

# HUMAN SUBJECTS HANDBOOK



**COPPIN STATE  
UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS**

Office of the Provost and Vice President for Academic Affairs  
2500 W. North Avenue Baltimore, Maryland 21216

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- ▣ Founding IRB Board Members:
 

<ul style="list-style-type: none"> <li>▪ Dr. Abeba Fekade</li> <li>▪ Dr. Theresa Harris</li> <li>▪ Dr. Gohar Karami</li> <li>▪ Dr. Richard Monk</li> <li>▪ Dr. Rolande Murray</li> <li>▪ Dr. Mary E. Owens</li> </ul>	<ul style="list-style-type: none"> <li>▪ Dr. Thaddaus Phillips</li> <li>▪ Dr. Michelle Pointer</li> <li>▪ Dr. Atma Sahu</li> <li>▪ Dr. Janet Spry</li> <li>▪ Ms. Peggy Thweatt</li> <li>▪ Dr. Maurice Wilson</li> </ul>
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Research is a vital part of academia and the purpose of this Institutional Review Board is to respect and protect the rights and welfare of individuals. It is generally agreed that a survey is a means of collecting data from a chosen group of people and research is a methodical examination and study of something for reaching new conclusions. However, the US DHHS Office of Human Research Participants (OHRP) specifies that research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The IRB is guided, to the extent that they are applicable, by principles as set forth in such nationally accepted documents as the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Actions will also conform to applicable federal, state, and local laws and regulations. This discussion explores perspectives, presents governing operational statutes and policies, and also reviews responsibilities.

### Perspectives

There are various perspectives regarding what constitutes the need for IRB approval. For example, one university permits Principal Investigators to self-determine if they are engaged in human subjects research and to only submit applications if requested by funders/sponsors; or if they are uncertain if IRB review and approval is necessary. At another university, the PI completes a designated form in situations of uncertainty and subsequently receives an IRB letter officially confirming no need for IRB approval or requesting additional information. Then too, a fellow university states: *“The IRB has sole authority to determine whether an activity meets the definition of Human Participant Research. Any activity that might represent human participant research should be submitted to the IRB for determination”*.

### Governing Statutes and Policies

#### **OHRP – Common Rule - §46.104 Exempt research**

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are **exempt** from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category...(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are **exempt** from this policy: (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

#### **BOR IV-2.10 – Policy on Human Subjects of Research**

Board of Regents Policy applies to all research activities and to all development, training, and improvement or other related activities containing a research and development component. Furthermore, it applies to any such activity performed on the premises of the University System of Maryland or its constituent institutions and to any such activity performed elsewhere by faculty, students, or employees under University System of Maryland

auspices...Furthermore, the IRBs will have the authority to determine whether or not any activity is covered by the policy and whether it requires review by an IRB. Also, In accordance with this policy, all University System of Maryland research activities which involve human subjects, regardless of the level of risk foreseen, require review and approval, prior to the initiation of the activity. An Institutional Review Board (IRB) shall have jurisdiction over all reviews and approvals in accord with procedures set forth in recognized documents, e.g. Federal Wide Assurance (FWA) and/or applicable regulations and policies including other policies adopted by the System or an institution. The System policy further states that officials of the system or an institution may not approve research that has not been approved by an IRB. As well, no official of the system or a constituent institution shall take any action intended to influence or coerce an IRB, or any of its members, to approve specific research.

### **CSU – Policy on Human Subjects - Handbook**

The Coppin State University IRB is charged with the responsibility of reviewing, prior to its initiation, all research (funded or not) involving human subjects. The IRB is concerned with justifying the participation of subjects in research and protecting their welfare, rights, and privacy. For research involving humans, Coppin State University is guided by the ethical principles as set forth in the Declaration of Helsinki, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>. In addition, the IRB follows the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations. All research (including interviews, surveys, and questionnaires) involving humans as subjects must be reviewed by the IRB. Applications may be exempt, expedited or full board. Decisions are categorized as accepted, conditions before acceptance or resubmission. Also, letters of exemption are issued. The determination under the exempt category is currently made by the CSU IRB Chair.

Information on the IRB may be found on the IRB website ([www.coppin.edu/irb](http://www.coppin.edu/irb)). Questions regarding applications, decisions and need for review may be sent directly to the IRB Chair, [mpointer@coppin.edu](mailto:mpointer@coppin.edu).

