNOSIS/CAUSE DK.....998	l. __|__|-|__|__|__|__| → MO YEAR	l. __|__| ROSTER # (GO TO 16m)
m. A sore throat not associated with a common cold? YES..... 1 → NO..... 2 (GO TO 16n)	m. YES .... 1 → NO..... 2 (GO TO 16n)	m. _____ → DIAGNOSIS/CAUSE DK.....998	m. __|__|-|__|__|__|__| → MO YEAR	m. __|__| ROSTER # (GO TO 16n)
n. Painful sores or ulcers in your mouth? YES..... 1 → NO..... 2 (GO TO 16o)	n. YES .... 1 → NO..... 2 (GO TO 16o)	n. _____ → DIAGNOSIS/CAUSE DK.....998	n. __|__|-|__|__|__|__| → MO YEAR	n. __|__| ROSTER # (GO TO 16o)
o. Small white spots in your mouth or throat? YES..... 1 → NO..... 2 (GO TO Q21)	o. YES .... 1 → NO..... 2 (GO TO Q21)	o. _____ → DIAGNOSIS/CAUSE DK.....998	o. __|__|-|__|__|__|__| → MO YEAR	o. __|__| ROSTER # (GO TO Q21)

16h-o. Ask Q16h-o exactly as written, repeating the lead question at least once every 2-3 questions. It is important to emphasize the phrase "since the (DISCHARGE DATE)" when asking the question.

If the recipient answers **"YES"** to any symptom in Q16h-o, follow the arrow across and ask Q17.

If the recipient answers **"NO",** go directly to the next symptom in 16.

17h-o. Responses to this question should include visits to a nurse, nurse practitioner, and physician's assistant, etc. Code **"YES"** if the recipient ever saw a doctor or other medical person because of these symptoms and follow the arrow across to ask Q18-20 before asking about the next symptom.

If the recipient answers **"NO",** go directly to the next symptom in 16.

18h-o. Enter the diagnosis given by the provider. We would prefer a diagnosis, but if the recipient does not know a specific diagnosis, probe for a general cause of the condition, as given by the doctor. Enter as much information as necessary in the line provided. Additional margin space may be used, noting the question to which the margin notes belong. Write "don't know" ***in quotes*** on the diagnosis line if the recipient states that the physician was unable to give a diagnosis or cause for the symptom. Use code 998 if the physician gave a diagnosis or cause, but the recipient does not know or remember it. Follow the arrow across to Q19.

19h-o. Ask for the date the recipient was first seen for the condition. Enter the month and year reported. If the date given is after the discharge date, follow the arrow across to Q20.

If recipients provide a month and year prior to their discharge date, remind them that we are only interested in conditions since the discharge date. Make appropriate edits to Q16-18 if it is ascertained that the condition was prior to the discharge date.

20h-o. Record the roster number of the physician or other medical person, remembering to fill out relevant provider information, as needed, on the roster page.

21. And finally, at any time since recovering from your hospitalization on [redacted] (DISCHARGE DATE), have you had any unexplained weight loss of 5 or more pounds in less than 2 weeks?

YES..... 1 → a. Did you see a doctor or other medical person for this?
NO..... 2 (THE END)

YES..... 1
NO..... 2 (THE END)

b. What did the doctor or other medical person say that you had?

_____
DIAGNOSIS/CAUSE
DK..... 998

c. When were you first seen for this condition?

|__|__| - |__|__|__|__|
MO YEAR

d. Who did you see for this condition?

|__|__|
ROSTER #

Thank you very much for completing this questionnaire. Your time and cooperation is greatly appreciated.

21. This question is assessing whether or not the recipient has experienced any weight loss of 5 or more pounds in a short period of time. This weight loss should not be due to their surgery e.g., while patient was recovering.

If the recipient answers "NO" or "NOT SURE," read the response, thanking the recipient for his/her time.

If the recipient answers "**YES**" to Q21, follow the arrow across to the dependent question Q21a.

21a. This question asks if the recipient saw a doctor or other medical person for the weight loss. Code the recipient's response "YES" or "NO."

If the recipient answers "NO," read the response, thanking the recipient for his/her time.

If the recipient answers "**YES**," proceed to Q21b.

21b. Enter the diagnosis given by the provider. We would prefer a diagnosis, but if the recipient does not know a specific diagnosis, probe for a general cause of the condition, as given by the doctor. Enter as much information as necessary in the line provided. Additional margin space may be used, noting the question to which the margin notes belong. Write "don't know" in *quotes* on the diagnosis line if the recipient states that the physician was unable to give a diagnosis or cause for the symptom. Use code 998 if the physician gave a diagnosis or cause, but the recipient does not know or remember it. Proceed to Q21c.

21c. Ask for the date the recipient was first seen for the condition. Enter the month and year reported. If the date given is after the discharge date, proceed to Q21d.

If recipients provide a month and year prior to their discharge date, remind them that we are only interested in conditions since the discharge date. Make appropriate edits to Q21 and Q21a-b if it is ascertained that the condition was prior to the discharge date.

21d. Record the roster number of the physician or other medical person, remembering to fill out relevant provider information, as needed, on the roster page.

Upon completion of the questionnaire, read the response, thanking the recipient for his/her time.

5.6 Tracking Recipient Close-outs and Completion of the Follow-up Visits

The blood center must assign appropriate closeout codes to every recipient either after completing the follow-up visit, or in the event that the visit was never performed. This can be accomplished using the RTS administrative computer. There are two types of closeout codes: that for the overall final study disposition of a recipient, and additional closeout codes to track the success of the components of the follow-up visits (e.g., phlebotomy, questionnaire). Fields for entering closeout information are located in the 6-month follow-up visit screen of the RTS system.

Once each recipient's final study disposition is determined, one of the codes listed in Box 5G should be selected. The selected code should best describe the reason a recipient did not receive a follow-up visit or indicate whether the visit was completed successfully. It is anticipated that the majority of recipients should be closed out by Month 12 after their enrollment visit date, with the exception of recipients who have had multiple transfusion events (see Section 4.9) after enrolling. The blood centers will be able to print out reports from the RTS administrative computer showing which recipients have been closed out, and those which need to be closed out. This will be monitored closely by the MCC.

Box 5G
RTS recipient close-out codes

Successful Complete: All components (questionnaire and repository sample) of follow-up visit were completed.

Partial Complete: Either questionnaire or repository sample for the follow-up visit could be completed. If this code is used, utilize the RTS comments section to explain further.

Active Refusal: This code should be used to signify that the blood center received verbal or written confirmation from the recipient that he/she is not interested in participating in a follow-up visit.

Passive Refusal: This code is for recipients who have been repeatedly contacted by letter, who have not returned messages left for them, or who have repeatedly not shown up for, or cancelled appointments.

Not Locatable: After all attempts at tracing have failed to locate or contact a recipient, this code should be selected.

Too Ill: Use this code if the recipient is too ill or mentally incompetent to receive a follow-up visit prior to the end of the 12-month window/grace period.

Moved: For recipients living in an area that makes a follow-up visit impossible.

Deceased: This code is for recipients who are deceased prior to receiving their follow-up visit.

Other: This code should be used judiciously, after the blood center determines that no other codes describe the situation more accurately. An example of this code's use may be for recipients who express an interest in any future study activities but are not available to receive a follow-up due to work or personal reasons.

Occasionally, either the phlebotomy or questionnaire will not be successfully administered to a recipient who otherwise participated in the follow-up visit. In this case the "Partial Complete" listed above in Box 5G should be entered to describe the final disposition of the study activities. Also, for any recipient who has a "Partial Complete" entered as his/her final disposition, the blood center must use the comments box to indicate why the recipient was unable to fully complete the follow-up visit.

5.7 Shipment of Completed Questionnaires to the MCC

It is recommended that blood centers make arrangements to ship batches of the completed recipient questionnaire to the MCC on a monthly or bi-weekly basis. Forms must be sent using a

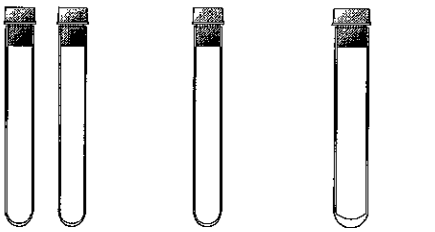
traceable, preferably overnight, courier mail service. The original questionnaires must be sent to the MCC. Therefore, before shipping any questionnaires, the blood center must make a copy of each questionnaire in its entirety for placement in the recipient's file, ensuring that data will not be lost if a shipment of forms is untraceable. The Provider Roster card should always remain at the blood center in the subject's file.

The MCC will provide the blood centers with a supply of Questionnaire Shipping Logs (Exhibit H). This shipping log should be completed for each shipment of questionnaires, and e-mailed or faxed to the MCC on the day that the shipment is sent. The shipping form has a place to enter the airbill tracking number, so the original shipping log should be retained at the blood center in the event that a shipment requires tracing.

FOLLOW-UP TESTING

CHAPTER 6

6. TESTING, REPORTING, AND NOTIFICATION OF RECIPIENT FOLLOW-UP SAMPLES



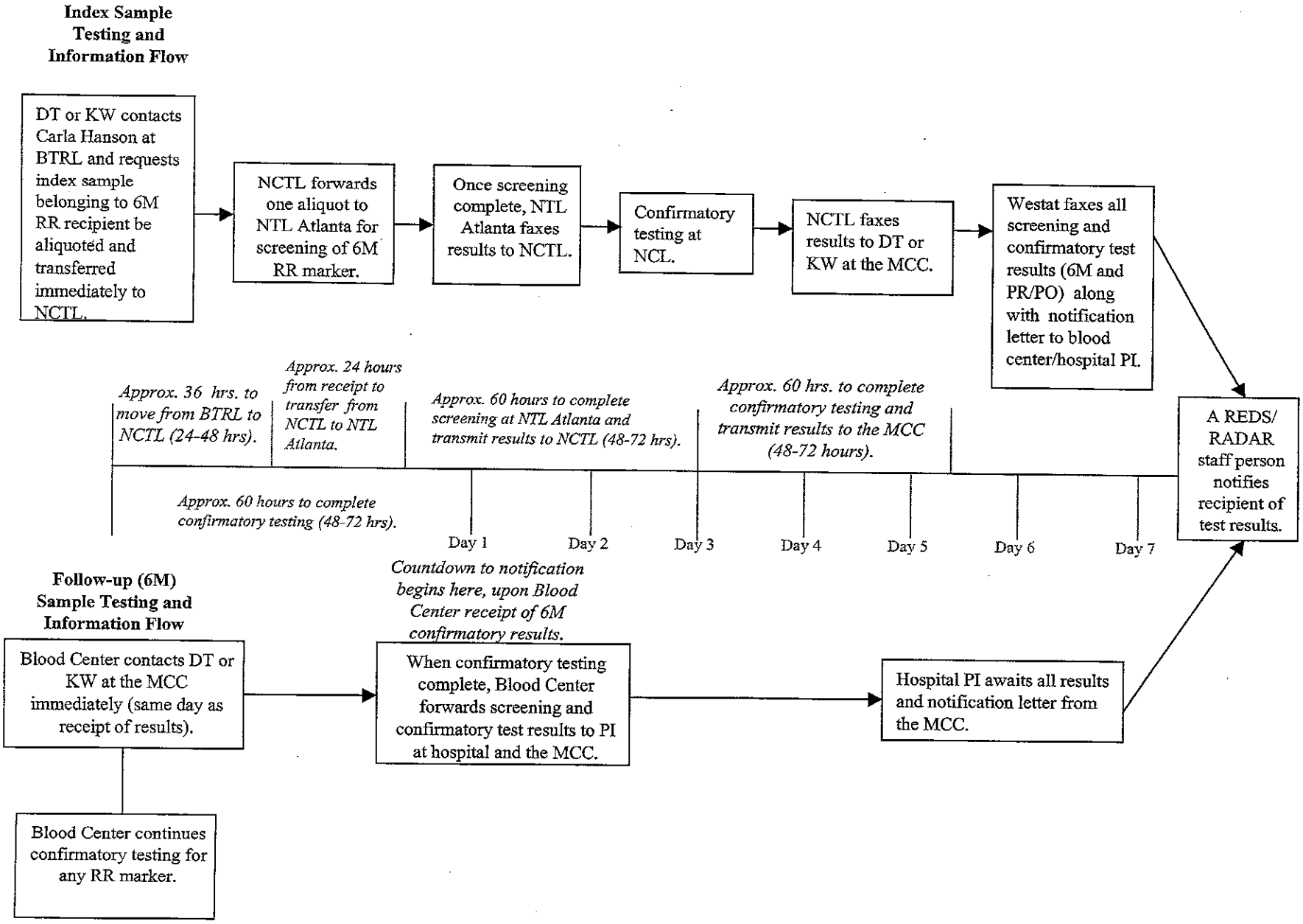
6.1 Testing of Recipient Follow-up (6M)* Samples

Each blood center is responsible for arranging viral marker screening for HIV-1/2 Ab, HCV Ab, HBsAg, anti-HBc and HTLV-I/II Ab on each recipient's follow-up blood sample. Additionally, the blood center is responsible for arranging appropriate confirmatory (or supplemental) testing on any sample which is repeat reactive for one or more markers. On these reactive recipients, all source documents for screening and any supplemental test results, regardless of result (e.g., non-reactive, confirmatory negative, positive, or indeterminate) should be transmitted to the MCC as soon as they become available. Section 6.4 has complete instructions for performing this task.

This chapter describes test result interpretations and procedures for reporting results to both the MCC and the recipient. Specifically, this chapter addresses (1) standard follow-up testing procedures, (2) procedures to follow when testing a recipient's index sample (the sample collected around the time of enrollment and stored in the central repository), (3) additional testing of recipient beyond the follow-up visit, as well as (4) each blood center/hospital's obligation to notify and counsel recipients of their test results appropriately. Figure 6 illustrates the activities surrounding testing, reporting, and notification procedures of the recipient follow-up sample, as well as the expected timeline for conducting these activities. This process of testing, reporting, and notifying recipients requires timely and efficient communication by all parties.

* (6M) designates the recipient's 6-month eligibility interval

Figure 6. RADAR Recipient Testing and Notification Timeline and Flowchart



6.2 Follow-up Sample Screening Assay Result

The blood center will be responsible for designating an appropriate REDS/RADAR research staff person to notify recipients of their test results. This person may be either at the hospital or at the blood center. **In the case of reactive follow-up samples, no notification should occur until all results (confirmatory and all index sample results) have been received and reviewed by the MCC.** Rare occurrences of delayed final test results may trigger an interim notification but only if agreed to by the blood center PI and the MCC, then an exception may be made to the previous statement.

6.2.1 Non-Reactive Screening Results on the Follow-up Sample

When follow-up sample screening results are returned from the blood center testing facility as non-reactive for all viral markers. It is the blood center's responsibility to notify the recipient of his/her results in the manner normally used by blood centers to notify donors who return for any follow-up research. Recipients should receive either written notification or verbal communication within 7 days of receipt of results that all viral marker assays are non-reactive. There are no study-related procedures or forms to be utilized. Blood centers should consider materials or procedures associated with Transfusion Transmitted Infection (TTI) Investigations that could be adapted for this purpose.

6.2.2 Repeatedly Reactive Screening Results on the Follow-up Sample

A reactive screening result on the follow-up sample will require that the blood center immediately contact the MCC as described in Section 6.3. The MCC will requisition the recipient's index (pre-transfusion/enrollment) sample from the Central Repository, BBI-BioTech Research Laboratories (BTRL). Arrangements will be made for the index sample to be tested through the Central Laboratory, the American Red Cross Biomedical Services National Confirmatory Testing Laboratory (NCTL), with the specific viral marker screening assays and any supplemental testing that may be required.

6.3 Notification of MCC by Blood Center of Reactive Follow-up Screening Results

An electronic template (see Exhibit I) has been created to be used for MCC notification of a reactive follow-up screening result. The form is intended to notify the MCC that a recipient's follow-up sample has a repeat reactive screening result, and that their index sample must be aliquoted and transferred to the Central Laboratory for testing. Blood centers should not wait to receive confirmatory results before sending this form to Westat but should use this template to immediately notify the MCC of the reactive screening results. At this same time, send any source documents via fax so that the MCC can verify there have not been any typographical errors on the form and prevent the possibility of pulling an incorrect index sample.

As indicated on the templates, centers must provide the recipient ID, the date of the follow-up draw, name of the blood center, the testing BUI number, and the reactivity of each marker. Please indicate if results are pending or if there are other problems in the comments section. The testing BUI number is the label on the aliquot used for testing. This will allow the MCC to distinguish between different draws from the same recipient. Because the information on this form is vital to the movement and testing of the recipient's index sample (within a short period of time), all fields must be completed.

The templates that have been developed for alerting the MCC may be sent via:

- electronic transmittal by e-mail (preferred method) or
- by fax (this is considered a back-up method)

Either method of communicating this information to MCC staff should be confirmed within a reasonable time (i.e. 4 hours or the next business morning). Confirmation may be done either:

- with an e-mail "Read" receipt verification
- a return e-mail from MCC staff or
- telephone confirmation.

Once the MCC has received this notification, steps for pulling and getting the index sample tested will be initiated.

6.4 Reporting of the Follow-up Supplemental/Confirmatory Results

Once any supplemental/confirmatory test results are returned to the blood center, source documents and any appropriate, completed confirmatory test results forms (for all results other than NR) should be forwarded to the MCC. These documents, which can be sent either electronically (attached to an email) or by fax, should be received by the MCC immediately after receipt at the blood center. The MCC will compare the test results of both the index and follow-up samples, apply the results to the MCC testing directives (see pages 6-11 to 6-19), and forward the Test Results Notification Letter (see Exhibits J and K) to both the blood center and hospital PIs.

Confirmatory test results forms are to be completed for all recipients with reactive follow-up test results. They have been designed to follow current blood center testing algorithms and are similar to those test results forms currently being completed for REDS confirmatory data. A recipient may be reactive for more than one marker and in such a case, a form must be completed for each reactive marker.

All test results forms, except the Recipient 6-Month Test Results Tracking Report, have been modified for electronic completion. The decision whether to complete the forms by hand or electronically is at the discretion of the blood center, but electronic completion and transmission is preferred. Two versions of each form have been created in Microsoft Word '97 and have been enclosed with each manual on a diskette. Forms for completion by hand are designated "Blank" at the beginning of each file name.

Upon opening the forms for electronic completion a window will pop-up asking if macros should be enabled or disabled. Please select "Enable Macros." Macros have been built into the forms so upon completion the form should automatically print 1 copy and reset to the top of the form. Also at the time of printing, the information at the top of any second pages is auto-filled to match the information given at the top of the first page (Recipient ID, date, blood center, and testing BUI number). To save a copy before printing, select "File" from the drop-down menus at the top of the screen, then "Save As." You must rename the file and change the file extension to ". doc."

The form can be navigated by pressing the Tab key or by using the mouse to move between fields. Please note that when indicated to complete a field, there are both text fields and drop down box fields. Selections can be made from the drop down boxes by clicking on the down arrow to the immediate right of the field, or by pressing the ALT button and the down arrow. After toggling to the appropriate text, press ENTER, then TAB to the next field. Text fields are not formatted in any way and the

appropriate response should simply be typed into the space provided. All boxes on the electronic form are check boxes and will be filled with an X upon clicking the left mouse button or by pressing the "X" or the spacebar on the keyboard.

6.4.1 Forms for Reporting RADAR Recipient Test Results for HBV and HCV (Exhibit L)

Blood centers should complete this form for all repeat reactive follow-up HBV (anti-HBc, HBsAg) and/or HCV test results.

