Ball State University
Office of Research Integrity
Human Research Protection Program (HRPP)
Policies and Procedures for Research Involving Human Participants

BALL STATE
UNIVERSITY

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Section 1. Human Research Protection Program at BSU

Human Research Protection Program (HRPP)

1. Prologue

The Human Research Protection Program (HRPP or Program) policies and procedures are based on applicable federal regulations, applicable state statutes, and Ball State University (BSU) Policies as they pertain to the conduct of human subjects research (HSR) at BSU.

These policies and procedures apply to all research activities of BSU faculty, staff, and students who are involved in HSR that falls under the jurisdiction of BSU's HRPP and Institutional Review Board (IRB). The requirements of the HRPP apply to all research involving human subjects regardless of funding source (e.g., federally funded, private foundation, etc.) or funding status (e.g., funded vs. unfunded).

- BSU's Federalwide Assurance #: FWA00000797
- BSU's IRB Registration #: IRB00001527
- BSU's current online submission system: IRBNet
- BSU's current online education system: CITI

2. Mission Statement

The mission of the BSU's HRPP is to protect the rights, welfare, and privacy of human participants who choose to participate in HSR. The program is committed to advancing strong ethical and responsible conduct of research, fair and equitable treatment of human research participants, and to ensure the right of voluntary informed participation for every human is respected.

To achieve this goal, BSU's HRPP not only ensures BSU is in compliance with federal regulations, but strives to adhere to higher ethical standards in its protection of HSR participants. In service of this mission, the HRPP endeavors to:

- Create an atmosphere of respect for and awareness of the rights and welfare of HSR participants at BSU;
- Maintain the public's trust in its research protection programs;
- Inform researchers about changes to federal regulations, guidance, best practices, and ethical principles that may impact their particular area of research;
- Educate faculty, staff, and students that conduct HSR about the ethical principles and federal regulations guiding research with human participants.
- Assess the effectiveness of the IRB in their review of research activities, facilitation of compliance of researchers with federal regulations, and protection of research participants; and
- When applicable, develop new tools, educational programs, policies, etc. that better serve the overarching mission of the HRPP.

3. Governing Principles

It is the policy of BSU that all HSR activities conducted under the oversight of BSU will be conducted in accordance with all applicable federal laws and regulations, including 45 CFR 46 ("The Common Rule"), the principles of the Belmont Report, applicable laws of the State of Indiana, and local IRB requirements.

A. Ethical Principles

The BSU IRB is guided by the ethical principles applied to all research involving humans as participants, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled: Ethical Principles and Guidelines for the

Protection of Human Subjects of Research (the "Belmont Report"). These principles are defined in the Belmont Report as follows:

- **Beneficence**: The sum of the benefits to the participant and the importance of the knowledge to be gained so outweigh the risks to the participants as to warrant a decision to allow the participant to accept these risks.
- **Autonomy**: Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.
- **Justice**: The selection of participants is equitable and is representative of the group that will benefit from the research.

B. Laws, regulations and principles applying to this policy

The following apply to this policy:

- 45 CFR 46 HHS Policy for Protection of Human Research Subjects (“The Common Rule”)
- The Belmont Report
- Nuremberg Code
- Declaration of Helsinki
- Professional ethical codes as applicable to the researcher(s)

When applicable the following apply:

- Family Educational Rights and Privacy Act (FERPA), to the extent that BSU educational records are used in research
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- Food and Drug Administration (FDA) regulations (clinicaltrial.gov)

4. Insitutional Review Board(IRB) Authority and Charter

BSU’s HRPP and IRB are established and empowered under the auspices of BSU’s executive authorities, and by the institution’s Federalwide Assurance (FWA) with the federal Office for Human Research Protections (OHRP).

IRB has the authority to ensure HSR that meets the applicable definition is designed and conducted in such a manner that protects the rights, welfare, and privacy of those participating.

Specifically, the IRB:

- May disapprove, modify, or approve studies based upon consideration of human participant protection aspects;
- Reviews proposed research, and has the authority to approve, require modification of, or disapprove of all research activities that fall within its jurisdiction;
- Has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research participants, including requiring progress reports from the investigators, auditing the conduct of the study, observing the informed consent process, and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human participants;
- May suspend or terminate approval of a study; and/or
- May place restrictions on a study.

