Guidelines for Human Biospecimen Storage, Tracking, Sharing, and Disposal within the NIH Intramural Research Program

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Contents

Preface

The intramural research program (IRP) at the National Institutes of Health (NIH) performs research from bench to bedside, leveraging extensive scientific resources and expertise. The IRP excels at innovative basic and clinical research that translates to new approaches to improve health through prevention, early detection, diagnosis, and treatment.

Breakthrough research would not be possible without the participation of individuals who selflessly donate biological specimens ("biospecimens"), which are used in research as a bridge between basic and translational research. It is our privilege to use human biospecimens, and we honor the donors with respectful use of biospecimens throughout the lifecycle of the research project. These guidelines provide information on the ethical storage, tracking, sharing, and disposal of human biospecimens within the IRP. There are many important regulations and policies on the ethical acquisition of human biospecimens, summarized in the *Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH*, which I encourage you to read.

The guidelines for human biospecimens were originally developed by a committee appointed by the NIH Scientific Directors, who approved them in 2007. The guidelines were revised and approved in 2012, and the current edition was approved in September 2019, by the Scientific Directors.

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

Introduction

All biospecimens collected by scientists in the NIH Intramural Research Program (IRP) should be handled and stored following the best practices available. To ensure proper stewardship of human biospecimens within the NIH IRP, the Deputy Director for Intramural Research (DDIR) and the Scientific Directors (SDs) of the NIH have endorsed guidelines for human biospecimen storage and tracking in relation to these topics:

1. Legal and ethical considerations
2. Collection and storage
3. Inventory database systems and tracking
4. Quality management practices including standard operating procedures
5. Custodianship
6. Disposal, sharing, or release
7. Shipping

Definition of Human Biospecimens

These guidelines apply to <u>all</u> human biospecimens, including--but are not limited to--blood and other body fluids, tissues, nucleic acids, and other direct derivatives from human tissues. Subsets of human materials and derivatives, such as extracted DNA, or derived cell lines that are traceable to a human subject or patients with linked identifiers or Personally Identifiable Information (PII) as well as those materials that cannot be linked to identifiers, should be handled as independent biospecimens. Examples include, but are not limited to, human cell lines, recombinant DNA, clones of human genes, and isolated infectious agents from humans. (NIH OTT Policy 500A, 2012)

Definitions demarcated with "*Pre-2018 Common Rule definition*" apply to research approved (or deemed to be exempt or for which no IRB review was required under the regulations) prior to the effective date of the 2018 Common Rule (January 21, 2019). Definitions demarcated with "*2018 Common Rule definition*" apply to all research approved by an IRB (or deemed to be exempt or for which no IRB review was required under the regulations) on or after January 21, 2019 and to research transitioned to the 2018 requirements in accordance with Human Research Protection Program (HRPP) policy.

While all biospecimens should be handled according to best practices, these guidelines apply specifically to human biospecimens that are classified as:

- *"Identified,"* meaning that they or their associated data are linked to a readily available subject identifier (*e.g.,* social security number, address, telephone

number, medical record number, *etc.*) (NIH Policy Manual, 3016 – Intramural Research Program Human Data Sharing Policy).

- *"Identifiable biospecimen" (2018 Common Rule definition)* meaning a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen (45 C.F.R. 46.102(6)).

- "*Individually Identifiable*"*(Pre-2018 Common Rule definition)* meaning that the identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimen (45 C.F.R. 46.102(f)(2)).

- *"Coded"* meaning that (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or materials pertain has been replaced with a number, letter, symbol, or combination thereof (i.e. the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or biospecimens (HHS OHRP Guidance, 2008). An example of biospecimens of this type are materials provide by the NIH Department of Transfusion Medicine, where additional materials can be requested, but have no PII directly available to the researcher.

- *"Unlinked"* meaning that the biospecimens were initially collected with identifiers but, before the research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the biospecimens to the sources. This does not preclude linkage with existing clinical, pathological, and demographic information so long as all individual identifiers are removed (NIH IRP Policy 3016 , 2015). Biospecimens provided through collaborations may fall into this category, where they were originally collected with PII, which has been stripped. (NIH OTT Policy 500A, 2012)

- *"Unidentified" or "Anonymized,"* meaning that the biospecimens are being maintained without identifiers of any kind. Surgical tissues, cadaveric tissues, foreskins, and swabs which are pathological waste or discarded materials would be considered anonymized. The act of unlinking biospecimens by re-coding them with an arbitrary code is also a form of anonymization.