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## GENERAL GUIDELINES

Protecting the rights and welfare of humans in research is an institutional policy of Coppin State University, with oversight delegated by the Provost and Vice President of Academic Affairs to the Institutional Review Board (IRB), as mandated by federal regulations 45 CFR 46.103 (b) (2). The Coppin State University IRB is charged with the responsibility of reviewing, prior to its initiation, all research (funded or not) involving human subjects. The IRB is concerned with justifying the participation of subjects in research and protecting their welfare, rights, and privacy.

For research involving humans, Coppin State University is guided by the ethical principles as set forth in the Declaration of Helsinki, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report:

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

In addition, the IRB follows the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations.

**ALL research** (including interviews, surveys, and questionnaires) involving humans as subjects must be reviewed by the IRB. If the proposed study has not been completely designed at the time a research proposal is submitted to a sponsor, provisional approval may be granted. **Full approval must be sought when the experimental plans are complete and before the involvement of human subjects in the project.**

*The IRB cannot and will not review protocols for projects that are already completed. If a project is already underway, research shall be immediately suspended until the protocol is reviewed.*

## RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR(S)

1. Principal investigators (PIs) acknowledge and accept their ethical and legal responsibilities for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Handbook.
2. It is the responsibility of principal investigators to provide a copy of the IRB- approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the IRB.
3. Principal investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. Any proposed changes shall not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate risks to the subjects.

4. PIs are responsible for reporting progress of approved research to the IRB, as often and in the manner prescribed by the IRB on the basis of risks to subjects, but no less than once per year or upon completion of the research project.
5. The IRB will immediately be informed by the PI of any injuries or other unanticipated problems involving risks to subjects and others.
6. When human subjects are recruited from sites other than Coppin State University, principal investigators will advise the appropriate officials of other institutions of the intent to admit human subjects and will follow whatever policies and procedures are required by that site. When there is frequent involvement of the human subjects from the same site, those institutions must possess an applicable HHS-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

*PI Does Not:*

1. PIs who intend to involve human subjects will not make the final determination of exemption from applicable Federal or CSU regulations. All research involving human subjects must receive approval by the CSU IRB.
2. No PI will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (45 CFR 46.116(f)). Any such activities resulting from emergency medical care will not be counted as research nor the data used in support of research.

## DEFINITIONS

### 45 CFR 46 - Definition

*Definitions are subject to change. Updates are available at*  
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

#### **Term**

#### **Human Subject**

"Living individual(s) 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." (45 CFR 46.102(f))

#### **IRB Approval**



"The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB, and by other institutional and Federal requirements." (45 CFR 46.102(h))

**IRB or Institutional Review Board**

"An Institutional Review Board established in accord with and for the purposes expressed in this policy." (45 CFR 46.102(g)) The IRB is an administrative body within Coppin State University, established by appointment from the Associate Vice President for Graduate Studies, Research and Evaluation, to protect the rights and welfare of humans who are recruited to participate in research activities conducted under the auspices of Coppin State University.

**Interaction**

"Communication or interpersonal contact between investigator and subject."

**Intervention**

"Physical procedures (for example, venipuncture) by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes"

**Minimal Risk**

"The probability and magnitude of harm or 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 test." (45 CFR 46.102(i))

**Private Information**

"Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

**Research**

"A systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." (45 CFR 46.102(d))

## IRB STRUCTURE

The IRB is composed of eight CSU faculty members, and one community member. The Board members represent diverse backgrounds in order to provide complete and adequate review of human research and its institutional, legal, scientific, and social implications. CSU Assistant States Attorney is available to assist in any legal matters.

## TYPES OF RESEARCH ACTIVITIES AND IRB REVIEW

The IRB reviews projects by one of three methods:

- Exempt from Full Board Review
- Expedited Review
- Full Board Review

The investigator may recommend the review category, but final determination of the category will be made by the IRB. A project may be subject to more comprehensive review at the discretion of the IRB.

### *Exempt from Full Board Review*

Certain categories of research qualify for exempt review. Exempt proposals are reviewed and certified by the IRB Chair. IRB Chair sends a copy of the certification to the Office of the Provost and Vice President for Academic Affairs (P/VPAA).

