Human Research Protection Program
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GUIDANCE ON USE OF BIOSPECIMENS

Definition of Biospecimens, Whole Genome Sequencing, and Identifiability

Human biospecimens include blood and other body fluids, tissues, and other biological materials obtained from living humans. Subcategories of human materials, like 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.

Whole Genome Sequencing is a procedure in which extensive information about an individual's genetic makeup can be gathered from a DNA sample.

The following definitions are provided in the National Institutes of Health's Guidelines for Human Specimen Storage, Tracking, Sharing, and Disposal within the NIH Intramural Research Program's guidance document.

- *"**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, Intramural Research Program, Policy 3016 (2015)
- *"**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 CFR § 46.102(e)(6), Protection of Human Subjects
- *"**Coded**"* means 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.
  See OHRP's Coded Private Information or Specimens Use in Research Guidance (2008).
- *"**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; see NIH's Policy 3016. 7 Biospecimens provided through collaborations may fall into this category, where they were originally collected with PII, which has been stripped; See HHS' Policy 500.
- *"**Unidentified**" or "**Anonymized**,"* meaning that the biospecimens are being maintained without identifiers of any kind. Surgical tissues, cadaveric tissues, 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.

Collection of Biospecimens and Consent Requirements

The ethical principles set forth in the Nuremberg Code highlight the importance of minimizing potential harm to participants by ensuring research is conducted in appropriate settings and with appropriately qualified individuals. This is especially necessary for research involving the prospective collection of biospecimens. Blood draws should be done by licensed phlebotomists, and testing sites must include facilities equipped with appropriate resources to reduce the likelihood of adverse events occurring. If participants will be responsible for collecting their own biospecimens at-home, researchers should provide instructions and appropriate materials, such as PPE, to facilitate the collection. If biospecimens will be shipped to the researchers, please contact the Office of Research Assurances for additional guidance on the transportation of these materials.

When obtaining consent from participants to collect biospecimens, the following elements are required:

Additional Elements of Consent for Research Involving Biospecimens
A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Broad Consent

Broad Consent is a type of consent obtained for the storage, maintenance, and secondary research use of identifiable private information or biospecimens without the need for additional consent, so long as the future use and activities are within the scope of the broad consent.

If obtaining broad consent from participants*, this must be distinctly separate from the consent for current research procedures. Participants must be given the option to consent to the research without consenting to the future use of their specimens.

**Please note that WSU IRB does not currently approve the storage, maintenance, and secondary research use for which broad consent is required.*

The following should be included in the consent for research involving broad consent
A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.

A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.
A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).
Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.
Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.
An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

CLIA Certificates and When to Return Results to Participants

When researchers obtain results from biospecimens collected from participants in their study that could indicate a potential health concern, the researchers have a duty to share these results with participants to uphold the Belmont principles of Respect for Persons and Beneficence. Please note that results don't have to be clinical to be returned to participants. If results are non-clinical, they should be referred to as "research results" when communicated to participants.

Consider the following scenarios for returning results to participants:

- ***Planned Investigator Offer*** – The investigator has a procedure in place to return results to participants and this is typically outlined in the consent.
- ***Participant Request*** – Upon the participant's wish, the investigator will share results with the participant. The investigator may or may not already have a plan in place to do this.
- ***Unanticipated*** – In cases of immediate danger or unexpectedly abnormal results, the investigator may return results to participants for the participant's health and safety.
    - *If this occurs, please submit a reporting form when deviating from planned study procedures. This may be considered an exception if it is done to reduce immediate harm to the participant.*

The **Clinical Laboratory Improvement Amendment (CLIA)** of 1988 applies to US sites that test human specimens for health assessment, or to diagnose, treat, or prevent disease. Labs must be CLIA certified when returning individual, patient-specific results to another entity*.

**This is required unless the tests are waived. Waived tests are those that are simple laboratory*

procedures that have an insignificant risk of an erroneous result. For a list of tests waived under CLIA, please see the following resource from CDC.

In Washington state, labs must apply for a Medical Test Site (MTS) license instead of a CLIA license. When obtaining the MTS license, the lab will receive a CLIA # in addition to an MTS #.

Tips for Communicating Results to Participants

Results should be communicated in a way that explicitly convey takeaway message and actionability to the participant. Additionally, it may be best to pair results with resources and reference information to help foster understanding. Results should include caveat statements addressing uncertainties if there are limitations to the validity of the results. When considering communication approaches, the researchers should consider the different needs, capabilities, resources, and backgrounds of their participants.

If the investigator plans on returning results to participants, the consent should include the following information:

- What results will be shared with participants,
- The risks and benefits of receiving the results,
- The time and process of communicating results to participants,
- The conditions under which the researchers will alert participants of urgent results,
- Whether results will be placed in a medical record and/or communicated to the participant's physician,
- When relevant, the participant's option to have results shared with family members.

Additional Resources

When using biospecimens for your research, you may also need to seek approval from the Institutional Biosafety Committee before you begin the research. Contact the WSU Biosafety Officer at 509-335-1585 or ibc@wsu.edu.

Hazardous Shipping Instructions from ORA

Medical Test Site certificates for WA state: https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/medical-test-sites-mts

Tests waived under CLIA: https://www.cdc.gov/clia/docs/tests-granted-waived-status-under-clia.pdf

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html