The IRB may also have a relationship with other institutional research review committees. The IRB functions independently of, but may work in coordination with, these other committees. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by institutional officials or other committees. However, those officials or committees may not approve research if it has been disapproved by an IRB.

BSU’s Vice Provost (VP) for Research is the ultimate leader of the HRPP and has responsibility and authority for implementation of this program. For purposes of compliance with federal regulations, the

VP for Research serves as BSU's Institutional Official (IO). Day to day operation of the HRPP is delegated to the Director, Office of Research Integrity (ORI) and the staff of the ORI. The VP for Research also ensures that the IRB remains able to function independently of other organizational entities.

5. Assurance of IRB Independence

The IRB has the mandate to act as an independent entity within the institutional structure of BSU.

The IRB operates independently of other organizational entities and academic departments. Except under certain situations, all decisions made by the IRB are binding and cannot be overturned or overruled by the University. The actions of the IRB, its chairperson, members and administrative staff in matters of human participant protection derive from the authority vested under federal regulations, separate and distinct from BSU.

It is the responsibility of VP for Research and the Director of the Office of Research Integrity (ORI) to maintain and enforce the independent nature of the relationship between the IRB and BSU.

6. Current Resource Allocation

Personnel, space, and equipment are allocated based on the needs of the IRB and ORI's support of the IRB.

IRB Research management	Equivalent to 2 FTEs
IRB Exempt reviewer and support	0.5 FTEs
Meeting Space	Yes, and as needed
Computers, copier, fax, printers, phones, etc.	Yes, and as needed
Training and other support	Yes, and as needed

The IRB Chairperson and the Director, ORI may make requests, in writing, to the IO for changes to the resources allocation in order to better suit the changing needs of the IRB and ORI's support of the IRB.

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Definitions

1. Definitions Applicable to All Sections

Adult: Defined by Indiana state law as "of full age" and "person in his or her majority," meaning a person at least eighteen (18) years of age.

Adverse Event (AE): An unexpected or unanticipated problem related or possibly related to participation in the research. AE may result from protocol deviations, participant or personnel minor injury, loss or stolen data, loss of multiple personnel, higher than expected participant withdraw rate, abnormal results, etc. An AE can also be any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the participant's involved in the research, whether or not considered related to the participant's involvement in the research. Adverse events encompass both physical and psychological harms.

Allegation of Noncompliance: An assertion of noncompliance made by a second party that must be proved, supported, or denied with evidence.

Anonymous: Information about a person, which has no identifying characteristics and cannot be linked back to an individual. When referring to collected data, any information about a living individual that is collected in a manner such that identifiers were never associated with the information and no one is able to identify from whom the information was collected.

Assent: An individual's affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents, guardian, or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Audit: A systematic and independent examination of a study, including research-related activities and documents, to determine whether the study was conducted according to the IRB approved protocol, informed consent properly obtained, and that the data was recorded, analyzed, and accurately reported.

Benign Behavioral Intervention (BBI): A procedure is physically invasive or alters the environment, mood, or physical state of a participant that is:

- Brief in duration
- Painless/harmless
- Not physically invasive
- Not likely to have a significant adverse lasting impact on participants
- Unlikely that participants will find the intervention offensive or embarrassing

Biospecimen: A quantity of tissue, blood, urine, DNA, RNA, or other human-derived biological material. Biospecimens are generally stored in a biorepository or biobank and are used for laboratory research.

Broad Consent: Participant permission to store and use data for future research as generally delineated in the consent form.

Certification: The official notification by the institution to the supporting federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human participants has been reviewed and approved by an IRB in accordance with an approved assurance.

Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Confidential/Confidentiality: How identifiable information, once obtained, is protected. This is an obligation and affirmative duty of the new data holder. In many situations confidentiality requirements will be dictated by an applicable law, regulation, or institutional policy. Unaltered audio/video/digital recordings will be considered confidential.

