

## UNIVERSITY OF KENTUCKY (UK) OFFICE OF RESEARCH INTEGRITY (ORI) RESEARCH BIOSPECIMEN BANK GUIDANCE

### Establishing a Biospecimen Bank for Research

A biospecimen bank (biobank) is defined as a facility where biological materials (e.g., serum, pathological specimens, genomic material) from human research subjects are stored. The design, operations, material collected, and plans for use and/or sharing for secondary research, determine which regulations apply and the level of IRB review and oversight required.

**Before proposing the establishment of a biobank, research investigators must consider whether the specimens he/she plans to collect would be readily available from a commercial supplier, clinical lab, or an already established research biobank within the institution. Absent scientific justification, the establishment of multiple independent biobanks collecting duplicate material increases the risk of tracking errors due to variability in practices and creates confusion on behalf of participants.**

Before establishing a bank, investigators are encouraged to review the comprehensive guidance regarding considerations beyond human subject protections, (e.g., infrastructure requirements, financial resources, facilities, custodianship, personnel training, intellectual property, etc.), is provided in the [Reference Section](#) below. This document will focus only on issues related to IRB review and human subject protection.

### IRB Submission of a Biobank Protocol

The IRB is charged with reviewing protocols for obtaining, storing and sharing information, verifying informed consent and protecting privacy and confidentiality of human specimens (e.g., blood samples, tissue) for research purposes. To establish a biobank, the Principal Investigator (PI) submits a Full or Expedited (as applicable) Review IRB application outlining the collection, storage, and sharing of biospecimens and if applicable, associated information.

### Information to Address in the Initial IRB Submission

Since there is extensive variation in how biobanks operate, the IRB submission should include sufficient information regarding the scientific goals, functions, and operational procedures. The following details are requested, including:

- Justification for establishing a separate bank (e.g., why material cannot be obtained from commercial supplier, clinical repository, or established research bank operating within the institution);
- the purpose of the biobank;
- the material to be collected and stored
  - leftover discarded tissue from clinical procedures; and/or
  - biospecimens collected as part of research);
- a list of any data that will accompany the specimen or be extracted from the medical record;

- management and physical storage of specimens and data, (e.g., how access secured; sharing according to terms of consent; destruction according to IRB approved protocol) and who will serve in this role;
- the type of donors (e.g., minors, adults, healthy participants, patients);
- diagnosis or conditions of study (e.g., specific disease area or broad unspecified use);
- with whom biospecimens will be shared, (e.g., anyone; internal researchers, external collaborators, academic only, commercial industry);
- whether biospecimens will be sold;
- mechanism for how biospecimens will be shared (internally/externally) including procedures for coding, de-identification, encryption, data-use agreements, etc.;
- role of an honest-broker\* in managing codes and de-identification prior to sharing with recipient researchers and who will serve in this role;
- management of provisions to protect participant privacy and data confidentiality;
- risks associated with a breach of confidentiality including impact on privacy, insurability, stigmatization etc.;
- the consent process (who obtains, documentation, place, time allotted);
- tracking participant choices where options are provided within the consent;
- length of time a biospecimens will be kept (indefinitely, end of research protocol);
- the ability and procedure for locating/contacting participants (re-consent, incidental findings);
- participant withdraw procedures;
- the process of re-consent of donors who are minors at the time of donation but turn 18 while the bank is active; and
- whether secondary research could involve genetic or genomic research or creation of cell lines.

*\*An honest broker is a neutral intermediary (person or system) between the individual whose tissue and data are being studied, and the researcher. The honest broker collects and collates pertinent information regarding the tissue source, replaces identifiers with a code, and releases only coded information to the researcher. An honest broker cannot be study personnel on the protocol or co-author on resulting research publications. See the [Health & Human Services De-identification instructions](#) for specifics on identifiers and allowable information. The honest broker retains a code which enables him/her to re-identify a donor should the donor choose to later withdraw, or should it be determined that an actionable result or incidental finding should be returned to the participant (see [Return of Research Results Guidance](#)).*

## Biobank Informed Consent/Authorization

The informed consent and authorization document describes the intended use and procedures for sharing material with others for future research. The purpose may be described as broad and unspecified to allow for a wide range of potential future uses in research. However, even when future use is unspecified, the consent document and process should clearly describe key biobanking concepts such as, unlimited medical record access, incidental findings and obligations to return research results, procedure to withdraw material, large-scale data sharing, etc. so that participants understand the implications of participating.

*CAUTION: AVOID SELF-IMPOSED LIMITS IN THE INFORMED CONSENT.*

*While you must implement IRB required limitations, be cautious in adding self-imposed limits that diminish the utility of the repository, without enhancing human subject protection.*

- If you choose to place limits on use, retention, or sharing and you communicate the limits in the informed consent, you must honor them. For instance, don't state in the consent that the specimen will not be used for genetic testing, if there is a chance that a secondary researcher would conduct such tests.
- If you provide the participant with options within the consent, you must operate according to the participant's chosen wishes. For instance, if you allow the participant to choose whether the specimen will be used for research on a single disease, or used for any type of health-related research, you must store, track, use, and share accordingly.

