

Understanding Human Subject Research Institutional Review Board

This guidance is written in order to ensure that faculty and students follow the Regis University Human Subjects Institutional Review Board (IRB) Policy. This information will help discern how to develop a project that does not require IRB review or to develop a project involving human subjects which the IRB review may deem exempt. (Exempt DOES NOT mean exempt from IRB review.)

The Office for Human Subjects Protections provides a variety of information that may be useful when dealing with human subjects research: <http://www.hhs.gov/ohrp/>.

I. Important Definitions

Research is defined by the regulations as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to the general base of human knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

To be considered research, the information contributing to the general base of human knowledge **must** be drawn from the results of a systematic investigation of participants. It is vitally important to understand the **GENERAL BASE OF HUMAN KNOWLEDGE**.

The **general base of human knowledge** is the knowledge that is expressed in theories, principles, research findings, and statements of relationships that can be applied to the human experience, populations, or environments. Knowledge gained in this manner may be used to identify patterns leading to further research or theory development, or information that may be disseminated indicating research results and conclusions.

The key elements are **conclusions** drawn from **particulars** such that **theories** or **principles** are derived. In this context, the particulars (data derived from regular observations made according to a specified method) are used to draw conclusions about specific premises (often hypotheses) that guide the overall inquiry. Furthermore, the conclusions drawn are theories or principles which, in the context of research with human participants, should refer to theories or principles about the human condition. That is, the conclusions may (but do not have to) apply to individuals and settings beyond those individuals and settings that were the focus of the inquiry. This type of information is usually disseminated—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. Masters' theses and Ph.D. dissertations are considered to present information contributing to the general base of human knowledge.

The general base of human knowledge is not limited to knowledge derived from quantitative studies. Qualitative studies also contribute to the general base of human knowledge through the use of focus groups, case studies, ethnographies, interviews, or

other means to identify general themes or theories that the reader can choose to transfer to another situation or continue researching.

A student project is considered research if it:

- Is conducted with the intention of drawing conclusions that have some general applicability and,
- uses a commonly accepted scientific method.

A. Understanding Systematic Investigation

- ***Systematic investigation*** attempts to answer research questions (in some research, this would be a hypothesis);
- Is methodologically driven, that is, it collects data or information in an organized & consistent way;
- The data are analyzed in some way, be it quantitative, qualitative, or mixed method;
- Conclusions are drawn or theories are developed from the results.

B. Defining Research with Human Subjects

The first question the IRB faces is whether the activity involves RESEARCH, and second, whether it involves HUMAN SUBJECTS.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through *intervention* or *interaction* with the individual.
 - *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
 - *Interaction* includes communication or interpersonal contact between investigator and subject.

OR

- (2) Identifiable *private information*.
 - *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 subject 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.

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II. Educational Activities that ARE NOT Human Subjects Research

Although all human subjects research requires prior institutional approval, not all data gathering by students constitutes human subjects research. To be research, an activity must be designed with the intent to develop or contribute to the general base of human knowledge. *Clearly, some classroom activities are designed to teach research techniques and have no such intent.*

A. Simulations of human experimentation and course-assigned data collection do not constitute human subjects research if the activities are designed for educational purposes **only**; and

- the data will not be shared outside the classroom (reporting of data within the class is acceptable because the activities were performed solely for classroom learning purposes); and
- the data will not result in a master's thesis, doctoral dissertation, poster session, abstract, other publication or presentation, nor meet capstone requirements; and
- the student volunteers or other participants are clearly informed that the activities are an instructional exercise, and not actual research.
- Data collection for internal departmental, school, college, or other administrative purposes.

B. Service surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or for developing new services or programs for students, employees, or alumni do not constitute human subjects research, as long as privacy of the subjects is protected, the confidentiality of the individual responses are maintained, and survey participation is voluntary. This would include professional societies or University consortia. The data could not be used at a later date for a new study contributing to the general base of human knowledge without IRB review.

- Information - gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves.

- Course - related activities [course work as part of a Master's Thesis, dissertation, degree requirement (capstone project), or other honor's program will not fall under this category] designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement, but are **NOT** intended for use outside the classroom.
- Biographic interviews about a specific individual for historic or publication purposes.
- Quality improvement projects are generally **NOT** considered research unless there is a clear intent to contribute to the general base of human knowledge **AND** use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance: irb@regis.edu. If quality improvement data surfaces from this work that would contribute to the general base of human knowledge, an application must be submitted to the IRB.
- A case presentation which is published and/or presented at national or regional meeting is **NOT** considered research if the case is limited to a description of the clinical features and/or outcomes of a specific patient and does not contribute to the general base of human knowledge. (Investigators should contact the IRB if they are uncertain as to whether or not they are contributing to the general base of human knowledge.)
- Coded private information that is **NOT** collected for the currently proposed projects does not need IRB review as long as the investigator cannot link the coded data back to individual subjects. If the data provider has access to the identity of the subjects (e.g. subject's names, addresses, etc.), the investigator must enter into an agreement with the data provider that states that under no circumstances will the identity of the subjects be released to the investigator. (Investigators cannot independently make this determination. These projects require verification from the IRB Chair or designee.)
- Some examples of non-engagement in research:

When an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research.

