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Biospecimens: What should be included in the Research Plan?

Biospecimens collected for study purposes only

Some research studies include the collection of biospecimens, such as blood, urine, or saliva, as part of the core study procedures. The purpose of the collection is described, with an explanation of how the collection will help the PI achieve the stated study aims. The IRB generally presumes that the samples will be fully consumed by the study procedures and that the PI will not retain and store any biospecimens once the study is over. The PI should explain that any extra biospecimens that are not used up will be destroyed.

Biospecimens collected for study purpose, and PI wants to retain extra material

In every study that involves the collection of biospecimens and the expectation that samples will be stored beyond the conclusion of the study itself, the PI must provide a biorepository plan (see below) in the research plan document. The consent form must provide each participant with the opportunity to decide whether or not to permit retention of biospecimens for purposes beyond those associated with the core study.

Biospecimen repository protocols

When collection, storage, and use of biospecimens is the study's principal purpose, the research plan should address the following questions in detail:

- a. Explain the source of the biospecimens.
- b. Describe where the biospecimens will be stored and who will be responsible for them.
- c. Describe how long the biospecimens will be stored, and what will happen at the end of that period.
- d. Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Also explain how downstream use of the specimens will be managed, and what will happen to left-over specimens.
- e. Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in a linked (identifiable) form.
- f. Explain whether the repository will have Certificate of Confidentiality protections.
- g. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.
- h. Describe data and/or specimen use agreements that will be required of users.

Biosafety Compliance

Principal investigators must ensure that all work with (including handling and shipping) human-derived samples and other potentially biohazardous materials complies with Johns Hopkins Institutional Policies and federal and state law. Compliance is monitored by the JH Biosafety Office and Biosafety Committee. Investigators conducting clinical and laboratory based research must register with the Biosafety Office (see links below).

Registration of Research with Human Tissue, Infectious Agents, Pathogens, Oncogenes, or Toxins" form: <http://www.hopkinsmedicine.org/hse/forms/HumanTissueRegistration.pdf>



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Registration of Research with Recombinant DNA form:

<http://www.hopkinsmedicine.org/hse/forms/RDNARegistration.pdf>