

BIOLOGICAL MATERIAL REPOSITORY PROCEDURES AND GUIDELINES

As a depositor of biological materials, _____ with a location at _____ (hereinafter referred to as "Institution" or "Principal Investigator") agrees to adhere to the procedures and guidelines of the Johns Hopkins University Genetic Resources Core Facility Biorepository & Cell Center ("Cell Center") as outlined below. Institution and Principal Investigator may be used interchangeably throughout this document, but reference to either shall mean the individual or entity depositing the material and identified above.

PURPOSE

Institution or Principal Investigator shall have the right to deposit the biological materials, identified and described in *Attachment A* ("Deposited Materials") with the Cell Center and Cell Center shall receive, store, replicate and distribute the Deposited Material on behalf of the Institution or Principal Investigator, upon and subject to the terms and conditions outlined below.

TERMS AND CONDITIONS OF DEPOSIT

A. Collection and/or Submission of Deposited Materials

1. Principal Investigator may submit Deposited Materials to the Cell Center from time to time. New biorepository users can set up an account by contacting the cell center director by phone (410-955-6327) or by completing and signing this Agreement and submitting by email to biorepository@jhmi.edu.
2. The Deposited Materials must be for use as research specimens only.
3. All specimens processed within the Cell Center will be held to the same College of American Pathologist (CAP) standards and are subject to quality monitoring.
4. All specimens for storage that not mammalian (virus, bacteria, fungi, etc) must be confirmed by Cell Center Director prior to deposit at facility.
5. Bodily fluids and isolated cells may be deposited at the Cell Center. To request consideration to deposit any material not specifically identified in this Agreement, contact the Cell Center director for further discussion.
6. Deposited Materials shall be submitted with an inventory list that includes: box position, designation/study fields, the species, and type of specimen ("Inventory List") like the one provided as *Appendix A* to this Agreement. Specimens deposited under the 'box rate' must submit an inventory of the number of boxes, the principal investigator, type of specimens included and the freeze date. The Cell Center is not responsible for the inventory within the boxes when specimens are stored under the 'box rate'.
7. Principal Investigator shall cryopreserve Deposited Materials in 1-2 cc Nunc-style cryovial ("Vials"). Note that Eppendorf tubes, tubes with rubber caps, and those larger than 2 cc are not accepted. When storing by the box, quality boxes measuring no larger than ten inches by ten inches (10" x10") can be stored within the facility.
 - a. Vials must have attached a typewritten, impervious label with the following minimum information: sample designation, sample type, Principal Investigator name, and date.
 - b. Samples from study subjects ("Subject Samples") must be de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule De-identification standard (45 C.F.R. 164.514) and at a minimum, shall not contain protected health information ("PHI") nor any patient identifiers such as social security number, name, or hospital number. The Principal Investigator is responsible for coding the Subject Samples to keep the subject's identity confidential. The code links to the subject's identity shall not be accessible by the Cell Center.
8. Fresh blood for peripheral blood mononuclear cells (PBMCs), lymphocyte, and plasma processing from yellow-top vacutainer tubes must be collected in two 8.5 ml acid citrate dextrose (ACD) vacutainer using a

21.5 or larger gauge needle. PBMCs and the plasma are separated from red cells by ficoll density gradient centrifugation. Please note that the plasma is diluted 1:1 with 1X PBS in this process. If desired, an aliquot of cells can be EBV-transformed (1×10^6 cells) and the remaining cells ($0.5-2 \times 10^7$) can be cryopreserved. Plasma is aliquoted as 0.50ml aliquots and stored at -80°C . Whole blood (1ml), lymphocytes (1-4 vials) and EBV transformed lymphocytes (1-4 vials) are stored at -180°C .

9. The data that the Cell Center houses pertaining to Deposited Material processing and banking are secured in a password protected database and is backed up to a reliable system that is capable of retaining, protecting, reproducing, and retrieving records.