- Centers must check off whether these results are for a follow-up sample, an index sample, or a follow-up redraw sample. Blood centers will be completing these forms mainly for routine follow-up draws. However, there may be an occasion when a sample is QNS, a vial is lost or broken, or the test results of the index and follow-up samples are unclear and the follow-up sample must be redrawn. All these may require the "Follow-up Redraw" box be checked. The index sample box will normally only be used by OBI or the MCC.

- In the next section, centers must provide the recipient ID, blood center name, follow-up draw date, and the testing BUI number.

- The following sections are for indicating which markers the recipient has been tested, the reactivity results and details for each, if required. Centers respond to all the sections by checking and completing the appropriate box or boxes if a recipient is reactive for HBV and/or HCV screening. If the recipient is reactive for more than one of these markers, details for each of the corresponding sections must be completed.

- Section I, Anti-HBc Results

  Check the "Not Done" box, if for some reason this assay is not performed because it is QNS or testing is not required for some other reason. Complete or select the name of the test manufacturer (Ortho or Abbott) for the field labeled First EIA. Indicate the reactivity in the "Reactive" box if the sample is reactive or "Non-reactive" if the sample is non-reactive.

  If the blood center testing algorithm uses a 'dual EIA' system i.e. two different manufacturers (currently only BCP uses "dual EIA" for anti-HBc), complete the name of the test manufacturer (Ortho, Abbott or Not Done) for the field labeled Second EIA. Check the "Reactive" box if sample is reactive or "Non-reactive" if the sample is non-reactive. This section must be completed if a secondary EIA is performed, regardless of result. This section does not need to be completed to show results of duplicate or triplicate testing as is done for the regular REDS forms.

- Section 2, HBsAg Screening Results

  Indicate if the screening result is reactive or non-reactive in the appropriate check box. Also, indicate by checking the "Not Done" box, if for some reason this assay is not performed because it is QNS or testing is not required for some other reason. Complete the name of the test manufacturer. Fill in the optical density (OD) and cut-off values for any sample that is repeat reactive for HBsAg. There is also a drop down box in front of the space for digits if a greater than symbol is needed. If both Ortho and Abbott tests are used, i.e. "dual EIA", complete both boxes. If only one is used, complete the information in the corresponding box and write in or select "Not Done" in the other.

- Section 3, HBsAg Confirmatory Results

  If there was no confirmatory testing performed on the follow-up sample check the "Not Done" box and the appropriate reason. For ARC centers, this might be because the first EIA was positive but the second EIA was negative. For OBI this might be because the sample was anti-HBc Positive.

  In the spaces provided, fill in the test name and manufacturer, as well as the neutralization percentage of the sample. Check the appropriate final interpretation box (Pos, Neg, or IND) only if confirmatory testing was performed, it is not necessary if the screening results are non-reactive.

- Section 4, Anti-HBs

  Most recipients will not have anti-HBs results and should have the "Not Done" box checked. If the assay is performed, indicate the quantitative value in MIU/ml, if available. Then check the "Positive (Immune)" box or the "Negative" box.

- Section 5, HCV Screening Results

  Check the "Not Done" box only if the assay is not performed. Check the reactivity in the "Reactive" box if sample is reactive or "Non-reactive" if the sample is non-reactive.

- Section 6, Confirmatory Results

  Check the "Not Done" box only if the assay is not performed. In the spaces provided, fill in the test name and manufacturer. Fill in the intensity of each band. If a band is present but no intensity is given, write in or select "present." If a band is not present write in or select "absent" or "0." Check the appropriate final interpretation box (Pos, Neg, or IND) if there has been HCV confirmatory testing performed.

6.4.2 Forms for Reporting RADAR Recipient Test Results for HIV and HTLV (See Exhibits M and N)

- Blood centers should complete these forms for all repeat reactive follow-up HIV or HTLV test results.
- Again, the type of sample must be identified by checking the appropriate box (follow-up , index, or follow-up redraw).
- As with the Test Results for HBV and HCV form, source documents must accompany completed forms. Blood centers are to provide the Recipient ID, blood center name, date of follow-up draw, and the testing BUI number.
- The format of the remainder of these forms is essentially the same as those currently in use for REDS confirmatory data. Please refer to REDS field memo #'s 90 and 91, which accompanied those forms for detailed instruction on their completion.

6.4.3 Instructions for the completion of the RADAR Recipient 6-Month Test Results Tracking Report (See Exhibit O)

This report lists the recipient ID, draw status, and date of every recipient scheduled for a follow-up visit during the previous month. The MCC will generate this report monthly using RTS data received from blood centers on the 5th of every month. Once received, the MCC will generate and distribute the report within 1 week. Blood centers should complete the form as follows.

- Fill in the testing BUI number for each recipient listed in the spaces provided.
- Circle the follow-up screening test result of each recipient listed (circle 1 if sample is reactive, circle 2 if sample is non-reactive). Reactive results will already be circled when you receive this form.
- Verify the draw status and test results of all recipients.
- For any recipient with reactive results, complete RADAR Test Results form(s) for that specific viral marker.
- Attach all source documents for those recipients who are NR on all screening tests. Source documents and confirmatory test results forms for those recipients with reactive results should have been previously forwarded to Westat.
- Forward all source documents to Westat.

- Destroy NAT aliquots stored temporarily in blood center freezer for all follow-up recipients with non-reactive serology results for ALL markers.

- MCC will list IDs with reactive screening results that have had ALL testing on both index and follow-up samples completed. Destroy NAT aliquots stored temporarily in blood center freezer for these IDs.

- Any IDs not listed to be destroyed should be held in the blood center freezer. If there any questions about a particular sample, please contact the MCC before destroying.

If any reactive result is not pre-circled, Westat must be notified **immediately** to ensure that testing of an index sample was not overlooked. If the draw status of a recipient is incorrect, please write in the correct information. Forward the completed form and all accompanying documentation to Westat within two weeks of its receipt at the blood center.

6.5 Notification of Blood Center and Recipient of Results of Reactive Follow-up Sample and Subsequent Index Sample Testing

The principles guiding test interpretation can be found as Exhibit P. These principles include how the test results will be communicated from the MCC to the blood center/hospital and an explanation of events surrounding possible further follow-up sampling and testing of the recipient. Once testing has been completed on both the follow-up and index sample, the MCC will refer to the MCC version of the testing directives for guidance in notification and/or further testing of recipients blood. For results that are straightforward, a letter (see Exhibit J) will be sent to the blood center/hospital based PI indicating the results of both the follow-up and index sample tests and a final conclusion based upon the testing directives. Dr. Steven Kleinman or his designee will review results that are not clear-cut or require further testing or follow-up. Subsequent to this, a letter, shown in Exhibit K will be sent to the blood center/hospital PIs.

Every attempt will be made to get these letters to the blood center/hospital PI within 7 business days of the receipt of the follow-up confirmatory results by the blood center. This time frame is mandated by several of the blood centers as standard operating procedure for notification of both donors and others who receive testing through their laboratories and the RADAR Study will comply with these mandates.

When a blood center receives a letter such as described above, the RADAR designated staff should review and verify the results with the local laboratory results. Next, this letter with the combined index and follow-up results should be compared with the blood center directives found as pages 6-11 to 6-19 at the end of this chapter. Verify the message to communicate to the recipient and to determine if further actions are necessary. Materials to be given to the recipient are at the discretion of each blood center but samples of each should be forwarded to the MCC to be kept on file for IRB and NHLBI inquiries. Please keep in mind that no personal information on the recipient other than the RADAR ID should ever be sent to the MCC.

If an additional follow-up blood sample is required by the testing directives, details will be determined and communicated on a case-by-case basis. The re-draw will essentially follow the same guidelines as for the follow-up phlebotomy, less the need to draw a repository tube. Routine serological testing will be performed at the blood center laboratory and any special testing will be determined by the specific assay required. All questions should be addressed to the MCC.

6.5.1 Routine Transfusion Transmitted Infection (TTI) Result Notification of RADAR Study Enrollees

In the event results of the index and follow-up sample testing indicate a possible Tranfusion Transmitted Infection (TTI), every effort must be made to communicate this information to the RADAR study enrollee as soon as possible. Each attempt must be well documented. Notification of the recipient may be in whatever form the RADAR site deems most appropriate and consistent with standard operating procedures at the respective hospital and blood center. Sample copies of material used (minus identifying information other than RADAR ID) should be supplied to the MCC if allowable. It is the responsibility of the RADAR staff to assure counseling messages include complete and accurate results for both the index and the follow-up sample, and that they correspond with information found in the blood center or MCC testing directives. All activities must also comply with regulations of the state in which the RADAR center is located and must also adhere to the policies of the local RADAR blood center/hospital (see Exhibit Q).

G. Blood Center HCV Testing Directive: Notification of Serology Results

	Index Sample Serology Result	6-Month Sample Serology Result	Interpretation/ Notification Message	Action
G1	EIA Negative	EIA Repeat Reactive, RIBA Negative	1) Probably not infected 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HCV NAT 3) Upon receipt of NAT test results at the blood center, refer to the HCV directive to notify recipient of combined test results
G2	EIA Negative	EIA Repeat Reactive, RIBA Indeterminate	1) Infection status uncertain [1,2] 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HCV NAT 3) Upon receipt of NAT test results at the blood center, refer to the HCV directive to notify recipient of combined test results
G3 **	EIA Negative	EIA Repeat Reactive, RIBA Positive	1) Probably infected [1] 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HCV NAT 3) MCC arranges shipment of Index sample for HCV NAT 4) Upon receipt of NAT test results at the blood center, refer to the HCV directive to notify recipient of combined test results
G4	EIA Repeat Reactive, RIBA Negative or Indeterminate	EIA Repeat Reactive, RIBA Negative	Not infected	1) Notify recipient of serology test results 2) No further action; recipient workup completed
G5	EIA Repeat Reactive, RIBA Negative or Indeterminate	EIA Repeat Reactive, RIBA Indeterminate	Possibly infected [1]	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HCV NAT 3) MCC arranges shipment of Index sample for HCV NAT 4) Upon receipt of NAT test results at the blood center, refer to the HCV directive to notify recipient of combined test
G6 **	EIA Repeat Reactive, RIBA Negative or Indeterminate	EIA Repeat Reactive, RIBA Positive	1) Probably infected [1] 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HCV NAT 3) MCC arranges shipment of Index sample for HCV NAT 4) Upon receipt of NAT test results at the blood center, refer to the HCV directive to notify recipient of combined test results
G7 **	EIA Repeat Reactive, RIBA Positive	EIA Repeat Reactive, RIBA Positive	Infected pre-surgery[1]	1) Notify recipient of serology test results 2) No further action; recipient workup completed

*** All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.**

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious
[2] Results may reflect either evolving seroconversion or false reactivity of HCV assays

H. Blood Center HCV Testing Directive: Notification of Combined Serology and NAT Results

	Index Sample Serology Result	Index Sample NAT Result	6-Month Sample Serology Result	6-Month Sample NAT Result	Interpretation/ Notification Message	Action
H1	EIA Negative	NT	EIA Repeat Reactive, RIBA Negative	Neg	Not infected	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
H2 **	EIA Negative	Neg	EIA Repeat Reactive, RIBA Negative	Pos	Probably infected [1]	1) Notify recipient of combined serology and NAT test results 2) Redraw (Type 3) and send for serology and NAT testing 3) Notify recipient of redraw test results and interpretation
H3 **	EIA Negative	Pos	EIA Repeat Reactive, RIBA Negative	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
H4	EIA Negative	NT	EIA Repeat Reactive, RIBA Indeterminate	Neg	Not infected	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
H5 **	EIA Negative	Neg	EIA Repeat Reactive, RIBA Indeterminate	Pos	Probably infected [1]	1) Notify recipient of combined serology and NAT test results 2) Redraw (Type 3) and send for serology and NAT testing 3) Notify recipient of redraw test results and interpretation
H6 **	EIA Negative	Pos	EIA Repeat Reactive, RIBA Indeterminate	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed

*** All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.**

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious

[2] Recent Infection: Infection may have occurred post-surgery, at surgery, or a few days to weeks prior to surgery

Redraw Type	Purpose	Timing
1	Test error or discrepancy	Recipient's earliest convenience
2	Verify result	Recipient's earliest convenience
3	Evolution in reactivity	No less than 4 weeks from 6-month follow-up visit

H7	**EIA Negative**	Neg	**EIA Repeat Reactive, RIBA Positive**	Neg	Probable recent infection that patient may have resolved [1, 2]	1) Notify recipient of combined serology and NAT test results 2) Redraw (Type 2) and send for serology and NAT testing 3) Notify recipient of redraw test results and interpretation
H8 **	**EIA Negative**	Pos	**EIA Repeat Reactive, RIBA Positive**	Neg	Infected pre-surgery; Patient may have resolved infection [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
H9	**EIA Negative**	Neg	**EIA Repeat Reactive, RIBA Positive**	Pos	Recent infection [1, 2]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
H10 **	**EIA Negative**	Pos	**EIA Repeat Reactive, RIBA Positive**	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed

*** All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.**

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious

[2] Recent Infection: Infection may have occurred post-surgery, at surgery, or a few days to weeks prior to surgery

Redraw Type	Purpose	Timing
1	Test error or discrepancy	Recipient's earliest convenience
2	Verify result	Recipient's earliest convenience
3	Evolution in reactivity	No less than 4 weeks from 6-month follow-up visit

H11	**EIA Repeat Reactive, RIBA Negative or Indeterminate**	NT	**EIA Repeat Reactive, RIBA Negative**	NT	Not infected	1) Actions previously completed following serology testing
H12	**EIA Repeat Reactive, RIBA Negative or Indeterminate**	NT	**EIA Repeat Reactive, RIBA Indeterminate**	NT	Not infected	1) Actions previously completed following serology testing
H13 **	**EIA Repeat Reactive, RIBA Negative or Indeterminate**	Pos	**EIA Repeat Reactive, RIBA Positive**	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
H14 **	**EIA Repeat Reactive, RIBA Positive**	NT	**EIA Repeat Reactive, RIBA Positive**	NT	Infected pre-surgery[1]	1) Actions previously completed following serology testing

*** All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.**

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious

[2] Recent Infection: Infection may have occurred post-surgery, at surgery, or a few days to weeks prior to surgery

Redraw Type	Purpose	Timing
1	Test error or discrepancy	Recipient's earliest convenience
2	Verify result	Recipient's earliest convenience
3	Evolution in reactivity	No less than 4 weeks from 6-month follow-up visit

J. Blood Center HIV Testing Directive: Notification of Serology Results

All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.

Does not currently account for HIV-2 testing/results

	Index Sample Serology Result	6-Month Sample Serology Result	Interpretation/ Notification Message	Action
J1	EIA Negative	EIA Repeat Reactive, WB Negative	1) Probably not infected 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HIV NAT 3) Upon receipt of NAT test results at the blood center, refer to the HIV directive to notify recipient of combined test results
J2	EIA Negative	EIA Repeat Reactive, WB Indeterminate	1) Infection status uncertain [1,2] 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HIV NAT 3) Upon receipt of NAT test results at the blood center, refer to the HIV directive to notify recipient of combined test results
J3 **	EIA Negative	EIA Repeat Reactive, WB Positive	1) Probably infected [1] 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HIV NAT 3) MCC arranges shipment of Index sample for HIV NAT 4) Upon receipt of NAT test results at the blood center, refer to the HIV directive to notify recipient of combined test results
J4	EIA Repeat Reactive, WB Negative or Indeterminate	EIA Repeat Reactive, WB Negative	Not infected	1) Notify recipient of serology test results 2) No further action; recipient workup completed
J5	EIA Repeat Reactive, WB Negative or Indeterminate	EIA Repeat Reactive, WB Indeterminate	Not infected	1) Notify recipient of serology test results 2) No further action; recipient workup completed
J6 **	EIA Repeat Reactive, WB Negative or Indeterminate	EIA Repeat Reactive, WB Positive	1) Probably infected [1] 2) Further testing is being performed	1) Notify recipient of serology test results 2) Arrange shipment of 6-month sample for HIV NAT 3) MCC arranges shipment of Index sample for HIV NAT 4) Upon receipt of NAT test results at the blood center, refer to the HIV directive to notify recipient of combined test results
J7 **	EIA Repeat Reactive, WB Positive	EIA Repeat Reactive, WB Positive	Infected pre-surgery[1]	1) Notify recipient of serology test results 2) No further action; recipient workup completed

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious
[2] Results may reflect either evolving seroconversion or false reactivity of HIV assays

K. Blood Center HIV Testing Directive: Notification of Combined Serology and NAT Results

All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.

	Index Sample Serology Result	Index Sample NAT Result	6-Month Sample Serology Result	6-Month Sample NAT Result	Interpretation/ Notification Message	Action
K1	EIA Negative	NT	EIA Repeat Reactive, WB Negative	Neg	Not infected	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
K2 **	EIA Negative	Neg	EIA Repeat Reactive, WB Negative	Pos	Probably infected [1]	1) Notify recipient of combined serology and NAT test results 2) Redraw (Type 3) and send for serology and NAT testing 3) Notify recipient of redraw test results and interpretation
K3 **	EIA Negative	Pos	EIA Repeat Reactive, WB Negative	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
K4	EIA Negative	NT	EIA Repeat Reactive, WB Indeterminate	Neg	Not infected	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
K5 **	EIA Negative	Neg	EIA Repeat Reactive, WB Indeterminate	Pos	Probably infected [1]	1) Notify recipient of combined serology and NAT test results 2) Redraw (Type 3) and send for serology and NAT testing 3) Notify recipient of redraw test results and interpretation
K6 **	EIA Negative	Pos	EIA Repeat Reactive, WB Indeterminate	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
K7 **	EIA Negative	Neg	EIA Repeat Reactive, WB Positive	Pos	Recent infection [1, 2]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
K8 **	EIA Negative	Pos	EIA Repeat Reactive, WB Positive	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious

[2] Recent Infection: Infection may have occurred post-surgery, at surgery, or a few days to weeks prior to surgery

Redraw Type	Purpose	Timing
1	Test error or discrepancy	Recipient's earliest convenience
2	Verify result	Recipient's earliest convenience
3	Evolution in reactivity	No less than 4 weeks from 6-month follow-up visit

K. Blood Center HIV Testing Directive: Notification of Combined Serology and NAT Results

All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.

	Index Sample Serology Result	Index Sample NAT Result	6-Month Sample Serology Result	6-Month Sample NAT Result	Interpretation/ Notification Message	Action
K9	**EIA Repeat Reactive, WB Negative or Indeterminate**	NT	**EIA Repeat Reactive, WB Negative**	NT	Not infected	1) Actions previously completed following serology testing as shown in directive J4
K10	**EIA Repeat Reactive, WB Negative or Indeterminate**	NT	**EIA Repeat Reactive, WB Indeterminate**	NT	Not infected	1) Actions previously completed following serology testing as shown in directive J5
K11 **	**EIA Repeat Reactive, WB Negative or Indeterminate**	Pos	**EIA Repeat Reactive, WB Positive**	Pos	Infected pre-surgery [1]	1) Notify recipient of combined serology and NAT test results 2) No further action; recipient workup completed
K12 **	**EIA Repeat Reactive, WB Positive**	NT	**EIA Repeat Reactive, WB Positive**	NT	Infected pre-surgery[1]	1) Actions previously completed following serology testing as shown in directive J7

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Footnotes

[1] Counsel as potentially infectious

[2] Recent Infection: Infection may have occurred post-surgery, at surgery, or a few days to weeks prior to surgery

Redraw Type	Purpose	Timing
1	Test error or discrepancy	Recipient's earliest convenience
2	Verify result	Recipient's earliest convenience
3	Evolution in reactivity	No less than 4 weeks from 6-month follow-up visit

L. Blood Center HBV Testing Directive

All patterns of reactivity other than those listed above will be reviewed by Steven Kleinman, M.D., or designee. Interpretation, notification message and action will be forwarded to the respective blood center.

