

ASSESSING WHETHER YOUR PROJECT IS “RESEARCH” REQUIRING IRB REVIEW

Certain activities may have the characteristics of research but do not meet the federal definition of human subject research requiring IRB review. Please complete the following table to determine if your project meets this federal definition*. A response of ‘yes’ to any of the questions may mean your project requires IRB review. If you respond ‘no’ to all of the questions, your project may not require IRB review and the [Appendix E: IRB Determination Form](#) should be submitted to IRBAdmin@du.edu for review.

	YES	NO
1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the activity involve obtaining information about living individuals?	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the activity involve interacting with humans or obtaining identifiable information about the subjects?	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the activity intended to generate new knowledge that will contribute to scientific literature (i.e. that revises or improves upon existing principles, theories, or knowledge?)	<input type="checkbox"/>	<input type="checkbox"/>
5. Are any of the project activities experimental (i.e. is there any testing of new or unproven treatments or strategies that are not yet known to be efficacious)?	<input type="checkbox"/>	<input type="checkbox"/>
6. Are the participants in the activity randomized to an intervention so that the results of the activity can be generalized to a larger population?	<input type="checkbox"/>	<input type="checkbox"/>
7. Does the activity involve additional risks imposed on participants in order to make the results generalizable beyond the participants themselves?	<input type="checkbox"/>	<input type="checkbox"/>
8. Is there an intent to publish or present the results of a human subjects research question to the scientific community?	<input type="checkbox"/>	<input type="checkbox"/>
9. Is there an evaluation/performance assessment part of the project in which information will be shared beyond those involved in or overseeing the program/process/system?	<input type="checkbox"/>	<input type="checkbox"/>
10. Will the results of a quality improvement program be disseminated outside the institution for the purpose of sharing the outcomes or implications of the project, not the process?	<input type="checkbox"/>	<input type="checkbox"/>
11. Will the activity be used to develop a problem statement, research questions, and/or theory-based hypotheses?	<input type="checkbox"/>	<input type="checkbox"/>
12. Is the study designed to prove a relationship or correlation?	<input type="checkbox"/>	<input type="checkbox"/>

***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.

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.

To qualify as human subject research and require IRB review, the proposed research must fulfill **BOTH** definitions of research and human subject.