

## **Clinical Core Policies/Procedures/Chargebacks**

**Policies and procedures** regarding the allocation of Specimen Repository resources are determined through the advice of an Advisory Committee for the Core. Weekly meetings involving the Repository and Database leadership provide ongoing guidance and feedback for the coordinated, strategic planning of these Clinical Core activities. These Clinical Core services are available to all CFAR investigators according to the following priorities (1 = highest):

- 1) AIDS-related, peer-reviewed funded projects;
- 2) Pilot studies of AIDS-related projects that are being developed for competitive, peer-reviewed funding;
- 3) Non-peer reviewed, publicly or privately funded, AIDS-related projects that are consistent with the overall objectives of the CFAR;
- 4) AIDS-related non-funded projects;
- 5) Projects that are not directly AIDS-related, but represent high quality research efforts by University investigators requiring specimen acquisition storage or utilization from HIV-infected patients.

Usage prioritization for these and related services are determined by consensus among the Advisory Committee, based on relative scientific and clinical merit versus the cost involved, whether in terms of finances, staffing demands, or the potential depletion of critically important, scarce patient samples. Investigators who utilize the Clinical Core are expected to pay for all research-related materials and reagents required for specimen acquisition, storage, process, and delivery. Access to clinical data is a service provided by the Core and, at the present time, no specific charge-back is associated with access to and utilization of clinical data within the database. However, requests for access will be reviewed by the Advisory Committee and assigned a priority score in order to triage the use of the Core. In the past, charge for specimen acquisition and storage was only assessed at the time specimens were removed from the repository; however, since the majority of specimens stored in the repository are not used immediately or within the immediate or short term time frame, the policy was changed several years ago to assess charges for specimens at the time the specimen is obtained and stored, according to established rates (listed in budget justification section). During the past funding cycle, the Clinical Core established more formal written policies regarding both the Database Projects and the Clinical Specimen Repository. These policies assure that all projects accessing the database are in strict adherence to IRB guidelines. Feedback from all key research staff and core users was solicited by email and direct contact during the conception and early evolution of these guidelines, and the policies were adapted based on this feedback to make the policies and procedures clearer and more practical. The Clinical Core faculty meets semiannually and utilizes these opportunities to adapt to feedback from staff and users, and to changes in research needs and goals.

### **Standard Operating Procedures for the CFAR Clinical Core Repository, CCB Room B-012, UAB, Birmingham, AL**

I. The 1917 Clinic CFAR Specimen Repository, under the direction of Dr. J. Michael Kilby, MD, Clinic Medical Director and CFAR Clinical Core Director, and Carl Zhang, Repository Supervisor, operates under the auspices of CFAR and ACTG guidelines. Its purpose is to offer quality specimen handling and processing for a broad range of HIV

clinical trials and corollary research initiatives, and to function as a long-term resource for investigators seeking historical specimens for data generation, assay and protocol development, etc. The Repository supports commercially funded as well as publicly funded studies, including selected investigator-initiated protocols within the UAB system.

II. The daily operations of the Repository are supported financially by the CFAR grant, other public grants, and by commercial support from pharmaceutical drug trials that use the services of the Repository. Billing is performed at regular intervals through the 1917 Clinic Financial Operations office. Charges for services will be clearly explained to all registered users of the Repository, and such charges may be adjusted periodically to reflect operating costs, including consumables and equipment, maintenance of facilities, etc. If charges must be adjusted, changes will be communicated to all currently registered users no less than 30 days prior to the date adjustments will go into effect.

III. The Repository will be open Monday through Friday, except for emergencies that prohibit operation such as extreme weather conditions, and holidays observed by UAB. These holidays include New Years, Martin Luther King, Jr. Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day (2 days), Christmas (1 day), and possibly one extra day around Christmas or New Years. **The Repository will not be open to accept specimens on weekends or the above-mentioned emergencies or holidays.**

IV. Specimens will be accepted on operational days, provided they meet minimum standards as per current policy documents. Any problems or data discrepancies will trigger a phone call to the designated contact person, or other remedial steps at the discretion of the Repository personnel, before the specimens are accepted for final processing. Specimens arriving late may be held for processing until the following day, except for time-critical samples requiring immediate handling. In any case, processing of specimens will always be completed within 36 hours of arrival at the Repository.