III. Educational Activities that ARE Human Subjects Research

If an instructor determines that there is a possibility that a student's proposed research project may result in a formal presentation or publication, he/she should recommend that the student submit the project for IRB review ***before*** beginning the study. There may be instances when a student or instructor wishes to use data for research that was previously collected for educational purposes. An application should be submitted to the IRB when a

student or instructor wishes to analyze the data with the intent of contributing to the general base of human knowledge.

Examples:

- An instructor is surprised at some of the unique findings that appeared when students completed surveys as part of a classroom activity. The instructor would like to do additional analysis on the data and submit it for presentation or publication when the course ends. The instructor's intent has changed and an IRB application is necessary because the instructor will now be analyzing existing data that was collected for a non-research purpose.
- An undergraduate junior Psychology major wishes to conduct research in the hopes of having a publication to list on her application to graduate school. She plans to devise an experiment, enroll subjects, analyze the results, and write a manuscript. This is human subjects research. Prior IRB review and approval is necessary.

IV. How To Get An Exempt Status Review of Human Subjects Research.

The time allowed the student should be considered when discerning how to guide them. These guidelines will help Faculty and Students meet 45CFR46.101(b) **Exempt** status in a more timely manner. However, if the project must go beyond exempt status the approval process for expedited and full board reviews are more time consuming. The amount of time depends on the research and its design.

*How do I get the Human Subjects IRB to grant 45CFR46.101(b) **EXEMPT** status to my project when they review it? (45CFR46.101(b) **Exempt does not mean exempt from IRB Review, it means exempt from full board presentation.**)*

Research is reviewed for 45CFR46.101(b) **Exempt** status by an IRB committee member if it involves very minimal or low risk. There are several **types of research that may qualify for 45CFR46.101(b) Exempt status**. In general, research which does not propose to disrupt or manipulate the normal life experiences of subjects, incorporate any form of intrusive procedures, or involve deception will be exempt from full Committee review. Projects that involve more than very minimal risk, and those that include any degree of deception, **do not** qualify for 45CFR46.101(b) **Exempt** status.

Please note that ***all of the rights and protection afforded to human subjects in research are required in 45CFR46.101(b) Exempt status cases***. Researchers engaged in human subjects research that qualifies for 45CFR46.101(b) **Exempt** status ***must still complete a Regis University IRB Exempt Study application form***. Researchers must engage in practices that minimize risk (physical, mental, emotional, financial, reputation, etc.) maximize benefit, and ensure privacy.

Any research involving protected classes or vulnerable populations of subjects conducted (such as prisoners, pregnant women, children, mentally disabled persons or cognitively impaired persons, terminally ill patients, the elderly, economically or educationally

disadvantaged persons, and survey research that involves HIV or AIDS information either with the general public or with vulnerable populations, research by a faculty member on her/his own students) is *rarely* 45CFR46.101(b) **Exempt** (see 45CFR46.401). Please consult the IRB Chair for clarification on any studies involving children. **Faculty proxies MAY NOT certify studies as 45CFR46.101(b) Exempt if they involve children as research subjects.**

If the project is human subjects research and the PI wants to attempt to have it approved as 45CFR46.101(b) **Exempt** use the categories below when developing the project. **ONLY** research activities in which involvement of human subjects will be in one or more of the categories specified below are eligible to receive 45CFR46.101(b) **Exempt** status certification.

- (A) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (B) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. *Note: According to 45 CFR 46.401, if the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*
- (C) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2 (above) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (D) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (E) Research and demonstration projects which are conducted by, or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in, or

alternatives to, those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- (F) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

V. Guidance on Informed Consent

Consent forms WILL NOT be required of projects that are reviewed by the IRB and determined to be 45CFR46.101(b) *Exempt* projects. However, the IRB strongly recommends that a letter or statement of consent be provided as appropriate to the situation. Survey forms are encouraged to include a statement of consent at the beginning of the form. Interviews or focus groups are encouraged to give a letter of consent to the participants.