The terms "biospecimens", "specimens", and "samples" can be used interchangeably. The guidelines apply regardless of whether the biospecimens were originally collected for

patient care-related purposes or for research. They also apply regardless of whether or not the individual from whom the specimen was originally collected is still living.

The guidelines do not apply to tracking and reporting of biological materials and derivatives that were obtained from commercial sources for use as “reagents”. For example, reagents would include human cell lines or tissues purchased from ATCC or other vendors. In addition, human biospecimens or their derivatives that are put into animals or biological inventions that have been derived from human biospecimens are not covered by these guidelines.

1. Legal and ethical considerations

Human biospecimens used by NIH intramural investigators or researchers for research purposes must be collected, stored, used, shared, and disposed of in accordance with the informed consent signed by the subject, or under a waiver of informed consent granted by an independent ethical review body called an Institutional Review Board (IRB) or Ethics Committee, in accordance with 45 CFR 46 -Protection of Human Subjects (HHS 45 CFR 46, 2017), as appropriate.

Generally, initial and continuing IRB review and approval is required for research using identifiable biospecimens as described above. However, under the Revised Common Rule, certain research may be subject to limited IRB review [§46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)], or not require continuing review under §46.109(f). For more information about whether and when continuing review is required contact the NIH Office of Institutional Review Board Operations (IRBO).

Research that involves coded biospecimens where the researcher does not have access to the code key or research that involves unlinked/anonymized biospecimens is called "not human subjects research." This type of research requires no initial review or determination by an IRB or IRBO. Certain human subjects research with biospecimens may be exempt from the requirement for initial and continuing IRB review and approval if the research involves temporary access to identifiable biospecimens, but the research data is recorded by the researcher in a de-identified manner. In this case, the researcher must have no way to link back to original subjects once he or she begins analysis. At the NIH, the NIH IRBO is authorized to determine whether a research activity using human biospecimens is exempt. The researcher must submit a request for an exemption to the IRBO by completing an application and submitting a protocol in the Clinical Research Operations, Integrated Research Information System (iRIS).

On 05 June 2019, the Department of Health and Human Services (HHS) through the HHS Press Office (HHS Press Office, 2019) stated that research involving the study, analysis, or use of human fetal tissue from elective abortions performed after 05 June 2019 is prohibited for all NIH intramural researchers. NIH intramural scientists may continue conducting research with HFT that was acquired prior to 05 June 2019 or acquired after 05 June 2019 from sources that can verify that the tissue was not obtained from an elective abortion. Detailed description of permissible research with HFT is outlined in the Sourcebook (NIH IRP Sourcebook, 2016).

2. Collection and storage

NIH investigators or researchers must safeguard individual privacy and handle PII in accordance with the Privacy Act of 1974, as applicable and appropriate.

When biospecimens are being collected from humans for research purposes or clinical specimens to be used for research purposes, the collection and storage process must adhere to and follow procedures appropriate for the type of biospecimen being collected and its intended uses. They must be handled in accordance with the U.S. Occupational Safety and Health Administration's Bloodborne Pathogens Standard (OSHA Standards, Booklet 3186-06R, 2003). Each laboratory collection or biorepository must have and adhere to a Standard Operating Procedure (SOP) for labeling, handling, and storage of biospecimens. Biospecimens containing select agents or toxins are regulated under 42 CFR 73 (HHS 42 CFR 73, 2012). Please contact the Division of Occupational Health and Safety and Health Specialist for further guidance on biospecimens classified as select agents or toxins.

NIH intramural researchers who collect and share biospecimens or data for research purposes from collections or biorepositories must consider certain ethical principles and regulations. A biorepository is defined as the infrastructure within which biospecimens are identified, collected, processed, stored, and distributed, if applicable. If biospecimens are being shared from an IRB-approved protocol, the researcher should have received consent from the subject to share for the planned research (i.e. consent specifies the possible research use(s)) or for unspecified future research, and the uses must be consistent with the permissions described in the informed consent. This principle applies whether the biospecimens will be identifiable or not. If identifiers are being shared, the recipient researcher should have IRB approval for the planned research. If identifiable results (e.g. coded and linked) will be returned to the sender, the sender should have IRB approval for the planned research collaboration.