Research activities in which the only involvement of human subjects will be in one or more of the following categories qualify for review under the exempt category (45 CFR 46.101(b):

1. "Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."
2. "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) 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."

***NOTE: Category 2 of Exempt from Full Board Review does not apply to research with subjects under the age of 18 except for the specific type of research that is observation of public behavior where the investigator does not participate in the activities being observed.***

3. "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 category 2 of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception

that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter."

4. "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."
5. "Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs."
6. "Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient, or agricultural chemical or environmental contaminant at or below the level and for a use found to be safe, by the Food and Drug Administration and approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture."

### Expedited Review

Expedited reviews do not require a convened meeting of the IRB.

**Note:** Research activities that may be funded by the U. S. Department of Health and Human Services may not use expedited review. These must be reviewed by the Full Board IRB (OPRR Report 99-01).

The chair of the IRB appoints a subcommittee of board members to review the proposal, and selects an appropriate communication method. The IRB members return their comments to the chair, who notifies the principal investigator of the results of the review. **Allow one month for an expedited review.**

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed through the expedited review procedure. The Expedited Review category does not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The categories in this list apply regardless of the age of subjects, except as noted (45 CFR 46.110).

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. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks 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 (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, non-pregnant 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. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization."
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.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual."
5. "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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See previous section listing categories, which qualify for exemption. 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."
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. See previous section listing categories, which qualify for exemption. 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."

### Full Board Review

The IRB schedules regular monthly meetings to review all proposals which do not fall into the Exempt or Expedited categories, or which the Chair determines full board review. Allow one month for a full board review.

### Deceptive Research

Any research that is deceptive requires full board review. **Research activities that do not fully disclose the purpose of the research to the subjects are considered "deceptive."** Any deceptive research should be carefully weighed in terms of the justification for the need to deceive the subject and alternative methods for conducting the research that do not involve deception. The IRB will decide if the information being withheld from the subjects is an important element in the subject's decision to participate. If the IRB decides that the information being withheld is an important element, then the research will not be approved. At a minimum, subjects must be informed in a consent form that full information is not being disclosed to them. Any research involving deception must involve a full debriefing.

### Classroom, Workshop, and Administrative Projects

Classroom curriculum projects, workshop evaluations, and administrative review projects need not be reviewed by the IRB if they are not research, results will not be distributed outside the classroom or institutional setting, or are used solely to evaluate or review a program in order to build a better program. If, however, the results of the project will be published or otherwise distributed, the project must be reviewed by the IRB. If in doubt, it is wise to have the project reviewed. The category of review (exempt from full board review, expedited review, or full board review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

## SUBMISSION, TIMEFRAME, AND REVIEW CONSIDERATIONS

Applications for IRB reviews are submitted on a form entitled, "Application to Use Human Subjects in Research." The form is included at the end of this booklet and available via the IRB Chair or web site.

- All materials, including the application form at the end of this Handbook, must be complete.
- Avoid technical jargon. All descriptive materials should be written for the lay reader. The informed consent document must especially be written in a non-technical and easily understood language appropriate to the language level of the subjects.
- Number all pages consecutively.
- For full board reviews, principal investigators and students are strongly encouraged to attend the IRB meetings to discuss their proposal. They will receive notification for date and time.

***The IRB cannot and will not review protocols for projects that are already completed. If the project is already underway, the research shall be immediately suspended until the protocol can be reviewed.***

## Review Criteria

In any review (exempt from full board review, expedited review, or full board review), the reviewers will determine that:

1. Participation of human subjects in the project is justified.
2. Risks to subjects are minimized by using appropriate procedures.
3. Risks are justified in view of anticipated benefits to the participants.
4. Selection of subjects is equitable. Justification is required if the subject population is restricted to one gender or ethnic group or by age.
5. Adequate provision is made for confidentiality of data and anonymity of participants in any published record.
6. Adequate provision is made for the rights and welfare of participants who are mentally, physically, economically or educationally disadvantaged.
7. Adequate provision is made for obtaining informed consent of the subjects, including those for whom English is not their first language.