B. Cost of Withdrawal; Access to and withdrawals of Deposited Materials

1. Only the Principal Investigator and those individuals so authorized by the Principal Investigator ("Authorized Personnel") may access the Deposited Materials.
2. The Principal Investigator must provide the Cell Center with a written Authorized Personnel list. The list of Authorized personnel Form is attached to this Agreement as *Appendix B*.
3. Authorized Personnel must provide identification to access Deposited materials or to deposit materials in the Principal Investigator's name.
4. Deposited Materials may be retrieved during the following hours of operation: Monday to Friday, 9am to 4pm EST. The Principal Investigator or Authorized Personnel must complete and submit a written notice of deposit or withdrawal request to the Cell Center at least 24 hours before the vial is intended to be withdrawn from storage. The Cell Center will make every attempt to fulfill the request within the same day.
5. There is a Fee for withdrawing Deposited Materials, this fee is subject to change.

C. Ownership and Transfer of the Deposited Materials

1. Johns Hopkins University ("JHU") owns all Deposited Materials collected by JHU investigators ("JHU Investigator").
2. Deposited Materials collected by non-JHU investigators are owned by the non-JHU institution and any other entity or individual having ownership in the Deposited Material. Nothing in this Agreement transfers ownership rights of any non-JHU Deposited Materials to Cell Center.
3. Transfer of Deposited Materials and transfer of ownership of Deposited Materials must be done through the Johns Hopkins Technology Transfer (JHTT) Office: mta@jhmi.edu, upon written request from Principal Investigator or JHU Investigator or their respective Authorized Personnel.

D. Transfer of JHU investigators' Deposited Material when a JHU Investigator leaves JHU

1. JHU Investigators must contact the Cell Center to make arrangements for their Deposited Materials *before* they leave JHU.
2. JHU Investigators will have four options:
 - a. Keep the samples at the Cell Center and pay an additional 16% charge (NIH excluded) for continued storage.
 - b. Transfer custody of the samples to another JHU Investigator or to the departing JHU Investigator's Department Chair.
 - c. Submit a written request to the Cell Center asking that the Deposited Material be discarded.
 - d. Ship samples to new location (pending approved Material Transfer Agreement, Department Chair approval needed).
3. If a JHU Investigator fails to make arrangements for Deposited Material when he or she leaves, then the Deposited Material will be discarded sixty (60) days after the JHU Investigator's paid quarterly or annual term has expired. Cell Center will use its best efforts to contact the JHU Investigator and his or her department prior to discarding the samples.

E. Releasing Deposited Materials to Others

Within JHU

1. Only the JHU Investigator or Authorized Personnel can authorize the release of Deposited Material to others.
2. JHU Investigator or Authorized Personnel must provide a written request to the Cell Center before the Cell Center can release the Deposited Material.

To Other Institutions

1. Only the JHU Investigator or Authorized Personnel can authorize the release of samples to other investigators or institutions.
2. JHU Investigator or Authorized Personnel must provide a written request to the Cell Center before the Cell Center can release the Deposited Material.
3. The JHU Investigator releasing the Deposited Material must contact JHTT to request the transfer to another institution: mta@jhmi.edu.
4. JHTT must approve the transfer before the Cell Center can ship samples to other institutions.

Study Subjects and/or Family members

1. Study subjects and/or family members cannot directly request that the Cell Center discard biosamples that were provided to Cell Center as Deposited Material.
2. Study subjects may withdraw consent to participate in a study by contacting the JHU Investigator responsible for their individual biosample. Should a study subject withdraw from a study, the JHU Investigator may request, in writing, that all samples and data for that study subject be destroyed.

F. Fee Structure

Institution and/ or Principal Investigators and JHU Investigators shall adhere to the fee structure set forth by the storage designation of by the vial/ specimen or by the box under the Box Rate policy.

The cost for storing Deposited Material in *Liquid Nitrogen, -80°C, 4°C, -20°C, or Ambient Temperatures* does not change based on storage temperature.

G. Payment

Principal JHU investigators will be charged quarterly if more than 500 samples are stored with the Cell Center or annually. Customers not within the Johns Hopkins network are subject to a single annual charge regardless of sample storage number. The Cell Center will invoice the Principal Investigators and/ or JHU Investigators on a quarterly or annual basis through the integrated billing platform. Invoices must be paid when due. Cell Center reserves the right to discard Deposited Material if invoices are not paid within sixty (60) days of the date of the Invoice. The Cell Center will use its best efforts to contact Institution, Principal Investigators and JHU Investigators to discuss alternative arrangements if payment is not received within 60 days of the Invoice Date.