Conflicting Interests: A situation or circumstance which may result in a member of the IRB, the ORI or other person involved in the HRPP, being rendered unable to make informed, unbiased decisions or could be perceived of as unethical. Some examples of conflicting interests as it pertains to this section include, but may not be limited to:

- An IRB member is the Principal Investigator (PI) on the protocol up for review.
- A member is directly related to the PI on the protocol up for review.
- A member has a financial interest in the protocol.
- A member has a personal or professional reason for which the member does not feel they can render a fair and impartial review of a protocol up for review.
- A member has actual Conflict of Interest/Conflict of Commitment (CoI/CoC), as defined in university policies, which directly impacts impartiality.

Department or Agency Head: The head of any federal department or agency, for example, the Secretary of Health and Human Services (HHS), and any other officer or employee of any federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

Federal Department or Agency: Federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human participants it conducts, supports, or otherwise regulates (e.g., U.S. Department of Health and Human Services, U.S. Department of Defense, or Central Intelligence Agency).

Family Educational Rights and Privacy Act (FERPA): A federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

Generalizable Knowledge: Research results intended to:

- Be published, presented and/or disseminated in some public manner;
- Contribute to an established body of knowledge or discipline;
- Be generalized to a larger population beyond the location(s) of data collection or population studied; and
- Be replicated in other settings or research.

Some examples of activities that typically are not considered generalizable include:

- Biographies, autobiographies, and journalistic interviews;
- Oral histories that are designed solely to create a record of specific historical events;
- Course/class evaluations whose sole purpose it is to improve the course itself or a professor's teaching methods;
- Classroom exercises solely to fulfill course requirements, to train students in research methods or to train students in the use of particular methods, techniques or devices; and
- Quality improvement/quality assurance activities designed to improve the quality or performance of a department or program where there is no intention to share the results beyond the BSU community.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): A federal law that protects personal health and medical information. This law provides privacy and security standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.

Human Subject/Participant: A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention: includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

Interaction: includes communication or interpersonal contact between investigator and participant in person or through electronic media.

Private information*:* includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information: is private information for which the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen: is a biospecimen for which the identity of the participant is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Subjects Research (HSR): Research that meets both definition of human subject/participant and research as defined in this policy.

Institution: Any public or private entity, or department or agency (including federal, state, and other agencies).

Institutional Review Board (IRB): A committee established in accordance with and for the purposes expressed in this policy.

IRB approval: The determination of the IRB that the research has been reviewed and may be conducted at BSU within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally authorized representative: An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the participant's involvement in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the participant's involvement in the procedure(s) involved in the research.

For purposes of this policy, this includes:

- Parents;
- Legal guardians;
- Persons operating under a power or attorney, durable power of attorney or health care power of attorney (and can consent for research purposes);
- In the state of Indiana, under certain circumstances, adult grandchildren and grandparents; and
- For research conducted in foreign countries and on foreign citizens, those persons that meet the applicable country's definition of "legally authorized representatives".

Limited Review: A review of certain exempt protocols by at least one voting member of the IRB to ensure maximum protections for the participant.

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 tests.

Minor: Under Indiana stated Federal law, a person less than eighteen (18) years of age unless the child meets the Indiana state law definition of an emancipated minor.

Modification: Any change made to a research protocol after it has been approved by the IRB. These changes can be to the research methodology, participant recruitment, instruments used, editorial changes, etc. Modification can be major or minor in nature.

Major Modification*:* Any change to an approved protocol where the risk/benefit assessment changes, participant rights are altered, health/welfare benefits and protections are altered, etc. These changes reflect a significant alteration to the approved research.

Minor Modification*:* Any change to an approved protocol where the risk/benefit assessment does not change, participant rights are not altered, health/welfare benefits and protections are not altered, etc. These changes reflect a non-substantial/administrative type alteration to the approved research.

Non-Compliance: Failure to follow the regulations or the requirements and determinations of the IRB.

Examples of non-compliance may include the following:

- Failure to obtain IRB approval for Exempt studies.
- Inadequate or non-existent procedures for the informed consent process.
- Failure to report adverse events or protocol changes.
- Failure to provide ongoing progress reports or closure confirmation upon completion.
- Failure to follow approved procedures for research.
- Enrollment of participants that fail to meet the inclusion or exclusion criteria of the protocol, which in the opinion of the IRB Chair or convened IRB, increase the risk to the participant.

