

Using or Sharing Data or Biospecimens for Research: When is IRB Approval Needed?

Primary Research

If an NIH investigator wants to share identifiable data or biospecimens with non-NIH investigators as part of the study aims in the current IRB-approved protocol, the purpose of the sharing (e.g. type of analysis being done at the other site) and the type of data/biospecimens being shared should be described in both the protocol and the consent and be approved by the IRB. For studies initiated after January 25, 2018, only 1 IRB may be utilized so it is likely a cooperative agreement, such as a reliance agreement, would need to be executed so that the external site has IRB oversight for the research.

Secondary Research

If the NIH investigator plans to obtain or use **identifiable** (including coded and linked) data or biospecimens collected clinically or under a different protocol to address new research aims that are not described in the current protocol, this would be considered *secondary* research, and a new protocol must be written and submitted for IRB approval. The PI would need to name the original protocol(s), explain whether the previous consent forms (if applicable) allowed for future research, and describe any limits on the future research or if the consent form was silent with regard to future research.

When the NIH investigator wants to share **coded** data/biospecimens with a non-NIH investigator for secondary research and will be receiving coded results that they **can link to specific participants**, a new protocol must be written and submitted for IRB approval. Again, the protocol would need to name the original protocol(s), explain whether the previous consent forms allowed for future research and sharing, and any limits on the future research or sharing, or if the consent form was silent with regard to future research or sharing.

When the NIH investigator wants to share **coded** data/biospecimens with a non-NIH investigator for secondary research but will be receiving only summary level results that they **cannot link to specific participants**, they do not need to seek IRB review/approval of a protocol for the research or sharing. If the NIH investigator wants to **completely anonymize** data/biospecimens and use it for secondary research, they also do not need to seek IRB review/approval. However, certain conditions apply.

- The original consent (when applicable) must allow for future research and sharing of data/biospecimens.
 - The planned research should be consistent with what was written in the original consent regarding future research (or allow for broad future research). If the planned research is inconsistent with the original consent, the data/biospecimens cannot be shared.
- If the original consent (when applicable) is silent on the issue of sharing data/biospecimens for future research, the investigator should contact the Office of IRB Operations to obtain feedback about whether sharing will be permitted.
- While the conditions above are not regulatory requirements, OHSRP views compliance with the language in the original consent form to be an important ethical issue.

If the data/biospecimens are already coded (or anonymized), and the NIH investigator has no way to link back to the original identifiers or if they were collected from individuals who are now confirmed to be deceased, the investigator may move forward with the research and sharing with no human subjects research protection-related approvals.

For a more detailed discussion of this topic please see the [videocast](#) and [slides](#) presented by Julie Eiserman and Dr. Jonathan Green (as part of the NIH OHSRP Education Series) titled, *Best Practices for the Approval and Conduct of Secondary Research, including Repositories*, which was presented in July 2019.

Below are examples taken from SACHRP's ([OHRP] Secretary's Advisory Committee on Research Protections) *Updated FAQs on Informed Consent for Use of Biospecimens and Data* which was last updated in March 2018.¹ The responses provided below reflect **HHS Common Rules issues**. Note that for tissues used to test and **FDA regulated** in vitro diagnostic devices, there may be additional FDA related issues or regulations that must be considered. Since NIH is not a HIPAA covered entity, the responses below do not include implications of HIPAA regulations on use of data and biospecimens.

Question: Tissue biopsies were obtained for clinical diagnostic purposes, which have now been satisfied. The patients did not provide study specific informed consent for the research use of the tissue specimens. The hospital pathology department is willing to provide a portion of the remaining biopsy specimens to an investigator who will perform research assays. In order to allow matching with relevant clinical information, the specimens will be provided with identifiers such that the investigator can readily ascertain the identity of subjects. Is consent of the patient from whom the biopsy was taken (or waiver of consent) required for the secondary research use?

Response: Yes. Under this scenario, informed consent of the subjects should either be obtained (using either study-specific or "broad consent") or waived under 45 CFR 46.116(f) because the samples are identifiable to the recipient investigator, and in any case, IRB review would be required.

Alternatively, if in this instance, the specimens will be coded such that the investigator will not be able to readily ascertain the identity of individuals, neither subject consent no waiver of consent is needed because the activity is not considered human subjects research.

Question: Blood samples were obtained for research purposes, with informed consent of the subjects, and the original study has been completed. The samples remain under the control of the original investigator. Another investigator wants to use a portion of the remaining samples to perform research completely unrelated to the original study. If the original consent stated that "...your sample will only be used for research on colon cancer," but the secondary user is interested in studying Alzheimer's disease, can the samples still be used if provided to the secondary user in a coded fashion?

Response: The secondary use of de-identified or coded samples is not research involving human subjects under 45 CFR 46. Biospecimens that are de-identified, coded, or anonymized and are not readily identifiable are no longer subject to human subject regulations. Thus, there is no

¹ *Updated FAQs on Informed Consent for Use of Biospecimens and Data* is available [here](#)

regulatory violation. Nevertheless, the original investigator and his/her institution have made an agreement with the subjects about use of their biospecimens, and in the case where secondary use of biospecimens is not compatible with the original consent, they have an obligation to honor that agreement.

Question: Blood samples were obtained for research purposes, with informed consent of the subjects, and the original study has been completed. The samples remain under the control of the original investigator. Another investigator wants to use a portion of the remaining samples to perform research unrelated to the original study. If the sample is identifiable to the secondary user, is this considered to be human subjects research under the purview of the IRB? If so, what are the consent considerations?

Response: Yes. This is human subjects research under the purview of the IRB. Consent will be needed if the research is unrelated, unless an IRB waives the requirements for informed consent. The IRB should consider whether the secondary use is compatible with, or has been excluded by, the terms of the original consent given by the subjects. An IRB cannot waive informed consent, however, if a subject was previously offered and refused “broad consent” for the proposed research. [This means “broad consent” as described in the 2018 Revised Common Rule requirements.]

In cases where the original consent is silent on the question of subsequent use of the specimens, the IRB needs to consider the original terms of the consent and determine whether a waiver might be appropriate or whether additional consent is required.

Question: A child is enrolled by his/her parents in a tissue banking protocol that involves storage of specimens for future research. Should there be a process in place for the child to give consent for continued storage and use of specimens when he/she reaches the age of majority?

Response: In and of itself, the retention of specimens in a biobank is not considered to be research involving human subjects. However, ongoing use of such specimens (e.g., continued analysis of specimens or data for which the subject’s identity is readily identifiable to the investigator(s)), or ongoing collection of identifiable information, is human subjects research. In these cases, it would be necessary for the investigator(s) to seek and obtain the legally effective informed consent of the now-adult subjects.

The IRB may consider, if appropriate, a waiver under 45 CFR 46.116(f) of the requirements for obtaining informed consent in order for the subjects to continue their participation in the research. Such a waiver may be considered at the time of initial review or during a subsequent amendment. Factors that may make it impracticable to conduct the research, and therefore would support a waiver, include the number of subjects, length of time since first enrolled, and ability to locate subjects.