BENAROYA RESEARCH INSTITUTE
Virginia Mason

BRI Institutional Review Board (IRB)

How to determine if your project is Research or Quality Improvement (QI)

Does your project require IRB oversight?

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How is “research” defined by the Federal regulations?

- A *systematic investigation* (including research development, testing and evaluation) designed to contribute to *generalizable knowledge*. *[Office of Human Research Protections (OHRP) - 45 CFR 46.102(d)]*

- An experiment involving a test article (drug, biologic, device, food or color additive, electronic product) and people who either receive the test article or serve as controls. *[Food and Drug Administration (FDA) - 21_CFR_56.102]*

If your project is “research”, does it involve “human subjects”?

- Human Subject: a living individual about whom an investigator conducting research obtains

  1. data through interaction or intervention with the individual, or

  2. identifiable private information *(i.e. PHI)*

45_CFR_46.102(f)

If your project is “research”, does it involve “human subjects”? (*continued…)*

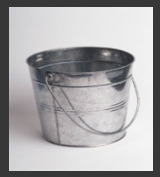
- Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.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

45_CFR_46.102(f)

Is your project "*human subjects research*"?

If your project is "*research*" and involves "*human subjects*", your project requires IRB oversight, but may qualify as "Exempt" from IRB review.

"You're in the bucket, but able to jump out."



Exempt research activities are ones which the only involvement of human subjects must meet one or more of the stipulated categories *45 CFR 46.101(b)*

IRB Exempt categories:

45_CFR_46.101(b)

1. 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.
2. 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 the 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.
3. 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 paragraph (b)(2) 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.

IRB Exempt categories: (*continued…*)

45_CFR_46.101(b)

4. 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 a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. 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.
6. 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.

NOTE: Contact the IRB Office for assistance on possible Exemptions for your project.

What is Quality Improvement (QI)?

- "A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product". *[Source: The Institute of Medicine]*

  - In general, QI projects are aimed at improving local systems of care (non-generalizable). If the intent is to promote "*betterment*" of a process of care, clinical outcome, etc, then the project may be considered quality improvement.

Questions for all activities that may require IRB oversight:

- **Is your activity a *systematic* investigation?**

AND

- **Is the activity designed to develop or *contribute to generalizable knowledge?***

The regulations require an activity that has *both* these features be classified as research and requires IRB oversight. "Having only one of these properties means the activity is ***not*** research and should not be treated as such by the IRB." *

Is your activity a systematic investigation?
45 CFR 46.102(d)

- A systematic investigation is characterized by order and planning; not done haphazard, but in a series of orderly actions *(e.g. randomized trial)*

  - Some form of study design is necessary, usually written in a protocol or study plan.
    - A report of an interesting case or occurrence is not research, because there was no study plan; however, a retrospective review of records looking for patterns meets this criterion for research because it would have a study plan. *(e.g. Retrospective Chart Review)*

Is the activity designed to develop or contribute to generalizable knowledge? *45 CFR 46.102(d)*

- Research is designed to contribute new knowledge to science and society (i.e., generalizable knowledge). The new knowledge may be proving a hypothesis, showing that a drug or device works or reporting on results of certain activities. The knowledge that results from research often drives other research projects, further contributing to science and benefiting society.

- The intent of collecting the information is to learn and apply what is discovered to a wider group of individuals than those included in the study and to publish the results in an outside publication *(e.g. a journal, trade magazine, conference proceedings, or periodical).*

Does my intent to publish alone make it "research"?

- **Per OHRP guidance:** *http://answers.hhs.gov/ohrp/categories/1569*

"If you plan to conduct a quality improvement project and publish the results, does this intent to publish make your Quality Improvement (QI) project fit the regulatory definition of research?

*NO, **the intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.** Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results."*

All "human subjects research" must be reviewed by the IRB *prior* to the conduct of said activity.

- Any project deemed human subjects research must meet BRI IRB requirements for protection of human subjects. Researchers conducting research must also meet HIPAA requirements regarding authorization to use or disclose protected health information. *45_CFR_46*, *http://www.hhs.gov/ocr/privacy/*
  - See the BRI web-site for additional information on submitting a new study: *http://www.benaroyaresearch.org/bri/clinical-investigators*

  NOTE: The IRB cannot retroactively approve any partially or fully completed projects deemed to be "human subjects research".

- Quality Improvement projects ***do not*** require IRB oversight. Project initiators should contact the IRB prior to activity for a determination. VMMC/BRI personnel (including Medical Staff) are allowed by HIPAA to use protected health information (PHI) for Quality Improvement projects without patient authorization.

What are some characteristics of "human subjects research"?