When researchers want to create a biorepository, which will contain identifiable biospecimens (including coded biospecimens with the code key), they must seek IRB approval. The protocol should explain the process for accepting biospecimens and data into the biorepository, as well as the process for distributing biospecimens and data for research use.

Human biospecimens in storage must have a unique identifier, should have a printed label and should contain either a one-dimensional (1D) or two-dimensional (2D) barcode with electronic record documentation. If the biospecimen is associated with PII, the identifier must enable the investigator to link the biospecimen to clinical or research data about the subject or patient, the protocol, and informed consent under which the specimen was collected, as well as an NIH Clinical Center Biomedical and Translational Research Information System (BTRIS) patient identification number, as appropriate. The label should be able to withstand all potential transportation and storage conditions.

Biospecimens with no PII (unlinked, unidentified, or anonymized materials) should be labeled in accordance with a SOP which must be developed in the custodian's laboratory, or by those maintaining the biorepository. Minimum information should identify biospecimen type and date of acquisition.

All biorepositories, whether large or represented by individual freezers in laboratories, should follow best practices for specimen storage and retrieval (ISBER Best Practices, 2018) (NCI BBRB Best Practices, 2016). Biorepositories should be operated using effective facility environments that include ambient temperature controls, good air circulation, lighting, and security with backup emergency power. Systems should be in place to allow for local and remote temperature monitoring of freezers, refrigerators, and other temperature-controlled environments. Biorepositories should have emergency preparedness plans that cover equipment failures and power interruption that include back-up storage capacity and back-up power supplies such as generators.

3. Inventory database systems and tracking

Human biospecimens stored at NIH under the Intramural Research Program should be tracked using a computer-based inventory system that records the location and detailed information of every biospecimen. (ISBER Best Practices, 2018) (NCI BBRB Best Practices, 2016).

Inventory systems should have the capacity to assign a unique identifier to each biospecimen, document custodianship, link and track aliquots or derivatives, and track significant events such as thaws, receipt and/or processing events, warnings, destruction, or

transfers out of the biorepository (NCI BBRB Best Practices, 2016). Systems should be able to generate reports on each of these conditions and activities and should be able to link to detailed information on clinical and other variables (*e.g.,* participant information, protocol number, informed consent, clinical and epidemiological data) to facilitate research and serve as an archive so that the information remains available for future use. Inventory systems must meet federal requirements related to data privacy and security, such as those outlined in the Privacy Act (DOJ Privacy Act 1974, 2015).

The inventory system should be able to provide data for the annual NIH-wide assessment of storage and tracking practices known as the Biospecimen Survey, as required by the NIH Reform Act of 2006 (109th U.S. Congress NIH Reform, 2007). Investigators who indicate in their annual 'Z' report that they work with human biospecimens must report the type of biospecimens currently stored, along with information about labels and tracking systems used in the Biospecimen Survey, which is separate from the NIDB Annual Report.

The tracking of historical collections of biospecimens obtained before guidelines were issued in 2008 should be upgraded to meet these revised guidelines when feasible with some approved exceptions. Tracking as a single entity should *only* be considered when entry and initiation of tracking of individual biospecimens within a historical collection is not feasible.

4. Quality management practices including standard operating procedures

All human biospecimen collections and biorepositories, whether large or represented by individual freezers in laboratories, should have written SOPs detailing the policies and procedures used to collect, process, handle, label, store, track, ship, and share biospecimens. Human biospecimens must be handled safely in accordance with OSHA regulations and recommendations, as applicable. The quality assurance program should include periodic (at least annually) evaluation of adherence to the standard operating procedures.

Repositories should perform an annual self-audit of the physical location of a random sampling of the biospecimens to confirm that the appropriate biospecimens are in the correct location, as indicated by the inventory system.