V. Specimens will be processed as per the accompanying Flow Chart and handled according to protocol or investigator instructions. Special instructions that deviate from expected procedures **must be sent with the specimen** to ensure they will be followed. Specimens will be stored at ambient or refrigerated conditions, or in -20 degree C, -70 degree C, -140 degree C, or liquid nitrogen freezers as appropriate.

#### VI. Access to Repository Facilities

A. Access to the physical space occupied by the Clinical Core Repository is limited to authorized personnel employed in the lab. UAB Housecleaning personnel are allowed when employees are present or when specific arrangements are made for floor cleaning outside normal working hours. Maintenance personnel can access the lab whenever there is an alarm situation or to perform needed repairs. Guests and others are usually allowed in the lab only when lab personnel are present.

B. Access to the Repository is controlled by a security door operated with cardkeys, and by locks on all lab doors. The doors are to be locked whenever no lab personnel are in the lab, and after normal working hours.

#### VII. Shipping of Specimens

A. Frequent shipments of processed samples and of whole blood are performed to fulfill protocol requirements.

B. All personnel are trained in IATA and DOT shipping regulations. Training is updated every 2 years. Training documents are stored in Repository files and in Nurse Manager files.

C. Shipments must comply with current IATA and DOT requirements, including labeling, packaging, and shipment alerts to receiving labs.

VIII. Retrieval of archived specimens will be handled as follows:

A. The request will be documented by the registered user on Form R-4, "CFAR Repository Specimen Retrieval Request."

B. Requests for specimens will include the Protocol / Project # for every registered study from which the requested samples are derived. The requestor will complete a separate Form R-4 for each protocol. If the samples requested are not registered to the requestor, the requestor must provide written documentation from the appropriate user, including the Protocol / Project #, authorizing retrieval of the specimens, **prior** to retrieval of the samples.

C. There is no charge for sample retrievals, since the incurred costs are built into the processing charges.

D. Please give 48 hours notice before samples are needed. Documents are required at the time of the request.

IX. Ownership of stored samples not linked to a registered user, or "abandoned" by a registered user, will default to Dr. J. Michael Kilby, CFAR Clinical Core Director, and will be handled or disposed of at his discretion.

X. If specimens are no longer wanted or must be disposed of for any reason, the registered user must provide a signed and dated document requesting such action, including the reasons for request and all information needed to specify the relevant samples. The Repository is not responsible for the disposition of such samples if they have been shipped or retrieved for use prior to the date of the request.

XI. Monitoring and maintenance of equipment in the Clinical Core Repository

A. All mechanical cryogenic storage devices and the HVAC system servicing the main freezer room are linked to a 24-hour alarm monitoring system operated by UAB Police / Physical Security. Alarm conditions trigger phone calls to UAB Campus Maintenance and to Repository personnel, per a call list possessed by UAB Police. Appropriate steps are taken on a case by case basis to insure the integrity of the stored specimens.

B. Maintenance of cryogenic storage devices and centrifuges is performed once annually. Actions may include cleaning filters, replacement of batteries, calibration of systems, etc.

C. The two biosafety hoods located in the Repository undergo annual recertification by the UAB Office of Biosafety. A current certification sticker is to be on each hood at all times.

XII. Safety Procedures

A. Appropriate safety apparel is to be worn by all personnel engaged in processing and handling of specimens. The Repository lab is a BL-1/BL-2 facility, and CDC Universal Precautions apply to all specimen handling activities. Required equipment includes eye protection, gloves, and either a lab coat or surgical gown. Open toed shoes or sandals are not allowed.