H. Unclaimed or Unpaid Deposited Materials

In the event Deposited Materials have gone unclaimed or unpaid for one hundred eighty (180) days, the unclaimed or unpaid Deposited Materials will be subject to de-identification and or disposal. The Cell Center's Notice of De-identification and Disposal of Deposited Materials is attached as *Appendix C*.

I. Warranties and liability

Institution and/or Principal Investigators and JHU Investigators acknowledge that the Cell Center operates as a convenience to investigators. Any Deposited Material delivered to Cell Center pursuant to this agreement is understood to be experimental in nature and may have hazardous properties. The Cell Center shall not be liable for any act or omission hereunder, including without limitation, any act in connection with any alteration, damage or losses to any Deposited Material delivered to Cell Center, even if the Cell Center is advised of the valuable nature of such Deposited Material. To the extent permitted under governing law, the Cell Center shall be responsible (as between Institution and Cell Center only) for the direct and actual costs of any loss, damage, alteration, cost or expense arising from the Cell Center's receipt, storage, replication or distribution of the Deposited Material, and only to the extent and in proportion to the liability caused by the willful misconduct or gross negligence of Cell Center, after any such time as the gross negligence or intentional misconduct has been determined by a court of competent jurisdiction. In no event shall JHU, the Johns Hopkins Health Systems, the Cell Center, its agents, its successors, and their respective directors, officers, members, employees, and agents be liable for any indirect, special, punitive or consequential damages arising from the use, alteration or loss of the Deposited Material.

By signing below, I acknowledge that I have read and that I agree to be bound by the Terms and Conditions of this Agreement.

Depositing Institution or Principal Investigator:

Signature & Date: _____

Title: _____

Print Name: _____

Accepted by Cell Center: _____ (Initial and Date)

Appendix A

INVENTORY LIST

(Columns 2 through 4 must be completed by the Principal Investigator or the JHU Investigator)

NOTE: "Deposited Material" shall mean the provided material(s) inventoried below and shall include any Progeny and Unmodified Derivatives thereof. Progeny is an unmodified descendant from the provided materials, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the investigator which constitute an unmodified functional subunit or product expressed by the provided materials, such as subclones of unmodified cell lines, purified or fractionated subsets of the provided materials, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

Box Position	Specimen (Deposited Material)	Species Type	Designated Study Fields

Appendix B

LIST OF AUTHORIZED PERSONNEL
(to be completed by the Principal Investigator or JHU Investigator)

Please list the individuals authorized to access Deposited Materials, i.e., Authorized Personnel.

Name	Title & Affiliation	Term of Authorization (Dates)
		From _____ To _____
		From _____ To _____
		From _____ To _____
		From _____ To _____
		From _____ To _____
		From _____ To _____
		From _____ To _____
		From _____ To _____

Appendix C

NOTICE OF DE-IDENTIFICATION AND DISPOSAL OF DEPOSITED MATERIALS
(to be signed by the Institution, JHU Investigator or Principal Investigator)

In the event Deposited Material has gone unclaimed /unpaid for 180 days, the Deposited Material will be subject to de-identification and or disposal. The Cell Center will use its best efforts to contact the Institution, JHU Investigator and/ or Principal Investigator to arrange for pick up of the Deposited Material or new assignment of primary investigator ownership.

De-identification is the process by which a collection of data is stripped of information which would allow the identification of the source of the data. De-identification will be performed in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule De-identification standard (45 C.F.R. 164.514). The strategy used for de-identifying datasets is to removing any protected health information ("PHI") as well as any JHU Investigator and/ or Principal Investigator information.

Disposal is the process by which the samples de-identified then bleached and disposed of as biohazardous waste.

I understand the implications of unclaimed or unpaid specimens and will abide by the Cell Center's guidelines and payment schedule.

Institution or Investigator Name (printed)

Signature

Date