Avera

Institutional Review Board

Submission Form: Determination of Human Subjects Research

NUMBER | HRP-100

The Avera IRB is required to review and approve all research involving human subjects. This application is intended to help you determine if your project is research, and therefore requires IRB approval.

After completing this form, if you think your project does NOT require IRB review and you need a formal determination letter, proceed as follows:

- *Complete the entire form, and email it and all relevant supporting documents (i.e., protocol, consent forms, grant, etc.) to the Avera IRB at IRB@avera.org. You should receive an IRB response within 10 business days.*

If after completing this form you think your project does need IRB review, stop using this form. You will instead need to submit the study (including a protocol, informed consent or waiver of informed consent, etc.) to the IRB through the electronic IRB submission system (Currently known as TOPAZ). If you don't already have a username and password to this system, please contact the IRB office. IRB@avera.org

Project Title

Current Status of the Project

Has the project already been conducted (i.e., data has already been collected and analyzed)?

☐ Yes ☐ No If yes, Avera IRB cannot make a determination regarding the study/project.

SECTION I: Specific activities that typically do NOT represent "Human Subjects Research" requiring IRB review. If applicable for your project, check the appropriate activity that it fulfills.

A. ☐ **Quality Improvement/Quality Assurance Activities**: The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

Note: *Please **complete Chart #1 on the following page,** which outlines the differences between a QI project and a research study.*

B. ☐ **Case Report:** The project consists of a case report or series which describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

Note: If a case report contains any of the 18 protected health information (PHI) identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.

C. ☐ **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.

The following activity is deemed not to be research:

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. If the focus includes generalizing to other individuals, then the activity may be research and should be evaluated against the definition of research (which is done below).

D. ☐ **Public Health Surveillance:** Public health activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, access, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

CHART 1: QI/QA Compared to Research

COMPLETE ONLY IF YOU SELECTED "A" ABOVE: QUALITY IMPROVEMENT/QUALITY ASSURANCE ACTIVITIES

HOW DOES QI DIFFER FROM RESEARCH?

Both research and quality improvement are investigations that may involve human participants, but they differ in important ways. This Worksheet can help you determine if your project is in fact QI, or potentially human subjects research. Please complete to help justify how your project is thought to be QI/QA.

	Human Subjects Research	Yes	No	Quality Improvement (QI)	Yes	No
Purpose	Designed to develop or *contribute to generalizable knowledge.*			Designed to implement knowledge, assess a process, *improve a program or delivery of care* with consideration of established or accepted standards.		
Starting Point / Intent	Intended to *answer a question* or *test a hypothesis.*			Knowledge-seeking is integral to ongoing management of a program or system, including a health-care delivery system.		
Design	Follows a specific protocol. *Designed to answer discrete research questions*. May be single or multicenter. Funding may be external or internal.			Adaptive, iterative. Generally single center only. Generally not externally funded		
Benefits	Intended *to benefit future patients/individuals*. Might or might not benefit current participants.			Intended to directly *benefit a process, system or program*; Might or might not benefit patients or individuals.		
Risks	May put participant at risk			Does not increase risk to patients, with exception of possible risks to privacy or confidentiality of data.		
Endpoint	*Answer a research question.*			*Improve a program, process or system.*		
Analysis	Statistically prove or disprove a hypothesis.			Compare program, process or system to established standards/best practices		
Adoption of Results	Intent to contribute to generalizable knowledge. Avenues for dissemination could include scientific presentation/publication			Intent to utilize results locally [e.g. for system enhancement] Insights from initiatives may be shared [e.g. in a QI journal]		
Publication/Presentation	Investigator obliged to share results.			QI practitioners/investigators encouraged to share reporting of insights.		

*Adapted from Children's Hospital of Pennsylvania: https://irb.research.chop.edu/quality-improvement-vs-research

If you tally the higher number of 'yes' marks under the QI header, your project is likely QI and is not human subjects research.

If you tally the higher number of 'yes' marks under the Human Subjects Research header, please submit your project (with a protocol) to the IRB.

