UNC Institutional Certification Request Form

Purpose

Use this form when UNC–Chapel Hill will serve as the institutional certifying official for data submission to dbGaP or another NIH-designated controlled-access repository. This form must be submitted to the IRB as part of an Institutional Certification request.

Instructions

- Complete all sections that apply.
- Submit this form and all required attachments to the IRB application or modification as instructed.
- If documents are pending due to a Just-In-Time (JIT) deadline, contact OHRE regarding

Provisional Institutional Certification

Principal Investigator Information

PI Name: _____ Department: _____

Email: _____ IRB Study Number(s): _____

Sample Source

Indicate the original source of the samples (check all that apply):

☐ Collected under the current UNC study, IRB number of status: _____

☐ Collected under a different UNC study, IRB Number(s): _____

☐ Obtained from an approved UNC Biorepository, Repository name: _____

Sample Collection Date

Were any samples collected prior to January 25, 2015?

☐ Yes ☐ No

If yes, indicate consent status:

☐ Collected without consent (Pre-2015 form required)

☐ Collected with consent (Pre-2015 with-consent form required)

Were any samples collected on or after January 25, 2015?

☐ Yes ☐ No (Post-2015 certification form required if yes)

Data Repository in which data will be entered

Repository name: _____

Risk Considerations

Are there foreseeable risks to individual participants or families from data sharing?

☐ Yes (explain): _____

☐ No

Are there foreseeable risks to groups or populations?

☐ Yes (explain): _____

☐ No

Data Identifiability

Select the description that applies:

☐ Data are anonymous

☐ Data are coded (key retained locally and not shared)

☐ Other (explain): _____

Informed Consent Review

☐ The applicable consent forms have been reviewed and are consistent with the data-sharing plan. You must upload referenced consent forms with the dbGaP language highlighted and complete the Excel consent review worksheet.

☐ Consent forms are not available. Explain: _____

Data Access Level

Individual-level data access:

☐ Controlled access – general research use

☐ Controlled access – disease-specific

☐ Unrestricted public access

Other limitations (if applicable): _____

Genomic Summary Results (GSR)

GSR Access Level:

☐ Controlled access (explain sensitivity): _____

☐ Unrestricted access

Attachments

☐ All applicable consent form versions

☐ NIH Institutional Certification form(s) signed by PI

☐ DMS Plan (include OSP number): _____

Investigator Attestation

I certify that the information provided is accurate and complete.

PI Signature: _____ Date: _____

IRB Use Only

☐ Protocol complies with 45 CFR 46

☐ Data sharing is consistent with informed consent

☐ Risks to individuals evaluated

☐ Risks to groups/populations evaluated

☐ De-identification plan is consistent with NIH GDS Policy

IRB Representative Signature: _____ Date: _____