IRB FREQUENTLY ASKED QUESTIONS

1. Who must apply for human subjects review through the IRB (Institutional Research Board)?

All Regis University faculty, students (graduate and undergraduate), and staff planning to conduct research with human subjects must submit an application for review and approval before starting to advertise, recruit or conduct research procedures.

2. Does your study meet the federal definition of research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

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). A useful definition of dissemination is that the material will be shared beyond the local setting.

   A. Obvious examples of dissemination are publication in a scholarly journal, presentation at a professional conference, or placement of a report in a library.
   B. Examples that are not dissemination 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.

3. Does your activity involve human subjects?

   A. Is the data being collected through intervention or interaction with the individuals?

   B. Intervention includes both physical procedures by which data are gathered (for example, 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 (45 CFR 46.102(f)) (e.g., surveys, focus groups, interviews).

   C. Does the data contain individually identifiable information? Meaning, the identity of the subject is or may be readily ascertained by the investigator or associated with the information (45 CFR 46.102(f)).
D. Is the information private? Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 45.102(f)).

4. Which form should I use?

A. Exempt Protocol Application: Use the exempt protocol application for research projects that involve minimal risk and fall under one of the exempt categories. Only the IRB Chair or a designated IRB staff member may determine if a protocol can be granted exempt status under the six categories described in 45 CFR 46.101(B). Thus, this category requires initial IRB review, but the study is then exempted from continuing review, unless any changes are made to the protocol.

B. Expedited or Full Board Protocol Application: The same form is used for both expedited and full board review.

5. What criteria is used to determine approval?

In order to grant approval to a research study, the IRB must find and document that the following criteria are met (per 45 CFR 46.116(A)(B)) at the time of initial approval and sustained through continuing review and requests for an amendment:

- Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes;

- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving international research, or vulnerable populations such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

Informed consent will be sought from each prospective participant or the participant’s legally authorized representative, in accordance with, and to the extent required by regulations (or a request to waive or alter the elements of consent must be approved);

Informed consent will be appropriately documented, in accordance with, and to the extent required by regulations;

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants;

When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data (this criterion applies to all studies).

When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, refugees, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

6. Will I need to submit an annual renewal?

Federal regulations (45 CFR 46.109 (E)) require the IRB to conduct a continuing review of expedited and full board research at intervals appropriate to the degree of risk, but not less than once per year. Therefore, a PI is required to submit an annual renewal form for IRB review and approval if the research will continue past the approved protocol’s expiration date. (The expiration date may be less than one year from the protocol’s approval date if the IRB determines an early review is appropriate to the degree of risk.)

There can be no “grace period” for a renewal after the expiration date of the protocol.

7. What if I have an unanticipated problem or adverse event?

It is the responsibility of the Principal Investigator to assess events that occur during the course of a research protocol. Unexpected problems or events whose nature, severity and frequency are not described in the information provided to the IRB or to the subjects must be submitted to the IRB for consideration if they involve risk to the
participants or others and are related to either a research intervention or interaction or to the conduct of the study in general. Examples include, but are not limited to: subject experiences, new scientific findings, unexpected complications, missteps in study procedures, or in consent documentation, or breaches of confidentiality. The PI must determine which of the following descriptions apply. The IRB will review reports and make a final determination, indicating agreement or disagreement with the PI’s assessment, and reasons for the determination.

An adverse event is an event that occurs during the course of the research that either causes physical or psychological harm or increases the risk of such harm or results in a loss of privacy or confidentiality to a research participant or to others. The IRB must determine with the help of the PI if such events are anticipated or unanticipated, and also if they are serious and related to the research.

Adverse Events that occur at the University or at an off-campus study site are required to be reported to the IRB on an adverse event report, within the following time frames:
- If the adverse event is serious and related to the research, it must be reported within two days of the discovery of the event.
- If the adverse event is less serious, it must be reported within five days of the discovery of the event.

8. How long should I keep my study records?
The Federal regulations on human subject protection in research require that all research-related records be retained for at least 3 years after the study has been completed. Individual funding sources, federal or private, may have increased record retention periods; check your funding source for this information.

All research records at the University shall be accessible for inspection and copying.

9. Do I have to attend the IRB meeting when my protocol is reviewed?
No. If the IRB has questions, or believes the investigator(s) could lend valuable insight for review, the IRB may contact the researcher during the meeting. Please be sure that contact numbers on the application are correct.

10. I want to administer my study in a language other than English. What do I do?
All consent documents and instruments must be translated. The IRB must certify that the translated documents translate equivalently in English.
11. I'm working with other researchers on this project. What should I do?  
The IRB will want to know the name of each person on the project. The protocol package on IRBNet should be shared with these researchers and their CITI certificates must be linked to the package being submitted for review.

12. What is CITI training?  
All principal and co-investigators are required to complete the online CITI training course for the protection of human participants in research before the IRB will approve a study. Investigators must renew their training every three years.

13. What happens if my protocol is not approved?  
The Committee will send its comments to you asking for revisions to your protocol. Changes must be submitted to the Committee for its review.

14. My protocol was approved, but now I want to modify it. How do I do that?  
Changes to a research protocol must be reviewed and approved by the IRB prior to their implementation. To submit proposed changes for IRB review, complete an IRB Request for Amendment/Modification for Approved Protocol and submit via IRBNet. Attach new or revised instruments, measures, consent documents, etc., as appropriate. Requests for modifications are reviewed at the same level as the original protocol - i.e., Full Review modifications are reviewed by the Full IRB.