Instructions:

- ✓ If your activity did not fall into one of the categories described in Section I above, continue to Section II to assess if you are engaged in human subjects research per the regulations set forth.
- ✓ If your activity did fall into one of the categories described in Section I above, skip section II, but proceed to section III. Then submit this completed form **and** your protocol or project summary, and any other relevant supporting documents (i.e., consent forms, grant, etc.) to IRB@Avera.org for formal assessment. You should receive an IRB response within 10 business days.

SECTION II. Activities subject to HHS human subject research regulations (45 CFR 46)

DEFINING RESEARCH & HUMAN SUBJECTS

Research is defined in the Code of Federal Regulations, 45 CFR 46.102(l), as a systematic investigation designed to develop or contribute to generalizable knowledge.
The Belmont Report states ". . . the term 'research' designates an activity designed to test a hypothesis or formal protocol that sets forth an objective and a set of procedures to reach that objective."

Generalizable knowledge is information where the intended use of the research findings can be applied to populations or situations beyond that study. Note that publishing the results of a project does not automatically meet the definition of generalizable knowledge.

Human subject is defined in the Code of Federal Regulations, 45 CFR 46.102(e), as a living individual about whom an investigator (whether professional or student) conducting research:
- Obtains information or biospecimens *through intervention or interaction with the individual*, and uses, studies, or analyzes the information or biospecimens; OR
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

1. Is the study a systematic investigation? (Systematic means having or involving a system, method, or plan.)
In other words, do you have a hypotheses or research question and a formulated plan to gather data that might support the hypothesis, or answer the research question?

Examples of studies that are systematic include:

- Gather information for the purpose of hypothesis building or testing
- Ask individuals the same sets of questions, or obtain the same kind of information from them.
- Apply the same measures in gathering the data – whether through interaction, observation, or experiment.
- Utilize data collection methods that can be replicated.

☐ Yes ☐ No
Please explain your answer here:

2. Is the study designed to contribute to generalizable knowledge? Generalizable knowledge *is information that will contribute to the field or area being studied, and may be of interest or applicable to people outside of your study population. Quality improvement (QI) and program evaluation projects are typically done to assess something specific and the results are not generalized or shared with others. Instead the results are kept with the investigator/department/hospital and are used internally to make improvements or guide decision making.*

- Your study contributes to generalizable knowledge if you intend for findings from it to be applicable to a larger population, or otherwise make the findings of it available for the development of knowledge beyond the scope of the study.
- If the study activities involving people are conducted solely for the purpose of fulfilling a course requirement,

they are not considered research because they are not designed to contribute to general knowledge. *However*, activities involving people that are conducted in conjunction with the requirements of a thesis or dissertation generally are research because the purpose of the thesis or dissertation is by definition to make a contribution to general knowledge.

☐ Yes ☐ No
Please explain your answer here:

Instructions:

- ✓ If you answered "No," to ***either*** question 1 ***or*** 2, skip questions 3-5 and proceed to Section III, then submit this completed form **and** your protocol or project summary, and any other relevant supporting documents (i.e., consent forms, grant, etc.) to IRB@Avera.org for formal assessment. You should receive an IRB response within 10 business days.
- ✓ If you answered "Yes," to questions 1 and 2, continue to the next set of questions.

3. Does the research involve obtaining information about, or biospecimens from, living individuals?

This might include information regarding a person's (or group of people's) opinions, thoughts, behaviors, or medical information. This does not include information gathered solely about an organization, event, or processes, or specimens/information from subjects who are now deceased.

Information about or biospecimens from an individual includes, but is not limited to, the following:

- Ideas, attitudes, opinions, feelings, experiences, thoughts, beliefs, assessments, reflections, etc., reported by an individual, even when the individual provides the information while working in a professional capacity.
- Information about living individuals that was gathered by another researcher or source.
- Information about living individuals gathered through the use, analysis or harvesting of cell lines, tissue, or the products of labor and delivery.
- Samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein.

☐ Yes ☐ No
Please explain your answer here:

Instructions:

- ✓ If you answered "No," to question 3, skip questions 4-5 and proceed to section III, then submit this completed form **and** your protocol or project summary, and any other relevant supporting documents (i.e., consent forms, grant, etc.) to IRB@Avera.org for formal assessment. You should receive an IRB response within 10 business days.
- ✓ If you answered "Yes," to question 3, continue to questions 4-5.