	Index Sample Serology Results		6-Month Sample Serology Results			
	HBsAg [1]	anti-HBc	HBsAg [1]	anti-HBc	Interpretation/ Notification Message	Action
L1 **	Pos	Pos	Pos	Pos	Chronic carrier [2]	1) Notify recipient of serology test results 2) No further action; recipient workup completed
L2 **	Pos	Neg	Pos	Pos	Chronic carrier [2]	1) Notify recipient of serology test results 2) No further action; recipient workup completed
L3 **	Neg	Neg	Pos	Pos	Recently infected [2]	1) Notify recipient of serology test results 2) Redraw (Type 2) 3) Recontact recipient with redraw test results
L4 **	Neg	Neg	Pos	Neg	Recent infection or false positive HBsAg [2,3]	1) Notify recipient of serology test results 2) Redraw (Type 3) 3) Recontact recipient with redraw test results
L5			Neg	Pos		1) MCC triggers testing of Index sample for anti-HBc 2) Based on anti-HBc Index sample result, see 5a below
5a	ND	Pos			Probable past infection or persistently false positive HBc	1) Notify recipient of serology test results a) If indicated in blood center SOP for donor notification, perform anti-HBs testing on 6-month sample to resolve results b) If anti-HBs not indicated in blood center SOP, then no further action; recipient workup completed

**** Westat will forward all positive results to Steven Kleinman, M.D., or designee, for review.**

Type of Redraw Sample		
Type	Purpose	Timing
1	Test error or discrepancy	Recipient's earliest conveinience
2	Verify result	Recipient's earliest conveinience
3	Evolution in reactivity	No less than 4 weeks from 6-month follow-up visit
All redraws tested for HBsAg and anti-HBc unless otherwise indicated		

Footnotes

[1] Positive is an EIA RR with a positive neutralization. Results of HBsAg EIA RR, non-neutralized have not been considered

[2] Counsel as potentially infectious

[3] Recent Infection: Infection may have occurred post-surgery, at surgery, or a few days to weeks prior to surgery

M. Blood Center HTLV Testing Directive

All Repeat Reactive Dual EIA HTLV results will be handled on a case-by-case basis and reviewed by Steven Kleinman, M.D. or designee. Interpretation, notification message and action will be forwarded to the respective blood center.

DeENROLLING PARTICIPANTS CHAPTER 7

7. DE-ENROLLING STUDY PARTICIPANTS

The informed consent documents for both blood donors and recipients state that participants may withdraw from the study at any time without penalty. In the event that a blood donor or a recipient notifies a blood center or study recruiter that they wish to withdraw from the RADAR Repository, the information should be collected from the donor or recipient using the RADAR De-Enrollment Form shown in Exhibit R.

Following are the three main reasons for de-enrolling a study participant:

1. A blood donor or a recipient notifies the blood center or the study recruiter that they wish to withdraw from the study

2. A recipient does not receive at least one RADAR Repository blood unit during a transfusion event at first admission.

3. It is not possible to obtain a donor blood specimen, or a pre-transfusion or post-transfusion sample from a recipient, or the sample collected is insufficient for future testing. Refer to sections 2.6, 3.3 and 4.6 of this manual, for information on obtaining a donor's repository specimen recipient's pre-transfusion and/or post-transfusion sample, respectively.

Box 7A

☛ Procedures for de-enrolling a study participant

1. Document the date the request is received from the donor or recipient.

2. Document the person's full name, address, telephone number, date of birth, and social security number, approximate date of enrollment, and reason for withdrawal.

3. If available, request the WBN or recipient study ID from the donor or recipient. If this information is not obtainable from the person wishing to withdraw, the blood center should utilize the stored signed consent forms and/or other means to obtain the information.

4. Send an email to the MCC (attn: Donna Smith, donnasmith@westat.com) with the individual's WBN or RADAR Repository study identification number. In the email, include the date of contact with the individual, the reason they wish to withdraw from the study, and the date the informed consent was signed. Do not send the MCC any identifying information such as the person's name or social security number.

If a donor notifies the blood center that they wish to withdraw from the study before their unit has been sent out to the collaborating hospital, the blood center should remove the RADAR "tagging" label placed on the unit at the time of donor enrollment. This unit must not be designated as a RADAR unit in the Transfusion Service computer at the hospital. The MCC will take the required steps to remove the person from the database and ensure that all frozen whole blood or plasma samples are retrieved from the central storage facility and destroyed. If samples are determined to still be stored at the blood center, the MCC will direct the blood center staff to the exact box location from which to remove processed tubes.

SAMPLE PROCESSING CHAPTER 8

8. SAMPLE PROCESSING AND STORAGE AT THE BLOOD CENTER

8.1 Overview

Each blood center is responsible for processing all donor and recipient repository samples according to the procedures outlined in this chapter. Each participating blood center will need to have a – 70° C freezer designated for temporary storage of both donor and recipient cryovials. Specimen cryovials will be stored in these freezers using a total of two sets of boxes. The first set will hold donor cryovials and the second set will hold recipient cryovials. All processed recipient samples and donor samples linked to enrolled recipients will be shipped to BBI-Biotech Research Labs (BTRL) from the blood center, along with a randomly selected group of unlinked donor samples on a semi-annual basis (every six months) for the donor samples and quarterly for the recipient samples. The MCC will direct the blood centers on the selection of these unlinked donor cryovials for shipment. All donor cryovials not selected for shipment to BTRL should be stored in the blood centers' REDS – 40° C or alternate – 70° C freezers until notified concerning their disposition near the end of the study. See Chapter 9 for more information on the shipping process.

8.2 Laboratory Supplies

Box 8A provides a list of required supplies for processing and storage of both donor and recipient repository samples. Many of the REDS blood centers may already have some of these supplies available from previous studies.

Box 8A
Laboratory supply list

Racks

- ✓ 7 or 10-ml sample tube racks; Red Nalgene Unwire, 6X12 holes, polypropylene
  CMS 273-070 - *racks*
- ✓ Whole blood racks – 4 rows with 10 apertures per row
  Sarstedt 93.1428 - *racks*
- ✓ Plasma racks- Nalgene Cryovial Holders, 5 rows with 16 apertures per row

(Box 8A continued)

CMS 03-337-7E - *racks*

Cryovials and Colored Inserts

✓ Whole blood cryovials – 1.5-ml microcentrifuge tubes with self-standing "o" ring and attachment loop

CST332-4 – *Vials*

CST345Y - *Yellow Donor Inserts*

CST345G - *Green Recipient Inserts*

✓ Plasma cryovials - 2.0-ml micro tubes with skirted base

Sarstedt 72.609 - *Vials*

Sarstedt 65.716.003 - *Red Donor Caps*

Sarstedt 65.716.005 - *Green Recipient Caps*

Miscellaneous

✓ Protective centrifugation caps for WB samples

Scientific Products Disposable 16 mm Ezee Topper Protective Caps for 10-ml tube-SPB3035-55

✓ 2" x 2" gauze squares

✓ Graduated transfer pipettes

✓ Centrifuge

✓ Vortex

✓ Personal protective wear

✓ Box and aliquot labels *(supplied by BTRL)*

✓ SO-LO -70 ° C laboratory freezer

✓ 2" storage boxes with 81 cell dividers

✓ Freezer racks (44) *(provided with -70 ° freezer)*

✓ REDS - 40 ° laboratory freezer and Forma freezer racks

8.3 Sample Volume Requirements

The total sample volume that is to be stored in the RADAR Repository per study participant is approximately 6-ml which must include a minimum of 1.0-ml of plasma as required by the study protocol. In the event that there is not adequate volume for both plasma aliquots *and* the whole blood

tube, the priority for repository storage is first to fill the plasma aliquots with available plasma and then to fill the whole blood aliquot with residual cells. Additional plasma volume and whole blood can be obtained for the recipient with a second specimen drawn post-transfusion during enrollment. The alternate procedure for handling samples with less than the needed volume is found in Box 8B. In order to provide RADAR Repository laboratory staff with a method to approximate this volume, each blood center's laboratory should mark an empty vacutainer at the 7-ml level. The extra 1-ml marked on the visual comparison tube should account for packed cells left in the bottom of the tube after removal of the 1.5-ml of whole blood, centrifugation, and removal of 4.0 ml of plasma, allowing for nearly 6-ml to be processed and stored. Keep this visual reference Vacutainer® tube in the RADAR Repository processing lab. Box 8B describes the optimal RADAR Repository volume per cryovial after processing.

Box 8B

Optimal sample aliquot volumes for storage in the RADAR Repository

- ✓ (1) 1.5-ml WB
- ✓ (1) 2.0-ml plasma (in the first cryovial)
- ✓ (1) 2.0-ml or Residual plasma (in the second cryovial)

8.4 Aliquot Volume Adjustment

It is important to record the correct tube volume for each specimen entered in the SIS. Any volume falling below the required 1.5-ml WB or below the 2.0-ml plasma must be documented in the SIS. When wanding in the aliquot tubes as described in Box 8C the system automatically defaults to the optimal volume amount unless the processor adjusts the volume. In the event that an aliquot falls below the required volume, the processor should adjust the volume recorded in the SIS using the aliquot volume adjustment codes card (Exhibit S).

The aliquot volume adjustment codes are bar code readable volumes requiring no manual adjustment by the processor. The aliquot adjustment codes allow the processor to wand in the decreased volume in 0.25 ml increments. The processor should always round down when adjusting the volume. For example, if a processor is accessioning an aliquot containing 1.65 ml of plasma, the processor should wand in the 1.50 ml bar code located on the aliquot volume adjustment codes card.

In the event that a plasma tube breaks during centrifugation or there is no specimen for any other reason for the RADAR Repository, a place holder tube will *not* be used and no volume will be recorded. Only record those vials with volumes greater than 0-ml.

8.5 RADAR Repository labeling system

The MCC will provide three types of labels to each of the blood centers which when used in conjunction with the RADAR Repository Sample Inventory System (SIS), will facilitate the tracking of cryovials, boxes, and racks. Each blood center will receive freezer rack labels, box labels, and aliquot labels, all of which are described below.

8.5.1 Freezer Rack Labels

One reusable brass tag is provided for each rack so that each freezer rack can be easily identified. For the -70° C freezer racks, place the tag on the top of the rack facing upward so that upon opening the top of the freezer the rack number is in plain view.

The number format for the rack labeling is " RADAR AAABB," where

AAA = Rack Number	001 –999
BB = Rack Contents	DO = Donor Whole Blood and Plasma RE = Recipient Whole Blood and Plasma (or serum)

Examples of Freezer Rack Tag Labeling

RADAR 012RE indicates that the rack:

- Is the 12th rack in the freezer; and
- Contains donor whole blood and plasma cryovials.

RADAR 004DO indicates that the rack:

- Is the 4th rack in the freezer;
- Contains donor whole blood and plasma.

8.5.2 Box Labels

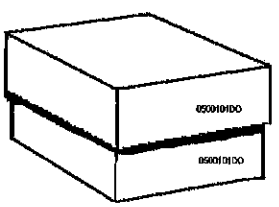
Box labels are designed to provide information on what type of samples are in the box, donor or recipient samples, and indicate in which rack number the box is located. For each individual 2" box, two box labels are provided. Box labels should be assigned in ascending sequential order and are designated to be placed on either a donor or recipient box. One of the two labels should be placed on the side of the base of each box and the other corresponding label should be placed on the side of the lid of the box. Make sure that the label is placed on the lid such that the label faces outward on the rack, aiding in the ability of laboratory staff to quickly identify the correct box when it is time for shipping. Each box and its corresponding lid should be marked with identical ID labels. Confirm that the label on the bottom and on the lid of each box matches. In the event that a label is damaged, skip a space in the rack and label the box with the next number in the sequence. The format for box labels is "AABBBCCDD," where:

AA = Blood Center	01 = ARC – Chesapeake 02 = ARC – Southeastern Michigan 03 = ARC – Southern California 04 = Blood Centers of the Pacific- Irwin 05 = Oklahoma Blood Institute 06 = Institute for Transfusion Medicine 07 = Florida Blood Services
BBB = Rack Number	001 – 999
CC = Box Number	01 – 13
DD = Rack Contents	DO = Donor Whole Blood and Plasma RE = Recipient Whole Blood and Plasma (or serum)

Examples of Box Labels

0500101DO indicates that the box of cryovials:

- Was collected at the Oklahoma Blood Institute;
- Is stored in the first freezer rack;
- Is the first box of the rack; and
- Is donor whole blood and plasma.



0407513RE indicates that the box of cryovials:

- Was collected at BCP;
- Is stored in the 75th rack;
- Is box number 13 (last box) of the rack
- Is recipient whole blood and serum.

8.5.3 Aliquot Tube Lab ID Labels

A set of cryovial Lab ID labels is provided for each RADAR Repository blood sample. The format for the cryovial labels is "AABBBBBBCCC," where:

AA= Blood Center	RA = ARC – Chesapeake RB = ARC – Southeastern Michigan RC = ARC – Southern California RD = Blood Centers of the Pacific-Irwin RE = Oklahoma Blood Institute RF = Institute for Transfusion Medicine RG = Florida Blood Services
BBBBBB = Sequential cryovial number in repository	000001 – 999999
CCC = Sample type	001 = Blood Tube 002 = Whole Blood 003 = Plasma (first tube) 004 = Plasma (second tube)

Examples of Lab ID Labels

RB-000004-002 indicates that the cryovial:

- Was collected at ARC – Southeastern Michigan;
- Is repository cryovial number 000004; and
- Is the (single) whole blood cryovial for that repository sample.

RA-001190-004 indicates that the cryovial:

- Was collected at ARC – Chesapeake;
- Is repository cryovial number 001190; and
- Is the second plasma cryovial for that repository sample.

8.5.4 Application of a Label to a Tube

To apply a tube label, hold the cryovial vertically and wrap the label around the cryovial starting with the *top* of the label. There will be an overlap with a clear flag area, but by wrapping from the top of the label to the bottom, the bar code and the identifying information will be clearly visible. Visual instructions are provided below in Figures 7 and 8.

8.6 Processing Donor Repository Samples

8.6.1 Setting Up For Donor Repository Sample Processing

Before donor repository samples are processed in the laboratory, each blood center must perform a manual reconciliation between the enrolled donors' WB sample specimens or retention tubes and the corresponding signed informed consents collected on the mobiles. In the event that there is a discrepancy, the blood center will need to investigate. It is essential that the blood center only process and store specimens from consenting donors. In instances where the donor sample specimen is to be retrieved from quarantine in order to be processed, use the table below to determine the location of the tube to be retrieved.

	Source of Blood Specimen		
	(1) 7 or 10 ml lavender top (EDTA) tube	**(2) Retention tube**	**(3) WB NAT tube**
Process tube at blood center within ➡	within 48 hours no longer than 7 days	within 72 hours no longer than 7 days	72 hours
Retrieve tubes for processing from ➡	RADAR designated rack	Quarantine- use SIS printout for direction on tube(s) to be retrieved.	Quarantine- use SIS printout for direction on tube(s) to be retrieved.

After retrieving the donor specimens to be processed for the repository, label all whole blood and plasma aliquot sample tubes. Label three cryovials for every enrollment sample collected from a consenting donor, e.g., one aliquot tube labeled for WB and two aliquot tubes labeled for plasma. Be sure to use labels from the same set of laboratory ID numbers. Apply the label following the instructions

provided in Section 8.5.4, as demonstrated in Figures 7 and 8, and place the empty cryovials in their corresponding racks. Donor whole blood (WB) and plasma cryovials should be stored together in separate sets of boxes. Before beginning the processing steps, label the 2" donor storage boxes as described in Section 8.5.2.

