AgingResearchBiobank

Informed Consent Questionnaire for Data

Data and the Informed Consent

Widely shared data from human subjects must be prepared in a matter consistent with the Informed Consent (IC). Informed consents may be tiered with a number of restrictions, broad with a general or global restriction applicable to all study participants, or broad in which there are no implied or explicit restrictions**. Note that if a tiered consent is used then an informed consent dataset delineating the restrictions each participant selected may be needed**. Please complete the following:

1. An exception from informed consent was received for this study and the IRB approved protocol for this study does not restrict the sharing of de-identified data. If yes, check box, initial, and stop here. If no, proceed to 2.

2. The informed consent has been reviewed and there are no implied or explicit restrictions on the wide sharing of clinical data and a tiered structure with respect to uses or other restrictions was not used. If yes, check box, initial, and stop here. If no, proceed to 3.

**If the informed consent contains explicit or implied restrictions, please consult the AgingResearchBiobank or an NIA Repository representative on the need for a participant level dataset regarding informed consent restrictions.**

3. The informed consent has been reviewed and a tiered structure was used such that study participants could opt-out of certain uses of their data, or the informed consent explicitly states or implies a general or global restriction applicable to all study participants. If yes, check box and continue to 3a:

3a. Study participants could opt-out of sharing data beyond study investigators (if yes, check box and proceed to 3b, leave blank if no and proceed to 3b)

3b. Study participants could opt-out of use or sharing of data for specific research purposes, or the informed consent globally restricted use of data to a specific purpose. If yes, check box and respond to sub-statements 3b.1 or 3b.2. If no, skip sub-statements and proceed to 3c,

3b.1. (General or global restriction) For all study participants the informed consent restricted use of their data to: *Describe briefly the research use restriction applicable to all study participants*

3b.2. (Tiered consent) Study participants could restrict use of their data to the following purposes: *Describe briefly the opt-in or opt-options for participants. For example, participants could limit use of data to 1) Alzheimer's disease or 2) for any purpose*

3c. Study participants could opt-out of sharing data with commercial entities or for a commercial purpose (If yes, check box, leave blank if no)

1. Submit a document summarizing any Study and/or site-specific restrictions/changes to the Study informed consent template regarding the use and storage of data with this Questionnaire.

The summary should include information on:

* restrictions on data use by non-Study investigators, if applicable
* restrictions on data use by research topic (e.g., disease or organ specific), genetic use restrictions, commercial entities, etc., if applicable
* changes to the restrictions for data use over time, including the effective date (s)
* site specific changes to the Study informed consent related to data use