Research projects named expedited or full board review MUST utilize consent forms unless a specific exception has been approved by the IRB [45CFR46.116(c & d)]. Please refer to the Regis University policy for the correct consent form template.

A. The following information is given to assist Faculty and Students in the process of development of informed consent:

- (1) A statement that the study involves research, a brief non-technical explanation of the purpose(s) of the research and the expected duration of the subject's participation, a description of the procedures to be followed (including the order in which they take place), and identification of any procedures which are experimental. Identify and distinguish procedures that are being performed solely for research purposes from any activities that would otherwise occur. Include information about audio- or videotaping and/or any records that may be accessed (e.g., educational records). Explain why the subject is being asked to participate in the study (e.g., You are being asked to participate in this research study because...). Provide expected duration of the subject's participation (e.g., time required to complete surveys). Ensure that the proposed time period is realistic for the procedures to be performed;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Discuss the retention or disposition of participants' data/records following conclusion of the research. [Note: Do not interchange the terms "confidential" (i.e., maintained in a way that prevents inadvertent or inappropriate disclosure of participants' identifiable information) and "anonymous" (i.e., identifiers were not collected or have been permanently removed)];
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. Principal Investigator for questions, concerns, or complaints about the study. Include contact information for research staff, as applicable. The person(s) listed should be knowledgeable about the research. Include area code or international dialing codes for phone and fax numbers. Provide IRB contact information for questions about subject rights and as a contact who is not part of the study team for participant concerns or complaints about the research: Example for questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the IRB Chair at Regis University, 3333 Regis Blvd., H4, Denver, CO 80221-1099; 303-964-3616; irb@regis.edu; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Explain payments or other incentives (e.g., class credit) to participate, including amount and schedule of payments. Compensation should be pro-rated (e.g., per session) and not contingent upon study completion. Explain the effect of a subject's decision to withdraw from the research on any compensation. If payments are offered, include the following: **By law, payments to subjects are considered taxable income.**

B. Additional elements to be included as appropriate to the study:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

If you have questions or need guidance, the Office for Human Subjects Protections provides a variety of information you may find useful when dealing with human subjects research. <http://www.hhs.gov/ohrp/>. Also, please feel free to contact the IRB Chair at irb@regis.edu any time you need guidance.

VI. Student Project Involvement with Sensitive Information and Protected Populations

Students **will not** conduct research or surveys with Protected Populations or deal with sensitive information or sensitive subjects without proper faculty oversight and supervision. Student projects in these areas will **only be allowed** when requested and justified by her/his faculty instructor and then approved by the Human Subjects IRB.

What is sensitive information or sensitive subjects?

Research can be considered sensitive if it involves the collection of information in any of the following categories:

- (A) Information relating to sexual attitudes, preferences, or practices;
- (B) Information relating to the use of alcohol, drugs or other addictive products;
- (C) Information pertaining to illegal conduct;
- (D) Information that if released could be damaging to an individual's financial standing, employability, or reputation within the community;
- (E) Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;

- (F) Information pertaining to an individual's psychological well being or mental health.
- (G) Genetic information;
- (H) Information pertaining to the HIV and or AIDS status of an individual;
- (I) Information pertaining to abortion, contraception, and stem cells.

VII. Student Project Involvement with U.S. Military Base and Installations Populations

Regis University respects and obeys the rules and guidelines that our government has put in place to protect its U.S. military populations and the sensitive information that has been entrusted to them. Students **are advised not** to conduct research or surveys involving U.S. military service women and men or any personnel on a U.S. military base because there may not be the time required to complete human subjects research within the time limits of a student's course work.

With a survey or research given involving this population, students will need to provide more documentation so sufficient time will be needed to complete these projects. In this case students will need to provide specific official approval documents. Often this may include a second IRB approval where the base or military installation has its own IRB. Student projects in these areas may be allowed when approved by the faculty advisor and with prior approval of the Human Subjects IRB. Students must make sure there is sufficient time to collect and deliver required documents to the IRB so that a review may be completed.

VIII. What are Protected Populations?

- (A) Children: Persons who have not attained the legal age for consent. When minors obtain age of majority (18 years of age) or are emancipated, they must be reconsented for further participation in the research;
- (B) Prisoners: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to a penal institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing;
- (C) Pregnant women;
- (D) Mentally disabled or cognitively impaired persons;

- (E) Terminally ill patients;
- (F) The elderly;
- (G) Survey research that involves HIV or AIDS information either with the general public or with vulnerable populations;
- (H) Economically or educationally disadvantaged persons;
- (I) Research by faculty member on her/his own students.