Figure 7: Applying a repository label to a bar code labeled vacutainer tube

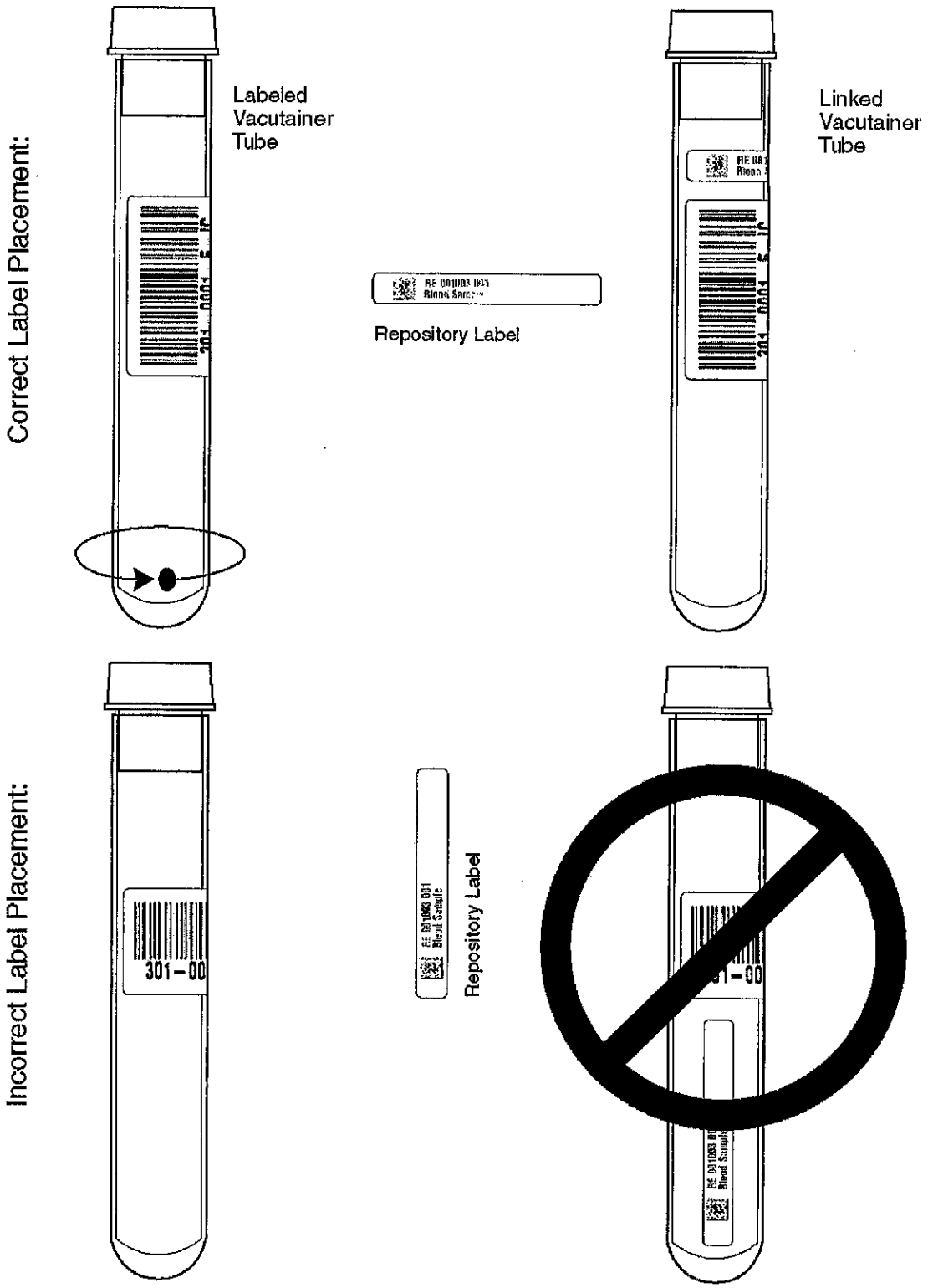
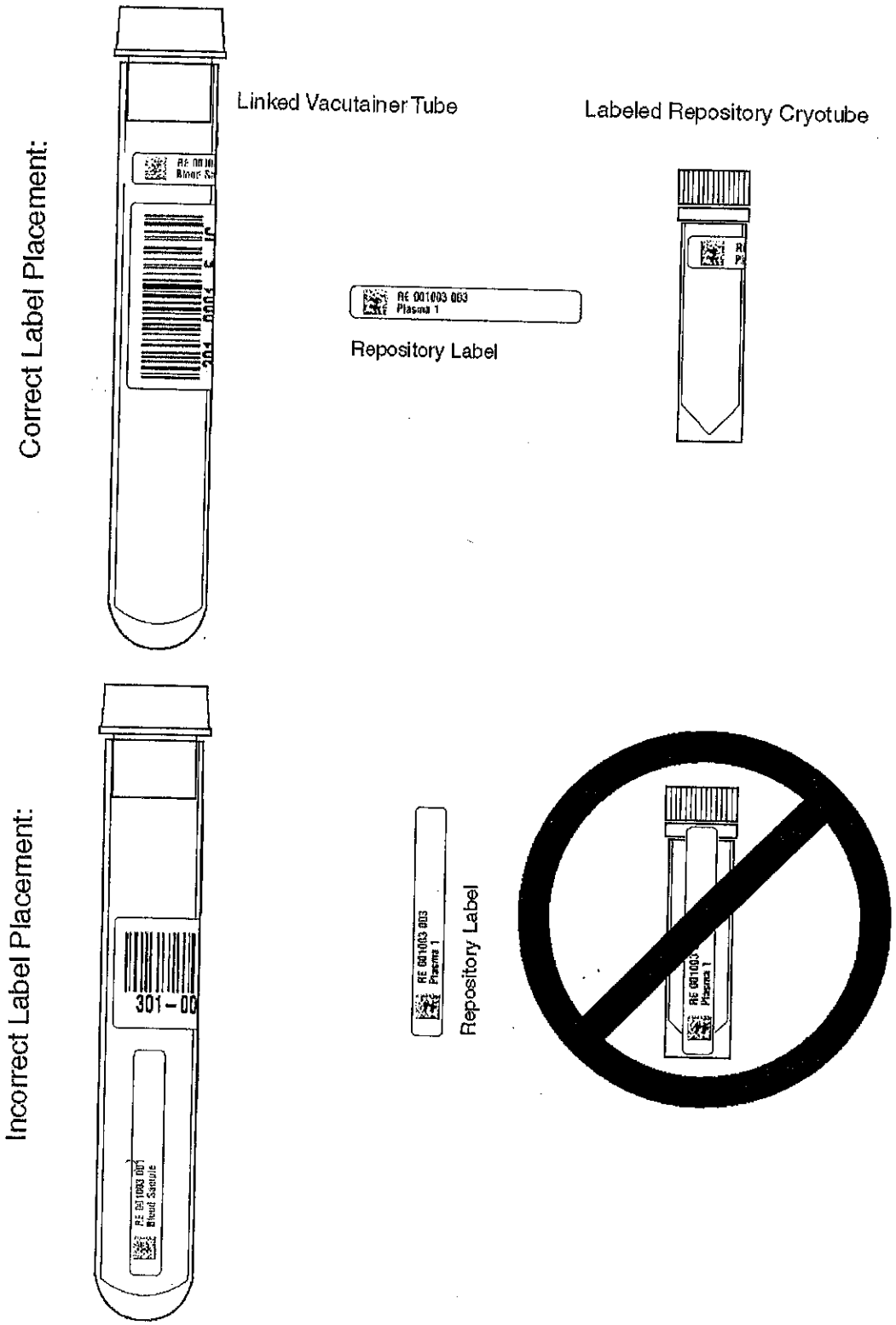


Figure 8: Applying a label to a cryotube



8.6.2 Instructions for Processing Donor Repository Specimens

Box 8C

Processing donor repository specimens

Laboratory staff should follow Universal Precautions and OSHA Bloodborne Pathogen Rules throughout the following sample processing procedures.

Donor Whole Blood

1. Place a Laboratory ID on the donor enrollment sample tube. This label will correspond to the aliquot lab ID labels already placed on the empty whole blood and plasma cryovials.
2. Vortex the original donation tube to re-suspend the blood cells evenly.
3. Gently remove the stopper from the tube using a 2" x 2" gauze square to cover the top of the tube.
4. Pipette 1.5-ml of whole blood from the donation sample tube into the cryovial using a clean transfer pipette.
5. Recap the donation sample tube. Use yellow inserts for all donor WB aliquot tubes.
6. Repeat procedures 2 through 4 for every donation tube until the working rack has been filled.
7. Retrieve a 2" donor storage box. This may be a new box or a partially filled box from the freezer. Donor plasma and WB cryovials may be placed in the same box.
8. Wand the box label into the SIS. In the event that an error message is displayed, check the box number. The SIS keeps track of boxes such that should a box be wanded in the SIS out of ascending sequential order an error message will be displayed. The error message will disappear when the box problem is corrected. See section 8.5.2 for further box labeling information.
9. Working with one donation sample tube at a time, wand in the SIS the WBN and the Lab ID label from the donation sample tube.
10. In the event that an aliquot volume falls below the default 1.5 ml, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. (see Exhibit S).
11. Wand the corresponding WB cryovial label, in the SIS. Should this sample be rejected by the system, place it in a rack labeled "Not Eligible" and investigate the consent status of this sample after you have finished with processing the other samples.
12. Place the cryovial in the donor box cell indicated by the SIS.

(Box 8C continued)

13. Repeat steps 9 through 12, filling the box row from left to right starting with the upper left-hand corner. The SIS will guide the placement of tubes in the box, proceeding through each row to the lower right-hand corner. The last cell in the box should remain empty (although each box has 81 cells, store only 80 cryovials per box).

14. Store the boxes in the –70 ° C freezer.

Donor Plasma

15. Centrifuge the donation sample tubes at 2500 rpm for 20 minutes to permit removal of the plasma.

16. Retrieve the rack containing the empty plasma cryovials. The processor should have previously labeled these empty plasma cryovials with aliquot Lab ID labels.

17. As you remove the donation sample tubes from the centrifuge, arrange them in sequence to match the empty plasma cryovials in the working rack.

18. Using a clean pipette, pipette 2.0-ml plasma from the donation sample tube to the first of the corresponding two plasma cryovials.

19. Pipette the remaining plasma into the second tube.

20. Cap donor plasma cryovials with red caps.

21. Repeat steps 17 to 20 until all samples have been processed.

22. Retrieve a 2" donor box. This may be a new box or a partially filled box from the freezer. Donor plasma and WB cryovials may be placed in the same box.

23. Wand the box label into the SIS. In the event that an error message is displayed, check the box number. The SIS tracks boxes such that should a box be wanded in the SIS out of ascending sequential order an error message will be displayed. The error message will disappear when the box problem is corrected. See section 8.5.2 for further box labeling information.

24. Working with one donation sample tube at a time, wand the WBN and Lab ID label from the donation sample tube into the SIS.

25. In the event that an aliquot volume falls below the default of 1.5 ml for whole blood or 2.0 ml for plasma aliquots, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. (see Exhibit S).

26. Wand the labels of the two corresponding plasma cryovials into the SIS, following step 25 should the volume for the residual plasma tube need any adjustment.

27. Place the filled plasma cryovials in the donor box cell indicated by the SIS.

(Box 8C continued)

28. Repeat steps 23 through 27, filling the box row from left to right starting with the upper left- hand corner. The SIS guides the placement of tubes in the box, proceeding through each row to the lower right-hand corner. The last cell in the box should remain empty (although each box has 81 cells, store only 80 cryovials per box).

29. Store the boxes in the appropriate rack in the –70 ° C freezer.

Box 8C - Alternate steps for
Processing donor repository specimens with less than adequate volume

1. Place a Laboratory ID on the donor enrollment sample tube. This label will correspond to the aliquot lab ID labels already placed on the empty whole blood and plasma cryovials.

2. Centrifuge the donation sample tubes at 2500 rpm for 20 minutes to permit removal of the plasma.

3. Retrieve the rack containing the empty plasma cryovials. The processor should have previously labeled these empty plasma cryovials with aliquot Lab ID labels.

4. As you remove the donation sample tubes from the centrifuge, arrange them in sequence to match the empty plasma cryovials in the working rack.

5. Using a clean pipette, pipette 2.0-ml plasma from the donation sample tube to the first of the corresponding two plasma cryovials.

6. Pipette the remaining plasma into the second tube.

7. Cap donor plasma cryovials with red caps.

8. Repeat steps 1 to 7 until all samples have been processed.

9. Vortex the original donation tube to re-suspend the blood cells evenly.

10. Gently remove the stopper from the tube using a 2" x 2" gauze square to cover the top of the tube.

11. Pipette 1.5-ml of whole blood/cells from the donation sample tube into the cryovial using a clean transfer pipette.

12. Recap the donation sample tube. Use yellow inserts for all donor WB aliquot tubes.

13. Repeat procedures 9 through 12 for every donation tube until the working rack has been filled.

14. Retrieve a 2" donor box. This may be a new box or a partially filled box from the freezer. Donor plasma and WB cryovials may be placed in the same box.

(Box 8C continued)

15. Wand the box label into the SIS. In the event that an error message is displayed, check the box number. The SIS tracks boxes such that should a box be wanded in the SIS out of ascending sequential order an error message will be displayed. The error message will disappear when the box problem is corrected. See section 8.5.2 for further box labeling information.

16. Working with one donation sample tube at a time, wand the WBN and Lab ID label from the donation sample tube into the SIS.

17. In the event that an aliquot volume falls below the default of 1.5 ml for whole blood or 2.0 ml for plasma aliquots, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. (see Exhibit S).

18. Wand the labels of the two corresponding plasma cryovials into the SIS, following step 12 should the volume for the residual plasma or whole blood tube need any adjustment.

19. Place the filled cryovials in the donor box cell indicated by the SIS.

20. Repeat steps 23 through 27, filling the box row from left to right starting with the upper left- hand corner. The SIS guides the placement of tubes in the box, proceeding through each row to the lower right-hand corner. The last cell in the box should remain empty (although each box has 81 cells, store only 80 cryovials per box).

21. Store the boxes in the appropriate rack in the –70 ° C freezer.

8.7 Processing of Recipient Repository Samples

8.7.1 Entering Recipient Consents Into the SIS

Before any samples can be processed and accessioned into the Repository, the recipients' consent study ID labels (suffix -IC) indicating that a sample is from a consenting recipient must be recorded in the SIS. Blood centers processing pre-transfusion recipient samples prior to obtaining recipient consent should refer to section 8.8. All other recipient samples collected should follow the procedures given in this section.

Box 8D

Entering recipient consent into the SIS

1. First, obtain the Patient Log Form received with the recipients' pre-transfusion or enrollment samples.

2. Manually count the number of recipient informed consent study ID labels found on the Patient Log Form (suffix -IC). Only count and enter actual study ID labels, do not enter copies of labels or any labels containing a -NC suffix. Write down the number counted. This step is important for later reconciliation with the number of recipient consent study ID labels actually entered in the SIS system.

3. Wand all original recipient informed consent bar code readable labels on the Patient Log Form(s) in the SIS. *It is essential to wand in the informed consent study ID labels found on the Patient Log Form before wanding in the actual recipient specimen tubes.*

4. Generate a SIS printout listing all recipient informed consent study ID labels wanded in from consenting recipients. Ensure that the number of consent labels entered in the system matches the number of recipient study ID labels manually counted in step 1.

5. Resolve any discrepancies before proceeding further with sample processing or retrieval. The SIS will only accept repository specimen tubes from recipients with consents already recorded in the system.

8.7.2 Setting Up For Recipient Repository Sample Processing

Label all whole blood and plasma aliquot sample tubes. Label three cryovials for every recipient pre-transfusion sample collected from a consenting recipient, e.g., one aliquot tube labeled for WB and two aliquot tubes labeled for plasma (or serum). For the 6-month follow-up sample, label these same three tubes plus three additional aliquots for NAT, for a total of six aliquots. Be sure to use labels from the same set of laboratory ID numbers for the three cryovials to be entered into the SIS for the RADAR Repository. The three cryovials designated for the NAT sample will utilize suffix -6M labels from the Recipient Study ID labels rather than using the 2-D Lab ID labels. It may be advisable to place overlapping tape on these labels, as they may not adhere well when frozen and then thawed for testing. Apply the labels following the instructions provided in Section 8.5.4 and place the empty cryovials in their corresponding racks.

Recipient whole blood (WB) and plasma cryovials should be stored together in one set of boxes. The three cryovials prepared from the NAT designated vacutainer will be held temporarily at the blood center in the -70° C freezer until such time as all testing has been completed on the index and 6-month samples. It may be necessary for the staff to access the NAT tubes quickly if testing is needed. Once the status of each recipient has been established, these cryovials will be destroyed.

Before beginning the processing steps, label 2" recipient storage boxes as described in Section 8.5.2 for the RADAR Repository cryovials. Use a separate storage box for the NAT cryovials. The following style labels have been provided:

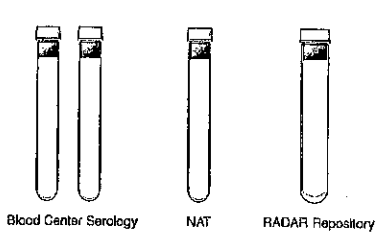
RADAR

Recipient 6-month NAT Aliquots

Processed Between

___/___/___ to ___/___/___

and should be applied to these boxes.



8.7.3 Procedure for Temporary Storage of the Designated NAT Tube From the 6-Month Follow-up Visit

Box 8E

Processing recipient 6-month NAT samples

Laboratory staff should follow Universal Precautions and OSHA Bloodborne Pathogen Rules throughout the following sample processing procedures.

Recipient 6-month follow-up NAT tube

1. Obtain the 6-month follow-up NAT sample tubes collected by study staff.
2. Centrifuge the tubes at 2500 rpm for 20 minutes to permit removal of the plasma.
3. Retrieve the rack containing the empty plasma cryovials. The processor should have previously labeled three empty plasma cryovials for each recipient with corresponding suffix -6M labels from the sheet of Recipient Study ID labels and not with a Lab ID label.
4. As you remove the recipient sample tubes from the centrifuge, arrange them in sequence to match the empty plasma cryovials in the working rack.
5. Using a clean pipette, pipette approximately 1.0-ml (minimum volume for each is 0.6-ml) plasma from the original recipient tube to the first of the corresponding two plasma cryovials.
6. Pipette approximately the same amount of plasma into the second and third tubes.
7. Cap recipient plasma cryovials with distinctive color caps.
8. Repeat steps 1 to 6 until all samples have been processed. These will *not* be wanded into the SIS.
9. Retrieve a 2" storage box that will be designated specifically for temporary storage of NAT cryovials. Labels with "RADAR Recipient 6-month NAT Aliquots" should be applied to these boxes. These cryovials should not be mixed in with cryovials designated for RADAR Repository storage but in a separate box and rack designated specifically for this purpose. They should also be easily accessible on short notice.
10. The NAT aliquot storage boxes should be held in the -70° C freezer at the blood center until notified otherwise by the MCC.
11. When the monthly RADAR 6-Month Test Results Tracking Reports are sent by the MCC to the blood center, a list will be included that will indicate which of these samples should be destroyed. Other samples that are to continue be held temporarily in the freezer or sent for further testing are discussed in Section 6.4.3.

8.7.4 Step-by-Step Procedures for Processing and Accessioning Recipient Samples

Box 8F
Processing recipient repository samples

(If the recipient sample has inadequate volume for *all* aliquot tubes –
Follow procedures described in Box 8C Alternate processing steps 2 through 23)

Laboratory staff should follow Universal Precautions and OSHA Bloodborne Pathogen Rules throughout the following sample processing procedures.

Recipient Whole Blood

1. Obtain the pre-transfusion samples from the hospital or in the case of the 6-month follow-up repository sample, obtain the 6-month follow-up sample collected by study staff.
2. Apply a Laboratory ID label to each of the collected sample tubes (the pre-transfusion, enrollment/post-transfusion, or 6-month follow-up sample tube) except the designated NAT tube.
3. Vortex the original recipient tube to resuspend the blood cells evenly.
4. Gently remove the stopper from the tube using a 2" x 2" gauze square to cover the top of the tube.
5. Retrieve the rack containing the empty WB cryovials. The processor should have previously labeled these empty WB cryovials with aliquot Lab ID labels.
6. Pipette 1.5-ml of WB from the recipient tube into the cryovial using a clean transfer pipette.
7. Recap the recipient sample tubes. Use green inserts for all recipient WB aliquot tubes.
8. Repeat steps 3 to 7 for every recipient tube until the working rack has been filled.
9. Retrieve a 2" recipient storage box. This may be a new box or a partially filled box from the freezer. Recipient WB and plasma aliquot cryovials may be placed in the same box.
10. Wand the recipient box label into the SIS. In the event that an error message is displayed, check the box number. The SIS tracks boxes such that should a box be wanded in the SIS out of ascending sequential order an error message will be displayed. The error message will disappear when the box problem is corrected. See section 8.5.2 for further box labeling information.
11. Working with one recipient sample tube at a time, wand in either the pre-transfusion or post-transfusion/enrollment recipient study ID label (suffix -PR or -PO) and the Lab ID label from the recipient sample tube in the SIS. Should this sample be rejected by the system, place it in a rack labeled "Not Eligible" and investigate the consent status of this sample after you have finished with processing the other samples.

(Box 8F continued)

12. In the event that an aliquot volume falls below the default 1.5 ml, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. (see Exhibit S).

13. Wand the corresponding WB cryovial label in the SIS.

14. Place the WB cryovial in the recipient box cell indicated by the SIS.

15. Repeat steps 11 through 14, filling the box row from left to right starting with the upper left- hand corner. The SIS guides the placement of tubes in the box, proceeding through each row to the lower right-hand corner. The last cell in the box should remain empty (although each box has 81 cells, store only 80 cryovials per box).

16. Store the box in the -70 ° C freezer.

Recipient Plasma (or Serum)

17. Centrifuge the recipient sample tubes at 2500 rpm for 20 minutes to permit removal of the plasma.

18. Retrieve the rack containing the empty plasma cryovials. The processor should have previously labeled these empty plasma cryovials with aliquot Lab ID labels.

19. As you remove the recipient sample tubes from the centrifuge, arrange them in sequence to match the empty plasma cryovials in the working rack.

20. Using a clean pipette, pipette 2.0-ml plasma from the original recipient tube to the first of the corresponding two plasma cryovials.

21. Pipette the remaining plasma into the second tube.

22. Cap recipient plasma cryovials with green caps.

23. Repeat steps 18 to 21 until all samples have been processed.

24. Retrieve a 2" recipient storage box. This may be a new box or a partially filled box. Recipient plasma and whole blood cryovials may be placed in the same box.

25. Wand the recipient box label into the SIS. In the event that an error message is displayed, check the box number. The SIS tracks boxes such that should a box be wanded in the SIS out of ascending sequential order an error message will be displayed. The error message will disappear when the box problem is corrected. See section 8.5.2 for further box labeling information.

