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IRB Process

The What and How of an IRB Review
GW Fall IRB Days
September 15-17, 2015

Overview

- Brief regulatory review
- Determining engagement
- IRB review types
- Criteria of Approval
- Breakout Sessions

Why is IRB Approval Important and How Does it Benefit Me?

- Opportunity for an objective look at research;
- Demonstrates to subjects that the investigator has taken appropriate measures ensuring their protection;
- Makes publishing possible- demonstration of IRB approval may be requested prior to publication.

The Belmont Report

- Published by the National Commission, 1979, the Belmont Report was written for the Protection of Human Subjects of Biomedical and Behavioral Research;
- Established three basic ethical principles that are at the crux of regulations for human research:
 - Respect for Persons
 - Beneficence
 - Justice

The Belmont Report

RESPECT FOR PERSONS:

Treat individuals as autonomous agents and provide additional protections for those with diminished autonomy

Participation in research must be voluntary and informed (comprehended)

INFORMED CONSENT PROCESS

BENEFICENCE:

“Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being”

Avoid harm to the extent possible by minimizing risks and maximizing benefits

Ensure that overall risks to study subjects do not outweigh the benefit to subject and to society

MINIMIZATION OF RISKS

JUSTICE:

Selection of subjects is for reasons of science, related to the purpose of the study

Fair distribution of benefits and burdens of research across society

Equitable selection of subjects

RECRUITMENT PROCESS & ELIGIBILITY CRITERIA

Informed Consent

- Must be prospectively obtained;
- Begins at recruitment;
- Should be a conversation between the person obtaining consent and the potential subject. This conversation should address all questions and concerns the subject may have regarding the research;
- Consent is a process- not a piece of paper. It does not end with the subject's signature, but must be reassessed during the course of the subject's participation in the study.

Vulnerable Populations

- Considered vulnerable by federal regulations:
 - Pregnant women or fetuses
 - Children
 - Prisoners
- Other groups to consider:
 - Cognitively impaired (older adults, TBI, mentally ill)
 - Educationally/economically disadvantaged
 - Non-English Speakers
 - Employees/students
 - Patients
 - Military

Risks in Research

- Defining and identifying risks (CABLES)
 - Cognitive/Psychological
 - Affective
 - Biological/Physical
 - Legal
 - Economic/Financial
 - Social
- Risk Assessment
 - Probability, frequency, magnitude of harm
- Plan to Minimize Risk
 - Study designed to minimize risk to subjects
- Monitoring Risks
 - Risks to subjects are proactively monitored and minimized for duration of research

How to Minimize Risk

- Develop studies and instruments that minimize the collection of information that could put a subject at risk. Want vs. Need;
- Minimize the use of identifying information (names, email addresses, phone numbers, etc.);
- In publications, providing too much information could lead to a possible identification of subjects. Try to focus on methods and results;
- Have a plan to maintain the subject's privacy and confidentiality of the study documents;
- Have a plan to refer subjects for help depending upon the study type and population you are working with.

Making a Determination of Engagement

Does Your Study Require IRB Review?

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Making a Determination

Q#1: Is it Research?

- A systematic investigation designed to develop or contribute to generalizable knowledge (including research development, testing and evaluation) 45 CFR 46.102(d)
 - Systematized - Having or involving a system, method, or plan
 - Investigation - Testing an hypothesis and permitting conclusions to be drawn (i.e., detailed, careful examination)
- Intended to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)
 - Publishing or presenting the results at a conference

Q#2: Does the Research Involve Human Subjects?

- A human subject is a living individual about whom an investigator conducting research obtains 45 CFR 46.102(f):
 - data through intervention or interaction with the individual;
 - OR
 - identifiable private information

Identifiable Private Information

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code;
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

What is and What is not Human Subjects Research (HSR)?

Not HSR

- Quality Assurance Project
- Project for Program Evaluation
- Oral history/Life Stories
- A Case Study
- Secondary/Aggregate data analysis only
- Class assignment/project only
- Research with deceased persons data

HSR

- Qualitative research
- Quantitative research
- Multiple or comparative case studies
- Projects involving experimental design and/or randomization
- Surveys, interviews asking about thoughts, opinions, feelings, etc.

Categories of Review and What They Mean

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Human Subjects Research Review: Categories

- Risk Level
- Determination involves the population being studied and the study procedures
- Level of risk will dictate the review category
- Review Categories
 - Exempt: Less than minimal risk to subjects
 - Expedited: Minimal risk to subjects
 - Full Board: Greater than minimal risk
- Minimal Risk means the probability and magnitude of discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102 (i)]

Exempt [45CFR 46.101(b)]

- Exempt from federal regulations. Only IRB can make this final determination;
- Requires registration only prior to implementation;
- Note that certain vulnerable populations cannot be included in this category (any prisoners and children with certain exceptions);
- Must meet one of the exempt research categories:
 - Research in educational settings
 - Educational testing, surveys, interviews or observation of public behavior
 - Research involving elected public officials
 - Research involving existing data (*retrospective only*)
 - Demonstration projects
 - Taste of food quality evaluation

Expedited Categories

[Federal Register: November 9, 1998 (Volume 63, Number 216)]

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required; (b) research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

Expedited Categories Cont'd

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Categories Cont'd

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Criteria of Approval

45CFR46.111

- Risk to subjects are minimized
- Favorable risk/benefit ratio
- Selection of subjects is equitable
- Informed consent will be obtained from each subject
- Informed consent will be appropriately documented
- Adequate provisions for monitoring of the data collected to ensure subject safety
- Adequate provisions to protect the privacy of subjects and to maintain confidentiality
- Additional safeguards in place for vulnerable populations

Review Process

- For any category of human subjects research, the following process occurs:
 - Once a study is submitted in its entirety, it is assigned to an OHR Staff member for preliminary review;
 - The OHR staff will contact the PI and primary contact with questions and clarifications about the study;
 - Once satisfactory, the study is forwarded for formal review either by a full committee review or a designee. Formal review may result in additional questions or stipulations;
 - When any stipulations are resolved, final approval is issued.

Breakout Session

Breakout Session for
Students and PIs to speak with OHR Staff

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Questions?

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