

## **DO I NEED IRB APPROVAL FOR MY PROJECT?**

### **What is an Institutional Review Board?**

Institutional Review Boards (IRB) examine research designs and determine if they meet federal regulations that protect human participants in research. The Michigan Department of Community Health (the only state agency IRB board in Michigan) describes their IRB as follows:

“Protecting the rights and welfare of those who participate in research is a fundamental ethical responsibility of the Michigan Department of Community Health Institutional Review Board "IRB". The Department meets this responsibility through an "Assurance of Compliance" with the Department of Health and Human Services regulations for the protection of human research subjects. The regulations are found in 45 CFR Part 46 ("Common Rule") and 21 CFR Parts 50 & 56."

These regulations are based on ethical principles established in the "Belmont Report." The Department's "Assurance of Compliance" applies to all research involving human subjects that in any way involves the Department, and not just to research that is federally funded or otherwise federally sponsored.”<sup>1</sup>

### **How do I know if I need IRB approval of my project?**

- **Is the project research or evaluation?**
  1. Research projects are conducted with the purpose of generalizing the findings to other programs, evaluations do not generalize.
  2. If the project is research, you need an IRB approval. If the project is evaluation, you do not need an IRB approval.
  3. Some projects are not clearly research or evaluation and if submitted to an IRB board, the board will determine which category the project falls into.
- **If you think the project could be research, an IRB can determine if the project meets federal regulations or is exempt from the regulations.**

The Michigan Department of Community Health provides the following guidelines for determining if your project requires IRB review and approval:

“There are two considerations to determine when IRB review is required:

---

<sup>1</sup> [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_32550-99784--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_32550-99784--,00.html)

1. Does the activity involve living humans?

This would include direct involvement (e.g. an intervention or interaction with someone) or indirect involvement (e.g. use of their tissue or personal information).

If living humans are clearly not involved in any way or any part of the activity, IRB review is not required.

2. Is the activity a systematic collection or analysis of data with the intent to generate new knowledge?

If living humans are involved in a systematic collection or analysis of data with the intent to generate new knowledge IRB review is required. The IRB must determine if the activity constitutes human subjects research or human subjects research that is eligible for exemption from approval.”<sup>2</sup>

- **What activities are exempt from federal regulations?**

The United States Department of Health and Human Services provides documentation regarding research activities that are exempt from federal research regulations. These exceptions are below.

“(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (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

---

<sup>2</sup> [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_32550-99784--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_32550-99784--,00.html)

- (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.
  - (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.”<sup>3</sup>
- **Whether your project is classified as research or evaluation, you may still need to examine how treatment data can be used. In general, under 42 CFR Part 2, the court cannot disclose treatment data for any reason unless the participant signs a release that is specific to the source or person receiving the data. There is an exception to this.**

---

<sup>3</sup> <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>

“2.52 - Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research;

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and

(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:

(i) The rights and welfare of patients will be adequately protected; and

(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.”<sup>4</sup>

### **Where do I find an IRB?**

There are a variety of IRBs, including but not limited to, commercial, private, governmental, and university. Any of these IRBs can review a research proposal. Governmental IRBs and university IRBs will usually review a research proposal for free while other IRBs may charge a fee. While cost is a factor when selecting an IRB, it is important to note that IRBs that do not charge a fee are typically large universities or governmental boards and, due to the volume of requests they receive, review of a proposal may take several months. IRBs can be found by contacting local universities or conducting internet searches. Local research consulting companies sometimes have their own IRB or can direct you to the board that they use. The Michigan Department of

---

<sup>4</sup> <http://cfr.vlex.com/vid/2-52-research-activities-19800377>

Community Health's IRB has also indicated that they would be willing to review specialty court research proposals.

### **What is involved in obtaining IRB approval?**

Each IRB has an individualized form that they will require you to submit for their board. However, all boards require some standard information. All boards will require a summary of your research protocol. This is usually a one to three page document describing the study you wish to conduct. If your research requires that participants sign a consent form, the board will need to review and approve the form. If you plan to use questionnaires, surveys, standardized interviews, etc., the board will review and approve the forms. If you solicit participation, the solicitation notice and method will need to be reviewed and approved. Additionally, you will be asked to answer questions regarding your study such as how the data will be stored, what the end product of the research will be, how participants will consent to participate in the research, and how children will give assent to participate.

Under the federal guidelines, there are protected groups of research participants called vulnerable subjects. These participants are:

- Children under the age of 18
- Mentally compromised or decision-impaired persons
- Women with reproductive potential
- Pregnant or lactating women
- Fetuses
- In-vitro fertilization
- Prisoners

If your project involves any of these vulnerable subjects, federal regulations require additional protective measures be taken. The IRB will determine if your proposal sufficiently protects these participants.