## Sample Repository/Registry/Bank Consent Template

The [Sample Repository/Registry/Bank Consent](#) document provides points to consider and template consent language describing risks, protections, and details regarding the collection, storage, and sharing of biospecimens and/or associated data. Because there is extensive variation in the design and operation of research repositories, a "one size fits all" template is not feasible. The template includes sample language for many different bank/registry operations. Include applicable language and delete other text.

## Secondary Researchers Use Agreement

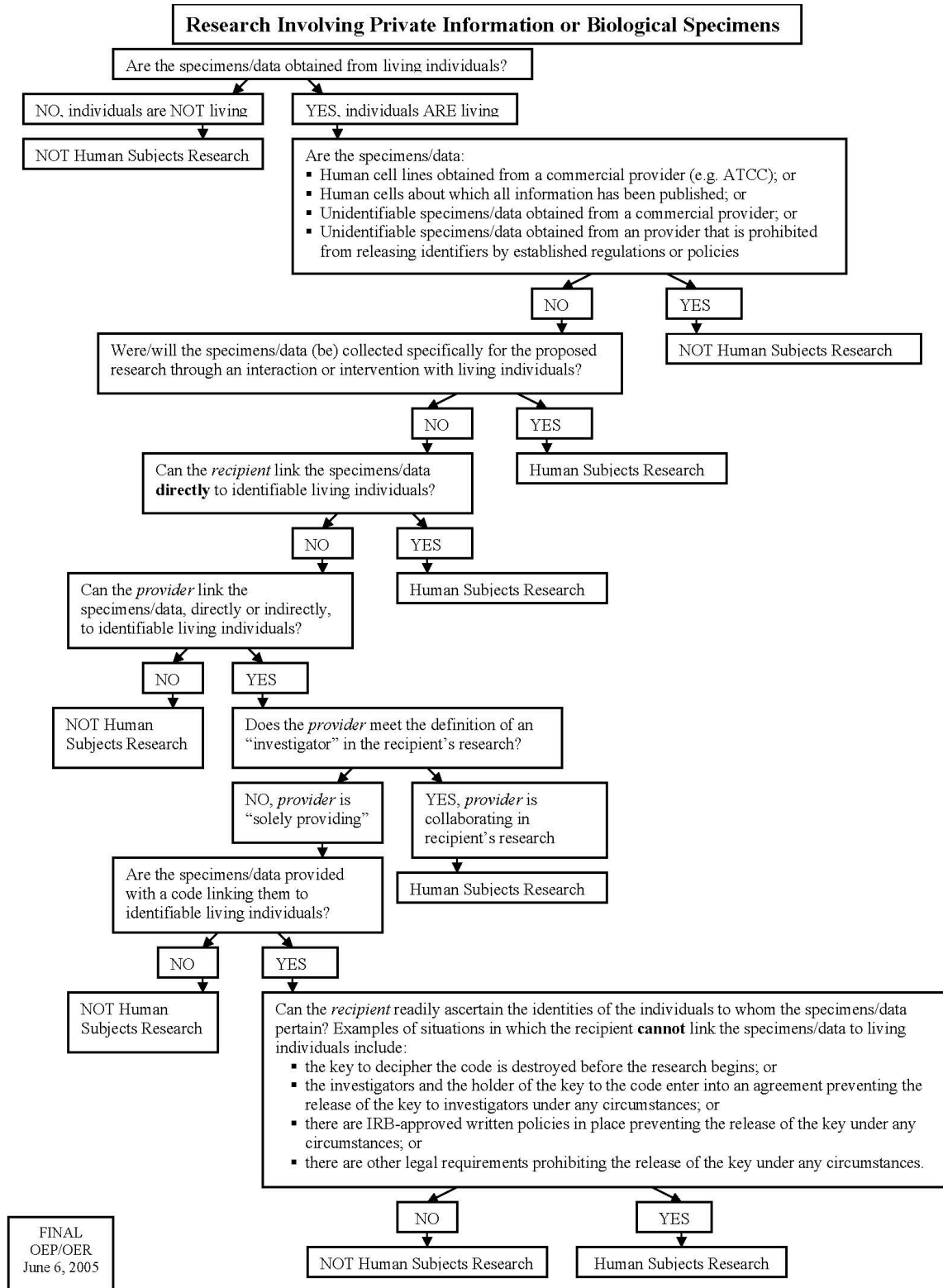
The bank may require recipient researchers to sign or agree to a Use Agreement. The agreement may specify that the recipient researcher will not attempt re-identification of specimens and that secondary research conducted will be consistent with the terms of the original bank informed consent. The agreement may also specify that bank personnel will serve as honest brokers and as such will not be involved in the conduct or reporting of the secondary research conducted by the recipient researcher. Ultimately, secondary research conducted by recipient researchers should be congruent with the uses described in the Bank Protocol, Informed Consent Form, and Use Agreement.

