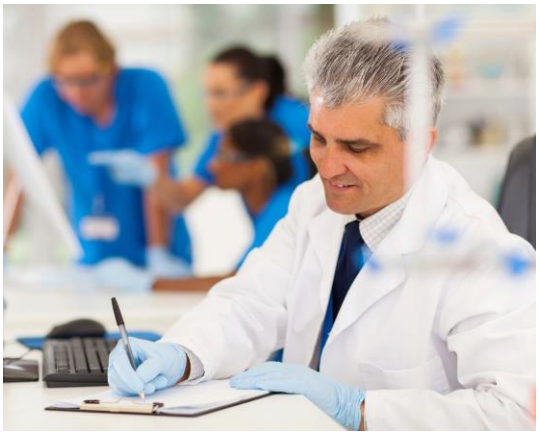
# Institutional Review Board

Academy of Nutrition and Dietetics

### What is an IRB?



An Institutional Review Board (IRB) is a group that reviews and monitors biomedical research involving human subjects. It has the authority to approve, request modification, or disapprove a research project, and continues to monitor its conduct. The IRB's main function is to protect the rights and the welfare of human subjects who participate in research.

### What does the IRB do?

1. Evaluate the ethics of a research proposal.
2. Review research protocols and related materials.
3. Protect the rights and welfare of research subjects.

### Where do you find an IRB?

Large institutions that are involved in research (universities and academic medical centers) generally have an IRB. There are also for-profit IRBs, which may regulate multi-site studies or work with institutions that do not have internal IRBs. Institutions must have agreements with each other in order to be covered under each other's IRB. Check with a compliance official at your institution, the research grants department, or an experienced researcher to find out if your facility has an internal or a cooperating IRB. You may also be interested in partnering with another researcher who is affiliated with an institution that has an IRB.

To find all currently registered IRBs, visit the Office for Human Research Protections Database at:
https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc

### Why do you need IRB approval?

- If you want to publish, you need to show IRB approval, or proof that the IRB determined the project was not research (exempt).
- The IRB is one part of ensuring that research is carried out in an ethical manner that protects your subjects.
- Under Federal Regulations, research projects involving human subjects need to be reviewed by an IRB. Anytime you are asking a research question involving human subjects, you should consider whether IRB approval is needed.

### To decide if IRB approval is needed, answer 2 questions:

1. Is it a Research project? Yes if…
   - It is a systematic investigation that includes research development, testing, and evaluation that may include collecting quantitative or qualitative data using surveys, testing procedures, interviews, or focus groups. Systematic investigation can also include collecting data for clinical trials and observing individual or group behavior.
   - It develops or contributes to generalizable knowledge that is intended to test or to develop scientific theories, hypotheses, or to draw conclusions that are intended to be applied beyond the population that is being studied.
   - Disseminates information beyond the immediate research setting in which it was collected.
2. Does it involve Human Subjects? A human subject is a living individual about whom an investigator obtains:
   - Data through an intervention or an interaction such as surveys, observation, focus groups, etc...
   - Identifiable private information about living individuals

If a project is considered to be research and will involve living human subjects, then it must be reviewed by the IRB. If you aren't sure, it is always better for the IRB to make the determination that it is or is not research or human subjects related. To determine if your research involves human subjects, see *Reference 1, Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?*

### What about quality improvement projects? Do they require IRB approval?

There is a difference between research and quality improvement projects. The Code of Federal Regulations defines research as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[1] Quality improvement, on the other hand, consists of "systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups."[2] The difference between these two activities is the generation of new knowledge that can be generalized to entire populations or settings versus using existing knowledge to improve health care and outcomes for a targeted, local health care institution or setting.[3]

To determine if your research involves human subjects, see *Reference 1., Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?*

### What is the relationship of informed consent to the IRB process?

An informed consent is an educational process that takes place between the investigator and potential study subject to ensure subjects are appropriately informed about the research study and how the research team intends to protect their welfare and information that may be collected. It provides potential subjects with information written in an appropriate reading level and obtains voluntary agreement to participate, usually but not always noted by signature.

It includes -

- Description and procedures of the study.
- Foreseeable level of risks and benefits.
- Alternative procedures are disclosed if they may benefit the subject.
- An explanation of compensation, if it applies, and other medical treatments which are available if an injury occurs.
- Frequently asked questions and answers.
- An explicit description that participation is voluntary and refusal to participate will not involve any penalty or loss of benefits.
- If personal information is collected, the informed consent will detail a plan on how the information collected will be protected.

The IRB reviews and approves your plans for obtaining informed consent.

### The process for IRB review is:

1. The researcher submits an application, informed consent document, data collection form(s), and any materials the subject will see.
2. IRB reviews the study protocol via a full meeting or expedited process, depending on the nature of the research.
3. IRB determines if the study protects the welfare and safety of the subject as presented.
4. IRB requests clarifications or modifications if needed from the researcher.
5. Once the IRB approves, the researcher will be notified, and only then can subjects be enrolled or data collected using only the materials and methods that have been approved.
6. IRB reviews the project annually for the duration of the research, unless otherwise stated.

### What are the types of IRB review?

1. Full—required when the study includes vulnerable subject populations or involves more than minimal risk. Full review requires a meeting of all members of the IRB.
2. Expedited—review is completed by one qualified IRB reviewer rather than requiring a meeting. This is usually granted when the study involves no more than minimal risk to the subject.
3. Exempt—review completed by one qualified IRB reviewer and determines that the study is not on human subjects and is not research. Exempt projects must still be reviewed by the IRB when any protocol changes are made.

**What does the IRB need to review to make their decision?**

- Description of the research including purpose, duration, subjects, and procedures, and all variables to be collected, including exact survey questions.
- Potential risks and benefits to subjects.
- Alternatives to participating.
- How the data will be stored to protect the confidentiality of the data.
- What compensation will be provided, if any.
- Any materials developed to conduct the study including surveys, data collection forms, and recruiting material.

**In addition, the IRB will want to know:**

1. *How are subjects identified and recruited?*

Email? Invitation letter? Study specific advertisement? Are they identified via their medical history?

2. *Who are the subjects?*

A description of the targeted population, including inclusion and exclusion factors, needs to be listed. If a vulnerable population (pregnant women, neonates, children under 18 years, prisoners, minorities, non-English speakers, cognitively impaired) is targeted, additional oversight may be necessary.

3. *How will you comply with HIPAA standards?*

Under the HIPAA privacy rule, an individual's health care and identifiable information are protected. Protected information can be used for research purposes with the subjects' permission or in certain cases with a waiver of HIPAA authorization.

4. *Where and how will the data be stored and for how long?*

Is the data being stored in a paper or electronic format? Is it coded or identifiable? If the storage is electronic, it should be encrypted and password protected. If it is paper, it should be in a locked office. Who will have access to these records?

5. *Who is the funding source for the project?*
6. *Who will be working on the project and what are their roles?*

**How can I pay for IRB review?**

Investigators should plan for and include IRB review costs as a budget line item under the start-up costs for their research project. Refer to the individual IRB's policies on fees for additional information.

**References**

[1] Code of Federal Regulations. Department of Health and Human Services. Effective July 14, 2009. 46.102. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. Accessed 05/16/2019.

[2] US Department of Health and Human Services. Health Resources and Services Administration. Quality Improvement. https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/qualityimprovement.pdf. Accessed 05/16/2019.

[3] Duke University Health System. Quality Improvement Activities in Health Care versus Research. https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/QI%20policy%20and%20checklist.pdf. Accessed 05/16/2019.