IRB 101: Levels of IRB Review & Starting the IRB Submission Process

WVU Office of Human Research Protections
Human Research Protections Program
The Belmont Report - Guiding Principles

// Respect for Persons
// Participants are autonomous; must protect those with diminished autonomy

// Beneficence
// “Golden Rule”

// Justice
// Burden of risk is equal among those who will benefit

The Common Rule

The regulations found at 45 CFR part 46 are based in large part on the Belmont Report and were written to offer basic protections to human subjects involved in both biomedical and behavioral research conducted or supported by HHS. ¹

In 1991, 14 other Federal departments and agencies joined HHS in adopting a uniform set of rules for the protection of human subjects, identical to subpart A of 45 CFR part 46 of the HHS regulations. This uniform set of regulations is the Federal Policy for the Protection of Human Subjects, informally known as the “Common Rule.” ¹

3 additional subparts

- Subpart B – pregnant women, fetuses, neonates
- Subpart C – prisoners
- Subpart D – children

Levels of IRB Review
IRB Responsibility & Authority

**Responsibility**
- Review of any Human Subjects Research conducted by or under the auspices of *any* WVU faculty, student, or staff
  - Louis A. Johnson Veterans Affairs Medical Center
  - WVU affiliate sites

**Authority**
- Require review
  - Submissions can be made in the [WVU+kc](#) system
- Approve, disapprove, or require modifications for approval
- Conduct continuing reviews
- Observe/verify changes and methods
- Suspend or terminate approval
What is Human Subjects Research?

Definitions

Must be Research

Systematic investigation design to contribute to generalizable knowledge

Must involve living individual(s) about whom an investigator, conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, analyzes the information or specimen
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
Levels of IRB Review

- Flex\Non-Human Subjects Research (NHSR)
- Exempt
- Expedited
- Full Board
- Clinical Trials and Non-Clinical Trials
Flex- Not Human Subjects Research (NHSR)

Protocol submission type in WVU+kc meant to register and confirm that the research doesn’t involve human subjects

In the Questionnaire - the first section is meant to determine if the research meets the definitions of research and human subjects

If one of these questions are answered with ‘no’ then the study may be NHSR
Examples of Not Human Subjects Research

- Most case reports
- Oral histories
- Classroom projects (if not intended for publication)
- Quality Improvement projects
Exempt Review
Exempt Review

Some human subjects research is exempt from IRB review by 21 CFR §56.104 and 45 CFR §46.101(b)(2)

6 distinct categories for exemption

If determine to qualify as exempt, the research must be reviewed and conducted in accordance with:
- WVU policies/procedures
- The Federalwide Assurance
- Federal guidelines
- Ethical principals in the Belmont Report

General Requirements:
- Must clearly explain why the research is no more than minimal risk
- If the investigator interacts or intervenes, it cannot be exempt
Exempt Category 1

**Regulation**

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - Research on regular and special education instructional strategies
  - Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods

**WVU Expectations**

- The study must look at standard teaching techniques, not new or experimental strategies or techniques.
- It can compare two standard teaching strategies, by observing the teacher or looking at papers or tests that would be part of the standard curriculum of the class.
- **No** interaction with minors on an exempt category 1 study.
Exempt Category 2

Regulation

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- Any disclosure of the human subjects’ responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

WVU Expectations

- **No** interaction with minors.
- ‘Public behavior’ does not include classroom observations
- Results should not be identifiable
- Investigator should submit all surveys, tests, recruitment material for review
- Cover Letter

*If sensitive topics are covered:

- A clear explanation of how anonymity will be ensured (if promised)
- Counseling services list should be provided
Exempt Category 3

Regulation

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:

- The human subjects are elect or appointed public officials or candidates for public office; or
- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

WVU Expectations

No interaction with minors.

No interaction between the observer and the persons (groups) being observed.
Exempt Category 4

Regulation

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.

