DO I NEED IRB APPROVAL FOR THIS RESEARCH?

There is a lot of confusion regarding what kinds of research needs IRB approval. Even within the Federal Regulations there is a fair amount of ambiguity. This handout is meant to assist you with determining whether or not the research project you or your students are doing falls under the caveat of IRB review processes. In order to determine this ask your elf the following?

1. **Is this project a research project as defined by the Federal guideline?**

   **Research** is defined by federal regulation as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR46.102(d)]. “Research” as defined by the Federal Regulations generally does NOT include operational activities such as defined practice activities in public health, medicine, psychology, and social work (e.g. routine investigation and disease monitoring, or routine evaluation of practice interventions in behavioral health). Studies designed to improve practice in business settings (quality improvement), quality assurance, fiscal or program audits, marketing studies, etc. are NOT considered research according to the Federal standards. However, if the intent is to use the findings from these studies to contribute to generalizable knowledge beyond the scope of the agency then the process may be considered research.

   If your project does not fit the definition of research then you do not need to apply for IRB review!

2. **Does your research project involve Human Subjects?**

   **Human Subjects**
   A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR46.102 (f), (1), (2)).

   If you are not collecting data from humans then you do not need to apply to IRB for review.

3. **Is this project resulting in generalizable knowledge?**

   **Generalizable Knowledge** Developing or contributing to generalizable knowledge means that intent or purpose of the systematic investigation is dissemination of findings. Common ways of disseminating results include publishing or presenting.

   To help determine the intent or purpose of the activity ask this question: would this project be conducted as proposed if the principal investigator knew that he or she would never receive any form of academic recognition for the project including publication of
results in a medical journal or presentation of the project at an academic meeting? If the project would remain exactly the same, the activity is likely not research.

**Gray areas:** Quality Improvement (QI) is not considered research if the primary intent of the QI is to inform or improve a local process. However, if your primary intent is to generalize the results outside of your local area the activity is research (umn.edu/irb).

If you project findings are not intended to go beyond the parameters of the specific venue where it was conducted (no publication or presentation beyond the agency/university) then the findings are not considered generalizable and you do not need IRB review.

4. **Is this project considered a systematic investigation?**

   **Systematic investigations** include observational studies, interview or survey studies, group comparison studies, test development, and interventional research.

   **Projects that are not systematic investigations** include oral histories, journalism, phenomenological activities.

   **Gray areas:** Case studies prepared and disseminated for educational purposes are not systematic investigations and therefore are not considered research. If you are unable to prepare the case study report without disclosing information that would make it possible to identify the patient, you must obtain permission from the patient before using their data. Please note the important difference between a case study that is not research and an experimental research study, with an “n-of-1,” (a research study with only one subject) that is human subjects research. Program evaluation may also fall into or out of this definition based on design and intent (umn.edu/irb, 2014).

**A Case Study** is understood to mean the collection and presentation of detailed information about a particular participant or small group, frequently including the accounts of subjects themselves. A form of **qualitative descriptive research,** the case study looks intensely at an individual or small participant pool, drawing conclusions only about that participant or group and only in that specific context. It may involve collecting data about participants using participant and direct observations, interviews, protocols, tests, examinations of records, and collections of writing samples. Case studies may also involve either retrospective or prospective study. A **retrospective case study** looks backwards and examines the incidence of certain factors in relation to an established outcome. A **prospective case study** looks forward and examines a particular individual or case for a particular outcome that may be associated with the presence/absence of relevant factors.
If the project is not a systematic investigation than you do not need IRB review.

If you are unsure of anything always err on the side of caution. In particular if you are working with vulnerable groups as defined by the Federal guidelines (prisoners, pregnant women, people with disabilities, children (defined as anyone under 18) or highly sensitive issues – sexual assault, abuse, victimization, etc. talk to the IRB Chairperson for further direction.

Case Study Projects – Unique Issues

Checklist to Determine Whether Case Study Needs IRB Review

IRB Review of Case Studies: Case studies generally fail to meet the federal definition of research because there is no intent to test a hypothesis via systematic analysis. As a result, case studies generally are not reviewed by the IRB provided that the study (a) does not involve a sensitive topic, (b) is conducted in a manner that protects subjects’ identity, and (c) does not involve at-risk or special populations.

If the case study seeks to use any of the following identifying information study must be submitted to IRB for expedited review (see Privacy Rule [45 CFR46.514(B)(2)])

- Names
- All elements of dates (except year) for dates related to an individual, including birth date, admission date, discharge date, or date of death
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes
- Telephone numbers
- Fax Numbers
- Electronic mail addresses
- Social security number
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
Any other unique identifying number, characteristic or code

Special populations: Exempt studies may not include participants from any of the following protected groups:
- Pregnant women, human fetuses, and neonates [45 CFR 46 Subpart B]
- Prisoners [45 CFR 46 Subpart C]
- Children [45 CFR 46 Subpart D]

IRB Review of “N of one” Studies and Case Series with Data Manipulation and Experimental Treatment: It is noted, however, that an “N of one” trial that uses an experimental treatment on a single subject, or a case series that incorporates levels of data manipulation (statistics) to allow possible extrapolation of the results to a larger population, would satisfy the federal definition of research. As such, these studies must be submitted to IRB for review.

Case Study/Case Series Checklist
This document is intended to assist researchers in assessing whether case studies or case series requires review by the Viterbo University Institutional Review Board (IRB). All items below must be satisfied for case studies to be absolved from submission to IRB. For questions relating to such projects, please contact the current chair of the Institutional Review Board. See IRB website for current chair contact information.

- The project does not involve sensitive topics, confidential information, or identifiers that could place a participant at risk if disclosed.
- The project does not involve persons from vulnerable populations.
- The project does not include data manipulation to include use of statistical methods such as subgroup comparison or compilation of observations in such a manner that might allow for generalization to a larger population.
- The project is a single case study, case series, or multi chart review reporting patient condition, treatment, outcome, or presentation that draws conclusions only about that participant or group and only in that specific context.
- The project is not an experimental intervention (“n of one”).
- The project does not offer incentives to participants (e.g., compensation, free treatments, or diagnostic work).
- The project does not include any added interventions to enhance the case study (additional treatments, diagnostic work, etc.).
- The faculty PI or advisor is fully aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.

Note: material in this section from University of Iowa Human Subjects Office/IRB Office of the Vice President for Research and University of Minnesota IRB.