ICTS Precision Medicine

MyIRB Application Guide for Data Sharing Consent

The MyIRB application will automatically draft consents with various options based on how the standard questions in the MyIRB application are answered. The questions and answers in this guide will populate the consent document with language for storage for future use, as well as data sharing language. It is up to the investigator to determine which template language aligns with their research protocol. In order to both comply with federal standards and maximize the scientific impact of the study, it is important to answer these questions with care.

1.25 Will any data from this project be stored for use in future research studies?

The first relevant question in MyIRB is 1.25. The default answer to this question should be yes. This question applies to all data from this project. The yes answer to this question will populate the consent with the appropriate language for future, unspecified research and mandatory or optional sharing. Optional data sharing is required in studies that hold the potential of benefit to the participant. In this case, there will be lines in the consent for the participant to choose to opt in or opt out of genomic data sharing. (link to OHRP Determination Letters).

1.26 Does this project involve the collection or use of biological samples?

The next relevant question in MyIRB is 1.26. There are multiple follow-up questions that are based on use and storage of biological samples. A yes answer to this question will pre-populate the draft consent with the language for future research, storing, and sharing of samples (if not already populated by question 1.25). Multiple follow-up questions are then asked with a yes answer.

1.26.a Will genetic/genomic research with biological samples occur as part of this study?

Answering yes to question 1.26a will insert language into the consent describing the Genetic Information Nondiscrimination Act (GINA).

1.26.b Do you plan to return any genetic/genomic results of testing or research conducted on biologic samples to participants (including either primary or incidental findings)?

Returning research results to participants is complicated ethically and technically, requiring a comprehensive plan involving communicating the risks and benefits of knowing the results, and appropriate follow-up. Therefore, the IRB expects a separate protocol for returning results. A yes answer will alert IRB analyst to look for a plan for returning results either in the protocol or as an attachment. It doesn't insert suggested language into the consent document.

1.26.d Will biologic samples be stored for future research?
If you are research protocol specifically describes storing biological samples, answering yes to this question will populate the consent with language for future research/storing/sharing. Within this language are optional paragraphs describing the future uses of the sample, if it’s to be shared outside the institution, and whether future use and data sharing is mandatory or optional for the participant.

1.26.e  Will genetic/genomic research occur as part of future research?

If the sample is being stored, the research project will have the most flexibility if this question is answered yes, even if there is no genotyping currently planned. Answering yes to question 1.26a will insert language into the consent describing the Genetic Information Nondiscrimination Act (GINA).

1.26.f  Will participants be able to request at a later time that the samples be destroyed?

At this point, the consent has already been populated with language for future research/storing/sharing. The consent will be populated with two paragraphs, where one of the two paragraphs needs to be deleted. The first paragraph corresponds to allowing the participant to request destruction of the sample and describes the process involved. The second paragraph describes the storage of the sample without any identifiable information in a biobank. The IRB analysts will look to make sure that the answer to this question is consistent with the protocol.

1.27  Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access?)

Institutions are responsible for assuring, through an Institutional Certification, that plans for the submission of large-scale human genomic data to the NIH meet the expectations of the Genomic Data Sharing Policy. The institutional certification is used to document that the IRB has agreed that broad sharing of data and/or samples is consistent with the consent that was obtained from the research participant. An IRB description of the process of institutional certification follows:

Commonly, an institutional certification will be requested by the National Institute of Health (NIH) to deposit genetic or genomic data and/or samples into one of their databases; however, a researcher may choose on their own to submit data and/or samples from their project to a large database/repository. The NIH genomic data sharing policy intends to ensure the broad and responsible sharing of genomic research data. The policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, regardless of the funding level. Therefore, the institutional certification may be required as part of your grant submission process. To determine whether the genomic data sharing policy applies to your grant, please work with the grants office and/or your program officer.

The institutional certification request is submitted within the IRB application. As part of the certification process, the IRB will review the IRB application, grant (if applicable), and consent forms that were used to obtain consent from the research participants. This review is conducted to ensure that the research participants consented to genetic research and broad sharing of their data and/or samples. The IRB will determine whether the data may be shared through "open-access" or "controlled-access". Additionally, the IRB will determine, sometimes in consultation with the investigator, whether any data use limitations should be placed on the data once it is deposited in the database/repository.

An institutional certification can be completed at any time while the study is open with the IRB. Requests for institutional certifications may be included at the time of new submission or later through submission.
of a modification form. Additionally, an institutional certification may be updated at any time while the study is open with the IRB. For example, you may need to update the institutional certification to include additional consent forms or to include additional outside institutions.

Note that the NIH recently updated their institutional certification template. Therefore, if you are requesting to update an old version an institutional certification, you may have additional requirements. Such requirements may include obtaining updated institutional certifications from the outside institutions.

The IRB handles the completion of institutional certifications for human data only. Certifications applying to non-human or animal data will be handled by other entities within the institution.

The following questions from the myIRB application provide details about the samples being collected or that have been collected and will be used in the study.

1.27a. **Select name/owner of the repository or database:**
   - **dbGaP:** selecting this option will open a text box with a drop down menu to select the relevant institute [1.27b].
   - Other NIH: selecting this option will open a text box with a drop down menu to select the relevant institute [1.27b].
   - Other: Selecting this option will open a text box for typing in the name of the repository.

1.27c. **Name of the individual to whom the letter should be addressed. Give the PO or the name of your program administrator in the relevant institute.**

1.27h. **Attach copies of the consent form versions that were actually used to obtain consent from participants to create the genetic/genomic data.**
   - Attach the draft consent for the study being submitted, if applicable.

1.27l. **Attach a completed spreadsheet for certification request.** [Template provided and instructions are provided in the MyIRB application].