B. All waste generated during processing or cleaning the hoods and benches are to be placed in red or orange marked biohazard bags. These bags are placed in appropriately labeled red barrels which are then picked up regularly by UAB Hazardous Waste Disposal personnel.

C. Spills of blood or other human body fluids are to be diluted with concentrated disinfectant or chlorine bleach, and absorbed into paper towels, which are then disposed of in marked biohazard bags.

D. The reagents used in processing tend to be low risk or nontoxic substances. However, all reagents regardless of hazard level must be appropriately labeled and stored.

E. Injuries in the Repository will be documented as per UAB policy. No open lacerations can be allowed while handling blood or specimens.

F. The eye- wash located beside the sink must be tested weekly, and the testing documented and initialed.

G. LN2 is piped into the freezer room from a microbulk tank outside the building. When interacting with the LN2, such as filling containers or handling specimens that have been immersed in liquid phase LN2, safety apparel will be used, including latex gloves under cryogenic mitts, lab coat, and face shield. All effort will be taken to avoid spilling the LN2.

H. Dry Ice (CO<sub>2</sub>) is used for frozen shipments. When interacting with the dry ice pellets, latex gloves and/or cryogenic mitts must be worn. Dry Ice is never to be placed in completely sealed containers. Venting must be provided.

XIII. This document may be updated as needed. Updated copies will be sent by email or fax to all currently registered users at least 30 days prior to implementation of the updates.

### **Policy Regarding Collection and Storage of Protected Health Information in the CFAR Specimen Repository at the UAB 1917 Clinic**

1. The personnel of the CFAR Clinical Core Repository, hereinafter referred to as the Repository, make no efforts to collect Protected Health Information, hereinafter referred to as PHI, with the exception of the Repository ID number. We avoid collecting all other PHI, instead labeling, storing, and tracking specimens using the 1917 Clinic Repository I.D. assigned to each patient for which research specimens are processed and stored, and / or study specific identifiers that may be linked in our database to the Repository ID.

2. Information on location and disposition of patient samples is logged in on paper records and an MS Access database. The paper records are stored in file cabinets, binders, and boxes stored in the Repository, which is locked when vacant. During operational hours, access to these documents is strictly controlled and limited to Clinic and Repository personnel with proper authorization. The Access database is stored on a secure server in the 1917 Clinic, and is subject to the same restrictions, including a firewall and limited permissions for access, as are the main Clinic databases. The Repository records are not associated physically or electronically with the 1917 Clinic records or databases, except for duplicated study tracking documents that as a rule, do not include PHI.

3. On occasion, we receive blood tubes or other specimen containers, or documents containing PHI, such as a name and / or medical record number. This information is not associated with stored specimens for any studies for which we currently process

samples. We routinely destroy specimen containers displaying such information, and do not use the information to track the specimens. Documents containing PHI are destroyed unless they are critical to study documentation, such as source documents. If such documents are retained, they are filed or stored with the same controlled access afforded all study documents, as outlined in paragraph 2.

4. The Repository has been in operation for nearly twenty years. Some of the tens of thousands of archived specimens may be labeled with PHI. All specimens, including those displaying PHI, are stored in the Repository labs and freezer rooms, which are locked when vacant. As stated for documents and records, access to all specimens are strictly limited to Repository personnel only, and are distributed to others only with proper authorization for research purposes approved by the UAB IRB.

5. The personnel of the Repository are covered under all applicable HIPAA provisions, and will make no attempts to collect or disseminate PHI in the course of current and future Repository operations.