Serious Non-Compliance: An action or omission in the conduct or oversight of research involving human participants that affects the rights and welfare of participants, increases risks to participants, decreases potential benefits, or compromises the integrity or validity of the research. Examples of serious non-compliance may include the following:

- Conducting non-exempt research without IRB approval.
- Enrollment of research participants while study approval has lapsed.
- Serious protocol deviations that may place participants at risk from the research.

Continuing Non-Compliance*:* A pattern of non-compliance that, in the judgment of the Director, ORI, the IRB Chair or convened IRB, indicates a lack of understanding of the regulations or institutional requirements that may affect the rights and welfare of participants. This pattern would be seen as compromising the scientific integrity of a study such that important conclusions could no longer be reached. It would suggest a likelihood that non-compliance would continue without intervention or frequent instances of minor non-compliance. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

Not Research or Not Human Subjects Research (Not HSR): Projects and other types of research that do not meet the definitions of human subject/participant and research as defined in this section of the policy. These projects may be sound research projects or classified as research in their own right, but they do not meet the applicable definitions in this policy.

Principal Investigator (PI): The person primarily responsible for submitting protocol materials, conducting the research, and overseeing research activities and responsible for actions of the research team. The PI has the ultimate responsibility for ensuring the proper and ethical conduct of the study. PI and investigator are interchangeable terms.

Privacy: An individual's right to control access to themselves and their information. In many situations privacy rights will be dictated by an applicable law, regulation, or institutional policy.

Protocol: A set of documents that are submitted for IRB review, which outlines the proposed research, research methods, protections, and safeguards, etc. These typically include the IRB application, informed consent(s), tests used, and all other materials to be used in the research project.

Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency. This includes the employees or agents of such public agency, its contractors, or persons or entities to whom it has granted authority, which is responsible for public health matters as part of its official mandate.

Quality Assurance/Quality Improvement Project (QA/QI): A project that is designed primarily for an organization's internal use that assess the effectiveness of a program, process or tool. While the QA/QI project may be set up like research, the results are not meant for generalizable knowledge. In general, needs assessments and program reviews fall into this category.

Note: If a person plans on using a QA/QI process or results in HSR, then it will be treated as HSR.

Reliance Agreement: An agreement between two or more IRBs with FWAs for single IRB review of a non-Exempt protocol.

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

For purposes of this policy, the following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected;
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters);
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; and
  Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

If a proposed study falls under one of the above categories but otherwise meets the criteria for HSR, it will be considered research.

Research misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.

Fabrication: Making up data or results and recording or reporting them.

Falsification: Manipulating research materials, equipment, or processes; or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Note: Research misconduct does not include honest error or differences of opinion.

Serious Adverse Event (SAE): A significant and serious event that was unexpected or unanticipated during the research study. SAEs have an immediate and significant impact on the rights and/or welfare of a research participant. Examples of SAEs include death, hospitalizations, permanent

damages, suspicious findings, birth defects/congenital anomaly, loss or stolen identifiable information/records.

Subject/Participant: A person that participates voluntarily in HSR and/or has identifiable information collected about them. For purposes of this policy subject and participant are synonymous.

Unanticipated/Unexpected Problem: An unforeseen event in terms of nature, severity, or frequency of occurrence, as documented in the protocol or other materials approved by the IRB. For human research, such materials may include the informed consent document, clinical investigators' brochure, product labeling, etc.

Written, or in Writing: Refers to writing on a tangible medium (e.g., paper) or in an electronic format.

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HRPP Organization and Responsibilities

1. Overview

The components comprising the HRPP and their responsibilities of the Program are described below.

2. Leadership of the Program and Responsibilities

A. Institutional Official (IO)

BSU's IO is the Vice Provost (VP) for Research.
As the Federalwide Assurance (FWA) Signatory Official, the AVP for Research is responsible for:

- Ensuring the IRB has sufficient administrative and administrative support to assist the IRB in fulfilling obligations as well as allocating space, and equipment;
- Leading BSU's HRPP overall;
- Appointing new IRB members and Alternate Members; and
- Periodically evaluating whether the number of IRB's is appropriate to the volume and types of human research reviewed, so that reviews are accomplished in a thorough and timely manner.

