

Institutional Review Board (IRB) Policy and Procedure Manual

Part I: Overview

A. Purpose Statement:

The purpose of this Institutional Review Board is to protect the rights and welfare of human research subjects recruited to participate in research, and to ensure compliance with applicable IU guidelines and federal regulations.

The IU Kokomo Institutional Review Board will assess suspected or alleged protocol violations, subject complaints, or violations of external regulations or university regulations. Such incidents may be referred to the Vice Chancellor for Academic Affairs, if appropriate. The IU Kokomo Institutional Review Board has the authority to suspend or terminate approval of research that is not conducted in accord with Institutional Review Board requirements or poses serious harm to subjects.

Indiana University (IU) and Clarian Health Partners (CHP) hold a joint Federal-Wide Assurance (FWA) with the Department of Health and Human Services (DHHS) for the Protection of Human Subjects in Research. This is a formal agreement between the University and the federal government that commits these institutions to comply with applicable regulations governing the conduct of research involving human subjects. Further, the FWA stipulates the procedures that will be followed to ensure compliance. This document may be reviewed on the Web (see left sidebar for link).

The National Institutes of Health Office for Human Research Protections (OHRP) provides guidance and educational materials for Institutional Research Boards and is located on the Web (see left sidebar for link).

B. Scope of Policy and Procedures

The IU Kokomo Institutional Review Board is an Institutional Review Board for Indiana University and is responsible for the review and approval of research involving human subjects conducted under the auspices of IU Kokomo. The IU Kokomo Institutional Review Board is not involved in certain types of research, such as research involving radiation or biomedical research.

When a research situation arises at IU Kokomo that is not adequately addressed with the local policies and procedures, the federal regulations and the relevant policy/procedure from IUPUI shall be used as a guide; and where appropriate the advice of experts shall be sought. Research that falls under the category of biomedical research or radiation research shall be forwarded to the appropriate IRB at IUPUI for their review.

Part II

Policy A, Numbers 1 & 2

Guidelines for Determining Whether to Submit a Proposal to the Institutional Review Board

1. Definition of Research with Human Subjects

All research that involves human subject conducted under the auspices of IU Kokomo must be reviewed and approved by the IU Kokomo Institutional Review Board. This includes all research categories defined in the regulations that would qualify for exempt, expedited, or full review, regardless of funding source.

The DHHS defines *research* as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Human subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Intervention includes “both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.”

2. Student Projects

Some student projects require Institutional Review Board review. However, classroom assignments that do not involve risk, and are not intended to, nor likely to lead to generalizable results, may not need to be reviewed.

Student studies that fit ANY of the descriptions below must be reviewed:

- A. Student projects that may place subjects at
- B. Student projects that are undertaken with the intent of adding to generalizable knowledge,
 - a. including ANY public presentation beyond the classroom type setting
 - b. including funded studies
 - c. including written presentation beyond the classroom/peer setting
- C. Student studies that are undertaken involving special populations including pregnant women, fetuses, prisoners, minors, or human in vitro fertilization.

Instructors are responsible for screening individual student research projects and making an initial determination as to whether the project may fall in the category of research. Institutional Review Board approval must be obtained prior to initiation of the research.

Policy B Review Schedule

Exempt proposals and most amendments and continuing reviews are reviewed weekly by a member of the Institutional Review Board. Applications must be received by **3:00 p.m. on Monday** in order to be reviewed within 7 working days.

Expedited proposals are reviewed weekly by two assigned faculty reviewers. Applications must be received by **3:00 pm on Monday** in order to be reviewed within 7 working days.

The Institutional Review Board meets monthly to review those projects requiring full review, according to the posted schedule. Applications must be received at least **two weeks** before the month's meeting, in order to be reviewed that month.

Investigators should allow sufficient time for review prior to the beginning date of the project. While projects are reviewed frequently, the entire process can take up to 4 weeks. Projects that require full Board review may take longer.

If it is determined your application requires full review and it has been submitted after the stated date, it will be held for the next month's meeting.

Current Full Committee Submission Deadline and [Meeting Dates](#) are posted on the IRB Website on a semester basis and are available through the Office of Research and Sponsored Programs at IU Kokomo (455-9205).

Policy C Numbers 1, 2, 3 Submission Guidelines For All New Studies

Policy C Number 1

The principal investigator is responsible for preparing a proposal for Institutional Review Board review prior to initiation of research, and is advised to allow adequate lead time for the Institutional Review Board process, since it is not uncommon to be required to amend some aspects of the proposal to bring it in line with federal regulations prior to approval.

