

Appendix E: DETERMINATION OF HUMAN SUBJECT RESEARCH

The IRB Determination Form is used to help the IRB and the researchers determine if a project requires IRB review by fulfilling the definition of **human subjects research** per federal regulations. This form also provides documentation that the IRB will use to review the project description and issue a determination.

Please allow at least ten (10) business days for review and a response.

E-mail completed form to: IRBAdmin@du.edu

Project Title

Section A Contact Information

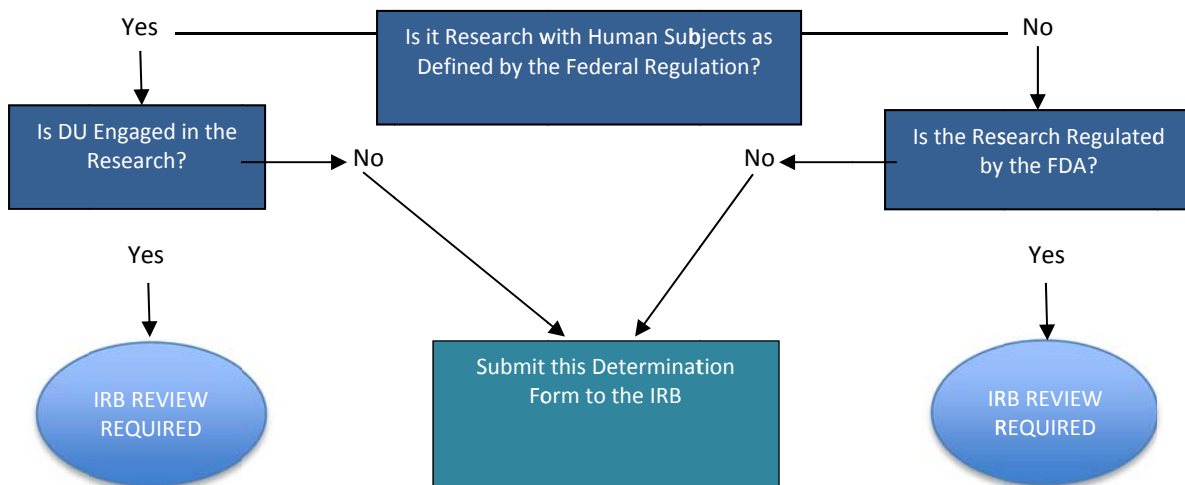
Name (last name, first name and credentials)

Department/College:

Faculty Sponsor (if applicable):

E-mail:

Submit this form to the DU IRB for a formal determination only if you think that your project does NOT require IRB review.



Section B Summary of Activities

B.1 Provide a *brief* description of your project. Include a description of what any participants will be asked to do and a description of the data accessed and/or collected.

B.2 If your study will involve interviews, focus groups, surveys, questionnaires, etc., provide a copy of all planned questions or sample questions. List all attachments:

B.3 Are all of the data used in this project publicly available, (e.g. blog, aggregate data, etc.)?

Yes

No

Section C: Is this Project Human Subjects Research as Defined by Federal Regulations?

Research is defined in the Code of Federal Regulations, 45 CFR 46.102(d), 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.”

Research generally does not include operational activities such as routine outbreak investigational and disease monitoring and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted for services.

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.

C.1 Do you have a specific research question or hypothesis?

C.2 Is your primary intent to generate knowledge that can be applied broadly to the group/condition under study?

Human subject is defined in the Code of Federal Regulations, 45 CFR 46.102(f)(1 or 2), as a living individual about whom an investigator obtains data through intervention or interaction or identifiable private information.

The specimen(s)/data/information must be collected from or be about live subjects. Research on cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects research.

C.3 Does this project involve intervention or interaction with a living individual or group of individuals? (e.g. confidential surveys, interviews, medical or educational testing)

C.4 Does this project involve access to identifiable private data or specimens from living individuals?	
C.5 Was the original data collection for the current project?	
C.6 Does this project consist exclusively of interviewing or surveying subjects about his/her area of expertise, with a focus on policies, practice, and/or procedures (e.g. the collected data does not focus on personal opinion or private information)?	
C.7 Is the project meant to record the stories, knowledge or experiences of individuals? Oral histories typically do not intend to answer a research question or hypothesis.	
Section D: Determining if DU is Engaged in Research	
DU is usually considered engaged in research if any of the following are true: <ul style="list-style-type: none"> • DU is the primary awardee on the grant or contract • DU is the only site • DU employees, students, or agents are obtaining consent/assent • DU employees, students, or agents are interacting or intervening with human subjects. Examples include online surveys, interviews, participant observations, invasive/non-invasive study procedures, manipulating the subject's environment for research purposes, or • DU employees, students, or agents are obtaining or receiving identifiable, private information or biological samples 	
Does conducting this project cause DU to be engaged in research?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If a protocol (research narrative) exists for this project it must be submitted for review. Submit this request along with any supplemental documents that may aid in review of your project to the University of Denver IRB at: IRBAdmin@du.edu	