## **MODIFICATION TO AN EXISTING APPROVAL**

From time to time, an approved project may need to be modified to adequately perform the scope of research. Before any change may take place to a protocol that was approved, the proposed changes must be reviewed by the IRB and approved. To modify an existing approval, a memo containing the following information must be sent to the IRB Chair:

- A list of the principal investigator(s) and subjects involved in the project
- The title of the project
- A list of the project's approval history
- A brief summary of the project
- A detailed description of the proposed modification(s).
- Any new or revised supplementary documents (letters, surveys, etc.).

## **CONTINUING REVIEW**

In its initial review of a proposal, the IRB will consider the extent of continuing review needed. Federal regulations (45 CFR 46) require review to occur on or before the twelve-month anniversary date of the previous IRB review. All proposals shall be reviewed at least annually, but in certain research the subjects are exposed to more than usual risk; such projects will be reviewed at more frequent intervals consistent with the research. This review interval will be determined at the time the research is approved and may be changed at the discretion of the IRB. Principal Investigators with approved protocols will be sent a reminder letter with a copy of the annual report to be completed and returned to the IRB Chair by the date indicated on the letter. The annual report is the mechanism by which a proposal is reviewed and approved for another period of time.

The annual report submitted by the PI must be processed in sufficient time for review and approval to occur before the expiration date established by the IRB (which is a maximum of twelve-months from the original approval date). In each such review, the principal investigator will be required to promptly report the status of the research activity, and any proposed changes in the research activity. If the research is still in progress, the investigator will affirm that the approved research protocol involving human subjects is being followed. It is important that these reports are completed and returned in a timely manner—failure to do so will result in a suspension of IRB approval for the project. A suspension of IRB approval mandates that any work involving human subjects must be terminated until approval has been secured again and requires submitting a new application to the IRB.

*If ongoing research is not approved for continuation by the expiration date established by the IRB, then the research shall be suspended until such review and approval occurs.*

## **NONCOMPLIANCE ACTION**

In any instance where IRB requirements are not being followed, the IRB shall inform the principal investigator, the appropriate department chair and dean, and the Provost and Vice President for Academic Affairs will be asked to enforce the requirements. In the event that the principal investigator does not comply, the IRB will terminate the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the action. If unanticipated problems, including noncompliance and termination, involving risks to subjects or others occur and when the research is funded by U.S. Department of Health

and Human Services (HHS) funds, these will be reported to the Secretary of HHS by the Associate Vice President for Graduate Studies, Research and Evaluation.

## **ARBITRATION**

Any matters requiring arbitration between the IRB and a principal investigator, or questions not resolved by the IRB, will be referred to the Provost and Vice President for Academic Affairs. The Provost and Vice President for Academic Affairs will meet with the IRB and the principal investigator, seeking a resolution of the differences, after which the IRB will meet again to reconsider the matter and render a decision. In no instance may any official of the institution overrule an IRB decision.

## **ADVERSE EVENT**

Federal policy (45 CFR 46.103(b) (5)) requires written procedures for "prompt reporting to the IRB of any unanticipated problems involving risks to human subjects or others." Investigators carry out the responsibility for timely reporting of adverse events to the IRB to ensure that the IRB is cognizant of any new information that might affect its assessment of the benefit-to-risk ratio of research study participation and/or the adequacy of research protocol provisions for protecting the welfare of research subjects. To report an adverse event, the IRB investigator should complete the CSC Adverse Event Form and submit it to the IRB Chair within three calendar days of identifying the adverse event. The IRB Chair will immediately share the information with the P?VPAA for review and consideration of next steps. A copy of the Adverse Event Report will be sent to the CSC Assistant States Attorney.

## **PREVENTING TRANSMISSION OF INFECTIONS**

Research activities that may put the research staff or subjects at risk of exposure to infectious or potentially infectious human materials must be performed in accordance with guidelines established by the National Institutes of Health, the National Committee for Clinical Laboratory Standards, and other applicable governing bodies.

## **RECORDS RETENTION REQUIREMENTS**

All records must be retained for at least three years after completion of the research, whether or not the records are linked to specific individuals. Records may include such items as research proposals, informed consent documents, progress reports, reports of injuries to subjects, and all related correspondence concerning the use of human subjects.

## **RACE/ETHNICITY OF SUBJECTS**

When collecting data, which might be aimed at, influenced by, or relevant to the racial/ethnic background of subjects, the subjects should be asked to specify their identity. Terms or classifications, which may be acceptable to subjects, are apt to change over time, but whichever terms are used should be appropriate for the particular sample from which data are being collected and for the purposes of your study. If citizenship



is important to your study, you may wish to ask that question separately. If alternative categories are more suited to your research, please submit them with an explanation.