5. Custodianship

Human biospecimens obtained by NIH researchers are federal property and must remain in the custody of NIH unless transferred via a specific written agreement such as an MTA, CTA,

CA (NIH OTT Policy 500A, 2012) or CRADA to an outside organization (NIH OTT Policy 400, 2012) or destroyed when appropriate (NIH OTT Policy 502, 2012). The investigator, or other institutional representative, such as the custodian, is responsible for ensuring that biospecimens are collected, processed, stored, and reported properly, as well as used according to what is allowed by informed consent documents, when applicable. There may be occasions when the custodianship of biospecimens is evaluated, and the decision is made to transfer oversight to a new investigator outside of or within their originating Institute/Center (IC). The guidance described below applies to all collections or any subset thereof, regardless of the study whether or not the protocol is still under IRB oversight (e.g. protocol status of "open" or "closed".").

The investigator or researcher as custodian is responsible for the effective transfer and its prompt reporting of the biospecimens, associated data (as appropriate), and consent documents to a new custodian should the investigator leave NIH or if a change needs to occur for other reasons. It is critical that when entire collections with >1000 samples are transferred or destroyed that the leadership of the IC/Division is aware of and approves the request to transfer or destroy, before it is implemented. There are a variety of reasons that a collection may no longer be of scientific value and consequently, the cost of continued storage may no longer be justified, and the Scientific Director may consult with the Principal Investigator or responsible party who has custody of the biospecimens. For example, destruction may be warranted if the biospecimens have been compromised in some way or if data associated with the biospecimens are no longer available. Those with overall responsibility for specimen collections must understand and approve either the transfer of a collection to another investigator outside of the IC/Division or the destruction or culling of the biospecimens.

6. Disposal, sharing, or release of NIH biospecimens

Biomedical research at NIH often relies on the collection, storage and use of human biospecimens. Every Institute has the responsibility for stewardship and oversight of Intramural collections. The Institute's Scientific Director and their respective technology transfer office or other administrative staff should work together on communicating to their IC staff its SOPs that outline policies, processes, and procedures on how to share, transfer, and track biospecimens with the research community inside or outside the NIH. NIH investigators must abide by the highest scientific and ethical standards to preserve the public's trust and the substantial investment these valuable research resources represent. NIH Investigators must abide also by the disposal or destruction, sharing, or release procedures described in the IRB-approved protocol.

Institutes should adopt procedures to evaluate at least biennially when and how to discard human biospecimens or make them available for sharing with other researchers as outlined in the IRB approved protocol or the signed MTA. When specimens are being shared from IRB-approved protocols, the sharing plan must be consistent with the permissions described in the informed consent, or the IRB must waive informed consent, or if the consent form is silent on sharing, the IRB Chair must review the specific scenario to allow the sharing. When identifiable biospecimens, including coded and linked, are being shared that were not collected under IRB-approved protocols, investigators should consult NIH IRBO for guidance. When completely anonymized biospecimens are being shared that were not collected under an IRB-approved protocol, the investigator does not need to submit an application or protocol for IRBO/IRB review. Investigators should follow the principles governing sharing of resources described in the Guidelines for the Conduct of Research in the Intramural Research Program at NIH (NIH IRP Sourcebook, 2016) and comply with the NIH relevant material transfer policies (NIH OTT Policy 500A, 2012).

7. Shipping

Packaging and shipping of human biospecimens must conform to all applicable regulations and standards, including, but not limited to, the U.S. Department of Transportation (DOT) (DOT PHMSA PHH50-0079, 2006), International Air Transport Association (IATA) standards (IATA Dangerous Goods Regulations, 2019) and guidelines (IATA Infectious Substances Shipping Guidelines, 2019). All personnel involved in shipping biological materials should be trained properly for both air and ground shipments. In addition, NIH researchers should use best practices to protect biospecimens from factors that could influence specimen integrity (i.e., temperature, humidity, light, structural quality, and spill containment) and to provide protection to workers, individuals involved in the transportation of the biospecimens, and the environment.

Conclusion

Human biospecimens are a valuable resource and are essential to the biomedical research conducted at the NIH. They must be collected, stored, tracked, and used, according to the highest scientific and ethical standards. These guidelines provide a framework for NIH scientists for properly handling human biospecimens, maximizing their use in research, mitigating possible risks, as well as ensuring subject or patient safety and rights.