1. The principal investigator (PI) and all co-investigators must review the educational material on the Web and satisfactorily complete the research with human subjects test. A copy (ies) of the verification of a passing test score will be required prior to Institutional Review Board approval. Doing this and forwarding verification along with other materials FIRST will alert the PI to issues that will need to be addressed in the proposal (see left sidebar for link).
2. The principal investigator should carefully assess the proposed research with regard to whether it best fits as exempt, expedited, or full committee review (see left sidebar for link). The Institutional Review Board will make the final determination about the appropriate level of review. In cases where the level of review is in question, the higher level of review will be required by the IU Kokomo Institutional Review Board.
3. The PI should prepare the following materials which are available on the Web at the following address: <http://www.iuk.edu/academics/research/humansubjects/main.html> for consideration of the Institutional Review Board:
 - Verification of Passing the Research With Human Subjects Test
 - Documentation of Review and Approval (DRA)
 - Checklist for Appropriate Level of Review (exempt, expedited, or full)
 - Summary Safeguard Statement (or Exempt Research Statement)
 - Informed Consent(s)
 - Copies of instruments, questionnaires, letters
 - Other as appropriate: package insert, letters of cooperation, HIPAA checklist, assent document

Policy C Number 2 Exempt, Expedited, and Full Review Criteria

Exempt Studies: These are studies that are exempt from Institutional Review Board review. The application must demonstrate:

1. **The research is minimal risk, and**
2. **Fits into one of the exempt categories:**
 - a. Research on instructional strategies that is conducted in established or commonly accepted educational settings;
 - b. Research (except research with minors) including the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior;
 - c. Research involving the collection or use of existing data, if these sources are publicly available, or the information is recorded by an investigator in such a manner that subjects cannot be identified;
 - d. Research and demonstration projects, which are conducted by or subject to the approval of Department or Agency heads;
 - e. Taste and food quality evaluation and consumer acceptance studies, if
 - Wholesome food without additives, or
 - 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 FDA, or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Studies: These studies may be reviewed by the Institutional Review Board through expedited review procedures. The application form must demonstrate:

1. **No more than minimal risk to subjects, and**
2. **Involve only procedures listed in one or more of the following categories:**
 - a. Collection of hair and nail samples
 - b. Collection of excreta and external secretion
 - c. Recording of data from subject 18 years of age or older using non-invasive procedures
 - d. Collection of blood samples in minimal amounts
 - e. Collection of dental plaque and calculus
 - f. Voice recording
 - g. Moderate exercise by healthy volunteers
 - h. Study of existing data
 - i. Research on an individual or group behavior that involves no manipulation of the subjects and is not stressful; and
 - j. Certain kinds of research on drugs and devices

Note: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research setting is not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

Full Review Studies: These studies either involve more than minimal risk and/or are being conducted with vulnerable populations.

1. **More than minimal risk to subjects, and/or**
2. **Research conducted with certain vulnerable populations**

Examples:

- a. Certain types of research with children, pregnant women, fetuses, and other vulnerable populations
- b. Research involving prisoners
- c. Research that involves experimental drugs or devices
- d. Research that involves invasive procedures
- e. Survey research that involves sensitive questions or is likely to be stressful for the subject.

Note: More detail regarding categorization is available (see left sidebar for link to the OHRP).

Policy C Number 3 Informed Consent Guidelines

The Informed Consent is one of the primary ethical responsibilities of the researcher, and it protects both the research subject and the researcher.

The Informed Consent should be written in language that is understandable to the subjects. When research involves individuals who are not able to provide an informed consent (such as minors), informed consent from a legally responsible party should be obtained. In such situations, the best practice is to also use an assent document.

The following should be included in the Informed Consent:

1. Heading: "IU Kokomo Informed Consent Statement," Title of Research, Number the Pages.
2. Invitation to participate: "You are invited to participate in a research study..."
3. Explanation of the purpose of the study.
4. Expected duration of the subject's participation.
5. Approximate number of subjects involved in the study.
6. Description of procedures to be followed. Identification of any experimental procedures.
7. Description of any reasonable foreseeable risks, discomforts or side effects to the subject.
8. Safeguards to be used to minimize the risks, discomforts or side effects.
9. Statement of anticipated benefits to the subject. **Separate** statement including any possible compensation for participation and terms (e.g. if subject withdraws, when compensation is earned etc).
10. Disclosure of appropriate alternative procedures or courses of treatment if applicable.

