PROJECT PLAN TITLE:

HUMAN RESEARCH DETERMINATION FORM

This form is only for use on projects that are not yet initiated and there is either a question whether it qualifies for human research or a Not human research determination might be required. The IRB does not issue retrospective determinations. If you are concerned that you have conducted human subjects research without prior approval from the IRB please contact our office at irb@umn.edu

INSTRUCTIONS:

- Prior to initiation, investigators are required to submit and the IRB is required to review Human Research for which University of Minnesota, Gillette, or Fairview is engaged.
- Student-Investigators should create the ETHOS submission, but their Advisor submit the Determination Form (HRP-503).
- Review the Investigator Manual (HRP-103) for additional information about projects that may or may not require IRB review and approval:
  - "What if I'm not sure my project requires IRB review?"
  - "How does quality improvement differ from research?"
- If the activity involves any of the following, **STOP** and develop a protocol for IRB submission and review:
  - The use of a drug in one or more persons other than use of an approved drug in the course of medical practice.
  - The use of a medical device or a tobacco product in one or more persons that evaluates the safety or effectiveness of that device.
  - Data regarding subjects or control subjects submitted to or held for inspection by FDA.
  - Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA.

- The IRB Office uses "WORKSHEET: Human Research Determination" (HRP-310) to make its Human Research determinations. Please consult that worksheet as a guide for the information you provide in Section 1.0.
- Complete Section 1.0 below with details about your proposed activity.
- If you need a determination for a grant-only submission, e.g., Training Grant or Umbrella Grant, be sure to indicate that explicitly in that section.
- After completing Section 1.0, create a new study in ETHOS and upload the entire document in lieu of an Investigator's Protocol and submit the study for IRB Office review.
- If, while reviewing this determination form, you discover that an activity is Human Research, consult the "Investigator Manual" (HRP-103) for further instructions.

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- If you need assistance, ***Email or call the IRB at*** *irb@umn.edu or (612) 626-5654*

PROJECT PLAN COVER PAGE:

Protocol Title	This should align with the ETHOS submission title.
Principal Investigator/Faculty Advisor	Name:
	Department:
	Telephone Number:
	Email Address:
Student Investigator	Name:
	Current Academic Status (Student, Fellow, Resident):
	Department:
	Telephone Number:
	Institutional Email Address:
Version Number/Date:	Include the current version number and date of this protocol.

1.0 Description of Activity

Describe the project and identify what kinds of activities will be involved. **Delete the italicized instructions below when providing your information.**

1.1 Purpose

Describe the purpose, specific aims, or objectives of the project. For example, is the activity limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting?

1.2 Procedures

Describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any. For example, will the project include interviews, surveys, or other assessments? Will the interview questions focus on policies, practices, and/or procedures (e.g. the collected data does not focus on personal opinion or private information)? Include the setting (location) for which the procedures will take place.

1.3 Program Evaluation/Quality Assurance Review/Quality Improvement Projects:

Answer these questions if you think your project might qualify as a Quality Assurance or Quality Improvement project. Type N/A and move to next section if this is not a QA/QI project. For each of the statements below, explain how each does or does not apply to the project.

- Seeks to develop new knowledge or validate new treatments rather than to assess the implementation of existing knowledge.
  ☐ **Yes** ☐ **No**
  Explain:
- The methodology employs a standard research design, such as randomization.
  ☐ **Yes** ☐ **No**
  Explain:
- The protocol is fixed with a rigid goal, methodology, population, time period, etc.
  ☐ **Yes** ☐ **No**
  Explain:
- The funding for the activity comes from the outside organizations such as the NIH or those with a commercial interest in the results;

☐ **Yes** ☐ **No**
Explain:

- There will be a delay in the implementation of results;
  ☐ **Yes** ☐ **No**
  Explain:
- The risks from the intervention to participants are greater than minimal.
  ☐ **Yes** ☐ **No**
  Explain:
- The program being implemented for a research purpose, or altered or controlled in some way to answer a research question.
  ☐ **Yes** ☐ **No**
  Explain:

1.4 **Data and/or specimens**

Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access and links to data sources.

- **Data and/or Specimen Collection and Analysis**
  Describe the data and/or specimens you will collect and how they will be analyzed.
- **Data and/or Specimen Collection Method**
  Describe how you will obtain the data or specimens. (Are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples from a lab?)
- **Identifiability of Data or Specimens**
  Indicate whether the data or specimens you collect for this activity can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one but the person giving you the data or specimens has the key to the code).

  Is your data de-identified? Visit the Health Information Privacy And Compliance Office and click on "A researcher may use PHI that has been de-identified" for a list of identifiers that must be removed to be considered de-identified.

  Is your data coded? Review OHRP's 2008 Guidance on Coded Private Information and Specimens Use in Research.