WVU Expectations

- Specify the time range of when documents were collected
  - No prospective collection
- A HIPAA Waiver is required if any medical information is being reviewed
- If identifiers are recorded at any time, or if the data is coded, the study is not eligible for exemption
- A list of variables being recorded must be submitted
Exempt Category 5

Regulation

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:

- Public benefit/service program
- Procedures for obtaining benefits/services under those programs
- Possible changes in or alternatives to those programs/procedures
- Possible changes in methods of payment for benefits/services under those programs

WVU Expectations

- Specify the public benefit or service program
- Specify what about the program is being evaluated
- Project is subject to the approval of a Federal Department or Agency head
Exempt Category 6

Regulation

Taste and food quality evaluation and consumer acceptance studies:
- If wholesome foods without additives are consumed; or
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe for agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protections Agency or the Food Safety and Inspection Service of the U.S. Dept. of Agriculture

WVU Expectations

Specify the food to be consumed, where it will be done, and any additives that are in the food.
Exempt Research & Children

Children can be subjects unless the research involves the use of survey or interview procedures.

Observation of public behavior involving children can be exempt only if the investigator(s) does not participate in the activity being observed.

Example: Observing children’s behaviors with each other at a public playground.
Expedited Review
Expedited Review

Expedited submission must be reviewed by the IRB

- Requires one or more experienced IRB reviewers
- Does not require a convened IRB review

7 commonly used expedited categories

General Requirements:

- Must be no more than minimal risk to subjects
- Identification of participants will not place them at risk of criminal or civil liability or be otherwise damaging
- Informed Consent must be sought or justification for a waiver of consent should be provided
Expedited Category 1

Regulation
Clinical studies of drugs and medical devised only when condition (a) or (b) is met:

a) Research on drugs for which an investigational new drug application is not required
   i. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for expedited review

b) Research on medical devices for which:
   i. An investigational device exemption application is not required; or
   ii. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its clear/approved labeling

WVU Expectations
The WVU IRB determined that any research that involves the use of a drug, whether FDA approved or not, must be reviewed at a convened full board IRB meeting
Expedited Category 2

Regulation
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  
a) From healthy, non-pregnant adults who weigh at least 110 lbs. 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 or children, considering age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it is collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8 week period and collection may not occur more frequently than 2 times per week.
Expedited Category 3

Regulation

Prospective collection of biological specimens for research purposes by noninvasive means
- Hair and nail clippings
- Teeth (standard of care)
- Saliva

WVU Expectations

Collection methods not involving general anesthesia or sedation
- Approval from the Institutional Biosafety Committee (IBC) is required
Expedited Category 4

Regulation

Collection of data through non-invasive 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.

Safety and effectiveness of an approved medical device are generally not eligible.

WVU Expectations

Physical exercise and some physical measures are included in this category.
Expedited Category 5

Regulation

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis)

Some research in this category may be exempt form the HHS regulations. This only refers to research not exempt.

WVU Expectations

Normally used with medical chart reviews

A HIPAA Waiver and variable list should be submitted
Expedited Category 6

Regulation

Collection of data from voice, video, digital, or image recordings
Expedited Category 7

**Regulation**
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, 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

**WVU Expectations**
- Typically involves a pre/post test interaction with subjects
- Consent form should be submitted
- All surveys should be submitted
Common Questions about IRB Submissions
Research Advertisements

Required Elements of an Advertisement

- Clearly state that it is research
- Does not imply a certainty of favorable outcome or other benefits
- Does not include exculpatory language
- Does not emphasize the payment or amount to be paid
- The purpose of the research is clear
- Eligibility criteria are clearly summarized
- Statement that the subjects are being audio/video recorded and that the recordings will be destroyed after the study (if applicable)
- Benefits are succinct
- Time commitment for participation is clear
- Location of research is provided
- Name, address, and email of the investigator’s department are provided (Letterhead)
- Contact person and method provided
- States that WVU IRB approval is on file
Informing Participants - Consent Forms/Procedures

**Signed Informed Consent**
- Used when the participant will be informed of the study and physically sign an informed consent form.
- Should be done when in-person research is conducted.