Appendices

Abbreviations

ATCC	American Type Culture Collection
BBRB	Biorepositories and Biospecimen Research Branch at NCI
BTRIS	Biomedical and Translational Research Information System
CA	Collaboration Agreements
CMV	Cytomegalovirus
CRADA	Cooperative Research and Development Agreement
CTA	Clinical Trial Agreement
DDIR	Deputy Director for Intramural Research
DOT	Department of Transportation
EBV	Epstein-Barr Virus
HRPP	Human Research Protection Program
IAA	Interagency Agreement
IATA	International Air Transport Association
IRB	Institutional Review Board
iRIS	Integrated Research Information System
IRP	Intramural Research Program
IRBO	(NIH) Office of IRB Operations
ISBER	International Society for Biological and Environmental Repositories
iPSCs	Induced Pluripotent Stem Cells
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NCI	National Cancer Institute
NIDB	NIH Intramural Data Base
OHSRP	Office of Human Subjects Research Protection

OSHA	Occupational Safety and Health Administration
PBMC	Peripheral Blood Mononuclear Cells
PHI	Personal Health Information
PI	Principal Investigator
PII	Personally Identifiable Information
RBC	Red Blood Cells
SD	Scientific Directors
SLA	Simple Letter of Agreement
SOP	Standard Operating Procedure
WBC	White Blood Cells

Biospecimen List

Blood or Blood Derivatives

Blood, Cells (buffy coat, WBC, PBMC, RBC, Clot)
Blood, Whole (Umbilical Cord, menstrual)
Blood, Serum/Plasma,

Body Fluid or Substances

Amniotic Fluid
Ascites or Peritoneal Cavity Fluid
Bile
Breast Milk

Bronchial or Pleural Fluids
Cerebrospinal Fluid (CSF)
Cerumen
Cervical Secretions
Colostrum
Eggs/Oocytes
Eye Fluids
Gallstones
Gastric Secretions
Nipple Aspirate
Pericardial Fluid
Prostatic Fluid
Rectal Secretions
Saliva/Buccal Cells
Sebum
Semen
Sputum
Stool
Swabs (any)
Sweat
Tears
Urine

Kidney Stones

Vaginal Secretions

Genomic

DNA
Protein
RNA

Human Cell Lines Derived at NIH or by Collaborators

Includes any transformed cell line (EBV, CMV, TERT, SV40, HPV, etc.)
Continuous cell lines (cancer cells, tumor cells, etc.)
iPSCs
Do NOT include commercially available cell lines

Tissues

Adipose
Adrenal Gland Specimen
Artery Tissue Specimen
Bile Duct Tissue Specimen
Bladder Tissue Specimen
Bone Marrow Specimen
Bone Specimen
Brain Tissue Specimen
Breast Tissue Specimen
Bronchial Tissue Specimen
Cartilage Specimen
Central Nervous System Tissue
Colon Tissue Specimen
Duodenal Tissue Specimen
Embryonic Tissue Specimen
Endocervical Specimen
Endometrium Specimen
Esophageal Tissue Specimen
Eye Tissue Specimen
Cataract Specimen
Fallopian Tube Specimen
Nail Specimen
Nasopharynx Specimen
Nerve Specimen
Nose Specimen
Oral Cavity
Ovary Specimen
Pancreas Specimen
Paraffin Tissue Blocks
Parathyroid Gland Specimen
Peritoneal Tissue Specimen
Pharynx Specimen
Placenta Specimen
Pleura Specimen
Prostate Tissue Specimen
Rectal Tissue Specimen
Skin Specimen
Small Intestine Tissue Specimen
Soft Tissue Specimen
Specimen from Non-Specified Site
Specimen of Product of Conception
Stoma Specimen

Human Fetal Tissue Specimen
Gallbladder Tissue Specimen
Gastric Tissue Specimen
Hair Specimen
Heart Tissue Specimen
Pericardial Tissue Specimen
Histopathology Slides
Ileal Tissue Specimen
Jejunal Tissue Specimen
Kidney Tissue Specimen
Liver Tissue Specimen
Lung Tissue Specimen
Lymph Node Specimen
Middle Ear Tissue Specimen
Miscellaneous Tissue Specimens
Muscle Specimen
Tendon Specimen
Thyroid Specimen
Testes Specimen
Thymus Specimen
Thyroid Gland Specimen
Tongue Specimen
Tonsil Specimen
Trachea Specimen
Ureter Tissue Specimen
Urethra Tissue Specimen
Uterine Cervix Specimen
Uterus Specimen
Vaginal Tissue Specimen
Vocal Cord Specimen
Vulva Specimen

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