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