26. Working with one recipient sample at a time, wand in both the pre-transfusion or post-transfusion/enrollment recipient study ID label (suffix -PR or -PO) and the Lab ID label from the recipient sample tube in the SIS.

(Box 8F continued)

27. In the event that an aliquot volume falls below the default 1.5 ml, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. (see Exhibit S).
28. Wand the corresponding WB cryovial label in the SIS.
29. Place the plasma cryovial in the recipient box cell indicated by the SIS.
30. Repeat steps 26 through 29 until all tubes are placed in a box.
31. Store the boxes in the –70 ° C freezer using the appropriate freezer rack.

8.8 Processing of Pre-transfusion Samples Sent to Blood Centers Prior to Recipient Enrollment

Some blood centers are processing all pre-transfusion samples prior to recipient consent and enrollment. These blood centers should follow the procedures described in Box 8G to properly process the samples and place them in a holding area. Subsequently these blood centers should retrieve and accession the correct samples into the SIS.

8.8.1 Setting Up for Processing

Label the pre-transfusion sample tube, the WB cryovial, and two plasma cryovials with Laboratory study ID labels. There should be three cryovials for every recipient pre-transfusion sample received at the blood center, i.e., one aliquot tube labeled for WB and two aliquot tubes labeled for plasma (or serum). Be sure to use labels from the same set of laboratory ID numbers. Apply the label following the instructions provided in Section 8.5.4 and place these empty cryovials in the appropriate plasma or whole blood processing rack.

In the event that there is not adequate volume for both plasma aliquots *and* the whole blood tube, the priority for repository storage is first to fill the plasma aliquots with available plasma (the minimum acceptable plasma volume per recipient is 1-ml per study protocol) and then to fill the whole blood aliquot with cells. Additional plasma volume and whole blood can be obtained with a second specimen drawn post-transfusion during enrollment.

8.8.2 Step-by-Step Procedures for Processing Pre-transfusion Samples Prior to Receiving Recipient Consent

Box 8G
Processing and storage of pre-transfusion samples before recipient consent and enrollment

(If the recipient sample has inadequate volume for all aliquot tubes – Follow procedures described in Box 8C Alternate processing steps 2 through 13)

Before processing the samples, label a zip-lock storage bag with the patient's name, medical ID #, and date of sample draw for each pre-transfusion sample. This bag will store the original pre-transfusion sample tube and up to three aliquot tubes processed for the recipient. After following the steps below, this bag should be placed in the holding area at the blood center until such time that it is retrieved for permanent storage in the RADAR Repository.

Recipient Whole Blood

1. Upon receipt of pre-transfusion samples from the hospital, vortex the recipient sample tubes to re-suspend the blood cells evenly.
2. Gently remove the stopper from the tube using a 2" x 2" gauze square to cover the top of the tube.
3. Retrieve the rack containing the empty WB cryovials. The processor should have previously labeled these empty WB cryovials with aliquot Lab ID labels.
4. Pipette 1.5-ml of WB from the recipient sample tube into the cryovial using a clean transfer pipette.
5. Recap the recipient sample tubes. Use green inserts for all recipient WB aliquot tubes.
6. Repeat steps 3 to 5, as necessary and place the WB aliquot for each recipient in the corresponding zip-lock bag.

Recipient Plasma (or Serum)

7. Centrifuge the recipient sample tubes at 2500 rpm for 20 minutes to permit removal of the plasma.
8. Retrieve the rack containing the empty plasma cryovials. The processor should have previously labeled these empty plasma cryovials with aliquot Lab ID labels.
9. As you remove the recipient sample tubes from the centrifuge, arrange them in sequence to match the empty plasma cryovials in the working rack.
10. Using a clean pipette, pipette 2.0-ml plasma from the original recipient tube to the first of the corresponding two plasma cryovials.

(Box 8G continued)

11. Pipette the remaining plasma into the second tube.

12. Cap recipient plasma cryovials with green caps.

13. Repeat steps 10 to 12 as necessary and place the two aliquots of plasma prepared for each recipient in the corresponding zip-lock bag.

Holding Area Storage

14. Place the zip-lock bags in a RADAR designated sample holding area in the –70 ° C freezer.

8.8.3 Retrieval of Specimens From the Holding Area Corresponding to Enrolled Recipients

Patient Log Forms indicating which recipients consented to be in the study should be delivered to the blood center laboratory on a regular basis. Those recipients who agreed to be in the study should have a recipient study ID informed consent label (suffix -IC) attached to the Patient Log Form in the "Consent Status" column. Follow the instructions found in Box 8D for entering recipient consents into the SIS.

Once the consent information has been recorded in the SIS, laboratory staff should retrieve the specimens of enrolled recipients from the holding area. The name, medical ID number, and date of draw should be listed on both the Patient Log Form and the zip-lock bag holding the pre-transfusion sample tubes in the holding area. Compare this information to select the recipient sample tubes to be removed from the holding area. Sample tubes in the holding area that are not accessioned into the SIS within a reasonable amount of time (i.e., 1 month) should be retrieved and discarded following blood center standard operating procedures.

Each zip-lock bag pulled from the holding area should contain the original tube the pre-transfusion sample was collected in and up to three cryovials (1 WB and 2 plasma). The laboratory staff must re-label each original tube with the unique recipient pre-transfusion study-ID label (suffix -PR) corresponding to that recipient. These labels should be stored at the blood center along with the consent forms and should be retrieved for this purpose. Box 8H describes the steps for accessioning these samples into the SIS for inclusion in the repository.

Box 8H

Accessioning recipient pre-transfusion samples from consenting recipients into the SIS after retrieval from the holding area

After retrieving the samples from the holding area that correspond to consenting recipients and labeling them with the appropriate unique recipient pre-transfusion study-ID label, follow the steps below to properly accession the samples into the SIS.

1. Retrieve a 2" recipient storage box. This may be a new box or a partially filled box from the freezer. Recipient WB and plasma aliquot cryovials may be placed in the same box.

2. Wand the recipient box label into the SIS. In the event that an error message is displayed, check the box number. The SIS tracks boxes such that should a box be wanded in the SIS out of ascending sequential order an error message will be displayed. The error message will disappear when the box problem is corrected. See section 8.5.2 for further box labeling information.

3. Working with one set of recipient tubes at a time, wand the pre-transfusion recipient study ID label (suffix -PR) and the Lab ID label from the empty pre-transfusion sample tube in the SIS.

4. In the event that an aliquot volume falls below the default 1.5 ml, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. This step must occur before wanding the aliquot label in the SIS (see Exhibit S).

5. If no volume adjustment is needed, wand the corresponding WB cryovial label in the SIS. Should this sample be rejected by the SIS place it in a rack labeled "Not Eligible" and investigate the consent status of the sample after all other processing has been completed.

6. Place the WB cryovial in the recipient box cell indicated by the SIS.

7. Continuing with the same set of recipient tubes, again wand the pre-transfusion recipient study ID label (suffix -PR) and the Lab ID label from the empty pre-transfusion sample tube.

8. In the event that an aliquot volume falls below the default 1.5 ml, use the Aliquot Volume Adjustment Codes card to record the new volume in the SIS. This step must occur before wanding the aliquot label in the SIS (see Exhibit S).

9. Next wand in the corresponding plasma cryovial label in the SIS.

10. Place the plasma cryovial in the recipient box cell indicated by the SIS.

11. Repeat steps 7-10 to accession the residual plasma tube.

12. Repeat steps, filling the box row from left to right starting with the upper left- hand corner. The SIS will guide the placement of tubes in the box, proceeding through each row to the lower right-hand corner. The last cell in the box should remain empty (although each box has 81 cells, store only 80 cryovials per box).

13. Store the box in the -70 ° C freezer using the appropriate freezer rack.

SHIPPING SAMPLES CHAPTER 9

9. SHIPPING DONOR AND RECIPIENT SAMPLES TO THE CENTRAL REPOSITORY

9.1 Overview of Shipment to the Central Repository (BTRL)

This chapter outlines the procedures to be followed when preparing to ship samples to the central repository facility, BTRL in Gaithersburg, MD. Cryovials processed and stored at the blood centers for the RADAR Repository will be shipped to BTRL according to a predetermined shipping schedule (see Exhibit T). The MCC will assign each blood center a unique shipping schedule that will direct each center to ship recipient samples quarterly and donor samples biannually. Because BTRL must be prepared to receive and process shipments, this schedule is firm and all centers should ship to BTRL only on their assigned dates. If problems arise with the ability of the blood center to meet this schedule, the MCC should be contacted immediately.

The shipment of recipient samples stored in the REDS – 70°C freezer is fairly straightforward and will not require that the samples be reboxed. The biannual shipment of donation or donor samples; however, will require pulling and reboxing of donor samples as directed by the MCC. The donor shipment will consist of samples linked to a recipient, as well as a random selection of donor samples not linked to a recipient. Unlinked donor samples not selected for shipment will be transferred to the REDS – 40°C freezer or other alternate freezer until their final disposition is decided at the end of the study. The possibility exists that we may need to access samples stored in the alternate freezer. This would be necessary should a donor sample subsequently become "linked" to a recipient through transfusion of products with a longer shelf-life than PRBC's (i.e. fresh frozen plasma), or in cases where a donor de-enrolls and a sample needs to be pulled for destruction. Each blood center should keep this in mind when organizing these original boxes in the alternate freezer. The MCC will provide box maps to aid in the selection of donor cryovials.

9.2 Shipping Supplies

Box 9A lists the supplies needed to ship and track samples being sent to BTRL.

Box 9A
Supplies needed when shipping samples to BTRL

- ✓ Box maps – *provided by MCC*
- ✓ Shipping directions-*provided by MCC*
- ✓ Shipping lists – *provided by MCC*
- ✓ 2" (81 cell) storage boxes - *provided by BTRL*
- ✓ Box labels for reboxed donor tubes - *provided by MCC*
- ✓ Shipping container airbill and necessary IATA labels - *provided by BTRL*
- ✓ Shipment form template - *provided by MCC (see Exhibit U or V)*
- ✓ Dry Ice - *provided by blood center*
- ✓ Infectious IATA shipping containers - *provided by BTRL*

9.3 Instructions for Shipping Recipient Samples

RADAR laboratory personnel will not have to rebox or pull tubes to prepare recipient samples for shipping. All full recipient boxes in the - 70°C freezer will be shipped on the assigned ship date every 3 months. These boxes, identified by the designation '–RE' at the end of the box ID # (see Chapter 8), should contain both whole blood and plasma (or serum). Procedures for pulling and shipping recipient boxes are outlined below in Box 9B.

Box 9B

Instructions for Shipping Recipient Repository Samples

1. On a quarterly basis blood centers will be notified by the MCC to identify all full recipient boxes and mark them as "shipped" in their SIS. The definition of a "full" box is somewhat at the discretion of the blood center, but should have at least 40 of the 80 cells filled. This should coincide with the regular delivery of SIS data on the fifth of the month (see Exhibit T).
2. Blood centers should request the infectious shipping containers, labels, and airbills from BTRL by contacting Misti Dowell at 301-208-8100, x 107 or Carla Chorley at 301- 208-8100, x. 110.
3. The Shipping Form should then be completed (except for the Airbill number and date of shipment) and faxed to Westat only (see Section 9.3.1 and Exhibit U).
4. Once the Shipping Form has been faxed to Westat, any additional newly filled recipient boxes should not be included with that shipment.
5. Once the form is received and verified at Westat, a box contents inventory will be printed and returned to the blood center for inclusion in the shipment. Freezer racks from the - 70°C freezer should remain at the blood center and should not be shipped to BTRL.
6. Centers should then prepare for shipment following their assigned schedule.
7. Blood centers should complete all missing information from the Shipping form and fax it to the contacts at BTRL, NIH, and Westat.
8. All recipient samples should be shipped on dry ice in their original storage boxes according to the latest International Air Transport Association (IATA) Dangerous Goods Regulations for shipping infectious substances.
9. Freezer racks from the - 70°C freezer should remain at the blood center and should not be shipped to BTRL.

9.3.1 Instructions for Completing the Recipient Shipping Form

Each RADAR shipment form must document the total number (0-10) of boxes included in each shipping container. Only one form may be used per shipping container/airbill. Blood centers may not mix shipments of donors and recipients. Once the blood center has identified boxes for shipment and has marked them as "shipped" in the SIS, the RADAR shipping form should be completed as stated above, and faxed to the MCC. Once a shipping form has been faxed to Westat, any additional newly filled recipient boxes should not be included with that shipment. Westat will verify the boxes listed on the form and return a box contents inventory to the blood center which should be included in the shipment. Blood centers will then ship on their assigned date and complete all missing information from Section I of the

shipping form. This form must be faxed to numbers and individuals as shown on Exhibit U. All recipient shipments must be in accordance with IATA regulations for Infectious Substances.

9.4 Instructions for Shipping Donor Samples

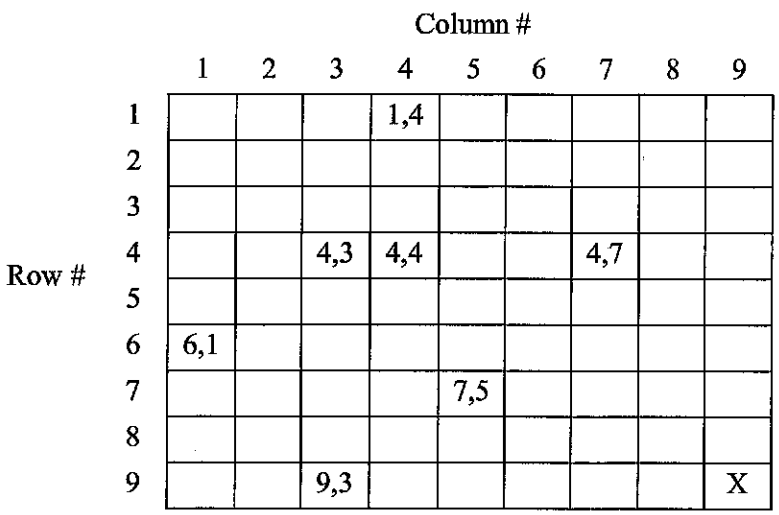
Shipping of donor samples requires that the donor tubes be pulled and reboxed at the time of shipment. This is necessary because the RADAR protocol requires that donor specimens linked to enrolled RADAR recipients and a sampling of donor specimens not linked to RADAR recipients be designated for permanent storage in the repository. Donation aliquots not linked and not randomly sampled will be returned to the blood centers' alternate freezer in the "original" donor storage box until the end of the study. The MCC will send appropriate instruction at the time of each shipment. A change in procedure beginning in July 2002 with Donor Shipping Wave 5, to separate the donors who are linked, designated as "LD", from unlinked donors designated as "UD", will allow for improved management at the biorepository and is described in the following sections.

Approximately 2-3 weeks prior to the blood center's ship date, the MCC will generate two separate lists in the form of storage box maps (see Figure 9A) for the shipment. One list will contain donations linked to recipients, and the other list will contain donations not transfused to RADAR recipients but that are sampled as a contemporary donor repository. To aid with distinguishing the lists they will be printed on colored paper, LD on yellow and UD on pink. You will not have both pink and yellow sheets for each original storage box ID # because more unlinked than linked donors are shipped and the linked donors are not equally distributed among the boxes. The reboxing of the donor samples will require three separate sets of boxes (see Figure 9B), one for LD, one for UD, and the original box. The MCC will provide corresponding colored labels for the reboxed samples.

Original donor storage boxes that are placed in the alternate freezer may need to be re-accessed due to transfusion of components with a longer shelf life or de-enrollees. Organize your alternate freezers to allow systematic easy access to these.

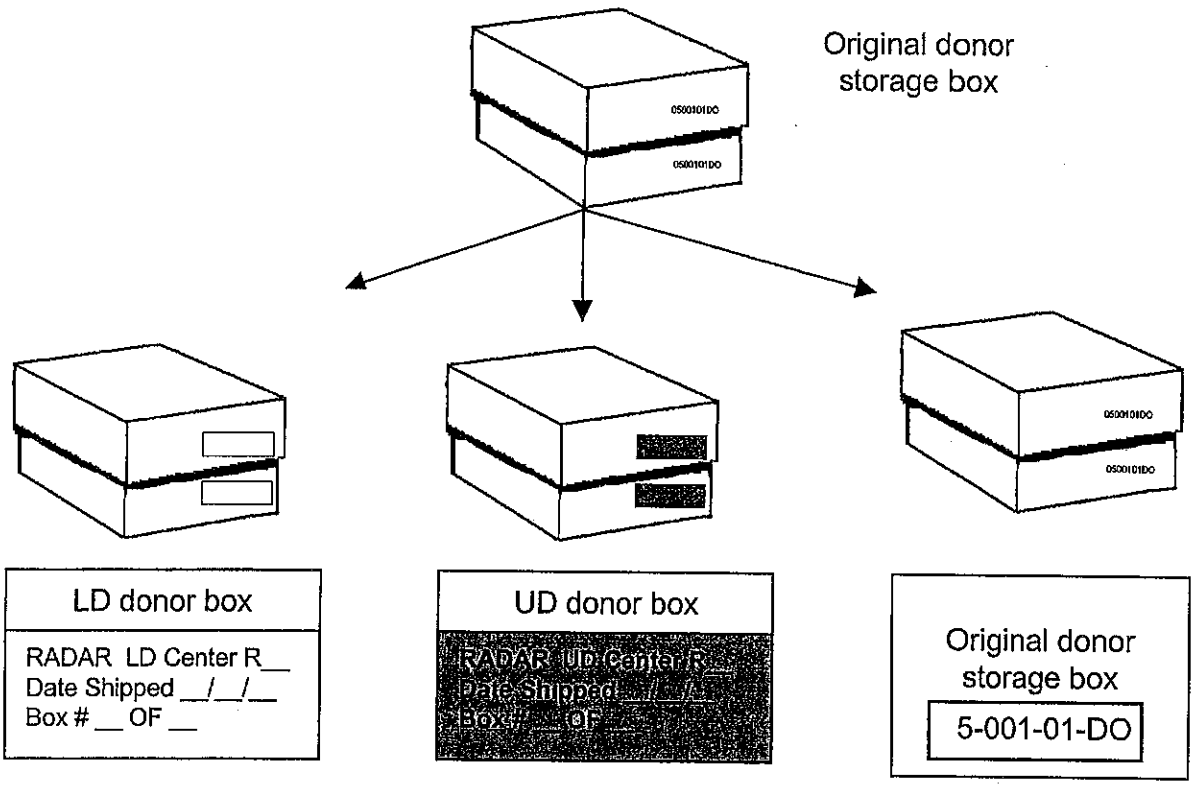
Figure 9A. Box Map Diagram – Example

Box #: 5-001-01-DO



		Lower Right Corner	
Aliquot Number	Row, Column	Aliquot Number	Row, Column
RE-012458-002	4,3	RE-012446-003	1,4
RE-012321-004	4,4	RE-012446-003	4,7
RE-012249-004	6,1	RE-012724-003	7,8
RE-012655-003	7,5	RE-012597-002	9,3

Figure 9B. Storage Box Diagram



Complete shipping form. Send to BTRL with other LD boxes.

Complete shipping form. Send to BTRL with other UD boxes.

Retain in RADAR or alternate freezer as instructed on box maps.

