

IRB Application Start Here

***** Contact irb@regis.edu if you have questions about whether a project is research or human subjects research prior to submitting through IRBNet *****

Is your project research? Your project may not be research.

Please note there are activities that are not considered Human Subjects Research:

- **Business Plans, Process Improvement Plans, Business Analysis, Feasibility Studies, Surveys, and Business Surveys** which are used to analyze a business or certain business processes that are specific to an organization are not generalizable knowledge and are not considered research.
- **Classroom activities** solely to fulfill course requirements or to train students in the use of particular methods or devices and, for which you have no desire to publish or share this information outside the classroom (e.g., at conference, on website, etc.).
- **Internal data collection** for Regis University departmental, school, or other institutional administrative purposes only (i.e., teaching evaluations, customer service surveys) and for which you have no desire to share or publish.
- **Information-gathering** where questions focus on things, products, or policies rather than about people or their thoughts (i.e., canvassing about inter-library loan policies or rising journal costs).
- **Coded data** that were not collected for the currently proposed projects as long as the investigator receiving the data cannot link back to the individual (e.g., national dataset with no identifiers).
- **Pilot studies** which are used to develop or test measures are not considered human subjects research as long as you have no desire to publish or share this information. If it is possible that the data collected in your pilot study will be used solely or in combination with other data for publication purposes, IRB review and approval is required before data collection begins.

Useful definitions

Systematic investigation: attempts to answer research questions, collects data in an organized or consistent way, the data is analyzed in some way (i.e., quantitative or qualitative), and conclusions are drawn from the results

Generalizable knowledge: investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population) or inform policy. For conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of investigation that will be disseminated).

Disseminated: the material will be shared beyond the local setting. Obvious examples of dissemination are publication in a scholarly journal, presentation at a professional conference, or placement of a report in a library.

Examples that are not disseminated information include oral presentation to a departmental group in fulfillment of a university requirement, sharing of results with an agency that cooperated in information collection, or internal presentation for utilization and review purposes.

So, is your project research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (For more information, [see 45 Code of Federal Regulations 46.102 \(d\)](#)).

1. Is your activity a systematic investigation designed to develop or contribute to a generalizable knowledge?

If you answered “yes”, please continue to question 2.

If you answered “no”, your project is not research and IRB review is not required.

If you are unsure, please contact irb@regis.edu.



Does your project involve human participants?

2. Is the data being collected through intervention or interaction with living participants?

If you answered “yes”, please continue to question 3.

If you answered “no”, your project is not considered research and IRB review is not required.

If you are unsure, please contact irb@regis.edu.

Useful Definitions

Intervention: includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant’s environment that are performed for research purposes.

Interaction: includes communication or interpersonal contact between investigator and subject (For more information, [see 45 Code of Federal Regulations 46.102\(f\)](#)) (e.g., surveys, focus groups, interviews).

3. Does your project involve intervention and/or interaction with the participants?

If you answered “yes”, please continue to question 4.

If you answered “no”, your project is not considered research and IRB review is not required.

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4. Does the data contain individually identifiable information? In other words, can the identity of the participant be readily ascertained by the investigator or associated with the information gathered (For more information, [see 45 Code of Federal Regulations 46.102\(f\)](#)).

If you answered “yes”, please continue to question 5.

If you answered “no”, your project is not considered research and IRB review is not required.

If you are unsure, please contact irb@regis.edu.



Useful Definitions

Private information: includes information about behavior that occurs in a context in which a participant can reasonably expect that no observation or recording is taking place, information for specific purposes by an individual, and which the individual can reasonably expect will not be made public such as a medical record.

Individually identifiable: the identity of the participant is or may be readily ascertained by the investigator or is associated with the information

5. Is the information private? Private information must be individually identifiable.

If you answered “yes”, your research involves human subjects and IRB review is required.

If you answered “no”, your activity is not research and IRB review is not required.

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