NIDDK Central Repository – Resources for Research (R4R)

Example Language for Informed Consents

The following is a list of the elements that should be present in the informed consent in order for samples to be submitted to the NIDDK Central Repository. Along with the listed elements, the NIDDK is providing some model language from various IRB-approved or published consensus documents. The model language is intended only as a guide or an example, and the NIDDK does not recommend any specific text. Each IRB has its own specific guidelines for acceptable informed consent language. In addition, it is important to note that investigators working with special populations or outside the U.S. may have special restrictions related to repositing of samples.

1. **Provide a description of the Repository.**

   Example: We are asking you [or your child] to provide a sample of _____, which will be sent to the NIDDK Central Repository, a research resource supported by the National Institutes of Health. The Repository collects, stores, and distributes biological samples and associated data from people with many kinds of disorders, from unaffected family members, and from other healthy people. The purpose of this collection is to make samples available for use in research for this study and health-related research in the future, after the current study is completed. Sending samples to the Repository may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases.

2. **Provide a description of how the subject's privacy will be protected.**

   Example: The Repository will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. Before the researchers in this study send samples to the Repository, each sample will be given a code number. Your name, or your child's name, and all personal identifying information, such as address, social security number, and date of birth, will be removed. Therefore, the Repository will not be able to give out your name, or other information that identifies you or your child, to the scientists who receive the samples. However, the Repository and scientists will have some data about you, such as age, sex, diagnosis, [fill in any other data types], race, and outcomes of the initial study.

3. **Provide information about potential risks and benefits of participation, including potential commercialization.**

   Example: You will not receive any direct benefit or payment for participating, but your sample may benefit the future health of the community at large or some particular group. Because other researchers will not have access to your identity, neither you nor your physician will get the eventual results of studies that might be performed using your sample. It is possible that data resulting from use of your sample may eventually be used in a research publication. In that event, your name or other identifying information will not be included, as this information will not be available to the researchers. It is important for you to understand that there is a small chance that

some research may yield results that may indirectly have a negative impact on insurability, employability, and/or family relationships of some individuals or groups of people. Sometimes, research results in findings or inventions that have value and may be patented or licensed, which could give a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but you will not receive any financial benefits nor will the NIDDK.

4. **Confirm the voluntary nature of the subject's participation**

Example: Your donation is voluntary, and if you choose not to participate there will be no penalty or loss of benefits to which you are entitled.

5. **Describe how data and samples already collected will be managed if a participant withdraws consent to continue participation in the study**

Example: You can change your mind and withdraw consent to participate in this study up until the end of the study. When study researchers receive written instructions from you to withdraw consent to continue participation in the study, they will not collect any more data or samples on you for the purpose of the study. Data and samples collected up until the time that you withdraw may be retained and used in order for the study to be scientifically valid. Data and samples sent to the NIDDK Repository will be given a unique code number and identifiable information will be removed. Data and samples that have been stripped of personal identifiers cannot be retrieved.

Refer to OHRP guidance related to Broad Consent and Withdrawal of Participants from Research

- Broad Consent
- Withdrawal of Participants

References

- NIGMS model informed consent
- CDC model informed consent
- NCI model consent

Additional repository description information that can be used by PIs applying for IRB approval

IRBs at institutions may request additional information about the repository. The following are a list of informational items about the repository that might be useful in preparing an IRB application.

1. **IRB oversight of the NIDDK Central Repository** – The NIDDK Central Repository will be under the supervision of an Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR 46 (The Common Rule). This research material may only be utilized in accordance with the conditions stipulated by the Repository IRB.

2. **Requests for samples** – An appropriate external panel will review all requests to use Repository non-renewable samples. That panel will include a bioethicist and other individuals with expertise in one or more areas including human genetics, clinical research, epidemiology, physiology, genetics of complex traits, statistical analysis, and molecular genetics research. NIH Program and Review staff are excluded from membership on this panel, but can provide appropriate guidance, background information, and technical assistance. Requests will be reviewed based on:
    - consistency with the terms of the informed consent under which the sample was submitted
    - the experience and qualifications of the applicant principal investigator and co-investigators to store and handle the requested materials safely and carry out the study
    - the adequacy of research environment to ensure safe handling of the requested materials and to carry out the study
    - ethical considerations
    - the significance of the proposed research project
    - the adequacy of proposed research design
    - the adequacy of the applicant principal investigator's funding resources to support the proposed study
    - the balance between potential exhaustion of a limited set of samples versus the relative importance of the research question.

3. **Usage agreement** - Every recipient investigator will be obligated to sign a Usage Agreement that stipulates the following conditions:
    - The project has the written approval, and continuing supervision, from an IRB that has executed an applicable Assurance with the Office for Human Research Protections for each research project that proposes to use human biological material acquired from the repository.
    - Recipient–investigators shall conduct only research that is encompassed within the scope of the associated Informed Consent Document, as applicable.
    - Recipient–investigators shall not attempt to ascertain personally identifiable information about the sample sources.

- Recipients shall return all new data derived from the samples and/or data received within one year after receipt of samples and/or data, or upon publication of research in which the new data were presented, whichever comes first, and annually thereafter. This will continue until the Research Project is completed
- Recipient–investigators shall not provide human biological material acquired from the repository to any other investigator, unless directed to do so by the NIDDK. Unused samples should be returned to the repository. All data must be destroyed or returned to the repository after the approved period of use.

References

- NIDA Policy on stored samples
- Other repository site