A shipping form must be completed (see Section 9.4.3 and Exhibit V) and faxed as instructed on the form. All donor samples should be shipped on dry ice according to the latest International Air Transport Association (IATA) Dangerous Goods Regulations for shipping infectious substances. Blood centers should request the infectious shipping containers from BTRL by contacting Misti Dowell at 301-208-8100, x 107 or Carla Chorley at 301-208-8100, x 110.

9.4.1 Box Maps

Biannually, according to the shipping schedule, the MCC will supply each blood center with box map diagrams identifying the exact donor tubes that are to be pulled for the linked donor and unlinked donor boxes for shipment to BTRL. The box map (see Figure 9A) will include both the box ID # and the donor aliquot ID label numbers. Positions of the tubes to be pulled and reboxed for the LD box or UD box will be exhibited on the box maps according to their positions within the box. The position of a tube is found by matching the correct row number with the corresponding column number. At the bottom of the box map you will find a list of the individual aliquot numbers corresponding to the cell positions indicated. All other tubes should remain in position in the "original" donor storage box, identified by the designation –"DO" at the end of the box number.

Although tubes are being pulled and reboxed, the only wanding necessary is of the original storage box label to indicate that this particular box has been accessed and must be either marked as "shipped" in the SIS or placed back in the RADAR –70°C freezer for the next sampling cycle or wave.

9.4.2 Reboxing Donor Repository Tubes

The MCC will provide labels for both the LD and the UD 2-inch cryovial storage boxes that will hold the selected donor tubes moved from the "original" storage boxes. Both box label types will include the RADAR center ID, date shipped and "Box #___ of___" designation. The labels are differentiated by having an LD or UD before the center ID (see Figure 9B) and the color corresponds to the box maps. Procedures for pulling and reboxing donor samples are outlined in Box 9C.

9.4.3 Instructions for Completing Donor Shipping Forms

A separate RADAR Shipment Form and airbill number must be used for each shipping container. Each RADAR shipping form must document the total number (0-10) of boxes included in each shipping container and also the type of box included (LD or UD). Blood centers should attempt to keep LD and UD boxes separated during the shipping process, but may consolidate them into a final container to avoid shipping two partial shippers. Blood centers may NOT mix shipments of donors and recipients. No boxes should be held at the blood center based on the fact that it is only partially filled, unless directed to do so by the box maps provided by the MCC. At the time of shipment both sections of the form must be completed and must be faxed immediately to the MCC and BTRL as indicated on Exhibit V. All donor shipments must be in accordance with IATA regulations for Infectious Substances.

Box 9C

Instructions for Pulling and Reboxing Donor Samples

1. Match yellow linked donor (LD) box labels to yellow box map lists and prepare 2 labels for each box that will be shipped to BTRL by writing in the date of shipment and the "linked donor box number __ of __".
2. Repeat process for pink unlinked donor (UD) list and labels.
3. Arrange empty 2-inch (81 cell) storage boxes with accompanying lids on the bench.
4. On the first box, place a yellow linked donor (LD) reboxing label on the side of the lid of the box and place a second identical label on the bottom of the corresponding box (See Figure 9B). Repeat for all subsequent LD boxes and for UD boxes with the pink box labels.
5. Begin working with the yellow sheets. Identify the first LD box ID #. From the RADAR – 70°C freezer, remove the box that is listed first on the linked donor box maps. This box will be referred to as the "original" donor storage box.
6. From the main menu of the SIS, select "Ship Boxes". At the "Boxes To Be Shipped" screen, wand in the box label from the "original" donor storage box. Although you may not be shipping this particular box, this procedure will indicate that this box has been processed and tubes have been pulled from it. If you are shipping the entire box, DO NOT place a rebox label on it, ship with tubes intact and complete the shipping form with the "original" box label ID #.
7. Using the box maps as a guide, remove all tubes indicated from the original box and place them into the corresponding new 2-inch storage box.
8. Place tubes into the new box working from left to right in each row; working the rows from top to bottom. Do not change the position of the cryovials that remain in the original donor storage box. Always leave the last cell of the new box empty (maximum of 80 tubes in a box).
9. It may take several original boxes to fill a new box. Once the new box is filled with pulled donor tubes, begin filling additional boxes as necessary.
10. Once all tubes indicated on the linked or unlinked box map have been pulled and moved to the new boxes, if indicated, place the original box in the – 40 °C (walk-in or alternate freezer) or return to a rack located in the – 70 °C freezer as instructed until further notice. Those boxes placed into the alternate freezer should be marked in the SIS as "shipped" while the box being returned to the routine RADAR – 70 °C freezer should <u>not</u> be marked as shipped.
11. Repeat steps 4 through 10 for each box map sent by the MCC.
12. Upon completion of pulling and reboxing donor tubes, prepare the boxes for shipment including copies of the box maps as an inventory list to BTRL following the IATA procedures for shipping infectious goods.

◆ The steps above are to serve as a guideline. Each center may adopt these processes or make minor modifications such as working both the linked (LD) and unlinked (UD) donation samples at the same time. Adapting this to your own style is acceptable as long as the staff performing the activity maintains the sample integrity and the accuracy of the re-boxing remains the priority.

DATA TRANSFER

CHAPTER 10

10. RADAR TRACKING SYSTEMS DATA TRANSFERS

10.1 Overview

As described in Chapter 1, the MCC has provided each blood center with two computer systems, the Recipient Tracking System (RTS) and the Sample Inventory System (SIS). The RTS is designed to track RADAR blood units that were transfused to eligible recipients at the hospital, as well as track and follow-up with the recipients who enroll in the study. There are two computers on which the RTS will be loaded—an administrative PC which in most cases is located at the blood center, and a laptop computer, primarily used by the study recruiter at the hospital. While both computers have the same program capabilities, the laptop used by the study recruiter will typically be used to enroll recipients and track eligible recipients who do not enroll. The RTS based at the blood center on the other hand, will be utilized primarily to record 6-month follow-up visits, close-out recipients, and update contact information as described elsewhere in this manual. The SIS, located in the blood center laboratory, is designed to inventory donor and recipient samples designated for storage in the RADAR Repository.

All linkages of information collected using the RTS and the SIS will be performed by the MCC, and will include utilization of monthly donation data routinely sent to them. Therefore, the routine transfer of specific tracking system information between systems and sites is integral to the creation and maintenance of accurate RADAR Repository databases at the blood center and at the MCC. Figure 10 depicts the flow of data between computer systems.

10.2 RTS Daily Data Backup

At the end of each day, or when the system is shut down, the RTS on both the hospital laptop and the blood center computer will prompt the user to perform a backup function. The backup function is designed to copy all information collected or updated on that machine to a 3.5" diskette (1.44 MB). The daily backup is particularly important to perform on the hospital laptop, so that in the event that the laptop is stolen or lost, the study has the most up-to-date information stored. This procedure requires the hospital-based study recruiter to always have a formatted diskette available and clearly labeled as an RTS backup diskette. The study recruiter should store these diskettes somewhere other than the laptop carrying case.

Users of the RTS must hit the "EXIT" button in order to activate the daily backup process. If the "EXIT" button is not selected, this crucial backup function will be by-passed. Additional instructions in backing up the system can be found in the RTS documentation located at the back of this manual.

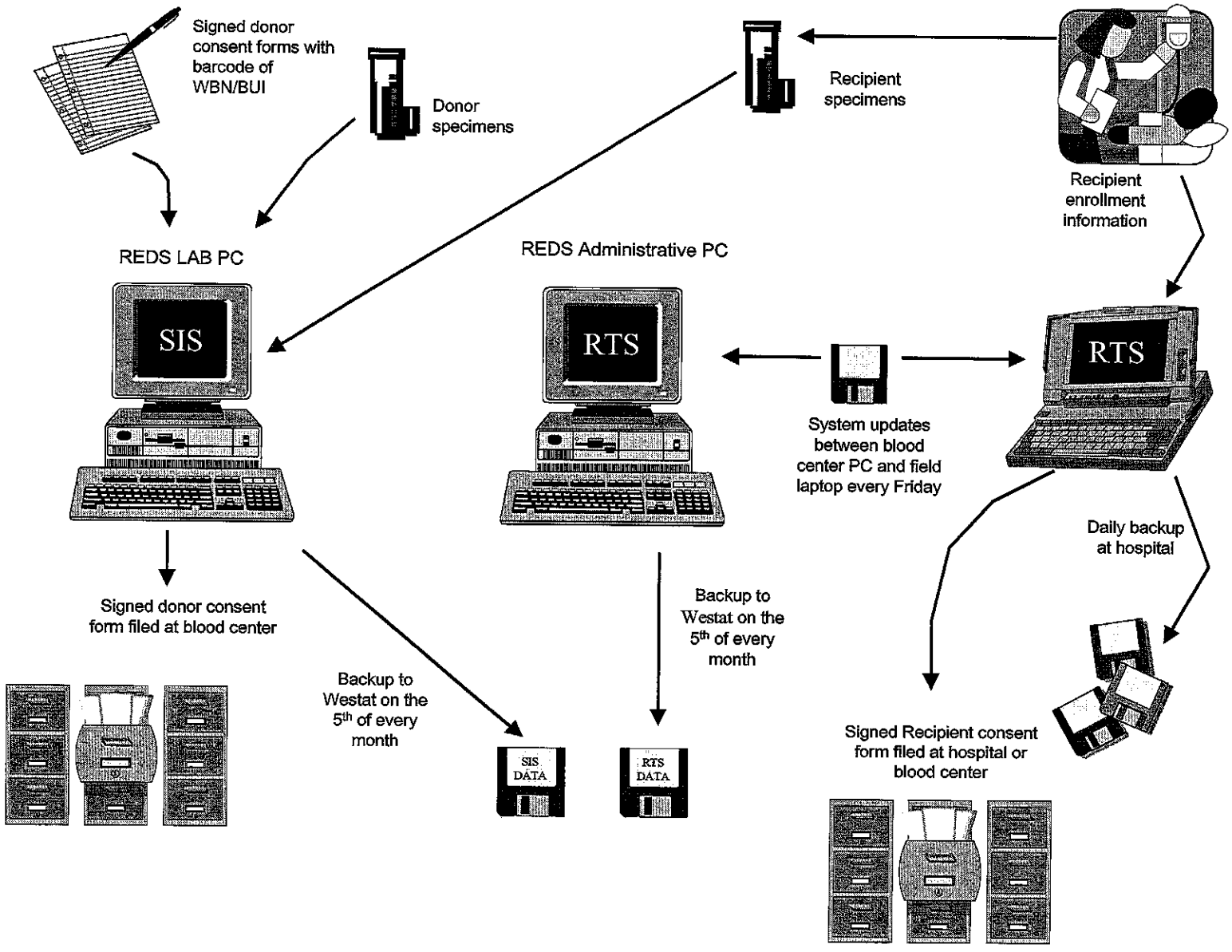
10.3 Routine Data Transfer Between the Blood Center and Hospital

A weekly swap of information between the study recruiter's laptop RTS and the blood center desktop RTS must occur so that both the blood center and hospital based staff have the most current information. New data from the hospital laptop must be transferred to the administrative computer at the blood center, and new data entered into the administrative computer from that week must be transferred to the hospital laptop. To accomplish this, at the end of each week the study recruiter should visit the blood center with his/her laptop computer. A backup data diskette like that described above in Section 9.2 should be made at that time, and transferred to the administrative computer using the Export/Import menu function in the RTS. *After* the data from the hospital laptop has been transferred to the administrative computer, a back up diskette should be made immediately from the administrative computer, and similarly transferred to the laptop computer. This ensures that all new data entered into the laptop from the week (i.e., recipient enrollment and eligibility information) can be accessed in the administrative computer, and likewise, that the laptop machine then has all new data on the continued follow-up of enrolled recipients.

10.4 Data Delivery to the MCC

On the fifth business day of each month, blood centers must send the MCC all information from the administrative RTS (blood center computer) and from the SIS laboratory computer. The RTS and the SIS are equipped with a function which copies and zips files to be sent to the MCC. These files should be sent to Himanshi Singh via e-mail or on diskette by a next-day courier service to the MCC, whichever method is preferred by the blood center. In addition to the information listed above, Exhibit W lists all deliverables, the date they are due at the MCC, and the method by which they should be delivered.

Figure 10. Data flow between computer systems



EXHIBITS

List of Exhibits

Exhibit A	Donor Consent Form
Exhibit B	RADAR Monthly Report for Ineligible Recipients
Exhibit C	Patient Log Form
Exhibit D	Recipient Consent Form
Exhibit E	Recipient Brochure
Exhibit F	Race/Ethnicity Card
Exhibit G	Provider Roster Card
Exhibit H	Questionnaire Shipping Log
Exhibit I	RADAR MCC Notification Form
Exhibit J	Recipient Testing Results Letter
Exhibit K	Recipient Testing Results Letter (Physician Reviewed)
Exhibit L	HBV and HCV Test Results Form
Exhibit M	HIV Test Results Form
Exhibit N	HTLV Test Results Form
Exhibit O	6-Month Test Results Tracking Report
Exhibit P	Principles Guiding Test Interpretation
Exhibit Q	TTI RADAR Center Obligations
Exhibit R	Subject De-Enrollment Form
Exhibit S	REDS Aliquot Adjustment Codes Card
Exhibit T	Shipping Calendar
Exhibit U	Repository Recipient Shipment Form
Exhibit V	Repository Donor Shipment Form
Exhibit W	Deliverables

Exhibit A

<Name and address of Blood Center> ARC Protocol # _____

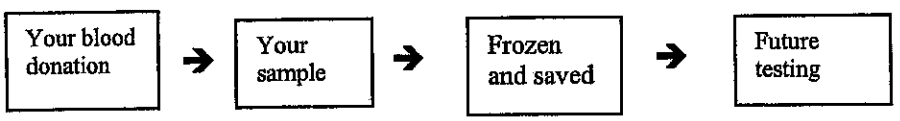
REDS ALLOGENEIC DONOR AND RECIPIENT (RADAR) REPOSITORY DONOR CONSENT FORM

INVITATION

REDS is a large blood safety research program sponsored by the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health. We invite you to participate in the REDS Allogeneic Donor and Recipient (RADAR) Repository. The RADAR program collects and stores blood samples for future testing from donors and from the patients who receive their blood. The goal of the RADAR repository is to monitor and improve the safety of the U.S. blood supply. Based on future medical advances, stored samples will be tested for viruses and other infectious agents or conditions that may be passed by transfusion.

DESCRIPTION

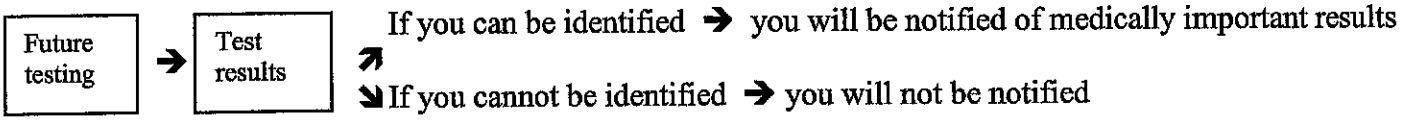
With your consent, a small blood sample will be taken from one of the tubes drawn at the time you donate blood. Your donated blood will be shipped to a specific hospital in this region. At the hospital, certain patients will receive the blood provided by donors in this study. If one of these patients receives your blood, he/she will be invited to join this study and to also provide a blood sample for storage. The study records will link your blood sample with the patient's sample. Neither you nor the patient will be able to learn each other's identity. If your blood is not used by a patient in the study, your blood sample may still be frozen, stored for several decades and used for future testing.



TESTING AND RESULTS

The NHLBI will own the blood samples. The REDS Steering Committee will control the review of all testing requests by REDS or outside investigators. In addition, a committee for the protection of human subjects (IRB) will review all future testing requests.

Depending on your test results, you may be asked to give another blood sample and/or to be interviewed. The blood center will inform you of test results that are medically important. Test result interpretation and counseling will be available from a nurse or physician from <Blood Center>. Your blood will **not** be tested for genetic traits that may be related to specific medical conditions **without your permission**. In certain circumstances (such as an unproven new test), testing may be done on samples portions from which your identity has been removed. We will not be able to notify you of these results.



CONFIDENTIALITY

All of your blood samples and test results will be labeled with a code number instead of your name. The link between the code and your name will be kept in locked files by the research staff at the blood center. While we will make every attempt to keep the results of this study confidential, confidentiality cannot be guaranteed. To provide additional protection, the blood center has obtained a Certificate of Confidentiality in accordance with Section 301(d) of the Public Health Service Act. This certificate will prevent study staff from being forced to identify you under a court order or other legal action. This protection lasts forever (even after death) for all study participants. Any results of the study will be reported as summaries that will not reveal your identity.

BENEFIT
Your participation will help scientists and doctors monitor the safety of the U.S. blood supply. You may personally benefit from future test results because they may reveal an undiagnosed medical condition for which you or your family members may wish to seek treatment.

RISK
The only risk to you from participating in this study is the possibility that notification of results from future testing may be unexpected or upsetting to you. At the time of such notification, you will be provided with more specific information about your test results. It is your decision whether to share your test results with others.

COMPENSATION
You will not receive any payment for participating in this study. All research tests will be free. Diagnostic testing and/or medical care for health problems discovered through these tests would be your responsibility. Since this research will use a blood sample that was taken as part of your donation, any compensation or treatment for potential research-related physical injury will be the same as that provided during voluntary blood donation.

VOLUNTARY PARTICIPATION
Participation in this study is entirely voluntary. You are free to withdraw from the study at any time without penalty. Your decision whether or not to participate will **not** change your current status as a blood donor. You will be given a copy of the signed consent form. If you decide to withdraw from the study at a later date, contact <*Principal Investigator*> at <*phone number*> and submit a written request to <*Principal Investigator*>at <*address*>.

It is important that we maintain current contact information for you. If your address changes, or if you have questions later, call the Principal Investigator listed above.

QUESTIONS
If you have any questions, please feel free to ask now. If you have questions about your rights as a research participant, now or in the future, you may call Roger Y. Dodd, Ph.D. at 301-738-0641.

CONSENT
I have read the description of this study and the potential risks and I have been given the opportunity to ask questions. I agree to participate and I understand that I may withdraw at any time after signing this form.

Name (print) _____

Signature _____ **Date** _____

Witness _____

[If translator was used to obtain consent] *Language used*_____
Signature of translator _____ *Date*_____

Exhibit B

RADAR MONTHLY REPORT FOR INELIGIBLE RECIPIENTS

Fax **this completed form to Suhela Pandit, (301) 517-4079**, on the 5th of each month (or the first business day after)

Report Month: _____ **to** _____

Blood Center:

- ☐ ARC – Chesapeake
- ☐ ARC – Southeastern Michigan
- ☐ ARC – Southern California
- ☐ Blood Centers of the Pacific–Irwin
- ☐ Oklahoma Blood Institute
- ☐ Institute for Transfusion Medicine
- ☐ Florida Blood Services

Hospital:

- ☐ Johns Hopkins University Hospital
- ☐ St. John Hospital
- ☐ Good Samaritan Hospital
- ☐ Little Company of Mary Hospital
- ☐ UCSF Medical Center
- ☐ Integris Baptist Medical Center
- ☐ Allegheny General Hospital

Section I. Provide the total number of cardiac, vascular, and/or orthopedic patients at this hospital that received at least one RADAR unit during the month. These numbers should include **both patients who were successfully and unsuccessfully enrolled.**

	Cardiac Patients	Vascular Patients	Orthopedic Patients	Total
Total Number of Patients Transfused with at least one RADAR unit	_____	_____	_____	_____

Section II. For all patients transfused with a RADAR unit, provide the total number of patients **not eligible** for enrollment due to at least one of the reasons listed below. In cases where a patient was excluded for more than one reason, please select the primary reason. For example an 86 year old patient that resides in another state would be counted only under the 2nd column, "> 85 Years of Age", not under the "residence out of region" column.