B. Director, Office of Research Integrity (ORI)

The Director, ORI is responsible for:

- Directing and overseeing the day-to-day aspects of the HRPP and IRB support functions and operations;
- Training, supervising, and evaluating IRB staff;
- Providing advisory support to the IRB and the Institutional Official (IO) on regulatory and policy matters;
- Developing and implementing procedures to effect efficient document flow and maintenance of all IRB records;
- Developing and/or assisting in developing policies and procedures for the protection of human participants and in response to changes in regulations;
- Reporting changes in IRB membership to the Office for Human Research Protections (OHRP);
- Coordinating and communicating with other IRBs and/or collaborating IRBs when appropriate; and
- Participating in investigations of allegations of non-compliance in conjunction with the IRB Chairperson.

3. Office of Research Integrity (ORI):

The ORI is responsible for:

- Providing administrative support to the IRB;

- Providing and maintaining an educational program designed to educate faculty, staff, and students involved in human research in the safe and ethical conduct of research that will protect human participants;
- Scheduling meeting dates and times, reserving meeting spaces and providing technical support;
- Conducting initial/pre-review of submitted protocols;
- Facilitating communication flow between the IRB and PIs;
- Maintaining meeting minutes and other required IRB documentation;
- Maintaining BSU's online submission system; and
- Maintaining BSU's online educational system.

4. The Institutional Review Board (IRB)

A. The BSU IRB

The BSU IRB will:

- Require each IRB member, principal investigator, staff member, and students involved in research to complete education in HSR;
- Review all research involving human participants before it is started, regardless of funding source or funding status; and
- Adhere to the principles of the Belmont Report and the established criteria set forth by the Department of Health and Human Services (DHHS) and any other applicable federal and/or state law, regulations or ethical principles.

B. IRB Chairperson

The IRB Chairperson is responsible for:

- Convening and conducting Full Board meetings;
- Ensuring that the appropriate type of review is conducted within all federal regulations and organization's policies and procedures;
- Making recommendations to the IO for new Board members;
- Keeping the ORI director and the IO abreast of administrative and resource needs and making requests based on the assessed needs of the IRB; and
- Participating in investigations of allegations of non-compliance in conjunction with the ORI director.

C. IRB Vice Chair

The IRB Vice Chair is responsible for:

- Serving as the Chairperson if the IRB chair is conflicted out of a review or meeting session or is otherwise unavailable (e.g., away at a conference; sick); and
- Acting as the Chairperson pro tem in the event that a new Chairperson is needed. The Vice Chair is not required become the next IRB Chairperson. The Vice Chair is not necessarily a Chairperson elect.

D. IRB Members (includes the IRB Chairperson and Vice-Chair):

Each IRB member's primary duty is the protection of the rights and welfare of individual human beings serving as participants of research.

IRB members are responsible for ensuring protocol reviews are conducted appropriately, ethically, and within the constraints of federal regulations, applicable state laws and any institutional policies.

IRB members are also responsible for:

- Completing applicable member training (e.g., training though BSU's online education system); and
- Attending at least 50% of scheduled meetings during the normal academic year.

Note: June and July will not count against members if they are unable to attend and the IRB typically does not meet in August.

- Disclosing any conflicts of interests that impact the reviewed protocols (e.g., member is listed as a research team member, PI is the spouse of a Board member), prior to any protocol review taking place;
- Ensuring that any required professional credential(s) that is required for their role on the IRB is maintained; and
- When possible, serving for a 3-year renewable term.

E. Types of Members

Community Member(s) (Nonaffiliated member(s)): Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

Non-scientific members: Nonscientific members are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.

Scientific members: Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.

Child Representative Member: The "Child rep" is expected to provide input on areas germane to their knowledge, expertise and experiences concerning child welfare and issues that may be unique to research involving minors.

