

**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 at AV01 and AV05, 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 (1997-2001). "Future studies" are those that may be done on samples of frozen serum or nucleic acids (1997-?). "Deleting the link to study data at the end of the study" refers to the removal from study records of the identity of the sample with the patient's study ID, gender, age, weight or other identifying information. "Not specifically required" means that asking the question was not required or that the patient indicated no preference for removal of identification or giving additional consent at the time of future laboratory analysis. Answer each question for both columns ("MSH Patients' Follow-Up only" and "Other studies").

**Scheduling blood collection**

- Complete Form 45 and send to the Medical Coordinating Center promptly after collection of any Core Laboratory specimens for the patient. Whenever samples are collected, you will complete the appropriate items of Part II with the collection date(s) and duplicate sample label(s).

**Collection procedures: FROZEN SERUM FOR NHLBI BIOLOGICAL SPECIMENS REPOSITORY:**

- at every annual visit (AV) collect one (1) 10-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
- 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 form Form 61 and one is a spare.
  - label the SERUM TUBE with a LABEL FOR THE CORRECT PATIENT-VISIT
  - DO NOT PUT ANY LABEL WITH THE PATIENT ID AND NAMECODE ON THE TUBE
  - 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:**

TO BE PROVIDED LATER

MSH PATIENTS' FOLLOW-UP PROTOCOL REVIEW AND COLLECTION OF SAMPLES (FOR NHLBI BIOLOGICAL SPECIMENS REPOSITORY AND CYTOGENETICS/ NUCLEIC ACIDS LABORATORY)	Clinic	CLINIC									
	Patient ID	FD									
	Namecode	NAMECODE									
	Annual Visit	AV									
	Visit Date	VIS-DT									

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

	<b>A. MSH Patients' Follow-Up Only</b>	<b>B. Studies Other than MSH Patients' Follow-Up</b>
<u>Present studies</u>		
1. Consent for sample collection granted?	(1) Yes (2) No	(1) Yes (2) No
2. If collected, delete link to study data at the end of the study? (Skip if not collected)	PR5 (1) Yes (2) NSR PR5MSHLK	PR5OTHCL (1) Yes (2) NSR PR5OTHLK
<u>Future studies</u>		
3. Consent for sample collection granted?	(1) Yes (2) No	(1) Yes (2) No
4. If collected, delete link to study data at the end of the study? (Skip if not collected)	FUT MSHCL (1) Yes (2) NSR FUT MSHLK	FUT OTHCL (1) Yes (2) NSR FUT OTHLK
5. If collected, is additional consent required at time of laboratory analysis? (Skip if not collected)	(1) Yes (2) NSR FUT MSHAN	(1) Yes (2) NSR FUT OTHAN

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
6. Frozen Serum Specimen	SERUM-DT	SERUMLBL
7. Cytogenetics/Nucleic Acids (Heparin tube)	CYT01-DT	CYT01LBL
8. Cytogenetics/Nucleic Acids (EDTA tubes)	CYT02-DT	CYT02LBL

**Part III. Certification**

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

Retain a copy of this form for your files. Send the original to the MSH Patients' Follow-Up Medical Coordinating Center, Maryland Medical Research Institute, 600 Wyndhurst Avenue, Baltimore, Maryland 21210. By FAX transmission to 410/435-4232. Thank you.