INELIGIBLE RECIPIENTS*				
< 18 Years of Age	> 85 Years of Age	Residence Out of Region	Immunocompromised, Transplant/Dialysis Patient	Total
_____	_____	_____	_____	_____

*** Allegheny General Hospital pre-screens individual patients for age and residence eligibility prior to distributing RADAR designated units will not typically have numbers to report in the first 3 columns of this table**

Exhibit C

RADAR PATIENT LOG FORM

Week of: _ _/ _ _/ _ _

Hospital: _____

Patient's Name	Medical ID #	Transfusion Unit ID Numbers ✓ RADAR units	Eligible? Y/N	Hospital Room #	Pre-transfusion sample date(s) of draw:	Consent Status: Place corresponding IC or NC label here.	Date sample sent to BC:
1) _____	_____	_____			__/__/__ __/__/__		__/__/__
2) _____	_____	_____			__/__/__ __/__/__		__/__/__
3) _____	_____	_____			__/__/__ __/__/__		__/__/__
4) _____	_____	_____			__/__/__ __/__/__		__/__/__
5) _____	_____	_____			__/__/__ __/__/__		__/__/__
6) _____	_____	_____			__/__/__ __/__/__		__/__/__

Exhibit D

R-Version date: 9/23/99

<Name and address of Hospital> ARC Protocol # _____

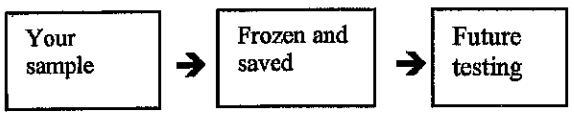
REDS ALLOGENEIC DONOR AND RECIPIENT (RADAR) REPOSITORY RECIPIENT CONSENT FORM

PURPOSE AND BACKGROUND

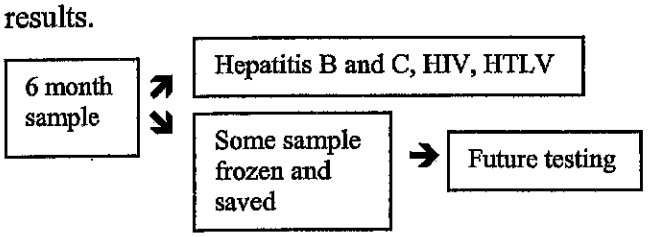
REDS is a large blood safety research program sponsored by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health. We invite you to participate in the REDS Allogeneic Donor and Recipient (RADAR) Repository. You are being asked to participate in this study because you recently received a blood transfusion at this hospital. The RADAR repository collects and stores blood samples for future testing from donors and from the patients who receive their blood. The goal of the RADAR study is to monitor and improve the safety of the U.S. blood supply. Based on future medical advances, stored RADAR samples will be tested for viruses and other infectious agents or conditions that may be passed by transfusion.

PROCEDURES

Some or all of the blood units you received during your transfusion came from blood donors who are also participating in this study. **We are asking for your permission** to freeze and store a sample of your blood which was drawn before your transfusion (about 1 tablespoon). The research nurse will **check your medical record** to obtain information about your transfusion, or any other that you may receive from <Hospital> in the next six months. In addition, she/he will ask **how to contact you** when you leave the hospital, and the name of your primary care physician and surgeon. The study records will link your blood sample with the donor's sample. Neither you nor the donor will be able to learn each other's identity.



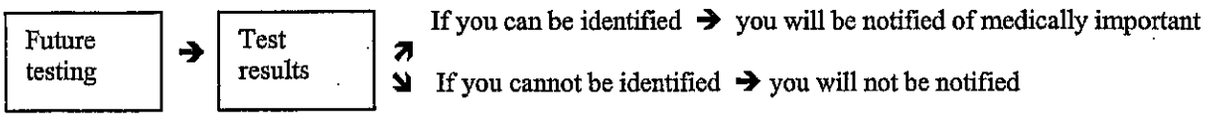
About **six months after enrolling in the study a research nurse will contact you** to meet for a brief interview and to draw a blood sample (about 3 tablespoons). This visit will be conducted at a location convenient to you, such as a hospital, blood donation center, your home, or your doctor's office. Part of this blood sample will be frozen, stored for several decades and used for future testing. The rest will be tested for hepatitis B and C, HIV (the AIDS virus), and HTLV (human T-lymphotropic virus). If any of these test results are positive, your blood sample taken at the time of your surgery will also be tested. The REDS research staff will notify you of all test results.



TESTING AND RESULTS

In the future, the samples will be tested for viruses and other infectious agents or conditions that might be passed by transfusion. The NHLBI will own the blood samples. The REDS Steering Committee will control the review of all testing requests by REDS investigators or outside investigators. In addition, a committee for the protection of human subjects (IRB) will review all future testing requests.

Depending on your test results, **you may be asked to give another blood sample** and/or to be interviewed. You may also be asked to give separate written consent to obtain medical records. The blood center will inform you of the results of tests that are medically important. Interpretation and counseling will be available from a nurse or physician from <Blood Center>. Your blood will **not** be tested for genetic traits that may be related to specific medical conditions **without your permission**. In certain circumstances (such as an unproven new test), testing may be done on portions of your sample from which your identity has been removed. We will not be able to notify you of these results.



CONFIDENTIALITY

All of your blood samples and test results will be labeled with a code number instead of your name. Identifying information will be kept in locked files by the research staff at the blood center. While we make every attempt to keep results of this testing confidential, confidentiality cannot be guaranteed. To provide additional protection, the blood center has obtained a Certificate of Confidentiality in accordance with Section 301(d) of the Public Health Service Act. This certificate will prevent study staff from being forced to identify you under a court order or other legal action. This protection lasts forever (even after death) for all study participants. Any results of the study will be reported as summaries that will not reveal your identity.

BENEFITS

Your participation will help scientists and doctors monitor the safety of the U.S. blood supply. You will also receive free testing for hepatitis B and C, HIV, and HTLV at the time of your six-month follow-up. If necessary, counseling will be available from a study nurse or physician at the time you are notified of these results. You may personally benefit from future test results because they may reveal an undiagnosed medical condition for which you or your family members may wish to seek treatment.

RISKS AND DISCOMFORTS

Potential physical problems due to your participation in this study are only those related to the routine procedure of obtaining blood samples. These minor complications might be discomfort from the needle, slight bruising, bleeding, or soreness at the site where the blood was obtained. There is a slight chance that results from future testing may be unexpected or upsetting to you. If you are notified of a test result, it is your decision whether to share your test result with others, such as family members, employers, or insurance companies. This study cannot predict how others may respond to this information.

TREATMENT AND COMPENSATION FOR INJURY

If you suffer physical injury as a direct result of having your blood drawn, <Blood Center or hospital> will assume responsibility for providing immediate medical treatment. This care will be provided to you without charge so long as you notify the Principal Investigator within fifteen days of the day of the injury, and you consent to the care offered. There is no provision for monetary compensation to you by the hospital, blood center, or NHLBI for such things as lost wages, disability, injury or discomfort resulting to you from such physical injury.

COMPENSATION

You will receive no payment for participating in this study. **optional: You will be reimbursed for reasonable travel expenses to and from the second study visit.* All research tests will be free. Diagnostic testing and/or medical care for health problems that are discovered through these tests would be your responsibility.

VOLUNTARY PARTICIPATION

Participation in this study is entirely voluntary. You are free to withdraw from the study at any time without penalty. Your decision whether or not to participate will **not** affect any benefits to which you would otherwise be entitled. You will be given a copy of the signed consent form. If you decide to withdraw from the study at a later date, contact <*Principal Investigator*> at <*phone number*> and submit a written request to <*Principal Investigator*>at <*address*>.

It is important that we maintain current contact information for you. If your address changes, or if you have questions later, call the Principal Investigator listed above.

QUESTIONS

If you have any questions, please ask the research nurse now. If you have questions later, call the research office at <Phone Number>.

CONSENT

I have read the description of this study and the potential risks and I have been given the opportunity to ask questions. I agree to participate and I understand that I may withdraw at any time after signing this form.

Name (print) _____

Signature _____ **Date** _____

Witness _____

[If translator was used to obtain consent] *Language used*_____
Signature of translator _____ *Date*_____

What Is The REDS Allogeneic Donor And Recipient (RADAR) Repository ?

The RADAR Repository is a collection of stored blood samples linking both blood donors and the patients (recipients) who receive their blood. These blood samples, from both the donor and recipient, will be used by researchers in the future to test for newly discovered viruses or conditions that could possibly be transmitted by blood.

Since 1989, the Retrovirus Epidemiology Donor Study (REDS) has helped to monitor the safety of the nation's blood supply. All donated blood is checked for known viruses that can be transmitted by blood, including HIV (the virus that causes AIDS). Today's blood supply is safe. In order to maintain a safe blood supply in the future, however, it is important to learn whether or not new viruses or disease-causing agents can be transmitted by blood transfusion. This is the purpose of the RADAR Repository.

Who Is Participating In This Study? Why Was I Asked?

The RADAR Repository is a cooperative effort between hospitals and blood donation centers. The study participants include blood donors and surgical patients like yourself. Because you have had an operation and blood transfusion at a participating hospital, you were invited to be in this important study.

What Does My Participation Involve?

Participation involves two brief visits with a study recruiter.

Visit 1 occurs at the hospital shortly after your surgery. At this visit the study recruiter will:

- Explain the study in more detail and review the consent form with you;
- Invite you to give your written permission to be in the study;
- Ask you a few questions about your general health and how to contact you in the future; and
- Obtain a small sample of your blood for storage.

Visit 2 occurs about 6 months after your surgery. A member of the RADAR Repository study staff will contact you to schedule your second study visit. Because this is an important visit, the staff will arrange for it to take place at a location convenient to you. At this visit the study recruiter will:

- Ask you a few questions about your health; and
- Obtain a small sample of your blood for testing and storage.

Your study records will be strictly confidential and only accessible to RADAR study staff. Neither you nor the donor will know the identity of the other person.

What Tests Will Be Performed On My Blood?

Part of the blood sample you give during the second visit will be tested for HIV, hepatitis B, hepatitis C, and HTLV (human T-lymphotrophic virus). If any of these tests are positive, we will test your first blood sample to see if you had the infection before your surgery. You will be notified about your test results, both positive and negative. The chance that your test results will be negative is very good, giving you reassurance that the blood you received during your surgery indeed did not contain any of these viruses.

In the future, your stored blood samples may be tested for other viruses or disease-causing agents. At that time, and with your permission, you would be told about any results of these tests that are significant to your health. If there are any questions about research test results, you may be invited to give another blood sample or be asked to provide some additional information.

Exhibit E

Exhibit F
RACE/ETHNICITY CARD

Please select from the list below the term that best describes your race:

White	Chinese
Black, African American	Filipino
Black, Caribbean	Hawaiian native
Black, other	Korean
Indian, North American	Vietnamese
Indian, South American	Japanese
Indian, Central American	Eskimo or Aleutian
Asian Indian	Other

Exhibit G

RECIPIENT STUDY ID: → |_|_|_|-|_|_|_|-|_|-|6|M|

Study ID

Please place label here or write in number.

PROVIDER ROSTER

ROSTER NUMBER	PROVIDER AND/OR FACILITY NAME PERSON: FIRST, LAST	ADDRESS/TELEPHONE
1		TEL:
2		TEL:
3		TEL:
4		TEL:
5		TEL:
6		TEL:
7		TEL:
8		TEL:
9		TEL:
10		TEL:

Exhibit H

QUESTIONNAIRE SHIPPING LOG

AX TO:	REDS Field Room, WB 295			
FAX #:	301-517-4079			
FROM:				
SITE:		HOSPITAL:		
FAX DATE: ___/___/_____		FAXED PAGE	of	(e.g., 1 of 2; 2 of 2)

SHIPMENT INFORMATION

Ship to address (Overnight couriers & UPS):	REDS Field Room, WB295 Westat 1441 West Montgomery Avenue Rockville, MD 20850 Telephone: 301-738-3618

Airbill Number: _____ Shipment method (if other than FedEx): _____

Date of shipment: _____ Number of questionnaires in shipment: _____

List Recipient Study ID's Below	List Recipient Study ID's Below	List Recipient Study ID's Below

MCC Use Only Date of arrival: _____ Number of questionnaires: _____ Verified by: _____

Comments: _____

Exhibit I

RADAR MCC NOTIFICATION FORM

FOR MCC NOTIFICATION OF ALL 6-MONTH FOLLOW-UP REPEAT REACTIVE RESULTS

- Only one form may be used per recipient.
- Form must be completed and e-mailed to the MCC immediately upon receipt of all 6-month follow-up repeat reactive results (no cover sheet needed).
- E-mail must be followed up with a phone call to the MCC.

NOTE: Communication to MCC must include confirmation within 4 hours or next business morning.
DO NOT leave a message on voice mail.
In the event of e-mail service interruption, please use the fax method as a back-up.

E-MAIL: kasiawachowicz@westat.com and deborahtodd@westat.com

PHONE TO: KASIA WACHOWICZ (240)314-2322 ~OR~
DEBBIE TODD (301)738-8315

If neither Kasia nor Debbie are available, please leave a message with the REDS secretary.

FAX (backup method) TO KASIA WACHOWICZ ~OR~ DEBBIE TODD AT (301)517-4079

Recipient ID: Draw Date (6-Mo. Sample):

Blood Center: Testing BUI Number:

Recipient is results for viral markers (check RR or NR for each viral marker)**:**

	RR	NR	Pending	Comments:
Anti-HBc	☐	☐	☐	
HCV	☐	☐	☐	
HTLV	☐	☐	☐	
HBsAg	☐	☐	☐	
HIV	☐	☐	☐	

Name of person completing this form:

Phone number of person completing this form:

Exhibit J

TO: [Blood Center PI]
[Hospital Based PI]

FROM: Steven H. Kleinman, M.D.
Deborah S. Todd, MT(ASCP)
REDS Medical Coordinating Center

SUBJECT: RADAR Recipient 6-Month Follow-up and Index Sample Testing Results

DATE: < Insert Current Date >

RADAR Recipient __< ID # >___ was found to have <u>< viral marker ></u> reactive screening results at your blood center when he/she returned for a follow-up visit approximately six months after receiving a transfusion with a RADAR product.

According to the RADAR protocol for a reactive 6-month follow-up sample, the recipient index sample, collected prior to or at enrollment, was tested for this same viral marker using routine screening assays. If found reactive, the index sample was also tested with appropriate supplemental/confirmatory assays.

Results for the index and 6-month sample testing are as follows:

Index Sample ID #: <u>< aliquot ID # ></u> Collected: <u>< date ></u>
Drawn **Pre/Post** transfusion

Nonreactive / Reactive on <u>< marker ></u> EIA
Positive / Negative / Indeterminate / Not Done on the <u>< name of assay ></u>

6-month follow-up Sample ID #: <u>< aliquot ID # ></u> Collected: <u>< date ></u>

Reactive on <u>< viral marker ></u> EIA
Positive / Negative / Indeterminate / Not Done on the <u>< name of assay ></u>

According to the RADAR testing protocol, it is recommended that the RADAR recipient be notified and counseled that he/she has the above results with the following interpretation:

[Insert notification message found in Blood Center directive].

Exhibit K

TO: [Blood Center PI]
[Hospital Based PI]

FROM: Steven H. Kleinman, M.D.
Deborah S. Todd, MT(ASCP)
REDS Medical Coordinating Center

SUBJECT: RADAR Recipient 6-Month Follow-up and Index Sample Testing Results

DATE: < Insert Current Date >

RADAR Recipient __< ID # >____ was found to have _< viral marker >_ reactive screening results at your blood center when he/she returned for a follow-up visit approximately six months after receiving a transfusion with a RADAR product.

According to the RADAR protocol for a reactive 6-month follow-up sample, the recipient index sample, collected prior to or at enrollment, was tested for this same viral marker using routine screening assays. If found reactive, the index sample was also tested with appropriate supplemental/confirmatory assays.

Results for the index and 6-month sample testing are as follows:

Index Sample ID #: _< aliquot ID # >_ Collected: _< date >_
Drawn **Pre/Post** transfusion

Nonreactive / Reactive on _< marker >_ EIA
Positive / Negative / Indeterminate / Not Done on the _< name of assay >_

6-month follow-up Sample ID #: _< aliquot ID # >_ Collected: _< date >_

Reactive on _< viral marker >_ EIA
Positive / Negative / Indeterminate / Not Done on the _< name of assay >_

According to the RADAR testing protocol, it is recommended that the RADAR recipient be notified and counseled that he/she has the above results with the following interpretation:

[Insert notification message found in Coordinating Center directive].

Results reviewed and interpreted by:

_____
Steven H. Kleinman, M.D., or designee

Exhibit L

RADAR Recipient Test Results For: HBV and HCV

Blood centers should complete this form for all repeat reactive 6-month HBV and/or HCV test results.
Attach all source documents.

ANY REPEAT REACTIVE 6 MONTH RESULT REQUIRES IMMEDIATE NOTIFICATION TO THE MCC

Type of Sample Tested (check one): ☐ 6-Mo. Follow-up ☐ Index ☐ Follow-up Redraw

Recipient ID _____-_____-_____ Draw Date ___/___/_____

Blood Center _____ Testing BUI Number _____

Check below and complete all sections that apply:

☐ Anti-HBc (complete section 1) ☐ HBsAg (complete section 2) ☐ HCV(complete section 3)

1. Anti-HBc Results

1st EIA Manufacturer _____ ☐ Reactive ☐ Non-Reactive

2nd EIA Manufacturer _____ ☐ Reactive ☐ Non-Reactive

2. HBsAg Screening Results

	Initial		Repeat		
Screening 1	OD	Cut-off	1st OD	2nd OD	Cut-off
Manufacturer _____	__.___	__.___	__.___	__.___	__.___
Screening 2	OD	Cut-off	1st OD	2nd OD	Cut-off
Manufacturer _____	__.___	__.___	__.___	__.___	__.___

HBsAg Confirmatory Results

☐ Check here if not done because (check one ➔): ☐ First EIA+ / Second EIA – OR ☐ Anti-HBc +

Test Name: _____ Manufacturer: _____ Percent Neutralization: _____ %

HBsAg Final Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate

3. HCV Screening Results: ☐ Reactive ☐ Non-Reactive

HCV Confirmatory Results

Bands
Indicate band intensity below. Select 0 if band is absent.

Test Name: HCV RIBA 3.0	5-HP/c100p	c33c	c22p	NS-5	hSOD
Manufacturer: Chiron	0 +/- 1 2 3 4	0 +/- 1 2 3 4	0 +/- 1 2 3 4	0 +/- 1 2 3 4	0 +/- 1 2 3 4

HCV Final Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate

Exhibit M

RADAR Recipient Test Results for: HIV

Blood centers should complete this form for all repeat reactive 6-month HIV test results.
Attach all source documents.