4. Does the research involve obtaining information or biospecimens through intervention or interaction with individuals and uses, studies, or analyzes the information and/or biospecimens?

Intervention includes:

- Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- e.g., drawing blood from subjects, timing subjects running laps, recording brain activity during sleep, etc.

Interactions involve:

- Communication or interpersonal contact between the investigator and the subjects, and can be in-person, through email or social media, or by completing a survey or interview or focus group.
- e.g., a street interview, an online survey recording posts on a blog or listserv, a mailed questionnaire,

etc.

☐ Yes ☐ No
Please explain your answer here:

5. Will you obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens from individuals?

Private information includes:

- Information about behavior that occurs in a context in which an individual can reasonable expect that no observation or recording is taking place.
- Information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public (e.g., a medical record, emails, certain listserv communications, class papers and exams, etc.)
- ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Biospecimens include:

- Samples or specimens of material, such as urine, blood, tissue, cells, DNA, RNA, and protein.
- ***Identifiable*** biospecimen is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

☐ Yes ☐ No
Please explain your answer here:

Instructions:

- ✓ If you answered "No," to questions 4 **and** 5, your answers indicate that your project is not human subjects research. Proceed to Section III below, then submit this completed form by email, and all relevant supporting documents (i.e., protocol, consent forms, etc.) to IRB@Avera.org for formal assessment. **You should receive an IRB response within 10 business days.**

- ✓ If you answered "Yes," to **either** question 4 **or** 5, **STOP**, your project DOES involve human subjects and you will need submit the study (including a protocol, informed consent or waiver of informed consent, etc.) to the Avera IRB through the electronic IRB submission system (Currently called TOPAZ). If you don't already have a username and password to this system, please contact the IRB office.

SECTION III: Investigator and Project Information	
PI Name (Last, First)	How are you affiliated with Avera?
Is this project being completed as part of an educational requirement? Yes or No	College or University (if applicable)
Phone Number	E-mail Address
Has this study been reviewed by the Avera Nursing Research Committee (NRC)? Yes or No If Yes, month of NRC Review**:**	
Project Title	
1. **Project Description** (Briefly describe the project and what you expect to do with your findings.)	
2. **Study Population** (Briefly describe the study population or subject of the research.)	
3. **Data Collection** (Briefly describe the data collection methods to be used.)	
4. **Provide your Justification** (Briefly explain why you think the project does not constitute human subjects research, and therefore does not need IRB review.)	

WHAT'S NEXT:

- ✓ Submit this completed form **and** your protocol or project summary, and any other relevant supporting documents (i.e., consent forms, grant, etc.) to IRB@Avera.org for formal determination. If further IRB approval isn't necessary, you will be emailed the signed Section V (on the following page) stating the IRB determined this project may proceed without review. **You should receive an IRB response within 10 business days.**
- ✓ If, however, the IRB determines that this is human subjects research and IRB approval is necessary, you will be notified by email and asked to submit a full application to the IRB thru TOPAZ. With this notification, IRB approval must be obtained before the project can begin.

Avera

Institutional Review Board
Determination of Human Subjects Research

NUMBER | HRP-100

SECTION V: IRB Determination (To be completed by Avera IRB Personnel)

Project Title

☐ The proposed activity as submitted DOES NOT constitute Human Subjects Research. IRB review is not required. This determination only applies to the activities described in this request. If there are any changes that may alter this determination, the investigator may request another written determination.

☐ The proposed activity as submitted DOES constitute Human Subjects Research. Submission of an IRB Application IS REQUIRED. IRB Approval must be obtained before the research can begin.
You will need submit the study (including a protocol, informed consent or waiver of informed consent, etc.) to the Avera IRB through the electronic IRB submission system (Currently called ***TOPAZ***). If you don't already have a username and password to this system, please contact the IRB office.

Authorized Avera IRB Personnel Printed Name: _____

Title: _____

Authorized Avera IRB Personnel Signature: _____

Assigned IRB Number: _____ **Date: _____**