## Is Additional IRB Review Needed for Secondary Research?

Yes, or possibly yes, unless the secondary researcher has obtained an official [Not Human Subject Research \(NHR\)](#) determination from the IRB. In making the NHR determination, the IRB considers whether the specimens were properly [de-identified according to HIPAA standards](#) prior to receipt by secondary researcher; the recipient researcher has no knowledge of or way to readily identify participants providing the specimens, and the bank personnel will not be involved in the conduct or reporting of the secondary research.

In addition, the proposed secondary use must be consistent with the use described in the original consent used to obtain the specimens. The [Sample Repository/Registry/Bank Consent Template](#) includes language to inform participants that it is possible that their specimen will be de-identified and shared with other researchers for future research, without the participant's additional informed consent.

The National Institutes of Health (NIH) provides a [Decision Chart](#) to aid researchers in determining whether secondary research with private information or specimens meets the criteria of human subject research.



## Not Human Subjects Research (NHR) Determination: *IRB Review Not Required*

To obtain an official IRB determination that secondary research does not require IRB review, the recipient researcher submits a description and/or the online [NHR Determination Form](#) for a determination of whether an activity qualifies as NHR.

## Human Subjects Research: *IRB Review Required*

IRB review is required if the recipient researcher (and personnel involved with the secondary research):

- wants to conduct research that goes beyond what is described in the Biobank Informed Consent;
- wants to use specimens in a manner that goes beyond the Biobank Use Agreement;
- needs participant identifiers to track outcomes in the medical record;
- can ascertain the identity of the donor through direct knowledge or associated information;
- has knowledge of the participant's surgical procedures in order to obtain fresh tissue for conducting analysis that is sensitive to decay.

IRB review and approval would also be required if biobank personnel wish to collaborate with the recipient researcher on the conduct, analysis, or reporting of the research.

## Secondary Research and Informed Consent

As part of the review, the IRB would consider the need for a research-specific consent and authorization for any secondary research. Informed consent may not be required if the IRB determines the recipient researcher's proposed use is consistent with the informed consent for the biobank and the terms of the Biobank Use Agreement.

If use is not consistent, additional consent may be required, or the researcher may submit a request to their IRB to alter or waive the requirement for additional consent. Specific criteria must be met for the IRB to consider approving a waiver. The IRB would likely not approve a waiver in cases where the recipient researcher has an opportunity to obtain informed consent from bank participants who have agreed to future contact. If a secondary researcher has knowledge of the participant's clinical care or surgical procedure, it will be difficult to justify that research-specific informed consent could not practicably be obtained.

Also, other regulatory statutes prohibit the IRB from waiving informed consent, even if data is de-identified, (e.g., Department of Defense Classified Research, [NIH Funded Genomic Data Sharing](#)).

### **National Institutes of Health (NIH) GENOMIC DATA SHARING**

INFORMED CONSENT FOR FUTURE RESEARCH USE AND BROAD SHARING IS REQUIRED FOR ANY SPECIMENS COLLECTED AFTER JANUARY 25, 2015 OR ANY USED TO GENERATE A CELL LINE AFTER JANUARY 25, 2015

- This includes discarded clinical specimens and specimens obtained for research.
- This includes identifiable and de-identified specimens

This NIH consent requirement is independent from IRB requirements. Therefore, NIH GDS policy requires consent for future use and broad sharing of genomic and phenotypic data, even if the study is Exempt or IRB review is not required. Consent must indicate whether individual genomic data will be shared in controlled databases and if genomic summary data will be shared in public scientific repositories. See the [Sample Repository/Registry/Bank Consent](#).

## REFERENCES:

- Ashley, Sonia, MAS, and Ira Goodman, CRA. "Establishing and Maintaining an Academic Biorepository." *JOURNAL OF RESEARCH ADMINISTRATION* XLVI.2 (2015). Society of Research Administrators International. 2015. Web. 18 May 2017. <<http://srainternational.org/publications/journal/volume-xlvi-number-2/establishing-and-maintaining-academic-biorepository>>.
- "National Comprehensive Cancer Network." *NCCN Points to Consider on the Best Practices for Biorepositories, Registries and Databases*. National Comprehensive Cancer Network, 2017. Web. 18 May 2017. <[https://www.nccn.org/clinical\\_trials/RepositoriesBestPractices.aspx](https://www.nccn.org/clinical_trials/RepositoriesBestPractices.aspx)>.
- "NCI Best Practices for Biospecimen Resources." *BBRB – Biorepositories and Biospecimen Research Branch*. National Cancer Institute, Mar. 2016. Web. 18 May 2017. <<https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf>>.