The currently recommended statement follows.

*Which best describes your racial/ethnic identity? (Please check all that apply.)*

- White, European American, Non-Hispanic
- Asian or Asian American Black, African American, Non-Hispanic
- Middle Eastern or Middle-Eastern American
- North African or North African-American
- Pacific Islander
- Hispanic or Latino American
- American Indian or Alaskan Native

*If none of the above choices apply to you, please use your own description:*

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- Decline to respond

## Obtaining Informed Consent

Informed consent will be sought from all prospective subjects (or their legally authorized representatives) unless waived by the IRB. Investigators should be sensitive to the possible need of an interpreter-translator for subjects who do not speak English or who speak English as a second language.

### DEFINITION

**Term**  
**Informed Consent**

**45 CFR 46 - Definition**

"A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release

the investigator, the sponsor, the institution or agents thereof from liability for negligence." (45 CFR 46.116; 21 CFR 50.20 and 50.25)

## **INFORMED CONSENT PROCESS**

Documented informed consent consists of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The signed consent forms and summaries shall be kept in the investigator's file for at least three years beyond the end date of the project. The consent form may be either of the following:

1. A written consent document (see sample at end of Handbook) that embodies the elements of informed consent. This may be read to the subject or the subject's legally authorized representative, but in any event the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
2. A "short form" written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

The IRB may waive the requirement of a signed consent form if: (a) this consent form is the only record linking the subject with the research and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (b) the research presents no more than minimal risk of harm to subjects, involving no procedures for which written consent is normally required outside the context of the research. Such a waiver might be appropriate where the research involves minimal risk, the rights and welfare of the subjects are not adversely affected, and the research would not be feasible without the waiver.

The waiver of a written informed consent document does not waive the need for subjects to give their informed consent. Subjects should be presented with an oral description of the research and other pertinent items from the next section "The Basic Elements of Informed Consent." A written script of the oral presentation must be submitted with the application form (at the end of this Handbook) and protocol.

*NOTE: Sample informed consent documents are included at the end of this Handbook.*

## **BASIC ELEMENTS OF INFORMED CONSENT**

The informed consent of subjects must be obtained by methods that are adequate and appropriate for the situation (see previous section). Informed consent is the agreement obtained from a subject, or from an authorized representative, for the subject's participation in an activity. The agreement, written or oral, entered into by the subject, may include no exculpatory language through which the subject is made to waive, or to appear to waive, any of the subject's legal rights, or to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The basic elements of informed consent are:

1. A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others, which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following additional elements of informed consent shall also be provided to each subject:

1. A statement that a particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

*NOTE: Sample informed consent documents are included at the end of this Handbook.*

## ADDITIONAL PROTECTIONS FOR SPECIAL POPULATIONS

### FETUSES, PREGNANT WOMEN, HUMAN IN VITRO FERTILIZATION

#### DEFINITIONS

<b>Term</b>	<b>45 CFR 46 - Definition</b>
<b>Fetus</b>	"The product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable." (45 CFR 46.202(c))
<b>In Vitro Fertilization</b>	"Any fertilization of human ova which occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means" (45 CFR 46.202(g))
<b>Nonviable Fetus</b>	"A fetus <i>ex utero</i> which, although living, is not viable" (45 CFR 46.202(e))
<b>Pregnancy</b>	"Encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy), such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus" (45 CFR 46.202(b))

**Viable**

"As it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration." (45 CFR 46.202(d))

### General Limitations

No research may be begun unless:

1. appropriate studies on animals and non-pregnant individuals have been completed;
2. except where the purpose of the activity is to meet the health needs of the pregnant woman or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;
3. individuals engaged in the activity will have no part in (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and
4. no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

### Activities Directed Toward Pregnant Women as Subjects

No pregnant woman may be involved as a subject in an activity unless: (1) the purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

A pregnant woman may be involved as a subject in an activity only if she and the fetus' father are legally competent and have given their informed consent. The father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

### Activities Directed Toward Fetuses in Utero as Subjects

No fetus in utero may be involved as a subject in any activity unless: (1) the purpose of the activity is to meet the health needs of the particular fetus, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose

of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

An activity permitted under this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

### **Activities Directed Toward Fetuses Ex Utero, Including Nonviable Fetuses, as Subjects**

Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity unless:

1. there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or
2. the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

No nonviable fetus may be involved as a subject in an activity unless:

1. vital functions of the fetus will not be artificially maintained,
2. experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and
3. the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other parts of this section.

