THE GEORGE WASHINGTON UNIVERSITY
OFFICE OF HUMAN RESEARCH / INSTITUTIONAL REVIEW BOARD
EMAIL: OHRIRB@GWU.EDU PHONE: (202) 994.2715
HUMANRESEARCH.GWU.EDU

# Human Subjects Research (HSR) Determination Form

Investigators needing an official determination of whether or not proposed activities are human subjects research requiring IRB review should complete this form. You may choose to use this form as a tool only and keep it as part of study records; you do not have to submit *this form* to the OHR, but OHR will review completed forms upon request and issue a determination*. If OHR determines that your study involves human subjects research, you will be directed to submit an IRB application to us in iRIS. Only GW-eligible PIs may submit this form to OHR for our review. Submit completed forms to ohrirb@gwu.edu for review.

**We recommend reaching out to journals and sponsors (if applicable) to see if they require formal determinations or IRB review for your study. Certain publishers and sponsors have specific requirements concerning IRB review.*

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|---|---|---|
| GW Principal Investigator (PI) Name: | Phone: | Date: |
| School or Department: | E-mail: | Degree: |
| Additional Contact Person: | E-mail: | Phone: |
| Project Title: | | |

| | | |
|---|---|---|
| Will this project take place at a site other than at a GW facility? | Yes ☐ | No ☐ |
| Did GW receive funding for this project? | Yes ☐ | No ☐ |
| If yes, did GW receive direct federal funding (e.g., NIH) for this project?* | Yes ☐ | No ☐ |

**If GW is the direct recipient of federal funding for the project and any site being paid by the grant/contract is engaged in human subjects research, GW is considered "engaged" in human research and this form cannot be used.*

**Is it human research under Department of Health and Human Services (DHHS) Regulations?**

- HHS Decision Trees for reference: click here

**A. "Human"**

**1)** Does activity involve human subjects (*living* individuals about whom an investigator conducting research collects data or biospecimens)? Yes ☐ No ☐

**2)** Does activity involve the prospective collection of information or biospecimens through **intervention** or **interaction** with the individual and uses, studies, or analyzes the information or biospecimens? Yes ☐ No ☐

- **Intervention**: physical procedure by which information or biospecimens are gathered **or** manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction**: communication or interpersonal contact with the individuals, including electronic interaction.

**3)** Does activity involve obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens? Yes ☐ No ☐

- **Private information**: information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or psychological information) or information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
- **Identifiable private information**: private information for which the identity of the subjects is or may readily be ascertained by the investigator or associated with the information. **Identifiable biospecimen**: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**B. "Research"**

**1)** Is the activity **systematic**? Yes ☐ No ☐

- **Systematic:** activity that involves data collection, either quantitative or qualitative, and data analysis to answer a question.

**2)** Is the activity an **investigation**? Yes ☐ No ☐
- **Investigation:** activity that involves development, testing, evaluation, and/or search for information.

**3)** Is the activity designed to **generate or contribute to generalizable knowledge**? Yes ☐ No ☐
- **Generalizable knowledge:** activity that draws general conclusions (knowledge gained may be applied to other populations outside of study), informs policy, or is universally or widely applicable; contributing to generalizable knowledge normally involves public dissemination of that knowledge.
  - Explain why or why not your study is generalizable:

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## Retrospective Data/Specimen Analysis Considerations

**C. Does the project involve retrospective data/specimen analysis of existing or secondary data?** *If no, skip to next section.* Yes ☐ No ☐

If Yes, provide a data collection sheet that lists the variables to be received and check one of the following:

**1)** The data/specimens to be used in the research do not contain identifiers **or** the provider of the data/specimens will remove all identifiers, including any codes, before providing data/specimens to the research team. Yes ☐ No ☐

**2)** Data/specimens to be obtained qualify as a Limited Dataset (only city/state/zip code, dates, and/or age are being obtained). Yes ☐ No ☐
- If a data use agreement (DUA) is necessary or you have questions about the DUA process, please contact the GW Office of Research Integrity at resinteg@gwu.edu.
- By selecting "yes," you assure you will not attempt to re-identify any individuals.

**3)** Data/specimens to be obtained are coded, but the holder of the key to identifiers and the GW investigator enter into an agreement (such as a code access agreement) prohibiting the release of the key to the investigator. Submit copy of agreement to OHR. Yes ☐ No ☐

**4)** GW PI has documentation of written policies from a repository/data source that prohibits the release of the key to GW PI. Submit documentation to OHR. Yes ☐ No ☐

**5)** The data (with or without identifiers) are all publicly available. Yes ☐ No ☐
- **Publicly available**: data that anyone can download and does not require an application or permission for access (i.e., if you have to provide any information to access/obtain the dataset).
  - Provide website link(s) to the publicly available data:

## Additional Considerations

**D.** Is it human research under FDA Regulations? (e.g., devices, drugs, biologics)? Yes ☐ No ☐

**E.** Does the research involve the use of human stem cells? Find more information here: OHR Stem Cells. Yes ☐ No ☐

**F.** Does your research involve genetic testing? Yes ☐ No ☐

## Quality Improvement Considerations

**G. Does the project involve quality improvement, not research?** *(If no, skip to next section).* Yes ☐ No ☐

If Yes, answer the following:

**1)** The goal of the project is to inform/improve the performance of the unit/site, not to establish scientific evidence to share beyond the scope of the unit/site. Yes ☐ No ☐

**2)** The unit/site administrators approve this as a QI project to be systematically implemented; activities do not require the consent of individual participants. Yes ☐ No ☐

**3)** The outcomes of the QI initiative will not be published or presented outside the local context. Yes ☐ No ☐

- If there is a possibility of publishing the outcomes of the QI initiative, the personnel involved will include the following statement with any publication: "This project was undertaken as a QI initiative, and as such was not approved by an IRB."

## Project Description

**5. Please provide a brief project description.** State the project's purpose and explain how you will be gathering or obtaining project information/data/specimens (including population categories [children, adolescents, adults], total numbers of human subjects and recruitment sites).

**FOR IRB USE ONLY**

☐ **THIS DOES NOT REQUIRE SUBMISSION TO GW OHR**

**Signature of GW OHR Reviewer** **Date**

**Justification for IRB Decision (if deemed necessary to provide):**

☐ **THIS STUDY DOES REQUIRE SUBMISSION TO GW OHR**

**Please see submission information here**

If your project is determined not to require IRB review now, but you project changes in such a way that it may meet the definition of human subjects research, please consult with OHR before proceeding. If you do not obtain IRB approval initially but later wish to use the data for generalizable purposes, you must submit to the IRB, and it may be determined that you are not permitted to use the previously collected data.