# Institutional Review Board (IRB)

## I. History and Background

The following information and links are provided so that persons interested in conducting clinical research will have immediate access to definitions, language, guidelines, and policies as recognized by relevant federal agencies. While accessing and reading this information is not required, it is strongly recommended. The conduct of clinical research is a privilege, not a right; it is incumbent on those engaging in the research process to do so with full knowledge and understanding of the rights, roles and responsibilities of the various parties involved.

### 1. Human Subjects Research Links

- The Belmont Report
- The Nuremberg Code
- Declaration of Helsinki
- Federal Regulations (45 CFR 46)

### 2. FDA Regulations

- Protection of Human Subjects - 21 CFR 50

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Institutional Review Boards - 21 CFR 56

II. General Information Regarding Criteria for IRB Approval of Research

All research that involves human subjects is subject to IRB review. Only an IRB Compliance Officer,Cchair or other Designated Institutional Official can defer a research proposal from review. Researchers should not make this determination; instead, all research should be submitted to the IRB for review and consideration.

Review Categories:

There are three levels of IRB review: Exempt, Expedited, and Full committee review. Additional information/explanation of these categories is given below. Note that the level of review that is titled Exempt does not mean that the proposed research is exempt from being reviewed (or submitted to the IRB). Instead, it is one of three possible levels of review to which research is assigned, and this assignment is made by an IRB official.

1. Exempt Level of Review

There are six specific categories of research that qualify for exempt status (for details, refer to Code of Federal Regulations. Title 45 Public Welfare. DHHS. Part 46. Protection of Human Subjects. Subpart A, Section 46.101 (b)). Typically, studies that qualify for Exempt status (1) involve no more than minimal risk, (2) do not include protected populations (pregnant women, prisoners, minors, institutionalized patients, and/or fetuses) and (3) preclude the gathering or use of identifiable information. Some IRBs expand the list of protected populations to include mentally impaired persons, persons unable to legally consent, and homeless persons.

Studies that qualify for Exempt status must meet at least one of the following categories:

1. Normal educational practices and settings

2. Anonymous educational tests, surveys, interviews, or observations

3. Identifiable subjects in special circumstances

4. Collection or study of existing data

5. Public benefit or service programs

6. Taste and food evaluation and acceptance studies

2. Expedited Level of Review

This type of review is reserved for studies that involve no more than minimal risk. Such reviews can be conducted by the following persons or a combination of these persons: IRB Chair, IRB members designated by the Chair, or a subcommittee of the IRB. 45 CFR 46 §46.102 defines minimal risk as follows: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during performance of routine physical or psychological examinations or tests.”

3. Full Committee Review

Other than those specifically listed above (studies that qualify for Exempt and Expedited levels of review), all research studies are subject to a full committee review. Principal Investigators may be asked to present their studies to the full IRB Board should their study be deemed Full Committee Review.

III. General IRB Instructions and Routing

OU-COM Medical Students and CORE Interns and Residents should contact the CORE Research Office (coreresearch@oucom.ohiou.edu , (740) 593-2380) regarding research projects and navigation.

Doctors Hospital investigators should proceed with the following:

a. Please complete and submit the Research Registration Form for each and every project you are involved with. This simple step will register your research with the Department of Research and Education.

b. In most cases, you will be required to complete IRB training. OhioHealth currently asks those invovled with clinical research to complete the CITI IRB training course Please contact the Department of Research and Education for assistance.

c. Typically, factors that will determine the requisite IRB path for your research include:

- Location of the proposed research project (hospital, private office, campus, etc.)
- Type of study beign proposed (retrospective, prospective, meta-analysis, etc.)
- Number and location of all research sites

d. Please do NOT submit research materials directly to your hospital’s IRB without first contacting the Department of Research and Education at (614) 566-8023.