**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 help 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 **Human Subjects Research Determination Form** should be submitted to [HSRrequest@du.edu](mailto:HSRrequest@du.edu) for review.

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| --- | --- | --- | --- |
| **YES** | **NO** | | |
| 1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? | ☐ | ☐ | |
| 1. Does the activity involve obtaining information about living individuals? | ☐ | ☐ | |
| 1. Does the activity involve interacting with humans or obtaining identifiable information about the subjects or identifiable biospecimens? | ☐ | ☐ | |
| 1. 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?) | ☐ | ☐ | |
| 1. 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)? | ☐ | ☐ | |
| 1. Are the participants in the activity randomized to an intervention so that the results of the activity can be generalized to a larger population? | ☐ | ☐ | |
| 1. Does the activity involve additional risks imposed on participants in order to make the results generalizable beyond the participants themselves? | ☐ | ☐ | |
| 1. Is there an intent to publish or present the results of a human subjects research question to the scientific community? | ☐ | ☐ | |
| 1. 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? | ☐ | ☐ | |
| 1. 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? | ☐ | | ☐ | |
| 1. Will the activity be used to develop a problem statement, research questions, and/or theory-based hypotheses? | ☐ | | ☐ | |
| 1. Is the study designed to prove a relationship or correlation? | ☐ | | ☐ | |

\***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 or biospecimens.

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