Type of Sample Tested (check one): ☐ 6-Mo. Follow-up ☐ Index ☐ Follow-up Redraw

Recipient ID ____-_____-____ Draw Date ___/___/_____

Blood Center _____ Testing BUI Number _____

HIV-1/2 EIA ☐ Not Done

Lab Performing Test: _____

Test Name/Manufacturer: HIV-1/2 EIA / _____

	Absorbance Level:	Cut-off Level:	**Interpretation:**	
EIA # 1	_____	_____	☐ Reactive*	☐ Non-Reactive
EIA # 2	_____	_____	☐ Reactive*	☐ Non-Reactive
EIA # 3	_____	_____	☐ Reactive*	☐ Non-Reactive

ANY REPEAT REACTIVE RESULT REQUIRES IMMEDIATE NOTIFICATION TO MCC

HIV-1 Western Blot ☐ Not Done

Lab Performing Test: _____

Test Name/Manufacturer: HIV-1 Western Blot/ _____

Standard Bands

p17/18	p24	p31	gp41	p51	p55	p66/65	gp120	gp160

Other Bands:

Name:				
Intensity:				

Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate

HIV-2 TESTING: ☐ Yes (complete and attach Page 2) ☐ Not Done

For Medical Coordinating Center Use Only:

HIV FINAL INTERPRETATION:

☐ Positive ☐ Negative ☐ Indeterminate

Lab Accession No.: _____

HIV TYPE INTERPRETATION (HIV POSITIVES ONLY): ☐ HIV-1 ☐ HIV-2 ☐ Untypeable

RADAR Recipient Test Results for **HIV**

Blood centers should complete this form for repeat reactive 6-month HIV test results.
Attach all source documents.

Recipient ID ____-_____-____ Draw Date ___/___/_____

Blood Center _____ Specimen ID/BUI Number _____

HIV-2 EIA

☐ Not Done

Lab Performing Test: _____

Test Name/Manufacturer: HIV-2 EIA/

	Absorbance Level:	Cut-off Level:	**Interpretation:**	
EIA # 1	_____	_____	☐ Reactive	☐ Non-Reactive
EIA # 2	_____	_____	☐ Reactive	☐ Non-Reactive
EIA # 3			☐ Reactive	☐ Non-Reactive

HIV-2 WESTERN BLOT OR OTHER SUPPLEMENTAL TEST

☐ Not Done

Lab Performing Test: _____

Test Name/Manufacturer: HIV-2 Western Blot/

Standard Bands

p16	p24	p24/26	p26	p31	p34	gp34	HIV-2Env Peptide	gp41
p55	p58	p68	gp70	gp105	gp120	gp125	gp140	

Other Bands:

Name: _____ _____ _____ _____

Intensity: _____ _____ _____ _____

Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate

HIV IFA

☐ Not Done

Lab Performing Test:

Test Name/Manufacturer: HIV IFA/

HIV-1	☐ Reactive	Titer: 1: _____	☐ Non-Reactive	☐ Non-Specific/Unsatisfactory
HIV-2:	☐ Reactive	Titer: 1: _____	☐ Non-Reactive	☐ Non-Specific/Unsatisfactory

Type Interpretation: ☐ HIV-1 ☐ HIV-2 ☐ Untypeable

Exhibit N

RADAR Recipient Test Results for: HTLV

Blood centers should complete this form for all repeat reactive 6-month HTLV test results.
Attach all source documents.

Type of Sample Tested (check one): ☐ 6-Mo. Follow-up ☐ Index ☐ Follow-up Redraw

Recipient ID ____-____-____ Draw Date ___/___/_____

Blood Center _____ Testing BUI Number _____

Screening EIA

Lab Performing Test: _____

Test Name/Manufacturer: HTLV - I/II EIA/

	Absorbance Level:	Cut-off Level:	Interpretation:	
EIA # 1	_____	_____	☐ Reactive	☐ Non-Reactive
EIA # 2	_____	_____	☐ Reactive	☐ Non-Reactive
EIA # 3	_____	_____	☐ Reactive	☐ Non-Reactive

Secondary EIA

☐ Not Done

Lab Performing Test: _____

Test Name/Manufacturer: HTLV - I/II EIA/

Other Manufacturer Not Listed Above (SPECIFY)

Interpretation: ☐ Reactive* ☐ Non-Reactive

ANY RESULT REACTIVE BY DUAL EIA REQUIRES IMMEDIATE NOTIFICATION TO MCC

Tertiary EIA: ☐ No ☐ Yes **IFA:** ☐ No ☐ Yes **RIPA:** ☐ No ☐ Yes

If "yes" to any of the above, complete and attach page 2.

Western Blot

☐ Not Done

Lab Performing Test: _____

Test Name/Manufacturer: HTLV - I/II WB/

Standard Bands:	p19	p21env	p24	p26	p28	p32	p36	p38tax
	_____	_____	_____	_____	_____	_____	_____	_____
	p42	gp46env	p53	gp68				
	_____	_____	_____	_____				

Other Bands:

Name: _____ _____ _____ _____

Intensity: _____ _____ _____ _____

Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate

For Medical Coordinating Center Use Only:

HTLV FINAL INTERPRETATION: Lab Accession No.: _____

☐ Positive ☐ Negative ☐ Indeterminate ☐ Alternate EIA Non-Reactive

HTLV TYPE INTERPRETATION (HTLV POSITIVES ONLY): ☐ HTLV-I ☐ HTLV-II ☐ Untypeable

RADAR Recipient Test Results for HTLV

Blood centers should complete this form for all repeat reactive 6-month HTLV test results.
Attach all source documents.

Recipient ID ____-_____-____ Draw Date ___/___/_____

Blood Center _____ Specimen ID/BUI Number _____

Tertiary EIA ☐ Not Done Lab Performing Test: _____

Test Name/Manufacturer: HTLV - I/II EIA/

S/C Ratio: _____ **Interpretation:** ☐ Reactive ☐ Non-Reactive

IFA ☐ Not Done Lab Performing Test: _____

Test Name/Manufacturer: HTLV - I/II EIA/

HTLV-I ☐ Reactive Titer: 1: _____ ☐ Non-Reactive ☐ Non-Specific

HTLV-II: ☐ Reactive Titer: 1: _____ ☐ Non-Reactive ☐ Non-Specific

Type Interpretation: ☐ HTLV-I ☐ HTLV-II ☐ Untypeable

RIPA ☐ Not Done Lab Performing Test: _____

Test Name/Manufacturer: HTLV - I/II EIA/

☐ HTLV-I Non-Reactive

☐ HTLV-I Reactive Bands: p24 p28 p40x p51 p53 gp68

☐ HTLV-II Non-Reactive

☐ HTLV-II Reactive Bands: gp21 p24 p38x p53 gp67

Other Bands:

Name: _____

Intensity: _____

Interpretation: ☐ Positive ☐ Negative ☐ Indeterminate/Non-diagnostic

RADAR
RECIPIENT 6-MONTH TEST RESULTS TRACKING REPORT

1. Record the Testing BUI ID.

2. Circle the result of each recipient listed below. Reactive results will already be circled when you receive this form.
*** NOTE: IF ANY REACTIVE RESULT IS NOT PRE-CIRCLED WESTAT MUST BE NOTIFIED IMMEDIATELY. ***

3. Verify the phlebotomy code and test results of ALL recipients.

4. For any recipient with REACTIVE results, verify that the appropriate RADAR test results form(s) have been completed and forwarded to Westat.

5. Attach all source documents, including those for recipients who are Non Reactive.

6. Discard NAT tubes indicated with a check mark in the 'YES' column as described in Operations Manual Version 3 Section 8.7.3.

VIRAL MARKER STATUS: R = Reactive, Circle 1. NR = Non Reactive, Circle 2. NT = Not Tested, Circle 6.

Blood Center:

Recipient ID	Phlebotomy Code	6-Month Visit Date	MCC Use Only	Testing BUI ID	For each recipient circle 1, 2 or 6 for each marker below																					Discard NAT Tubes	
					HBV									HCV			HIV						HTLV				
					HBc			HBsAg			Anti HBs						Ab			p24Ag							
					R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	YES	NO
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		
					1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6		

Exhibit O

RADAR
RECIPIENT INDEX TEST RESULTS TRACKING REPORT

1. Verify that the Recipient ID Suffix matches the sample that was tested. Strike through with a single line and initial if you are making a correction to the Recipient ID or if the sample was not tested.

PR for Pre-Transfusion sample. PO for Post-Transfusion sample.

2. Fill in the Testing BUI ID.

3. Circle the result of each recipient listed below.

4. For any recipient with REACTIVE results, complete RADAR test results form(s) for that specific viral marker.

5. Attach all source documents, including those for recipients who are Non Reactive.

6. Forward completed forms and all source documents to Westat.

VIRAL MARKER STATUS: R = Reactive, Circle 1. NR = Non Reactive, Circle 2. NT = Not Tested, Circle 6.

Blood Center: OKLAHOMA BLOOD INSTITUTE

Recipient ID	Draw Date	MCC Use Only	Testing BUI ID	For each recipient circle 1, 2 or 6 for each marker below																				
				HBV									HCV			HIV						HTLV		
				HBc			HBsAg			Anti HBs						Ab			p24Ag					
				R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT	R	NR	NT
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6
				1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6	1	2	6

Exhibit O

Exhibit P

Principles Guiding Test Interpretation and Further Follow-up Sampling of RADAR Recipients
January 2001

Communication of test results from Westat

1. Results of both index and six-month testing for recipients with positive six-month screening test results will be communicated to centers from Westat using a standardized reporting letter.

    a. Confirmed positive results (all markers other than anti-HBc) will be reviewed by Dr. Steven Kleinman or another senior investigator.
    b. Unusual/unanticipated results will be reviewed by Dr. Steven Kleinman or another senior investigator.
    c. All other results (e.g. those with no evidence for infection and those without test discrepancies) will be signed out by Westat staff using designated review algorithms. These algorithms will also be distributed to field staff.

Further follow-up sampling (beyond routine six-month follow-up)

1. Further follow-up samples for serologic testing (and NAT for HCV/HIV) for any of the viruses will be requested from recipients in the following circumstances:

    a. The six-month sample results indicate a new (or probable new) infection. The purpose for follow-up sample collection is to verify the results (i.e. rule out lab error). The sample can be collected immediately.
    b. The index and six-month samples do not conform to the expected natural history of infection. (e.g. test error is suspected on one of the two study samples). This sample can be collected immediately.
    c. The six-month sample is indeterminate and indicates a possible evolution of serologic reactivity. The purpose for follow-up sample collection is to evaluate this possible serologic evolution. The sample should be collected at an interval of one month following the last sample collection.

2. If there has been no evolution in serologic test reactivity between index and six-month follow-up samples (e.g. both are confirmatory negative or both are confirmatory indeterminate), the recipient will be counseled as uninfected. There will be no need for a further follow-up sample.

NAT for HCV or HIV

1. NAT testing of the six-month follow-up sample (and, if necessary, the index sample) for HIV or HCV will be performed in Dr. Busch's lab at BCP according to REDS algorithms. Results may not be available until two weeks following serology results; therefore, NAT results will not be available at the time the initial counseling message is delivered to recipients.

2. NAT testing for HIV or HCV will be performed in two circumstances:

    a. to determine (verify) infection status
    b. to determine whether infection occurred pre or post study entry.

3. Due to the importance of conserving index sample volume, NAT on the index sample will be restricted to circumstances in which the information is vital for result interpretation.

HBV

1. Due to the importance of conserving index sample volume, HBsAg on the index sample will be restricted to circumstances in which the information is vital for result interpretation. In some cases (anti-HBc negative index sample and positive 6 month sample), index HBsAg results will not be available at the time the initial counseling message is delivered to recipients.

2. In some circumstances, anti-HBs testing may be needed and will be obtained from the ARC NCTRL (Dr. Sue Stramer's lab) if not routinely performed at the blood center.

3. In rare circumstances, HBV NAT may be needed to further clarify results. Arrangements to perform this testing will be made as necessary.

Exhibit Q

Routine TTI result notification of RADAR study enrollees
Obligations of RADAR centers
January 2001

1. Assure that routine TTI test results are transmitted to each study enrollee who gives a bloods sample at the six-month follow-up visit.*
    a. Document either that results were transmitted to the study enrollee or that multiple attempts to communicate results to the study enrollee were unsuccessful.
    b. Assure confidentiality of results transmission.
2. A center may use whatever mechanism of notification it deems appropriate. If a written notification method is used, a center will use its own written materials (notification letters, information sheets). Copies of these materials should be supplied to the RADAR Coordinating Center.
3. Assure that the counseling message to study enrollees with non-negative results conforms with:
    a. the interpretation provided by the RADAR Coordinating Center.
        i. For samples for which the index sample is not negative, follow procedures (as specified in the RADAR field memo on study enrollee notification) regarding initial counseling, subsequent counseling for pending results (e.g. NAT results), and further follow-up specimen collection.
        ii. Assure that further counseling is performed when subsequent test results are received by the center.
    b. all regulations of the state in which the RADAR center is located.
    c. policies of the local RADAR blood center (or other institution) conducting the research.
        i. For samples for which the index sample is negative and the six-month follow-up sample is confirmed positive, inform the study enrollee of the possibility of infection from transfusion and follow the centers' SOP for post-transfusion case investigation, if required.

*Definition of RADAR routine TTI results: These are defined as HIV ab, HTLV ab, HCV ab, HBsAg, and anti-HBc results on the six-month follow-up sample. If any of these assays are non-negative, then routine TTI results will also include testing of the index sample for that marker, prior to notification of the study enrollee. Non-negative results for HIV or HCV will, in certain cases, trigger NAT testing of the six-month and/or index samples for the respective virus.

Exhibit R
SUBJECT DE-ENROLLMENT FORM*

Recipient **Donor**

Date of request to be removed from RADAR Repository: __ __/ __ __/ __ __

First name: _____ **Middle Initial:** _____
Last name: _____

Date of birth: __ __/ __ __/ __ __

Address: _____
City:_____ **State:** _____ **Zip:** _____

Home phone number: _____
Work phone number: _____

Social Security #: _____

Date of study enrollment: __ __/ __ __/ __ __

For donor, WBN/BUI of donation:

_____

For recipient, study ID label number *(upper right hand corner of consent form)*:

_____

Reason given for wanting to withdraw:

_____

---

*This form should <u>not</u> be returned to the MCC. Email pertinent information as outlined in Chapter 7 to the MCC.

Exhibit S

REDS Aliquot Adjustment Codes Card

VOL FULL

VOL 1.75

VOL 1.50

VOL 1.25

VOL 1.00

VOL 0.75

VOL 0.50

VOL 0.25

VOL -.25

VOL 0.00

Exhibit U

Version: July 2002

RADAR REPOSITORY
DONOR SHIPMENT FORM

AX TO:

(301) 208-8829 Misti Dowell(BTRL)
(301) 517-4079 Kasia Wachowicz (Westat)
(301) 480-0868 Luiz Barbosa (NIH)

Ship Samples to:
BTRL
ATTN: Misti Dowell
217 Perry Parkway
Gaithersburg, MD 20877

INSTRUCTIONS:

1. Only one form may be used for each shipping container/airbill.
2. Complete shipment form and immediately fax to the appropriate contacts at NIH, Westat and BTRL using the numbers listed above.

Section I

Airbill Number: _____ **Date of Shipment:** _____

Blood Center:
- ☐ ARC – Chesapeake
- ☐ ARC – Southeastern Michigan
- ☐ ARC – Southern California
- ☐ Blood Centers of the Pacific–Irwin
- ☐ Oklahoma Blood Institute
- ☐ Institute for Transfusion Medicine
- ☐ Florida Blood Services

Name of Person who Prepared Shipment: _____

Phone: _____ **Fax:** _____

Section II

Type of Shipment:

Enter the total number (0-10) of each type of freezer box included in this shipment

- **Indicate the type of donor sample box in this container by marking box LD (Linked Donor) or UD (Unlinked Donor). Donor boxes in this shipper are labeled:** (example: box 1 out of 70, box 2 out of 70, etc)

Number of **Donor** boxes included in this container (max. 10): ☐

For complete shipped boxes		For re-boxed shipped boxes (example 1 out of 70, etc.)	
		LD UD	**LD UD**
- DO	- DO	☐ ☐ _____OF_____	☐ ☐ _____OF_____
- DO	- DO	☐ ☐ _____OF_____	☐ ☐ _____OF_____
- DO	- DO	☐ ☐ _____OF_____	☐ ☐ _____OF_____
- DO	- DO	☐ ☐ _____OF_____	☐ ☐ _____OF_____
- DO	- DO	☐ ☐ _____OF_____	☐ ☐ _____OF_____

All shipments must be in accordance with IATA regulation for Infectious Substances.

BTRL Use Only:

Date of Arrival: _____

Verified Number of Boxes (initial): _____

Signature: _____

When complete, please fax to Westat and blood center to acknowledge receipt.

Comments:

_____

_____

_____

_____

Exhibit V

Version: July 2002

RADAR REPOSITORY
RECIPIENT SHIPMENT FORM

AX TO:
(301) 208-8829 Misti Dowell(BTRL)
(301) 517-4079 Kasia Wachowicz (Westat)
(301) 480-0868 Luiz Barbosa (NIH)

Ship Samples to:
BTRL
ATTN: Misti Dowell
217 Perry Parkway
Gaithersburg, MD 20877

INSTRUCTIONS:
1. Only one form may be used for each shipping container/airbill.
2. Complete shipment form and immediately fax to the appropriate contacts at NIH, Westat and BTRL using the numbers listed above.

Section I

Airbill Number: _____ **Date of Shipment:** _____

Blood Center:
- ❑ ARC – Chesapeake
- ❑ ARC – Southeastern Michigan
- ❑ ARC – Southern California
- ❑ Blood Centers of the Pacific–Irwin
- ❑ Oklahoma Blood Institute
- ❑ Institute for Transfusion Medicine
- ❑ Florida Blood Services

Name of Person who Prepared Shipment: _____

Phone: _____ **Fax:** _____

Section II

Type of Shipment:
- Enter the total number (0-10) of each type of freezer box included in this shipment (i.e. Recipient (RE), Donor)
- For any recipient boxes being shipped, record the box ID numbers ending with the suffix "RE".

Number of **Recipient** Boxes **(RE)** included in this container (max. 10): ☐

- RE	- RE	- RE
- RE	- RE	- RE
- RE	- RE	
- RE	- RE	

All shipments must be in accordance with IATA regulations for Infectious Substances.

BTRL Use Only:

Date of Arrival: _____

Verified Number of Boxes (initial): _____

Signature: _____

When complete, please fax to Westat and blood center to acknowledge receipt.

Comments:

_____

_____

_____

_____

Exhibit W

Deliverables

Deliverable	Due at MCC*	Method of Delivery
♦ RTS Back-up	5th of each month	diskette by FedEx Overnight or email attachment
♦ SIS Back-up	5th of each month	diskette by FedEx Overnight or email attachment
➢ Ineligibles Tracking Form	5th of each month	email attachment or fax
♦ Monthly Donation Data	15th of each month	diskette by FedEx Overnight or email attachment
✓ MCC Notification Form	Immediately upon receipt of reactive 6M result at blood center	email attachment or fax (back-up method only)
✓ Confirmatory Test Results Forms (with source documents)	Within 3 business days of receipt of confirmatory results at blood center	email attachment or fax
✓ Recipient 6-Month Test Results Tracking Report	Within 2 weeks of receipt at blood center	by fax or FedEx Overnight
➢ Completed Recipient 6-Month Questionnaires	At least once monthly in batches	by FedEx Overnight
➢ Questionnaire Shipping Log	At least once monthly included with questionnaires	by FedEx Overnight
✓ Shipping Form	Day of donor or recipient sample shipment	by fax

Legend:
- ♦ Contact: Himanshi Singh - (301) 517-8087
- ✓ Contact: Kasia Wachowicz - (240) 314-2322
- ➢ Contact: Suhela Pandit - (301) 738-6318

*Due on date indicated or next business day if date falls during a weekend or holiday