

**PROTOCOL REVIEW AND COLLECTION OF SAMPLES
FOR NHLBI BIOLOGICAL SPECIMENS REPOSITORY AND
CYTOGENETICS/ NUCLEIC ACIDS LABORATORY**

Review blood specimen collection protocol:

- Frozen serum for the NHLBI Biological Specimens Repository sample collection is scheduled at every annual visit, and specimens for the Cytogenetics/Nucleic Acids Laboratory are scheduled once more in the course of follow up, unless refused on the patient's Individual, signed informed consent.
- Review the patient's signed informed consent form.
- Complete Specimen Collection (Form 45 Part I) according to permission for collection, labeling, storage and use of specimen(s) from the signed informed consent form. The requirements for consent for blood sample collection, labeling, storage and use vary among the Clinical Centers. The questions in Part I are designed to be answered by all Clinical Centers for any patient. "Present studies" are those to be done during the conduct of the MSH Patients' Follow Up - Extension I (2003-2007) on fresh blood or blood products. "Future studies" are those that may be done on samples of frozen serum or nucleic acids (2003-ff). At the end of the study, the MCC will remove from study records the link between the sample and the patient's study ID or other identifying information. "Not specifically required" means that asking the question was not required or that the patient indicated no preference for additional consent at the time of future laboratory analysis.

Scheduling blood collection

- Record on the same Form 45 all samples collected *within an Annual Visit window*, whether collected on the same day or on different dates. Whenever samples are collected, complete the appropriate items of Part II with the collection date(s) and duplicate sample label(s). FAX Form 45 to the Medical Coordinating Center promptly after collection of any Biological Specimens Repository or Cytogenetics/Nucleic Acid Laboratory specimens for the patient.

Collection procedures: FROZEN SERUM FOR NHLBI BIOLOGICAL SPECIMENS REPOSITORY:

- At every annual visit (AV) collect one (1) 11-ml serum separator tube for every patient with consent for collection.
- Spin at 3,000 RPM for at least 5 minutes.
- Decant serum into 5-ml shipment/storage tube (cryovial).
- Four pre-printed TOUGH-TAG® duplicate labels are provided for each sample. All four identify the sample with a unique four-digit number (# 9999). One duplicate label is for the serum tube, one is for Form 45, one is for Form 61 and one is a spare.
 - label the SERUM TUBE (CRYOVIAL) with a LABEL FOR THE CORRECT PATIENT-VISIT;
 - DO NOT PUT ANY LABEL WITH THE PATIENT ID OR LETTER CODE ON THE CRYOVIAL;
 - affix a duplicate label (Same #9999 Label 2/4) on Form 45 Item 6B;
 - if you make a mistake, or if you need to label the serum separator tube, you can use the spare, duplicate label WITH THE SAME #9999 FOR THE SAME PATIENT-VISIT;
 - be sure to keep one of the four duplicate labels for Form 61 at the time of shipment (may be several months later);
- freeze to -70° C and keep frozen until time to ship;
- store samples until you have enough for a batch shipment (LIMIT: ONE SHIPMENT PER CLINIC PER YEAR except Clinic 08);
- COMPLETE FORM 45 AND FAX PROMPTLY TO THE MEDICAL COORDINATING CENTER FOR VERIFICATION OF SAMPLE LABELING;
- for shipment procedures, see Form 61.

Collection procedures: SAMPLES FOR THE CYTOGENETICS/NUCLEIC ACIDS LABORATORY:

PROVIDED SEPARATELY

MSH PATIENTS' FOLLOW UP (EXTENSION I) PROTOCOL REVIEW AND COLLECTION OF SAMPLES FOR NHEB BIOLOGICAL SPECIMENS REPOSITORY AND CYTOGENETICS/ NUCLEIC ACIDS LABORATORY	Client: MANIC								
	Patient ID: PK								
	Letter Code: NAME/DUE								
	Annual Visit: AK							A	V
Visit Date: YS-DT									

Part I. Review of Blood Specimen Collection Specifications from Informed Consent Form:

A. MSH Patients' Patients' Follow Up - Extension I Only

Present studies

1. Consent for sample collection granted? (1) Yes (2) No **PKS**

Future studies

2. Consent for sample collection granted? (1) Yes (2) No **FUTMSHCL**

3. If collected, is additional consent required at time of laboratory analysis? (Skip if not collected)

(1) Yes (2) NSR **FUTMSHAN**

Yes = Consent specifically granted
 No = Consent specifically NOT granted
 NSR = Consent not specifically required

Part II. Sample Collection at this Annual Visit

Specimen	A. Collection Date	B. Duplicate Label
4. Frozen Serum Specimen	SERUM_DT	SERUMLBL
5. Cytogenetics/Nucleic Acids (Heparin tube)	CYT01_DT	CYT01LBL
6. Cytogenetics/Nucleic Acids (EDTA tubes)	CYT02_DT	CYT02LBL

Part III. Certification

Checked for completeness and accuracy	
A. Signature	
B. Certification number	
C. Date	

Retain a copy of this form for your files. FAX promptly to the Medical Coordinating Center, 410/435-4232. Thank you.