- One of the main goals of the project is to advance general knowledge in the academic, scientific, or professional community.
- The project will have a specific hypothesis or research question(s).
- The project involves an organized review of relevant literature.

What are some characteristics of "human subjects research"? (*continued…)*

- The project will be conducted using a research design that will lead to scientifically valid findings. Elements of a research design include: control groups; random selection of subjects, statistical tests, sample design, etc.
- Most of the patient/subjects are not expected to derive a personal benefit from the knowledge gained.
- One goal of the project is to generate, evaluate or confirm an explanatory theory or conclusion and invite critical appraisal of that conclusion by peers through presentation and debate in public forums.

What are some characteristics of Quality Improvement projects?

- The main goal of the project is to improve patient care, a clinical program or service.
- The project identifies specific services, clinical practices, or clinical processes or outcomes within a department, clinical program or facility for improvement.
- The project team may review available literature, comparative data, clinical programs, or practices at other institutions to design a plan, but do not plan a full scientific literature review.

What are some characteristics of Quality Improvement projects? (*continued…)*

- The project design uses established quality improvement methods aimed at producing change at VMMC/BRI.
- The project design does not include sufficient research design elements to support a scientifically valid finding.
- Most of the patients who participate in the project are expected to benefit from the knowledge gained.
- The project does not impose any risk or burden on the patients.
- Federal regulators have made it clear any publication describing a project as "***research***" should have received prior IRB review and approval. Therefore, *projects determined to be QI initiatives should not be published as "**research**".*

What does the IRB look for when determining if your project is research?

- The "***Primary Intent***" should be clear in the purpose/aim statement for the specific project.
  - If any of the following criteria are met, then the project receives consideration as to whether IRB review is required:
    - Generalizability—if the primary intent of the project is to generate generalizable results.
    - Additional risk or burden—if the project will impose risks or burdens beyond the standard of practice to make the results generalizable.
    - Design—if a project involves randomization or an element that may be considered less than standard of care.

The following examples are NOT human subjects research:

- **Quality Improvement** – Projects aimed at improving local systems of care. The intent is to promote *"betterment"* of a process of care, clinical outcome within the institution.

- **Quality Assessment** – activities that determine whether aspects of medical practice conform to established standards.

- **Quality Assurance** – Process of reviewing, analyzing or evaluating patient or provider specific data that may indicate (the need for) changes in systems or procedures that improve quality of care. The knowledge generated is typically for local, immediate application within the institution.

- **Outcome analysis**: Projects in which medical records are reviewed to evaluate the outcome of medical treatment or the course of patients with a specific medical condition. Results are not compared to an established standard.

The following examples are NOT human subjects research: (*continued…)*

- **Resource utilization review**: Medical record review conducted to evaluate the use of resources in a specific health care activity.
- **Public health practice**: e.g., surveillance (monitoring of diseases) and program evaluation (immunization coverage, or clinical preventive services such as mammography).
- **Education**: transferring information from one group of people to another – i.e., teaching somebody something.
- **Medical practice**: designed to enhance the well-being of a patient or others. Includes ***innovative therapy*** – still designed to benefit an individual patient, but the desired outcome is to some degree unproven. ***Medical practice for the benefit of others*** – donating blood, for example, in which the goal is to benefit a well-defined group of people in a predictable way.

Some of the issues the IRB is seeing:

1. NO definitive plans/summary available *(work in progress)*
2. Project started/completed without IRB oversight or internal IRB determination of QI vs. Research *(run the risk of being rejected for publication)*
3. Sometimes the “intent” of project initiator is uncertain or changes after review *(i.e. they may or may not want it to be considered research)*
4. IRB determines project is “not human subjects research”, however funding agency disagrees.
5. Government or Foundation funding?
   - If research, BRI Grants Department handles submission
   - If non-research, VM Foundation will handle submission

Current Process for Reviewing QI Projects:

What information does the IRB need to determine if a project requires IRB oversight?

1. All related documentation and literature related to project. (e.g. project summary, survey, data collection sheet, detailed description of plan)
2. What is your “intent”? Do you consider this research or would like it to be for the purposes of your grant and/or sponsor?
3. Timeframe when your determination is needed.
4. Has project already been started or completed?
5. Was a determination ever given by VMMC or another entity that IRB oversight was not necessary? If so, this should be included.

BRI IRB SUPPORT STAFF:

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Endnotes

*Amdur, R. J., Speers, M., & Bankert, E. (2006). Identifying intent: Is this project research? In R. J. Amdur & E. A. Bankert (Eds.), Institutional review board management and function (pp. 101-105). Sudbury, MA: Jones and Bartlett Publishers.