

Electronic Institutional Certification Document

Survey Flow

Block: Default Question Block (1 Question)
Standard: Block 1 (11 Questions)
Standard: Block 2 (9 Questions)
Standard: Block 3 (9 Questions)
Standard: Block 4 (5 Questions)

Page Break

Start of Block: Default Question Block

Q1 Please complete the following survey to the best of your abilities with the correct information from your research project. Once you have completed and submitted the survey, the information provided will be reviewed and the IRB will reach out if any other questions arise. Once a satisfactory review of the information is complete and approved by the IRB then the completed certification will be sent for necessary signatures (PI and Institution VP) before it is then submitted to the NIH. The review of the submitted materials is to confirm the data meets the following expectations, as defined in the [NIH Genomic Data Sharing Policy](#):

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
- Any limitations on the research use of the data, as expressed in the informed consent documents.
- The identities of research participants will not be disclosed to NIH designated data repositories.
- An Institutional Review Board (IRB) and/or Privacy Board, and/or equivalent body, as applicable, has reviewed the investigator's proposal for data submission and assures that:
 - The protocol for the collection of genomic and phenotype data is consistent with 45 CFR Part 46.
 - Data submissions and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained.
 - Consideration was given to risks to individual participants and their families associated with the data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
 - The extent relevant and possible, consideration was given to risks to groups or populations associated with submitting to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
 - The investigator's plan for de-identifying datasets is consistent with the standards outlined in the [NIH Genomic Data Sharing Policy](#).

Please note that each institution may have specific guidelines and policies that require additional information or submissions to the IRB.

End of Block: Default Question Block

Start of Block: Block 1



Q24 Name of the NIH Genomic Program Administrator ([GPA](#))?

Q25 Name of the institution submitting the certification?

Q26 Original study name?

Q27 Provide the name of the research project- NOTE, it may or may not match the original study name:

Q2 Principal Investigator name:

Q6 Principal Investigator email:

Q3 Principal Investigator institution name:



Q4 Grant Title:

Q5 Grant Number:

Q28 Is this a [multi-site study](#)?

Yes (1)

No (2)

Display This Question:

If Q28 = Yes

Q29 If yes, please list the contributing institutions below:

End of Block: Block 1

Start of Block: Block 2

Q7 Was the data collected using an IRB Consent Form from your current Institution?

- Yes (1)
- No, please specify which institution (2)
-

Q10 Did each subject sign their Consent Form?

- Yes (1)
- No (2)
-

Display This Question:

If Q10 = No

Q11 If consent was not obtained, how was the data collected and stored?

Q23 Was the data collected before January 25, 2015?

- Yes (1)
- No (2)
-

Q8 Please provide the date range in which the data was collected:

Q9 Please indicate how data will be shared:

- Controlled Access (1)
- Unrestricted Access (2)
- Other, please specify (3) _____

Display This Question:

If Q9 = Controlled Access

Q12 The NIH requires all studies selecting controlled access to select one of the standard [Data Use Limitations \(DUL\)](#). Please choose from one of the below options:

- General Research (1)
- Health/Medical/Biomedical (HMB) (2)
- Disease specific, please specify (3) _____
- Other, specify custom needs (4) _____

Q31 Do you need to indicate additional modifiers to the standard DUL's?

- Yes (1)
- No (2)

Display This Question:

If Q31 = Yes

Q30 Please choose any additional modifiers to the standard DUL's

- IRB approval required (1)
- Publication required (2)
- Collaboration required (3)
- Not-for-profit use only (4)
- Methods (5)
- Genetic studies only (6)

End of Block: Block 2

Start of Block: Block 3

Q13 The below will be accepted in instances where your current institutions IRB did not review the protocol under which the original samples or phenotype data were collected. Please send the consent documents to the appropriate IRB email address and indicate in the spaces below how each issue was addressed in the consent documents. You may also list where this information can be found in the emailed consent documents.

1. Original consent forms (with completion of section 3.)
2. Certification from the Reviewing IRB or from the biospecimen bank/repository from where the sampled were received, in lieu of the original consent forms.
3. Documentation from the Reviewing IRB or from the biospecimen bank/repository that the original consent obtained was not inconsistent with the proposed data sharing.

Q14 Can research study data be shared and to what extent?



Q15 Please list the appropriate/approved research uses of the data?

Q16 Specific uses that the research data is excluded from?

Q17 Extent to which subjects were informed of the possible impacts and risks, to themselves and family, due to the collection of genomic data?

Q18 Extent to which subjects were informed of the possible impacts and risks, to themselves and family, due to the submission of the genomic data to the NIH designated Genomic Data Repository?

Q19 Was your data submitted to an unrestricted repository?

- Yes (1)
- No (2)

Display This Question:

If Q19 = Yes

Q20 Consent language that informs subjects that data will be shared in an unrestricted repository?



Q21 Describe the entire process of how the data will be de-identified including a statement that the dataset will not include any of the [18 identifiers listed in the HIPAA regulations](#):

End of Block: Block 3

Start of Block: Block 4

Q34 Please provide any additional information that would be useful for the IRB to know as the Institutional Certification begins:

Q22 How fast is Certification needed?

Q32 I, as the investigator at the certifying institution, agree that the above is accurate to the best of my knowledge: (Print Name)

Q33 Title of certifying institution investigator:

Q35 Date of submission/completion of electronic institutional certification request:

End of Block: Block 4