**Waiver of Informed Consent**
- Used when the participant will not be informed of the study and they will not physically sign an informed consent form.
- Justification as to why the research is minimal risk to the participants must be provided in the submission.

**Waiver of Documentation of Consent**
- Used when the participant will be informed of the study but will not physically sign an informed consent form.
- Typically requested when conducting online surveys.
Informing Participants – Cover Letters

Used most commonly in survey or interview studies instead of receiving signed informed consent

Required Elements of a Cover Letter

- Should be on the PI’s department letterhead
- Statement that the research has been reviewed and acknowledged by the WVU IRB
- Statement that the research is in partial fulfillment of a course, thesis, etc. (if applicable)
- Purpose of the study
- Inclusion criteria
- Statement of anonymity or confidentiality
- Statement that the subjects is being audio/video recorded and that the recordings will be destroyed after the study (if applicable)
- Statement that subjects don’t need to answer every question
- Statement of the time commitment to participate
- Statement of voluntary participation
- Optional counseling services (if applicable)
HIPAA Waiver

- The use/disclosure of protected health information (PHI) must involve no more than minimal risk to privacy

- Completed form must be attached with protocol submission

Include the following in the protocol submission

- Plan to protect the identifiers from improper use
- Plan to destroy identifiers at the earliest opportunity
- Must be written assurances that PHI will not be reused/disclosed, except as required by law
- Statement explaining why research could not practically be conducted without the waiver
- Statement about why the research could not practically be conducted without accessing the PHI
Starting the IRB Process
CITI Ethics Training

Course requirements can be found on the IRB Training page. Use the login button on this page to link CITI to WVU+kc.

Any WVU personnel listed on an IRB protocol must take one of the following:

- Biomedical Research Investigators OR Social & Behavioral Research Investigators course. The title of the completed course should match these options.
- The Human Subjects Research training(s) are found under “Question 3: Human Subject Research (IRB)” of the ‘Add a Course’ link on the homepage, after logging into CITI.

Principal Investigators (PI) and Co-Investigators (Co-I) must complete:

- Conflicts of Interest training.
- The Conflict of Interest training course is found under “Question 2: Conflict of Interest” of the ‘Add a Course’ link on the homepage, after logging into CITI.
Requesting KC Permissions

Before you can create an IRB protocol in WVU+kc, you will need to be granted the appropriate role to do so.

Submit a request to Information Technology Services (ITS) to request IRB protocol creator access.

This training video explains how to submit a protocol, create and submit amendments/renewals, search for protocols, and other various functions of the IRB Protocol module of WVU+kc.
WVU+kc Requests

Request access or assistance for IRB Protocols, Internal Grants and Proposals.

Please select the type of request or issue you have *
- I need access to WVU+kc
- I need assistance using WVU+kc
- Other WVU+kc request

WVU+kc Access Information
Proposal (KC Blue Sheet) Access: Request to create and submit external funding proposals to the Office of Sponsored Programs for institutional review.

IRB Protocol Access: Request to create and submit human subject research protocols to the WVU Institutional Review board (IRB) for review via WVU+kc.

What type of access do you need? *
- I need to submit a proposal (KC Blue Sheet)
- I need to submit an IRB Protocol

Please enter your WVU email address *

Request
IRB Protocol Guidance

// KC Test (https://kualtest.wvu.edu/kc/portal.do?selectedTab=portalDashBoardBody)

Guidance documents can be found on the IRB Guidance page of the ORIC website (https://oric.research.wvu.edu/services/human-subjects/irb-checklists-guidance)

Templates for consent forms and waivers can be found on the IRB Forms page of the ORIC website (https://oric.research.wvu.edu/services/human-subjects/forms)
Questions?
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