11. Statement describing the extent to which confidentiality of records identifying the subject will be maintained, including subject's identity to be held in confidence in reports in which the results of the study may be published and that the Institutional Review Board or its designees may review research records.
 12. Statement of additional costs to the subject that may result from participation in the research, if any. Standard Injury Compensation Statement and/or explanation of compensation available if injury occurs (if appropriate).
 13. Investigator's name and telephone number and statement that subject's may call and ask questions about the study or a research-related injury.
 14. Statement of whom to contact about subjects' rights as a research participant.
 15. Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may refuse or discontinue participation at any time without jeopardizing the investigator's interest in the subject.
 16. Statement of consent to participate in the study.
 17. Include appropriate signature and date lines.
- If an investigator believes that one or more elements of the Informed Consent does not apply, the PI must indicate rationale for this in writing and request a waiver.

Policy D Researcher Responsibilities Numbers 1, 2, 3

Number 1 Application

ALL IU Kokomo investigators must submit an application detailing the involvement of human subjects in the research project. Please refer to the submission guidelines. All documents must be typed (10-12 point font) on a current edition of the forms and **personally** signed by the principal investigator and the faculty sponsor, when required, or the application will be returned to the investigator.

Requests for approval to use human subjects should be submitted to the IU Kokomo Institutional Review Board in the Office of Research and Sponsored Programs. The forms must be completed according to the instructions provided. Downloadable forms are available on the IU Kokomo Institutional Review Board Website. For Exempt studies, two copies are required. For Expedited Studies, three copies are required.

For Full Review Studies, ten copies are required.

Number 2 Commencement of Research

Research may not begin until and unless final written approval or acceptance has been received from the IU Kokomo Institutional Review Board. This includes any and all contacts with human subjects (or work with documents on, or from, human subjects) and all categories of research. This restriction applies not only to the initial application, but also to any amendments or continuations.

Investigators may not institute changes to their research prior to receipt of written final approval for the change. The regulations governing research involving human subjects and our Letter of Assurance with the federal government preclude the granting of retroactive approval.

Subjects should not be recruited in any manner before Institutional Review Board final approval is received. Any documents recruiting subjects must be submitted to the Board with the application. This includes: fliers, e-mails, letters, newspaper and other media advertisements. Offers of compensation must not be in print larger than that used in the document generally. Other benefits cannot be over-emphasized.

Number 3 Reports to the Institutional Review Board

The principal investigator is required to provide written documentation of:

- Any changes to the study protocol
- Any changes to the informed consent
- Termination of the study (if the study is prematurely halted)
- Continuation of the study (at designated intervals)
- Completion of the study
- Adverse events

Changes in protocol or consent must be approved before being implemented. Forms for reporting to the Institutional Review Board are available on the website or through the Office of Research and Sponsored Programs (455-9205).

Policy E: Institutional Review Board Responsibilities for All New Studies

In its review of protocols, the IU Kokomo Institutional Review Board determines that the following requirements have been satisfied:

1. Risks to the subjects are minimized.
2. Risks to the subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent meets the requirements of the federal regulations and provision is made to obtain an informed consent from each subject or the subject's legally authorized representative.
5. The research plan makes adequate provision to ensure the safety of subjects.
6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Reviewer Checklist

Members of the Institutional Review Board who review studies at all levels (exempt, expedited, and full review) will use a systematic reviewer checklist to ensure that all aspects of the application are complete and satisfactory.

For exempt studies, one reviewer will complete the exempt checklist. When the study is accepted as exempt, a copy of the complete application packet, along with the checklist, and copy of the letter of acceptance of the exempt study will be placed in the Institutional Review Board file. If there are any aspects of the application that are incomplete, this will be communicated in writing to the principal investigator and must be corrected prior to acceptance.

For expedited studies two reviewers will complete the review and checklist for expedited and full. The two reviewers will meet and discuss findings of their reviews, and agree on findings. The findings of the two reviewers may include approving, approving with provisions, and tabling the study. A written summary of findings will be sent to the principal investigator. Copies of the complete application packet, reviewer's comments, letters and communications, and approval shall be placed in the Institutional Review Board file.

For full review studies each member of the Board will complete the review checklist prior to the Institutional Review Board meeting (ensuring a detailed look at the completeness and soundness of the study). Copies of the studies to be reviewed will be available to all the Institutional Review Board committee members at least 5 days prior to the meeting. The Institutional Review Board will deliberate and may approve, approve with provisions, table, or disapprove the study. A written summary of findings will be sent to the principal investigator. Copies of the complete application packet, reviewer's comments, letters and communications, and approval shall be placed in the Institutional Review Board file.

