Not Human Subjects Research Application

General Information

This form is applicable for research involving biospecimens and/or data that will not contain personal identifiers or cannot be linked to identifiers by any NIH staff person who is collaborating in the research. A determination of "Not Human Subjects Research (NHSR)" is not possible if any members of the NIH research team will have a way to re- identify the materials. This includes scenarios in which an NIH PI or Associate Investigator shares coded and linked data with another NIH researcher and intends to receive results that they can link back to subjects.

This form can also be used to request determinations for projects that involve prospective collection or use of biospecimens and/or data but are not considered research at all. In this case, a determination of "Not Research" will be provided.

Project Information

Please enter the full title of your project:

Project Summary:

State the project objectives and any planned methods and analyses (e.g., analysis of data, laboratory assays, generating genomic data, etc.)

Does the project involve NIH employees or staff obtaining information or biospecimens through intervention or interaction (including observation) with patients or research subjects for research purposes?

Select

What is the purpose of the project?

Check all that apply. Most projects will involve only one of these activities listed below.

Notes: *(See starred checkbox descriptions below)*

* Quality Assurance/Quality Improvement involves systematic, data-guided activities which are designed to evaluate and bring about improvement in a practice, method, system, service or product (and may result in the development of new practices, methods, systems, services or products).

** A case report may involve up to three clinical cases. The information collected may include medical history and other relevant information which was initially collected for the purposes of analyzing and diagnosing the individual's condition and/or for instructional purposes. The original information was not collected with any intent to test hypotheses or otherwise produce 'generalizable' knowledge.

- ☐ **Research**
- ☐ **Testing the effectiveness of a laboratory assay**
- ☐ **Clinical Consulting**
- ☐ **Quality Assurance/Quality Improvement***
- ☐ **Evidence-Based Practice**
- ☐ **Public Health Surveillance**
- ☐ **Program Evaluation**
- ☐ **Case Report (includes 3 patients or less)****
- ☐ **Case Series (includes more than 3 patients)**
- ☐ **Other**

Please specify:

Which materials are involved in this project? (*Check all that apply.)*

☐ Tissue/blood or blood products/DNA/RNA/other biospecimens

Please specify:

☐ Fetal tissue

☐ I confirm below:

I have reviewed the Policy and Procedures for the Use of Human Fetal Tissue and will complete all requirements prior to beginning my research.

☐ Human embryonic stem cells (hESCs)

☐ I confirm below:

I have reviewed the requirements for hESC Use in the IRP and will complete all steps prior to beginning my research.

☐ Induced pluripotent stem cells (iPSCs)

☐ I confirm below:

I have reviewed the requirements for iPSC Use in the IRP and will complete all steps prior to beginning my research.

☐ Other type of cell lines

Please specify:

☐ Clinical data

☐ Research data

Please specify:

☐ Survey/Interview/Focus Group Data Imaging data

Please specify:

☐ Genomic data

☐ I confirm below:

I have reviewed the NIH Genomic Data Sharing Policy and my responsibilities as an IRP investigator under the GDS policy and will complete all steps, as applicable, prior to beginning my research.

☐ Biospecimens or data from individuals who are all deceased

☐ Audio recordings

☐ Video recordings

☐ Other

Please specify:

Where were the biospecimens and/or data originally collected? If being newly collected, where will they be collected?

Check all that apply. If unsure, please consult with your collaborator or the provider of the materials.

☐ NIH

☐ Outside of NIH

☐ Unknown

If outside of NIH, please provide the name of the institution/company/website:

What is the source of the materials?

Check all that apply. If unsure, please consult with your collaborator or the provider of the materials.

☐ NIH IRB approved protocol - Open

☐ NIH IRB approved protocol - Closed

☐ External IRB approved protocol

☐ Medical records or other clinical records

☐ Biospecimens collected for clinical purposes only (i.e., pathological waste)

☐ A repository (biospecimens and/or data)

☐ On-line resource (not a repository)

☐ Commercial entity (biospecimens and/or data are being purchased from a company)

☐ Data or biospecimens will be newly obtained from humans as part of this project

☐ Other

If other, please specify:

Are the biospecimens and/or data already in the possession of the NIH project team? *(Select one)*

Select

If all or some of the biospecimens and/or data are already in the possession of the NIH project team, explain how the NIH project team obtained access. *If not applicable, state N/A.*

If you responded "some yes, some no" explain why, e.g., some biospecimens and/or data will be collected in the future.

Which of the following types of materials will any member of the NIH staff access (look at or review), receive or analyze at any point during the project?
Check all that apply. If unsure, please consult with your collaborator or the provider of the materials.

☐ Identifiable biospecimens and/or data

☐ Coded and linked biospecimens and/or data with access to the key

☐ Coded and linked biospecimens and/or data with no access to the key

☐ Totally anonymized biospecimens and/or data (no one anywhere holds the code key or link to identifiers)

Are the materials currently identifiable to an NIH project member (including via a key)?

Select

If the biospecimens or data are currently identifiable, explain that NIH project member's role in this project.

If the biospecimens or data are currently identifiable, and the intention is to fully anonymize the biospecimens and/or data before conducting any activities, explain who will do this, and how it will be accomplished.

Be sure to consider and address whether there is a possibility that a member of the NIH project team might still be able to re-identify the materials after anonymizing. For example, he or she might be able to do so, based on previous knowledge or interaction with the patients or subjects or prior use of these materials; or based on certain included data points or certain features of the biospecimens or data.

What will the NIH project staff be returning to the collaborator/individual who shared the biospecimens and/or data with them? *Check all that apply.*

Please note: If the NIH project team will receive results that they can link to identifiers as part of a research collaboration, the PI must seek prospective IRB review and approval for the planned research. This project is not eligible for a determination of "Not Human Subjects Research". Do not submit this form.

☐ Coded results will be returned to the sender who can link them to identifiers

☐ Anonymous or coded results will be returned, but neither the sender nor the recipient will have a link to the code-key that identifies specific individuals

☐ Only aggregate results will be returned (e.g., summary statistics, not individual line-item data)

☐ Nothing; no results will be returned

☐ N/A

Additional Comments: