



This document is intended for investigators and coordinators who are creating an Exempt protocols for submission to the WVU IRB for review. This guidance document will present the current regulations ([§46.101](#)), followed by a brief summary of the WVU IRB expectations and steps that are taken to ensure the protection of human subjects in research. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

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Requesting WVU+kc Access

Anyone who needs to create or edit an IRB protocol needs to request access from ITS. To submit the request, please follow the steps under the *Training* section of the [WVU+kc page](#) of the ORIC website. There will be a short tutorial video on how to use and navigate the electronic submission system. **It is highly recommended that new users watch this video.**

CITI Training Requirements

Anyone listed on the study, regardless of his/her assigned role, must complete one of the following courses in Human Subjects Research:

1. Biomedical Research Investigators (Human Subjects Research)
2. Social and Behavioral Research Investigators (Human Subjects Research)

Note: Abbreviated or Responsible Conduct of Research (RCR) versions of the biomedical or social and behavioral courses cannot be accepted.

Only Primary and Co-Investigators are required to complete the following course, in addition to the training listed above:

3. Conflict of Interest

Exempt Category 1

Regulation

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

WVU IRB Expectations for Exempt Category 1

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. There can be no interaction with children (anyone under 17) 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:

- i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- 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.

WVU IRB Expectations for Exempt Category 2

Children (ages 7 – 17) cannot be involved in research that involves interaction with the researcher or the study team. Procedures should be limited to educational tests (administered by their teacher) or the observation of public behavior. Public behavior does not include classroom observations. Participants, even those 18 or older, cannot be identified (either directly or indirectly). If participants can be identified, the information that is recorded as part of the research cannot reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, or reputation.

The investigator must submit a copy of all surveys, educational tests, survey scripts, and recruitment material that will be provided to the participants. Also, a clear explanation of what information is being recorded and how it is being done.

Any survey, interview, or focus group study must be accompanied by a cover letter (see the template on oric.research.wvu.edu under forms). The cover letter needs to be edited for the study and added to the attachments. WVU feels that cover letters suffice for exempt studies making the use of consent form and signatures unnecessary.

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)[Exempt Category 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.

WVU IRB Expectations for Exempt Category 3

There may be 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 IRB Expectations for Exempt Category 4

When submitting a protocol for category 4, please give the time range of when the documents were collected, e.g. all medical records for diabetics seen at the clinic between 2014 and May, 2017. Be aware that a [HIPAA Waiver](#) is required if any medical information is being reviewed. If medical information is being recorded or a code is being used to match the record with the data, the study cannot be exempt; but it is more likely to qualify as an expedited category 5 study. A variable list will be required in the attachments. The answer to Confidentiality when looking at medical records, or specimens or other existing data is 'yes' because the data is identifiable even if it recorded without identifiers.

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:

- 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.

WVU IRB Expectations for Exempt Category 5

There should be a statement making it clear that this is a public benefit or service program and what is being evaluated.

Exempt Category 6

Regulation

Taste and food quality evaluation and consumer acceptance studies:

- i. If wholesome foods without additives are consumed; or
- ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

WVU IRB Expectations for Exempt Category 6

Please be clear where the food is being consumed and by whom.