Policy F. Researcher and Institutional Review Board Responsibilities Regarding Studies Once Begun Numbers 1,2,3,4

Policy F Number 1 Study Amendments

Investigators are required to report any proposed changes to their research study via a Study Amendment Form. Investigators must report any changes, regardless of the level of the original review and the significance of the change.

Reference the original title of the study, the principal investigator, and the proposal identification number. Any changes to the title, project beginning or ending dates, or the investigator should be described in section 1. If the investigator's appointment does not carry an approved rank code, then both the investigator and the sponsor must sign the form.

Amendments involving minor changes that pose no more than minimal risk to subjects will be reviewed on a weekly basis according to the weekly review schedule. Amendments involving more than minor changes or more than minimal risk will be reviewed by the full IU Kokomo IRB, according to the full committee review schedule.

Changes may not be implemented until final written approval is received from the IU Kokomo IRB.

A Study Amendment Form is available on the Website or through the Office of Research and Sponsored Programs (455-9205).

Policy F Number 2 Study Continuing Review

Studies are approved for a designated period of time that will not exceed one year. For studies that will continue beyond one year or beyond the designated study period, a Continuing Study or Study Termination Report must be completed by the PI and approved by the IU Kokomo Institutional Review Board prior to the end of the designated time.

Studies involving greater risk may be reviewed at a shorter time interval, as designated by the Institutional Review Board and specified on the Institutional Review Board approval.

Exempt studies do not require continuing review.

The IU Kokomo Institutional Review Board will send out a call for continuing review or completion with a copy of the Continuing Study or Study Termination Report form with a copy of the Approved Consent Form(s) approximately one month before it is due in the IU Kokomo IRB office. The Continuing Study or Study Termination Report Form is available on the Website or through the Office of Research and Sponsored Programs (455-9205).

Principal Investigators who disregard the call for continuing review should recognize that the Institutional Review Board approval is only valid for the specified period of time, and the Institutional Review Board has the authority to halt research that does not comply with the guidelines.

Policy F Number 3 Study Completion

When the study is completed or terminated the Principal Investigator must complete and submit the Continuing Study or Study Termination Report Form. The IU Kokomo Institutional Review Board will send out a call for this approximately one month prior to the anticipated completion date.

Principal Investigators who are completing studies at **all levels** are required to comply (exempt, expedited, and full reviews).

The IU Kokomo Institutional Review Board considers a study complete when data analysis is completed, or when all data have been collected and all the data have been de-identified so that there is no link whatsoever between the data and any subjects.

Policy F Number 4 Reporting Adverse Events

Any adverse experience associated with a study must be reported to the IU Kokomo Institutional Review Board within 3 working days after the incident. The report should be in letter format containing the following:

1. Study number and title to which the incident relates
2. Description of the incident

3. Principal investigator's assessment of the incident, outlining any changes and the significance/relevance to the study, e.g., changes in risk/benefit ratio.
4. Any changes that need to be made to the consent statement, plus the revised form.
5. Identification of the principal investigator and the principal investigator's signature

Policy G: IRB Records

The Institutional Review Board maintains the following files:

1. Minutes of the IU Kokomo Institutional Review Board meetings.
2. Curriculum Vitae (that include professional development re Institutional Review Boards) for all Institutional Review Board committee members.
3. Original protocols and copies of forms and memoranda sent to, and received from, investigators.
4. Proposals not yet reviewed.
5. Proposals from which approval has been withheld and for which suitable remedial action has not yet been taken.
6. Correspondence.
7. Proposals are kept for three years following completion of research, and are then destroyed or placed in separate secured storage.
8. Each new Proposal shall be assigned a unique identification number, according to the following format: calendar year (2 digit) followed by calendar month (2 digit) followed by study number (2 digit) and the appropriate letter: Exempt-X, Expedited-EXP, and Full-F review.

Policy H Conflict of Interest

Each proposal reviewed by the Institutional Review Board shall be reviewed by neutral member(s) of the IU Kokomo Institutional Review Board. Each investigator that has a conflict of interest in a study that he/she is participating in must fully disclose the conflict of interest to the Institutional Review Board on the Documentation of Review and Approval.

If an Institutional Review Board reviewer perceives that there is a conflict of interest with a study being considered, the reviewer will not participate in the review at expedited or full levels, and will not be responsible for determining exempt status.

Generally, the areas for a conflict of interest include financial interest (reviewer could financially benefit or lose from a study), scholarly interest (reviewer's own study or study of a close colleague), or personal interest (e.g. study subjects may be family members).

During a full review of a study being considered, Institutional Review Board members with a conflict of interest will step out of the meeting room and will not participate in the discussion or vote on that agenda item.