### **Chargebacks**

At the request of the UAB CFAR grant reviewers during the previous funding cycle, the specimen repository established set fees for storage and processing of specific types of blood and tissue samples. For example, the charges for some of the most common repository requests are as follows: for processing viable peripheral blood mononuclear cells, \$25 per sample; for storage only of viable PBMCs, \$2; for generating a plasma sample, \$4; for storage only of a plasma sample, \$1.25; and for preparing cervical or vaginal washings, \$2 (see Table below for complete list). These fees, which have not changed substantially over several years, have been generally acceptable for all of our users. The total chargeback recovery during the most recent funding year was \$163,447 or approximately 40% of the total direct costs for the entire CFAR Clinical Core. It is anticipated that as the usage of the repository service continues to increase over the next several years--particularly as multicenter networks including those related to microbicides and other HIV prevention protocols, HIV experimental vaccines and non-HIV vaccines continue to collaborate with the CFAR to share infrastructure and promote economies of scale in lab processing and storage. We project that our total chargeback recovery from the repository service alone will approach 50% of all CFAR Clinical Core costs during the next funding period. At the present time, there are not chargeback policies in place for the other two Clinical Core services, the Database/Informatics group and the Research Training services. A portion of the database investigators and staff salaries are subsidized through non-CFAR networks such as the ACTG, AVEU, and specific industry research protocols. As the scope and scale of the Database/Informatics services continues to increase, it is anticipated that in the future when collaborations with multi-site networks or private corporations are being planned, predetermined chargeback fees will be utilized to assist with recovering the costs of the Database/Informatics service as well. To date, as the field of computerized informatics is still in rapid flux and specific standards have not been set regarding itemized fees for storing and analyzing data analogous to storing and analyzing patient samples, this approach has not yet been feasible.

S type	Description	Cost
AMP SUP	Supernatant from amplified coculture	\$1.25
cervical wick	Cervical swab	\$2.00
Crasp	Cervical aspirate, AVEU specific sample	\$2.00

CSF	Cerebrospinal fluid	\$3.00
CSF pellet	Nonviable cell pellet from cerebrospinal fluid	\$1.25
CSF.SS	Cerebrospinal fluid, storage only	\$2.00
Cul-C	Cultured viable PBMC	\$15.00
EBV Cells	Epstein-Barr virus transformed cells, viable, AVEU specific sample	\$2.00
Hybrid Capture	Nonviable cell pellet processed for Digene Hybrid Capture Assay	\$15.00
Iwash	Intestinal wash fluid, AVEU specific sample	\$1.25
Nwash	Nasal wash fluid, AVEU specific sample	\$1.25
parotid	Saliva or fluid from oral wash, AVEU specific sample	\$1.25
PBMC	Viable Peripheral Blood Mononucleocytes	\$25.00
pbmc.s.cult	Quick-frozen nonviable PBMC pellet from culture, storage only	\$1.25
pbmc.snap	Quick-frozen nonviable PBMC pellet	\$15.00
pbmc.snap.ss	Quick-frozen nonviable PBMC pellet, storage only	\$1.25
pbmc.ss	Viable PBMC sample, storage only	\$2.00
pbmca	High-density viable PBMC sample, AVEU specific sample	\$35.00
pbmcp	Viable PBMC sample from pediatric patient	\$35.00
Pjac	Pre-ejaculate fluid, AVEU specific sample	\$1.25
Plasma	Plasma sample	\$4.00
plasma.pcr	Plasma for PCR, AVEU specific sample	\$4.00
Plasma.ss	Plasma, storage only	\$1.25
PLP	Presumed Low Passage Isolate, supernatant from culture plate	\$1.25
PMN	Dextran processed polymorphonuclear cells	\$15.00
RBC	Whole blood pellet, nonviable	\$3.00
RWash	Rectal wash, AVEU specific sample	\$1.25
rwick	Rectal wick, AVEU specific sample	\$1.25
Sem-cells	Cells from semen sample	\$25.00
Sempl	Seminal plasma	\$4.00
sempl.ss	Seminal plasma, storage only	\$1.25
Serum	Serum sample	\$3.00
Serum.ss	Serum, storage only	\$1.25
slurry	PBMC and supernatant mixture, nonviable	\$1.25
Stool	Stool specimen	\$1.25
SUP	Supernatant from coculture	\$1.25
Urine	Urine sample	\$2.00
V-Wash	vaginal wash fluid	\$2.00