An activity may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

### **Activities Involving the Dead Fetus, Fetal Material, or the Placenta**

Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

## PRISONERS

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research this section describes additional safeguards for the protection of prisoners involved in research.

### DEFINITION

<b>Term</b>	<b>45 CFR 46 - Definition</b>
<b>Prisoner</b>	"Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing." (45 CFR 46.303(c))

### Composition of the IRB

At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. A prisoner representative will supplement the IRB committee to review any research projects involving prisoners.

### Additional Duties of the IRB

The IRB shall review and approve research only if it finds that:

1. the research is in a permissible category (see next section);
2. any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other

- procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. the information is presented in language, which is understandable to the subject population;
  6. adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
  7. where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentence, and for informing participants of this fact.

### **Permitted Research Involving Prisoners**

Biomedical and behavioral research may involve prisoners as subjects only if the proposed research involves solely the following:

1. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
2. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
3. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only (when DHHS funding is sought) after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register of the intent to approve such research; or
4. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only (when DHHS funding is sought) after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.



## CHILDREN

### To What Does This Section Apply?

In general, any research involving children as research subjects requires IRB review and approval. The "exempt" category of research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

### DEFINITIONS

<b>Term</b>	<b>45 CFR 46 - Definition</b>
<b>Assent</b>	"A child's affirmative agreement is needed to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent." (45 CFR 46.402(b))
<b>Children</b>	"Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be Conducted." (45 CFR 46.402(a))(In Oregon, the age of maturity is 18.)
<b>Guardian</b>	"An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care." (45 CFR 46.402(e))
<b>Parent</b>	"A child's biological or adoptive parent." (45 CFR 46.402(d))
<b>Permission</b>	"The agreement of parent(s) or guardian to the participation of their child or ward in research" (45 CFR 46.402(c))

### Research Not Involving Greater than Minimal Risk

The IRB will approve projects in which no greater than minimal risk to children is presented, only if:

1. adequate provisions are made for soliciting the assent of the children and

2. the permission of their parents or guardians is obtained.

### **Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subjects**

The IRB will approve projects in which more than minimal risk to children is presented by

1. an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or
2. by a monitoring procedure that is likely to contribute to the subject's well-being, only if:
  - the risk is justified by the anticipated benefit to the subjects;
  - the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
  - adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

### **Research Involving Greater than Minimal Risk and No Prospect of Direct Benefit to Individual Subjects, but Likely to Yield Generalized Knowledge about the Subject's Disorder or Condition**

The IRB will approve projects in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if:

1. the risk represents a minor increase over minimal risk;
2. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
3. the intervention or procedure is likely to yield generalized knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
4. adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

### **Research Not Otherwise Approvable which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children**

The IRB will approve projects in this category only if:

1. the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
2. when DHHS funding is sought, the Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (a) that the research satisfies the conditions of the above categories, or (b) the following: (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research will be conducted in accordance with sound ethical principles; (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

#### **Requirements for Permission by Parents/ Guardians and Assent by Children**

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB, the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with general informed consent provisions.

In addition, the IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For research involving greater risk and no prospect of direct benefit to subjects, permission is to be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the permission requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an

appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Permission by parents or guardians shall be documented.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented (see sample form at end of Handbook).

### **Wards**

Children who are wards of the State or any other agency, institution, or entity can be included in research only if such research is:

- A. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- B. related to their status as wards; or

If the research is approved, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in *loco parentis*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

### **OTHER GROUPS**

Other groups, such as cognitively disabled, elderly, economically disadvantaged, the very sick, and the institutionalized, are described as vulnerable populations by The Belmont Report and are therefore provided appropriate protection when used as subjects in research, such as assuring voluntary informed consent.

#### **NOTICE:**

**IRB forms are located on the website and application are submitted through the website:**

**[www.coppin.edu/irb](http://www.coppin.edu/irb)**