Prisoner Representative Member: The "Prisoner rep" is expected to provide input on areas germane to their knowledge, expertise and experiences concerning the criminal justice system, incarcerated persons, and issues that may be unique to research involving prisoners.

Student representative: The "Student rep" is expected to provide input on areas germane to their knowledge and provide perspectives on student related issues. BSU, as an institution of higher education, will make reasonable efforts to have a "Student rep" on the committee. The Student rep will serve as a regular member with all applicable roles and responsibilities.

Alternate Members: Alternate Members will fulfill the duties of a primary voting member when the primary member is recused or otherwise absent. Alternate Members are exempt from the attendance requirement.

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HRPP Policy Development, Implementation, and Maintenance

1. Policy and Procedure Development and Implementation

Policies and procedures are developed and implemented to ensure effective and consistent operation of the Human Research Protection Program (HRPP).

The ORI is responsible for the implementation and communication of HRPP policies and procedures. The Director, ORI (or their designee) and the HRPP Manager will monitor new regulations, guidance, etc. and in conjunction with the IRB Chairperson (or their designee) update the appropriate IRB policy(s) accordingly.

New or updated policies will be submitted to the Full IRB at the next regularly scheduled meeting for final review and discussion. Final policy drafts will be voted on by the IRB for formal approval recommendation to the BSU Institution Official (IO). The IO will then approve, reject, or recommend revisions to the submitted policy.

All developed policies and procedures and accompanying materials (e.g. forms, guidance) that pertain to researchers, participants, and faculty members will be published and made available on the IRBNet and the ORI website.

When a policy and procedure represent a significant change to existing policy, processes or procedures, the effective date will be set to allow for communication, including education and planning, for operational changes.

2. Policy and Procedure Maintenance

The ORI is responsible for maintaining HRPP policies and procedures. The IRB Policy Subcommittee will review existing policies and procedures. In addition, policies and procedures will be developed or updated as needs are recognized or change.

Human Subjects Research (HSR)

1. Overview

Federal regulations define human subjects research as described below. All research involving human subjects that fit either the DHHS or FDA definitions must be approved by an IRB before being conducted.

This policy describes federal definitions, the scope of HSR, and the process by which determinations are made.

2. Definition

A. Definition of Research (45 CFR 46. 102)

Research is defined as “a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

A systematic investigation is usually recognized by the fact that there is a predetermined and organized method [of data collection and analysis] to study a specific topic, answer a specific question, test a hypothesis, or develop a theory. It includes surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, evaluations of social or educational programs, cognitive and perceptual experiments, and medical chart review studies.

Generalizable knowledge means investigations designed to allow drawing of general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications and presentations), regardless of whether publication or presentation actually occurs.

The 2018 Common Rule specifically excludes the following activities:

- Scholarly and journalistic activities (for example, oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
- Public health surveillance activities
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order or criminal investigative purposes
- Authorized intelligence, homeland security, defense, or national security mission operational activities

B. Definition of Human Subject (45 CFR 46. 102)

Human subject is defined as a "living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Research about deceased people does not meet the federal definition of research with human subjects.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Private information includes 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 given or may be readily ascertained by the investigator or is associated with the information) in order for obtaining the information to constitute research involving human subjects.

3. Determination of HSR/ non-HSR

Not Research or Not Human Subjects Research (Not HSR) are defined as projects and other types of research that do not meet the definitions of human subject/participant and research as defined in this section of the policy. These projects may be sound research projects or classified as research in their own right, but they do not meet the applicable definitions in this policy.

A. Procedures

ORI staff will review and assess whether the protocol is required to be reviewed by IRB. ORI staff may consult the designated reviewer(s) to make determination.

ORI staff may request additional information from investigators, as necessary, to ensure there is sufficient information to make a determination about whether the activity is defined as research involving human subjects.

After completing initial review, ORI staff will make one of the following determinations.

- The protocol is not Human Subject Research (Not HSR) and may be conducted without IRB review or exemption.
- The protocol is HSR and, thus, must be reviewed by the IRB or exempted.

B. Inquiries of HSR Determination

As a service to the BSU research community, the IRB allows researchers who are unsure whether their project is HSR to submit an IRB HSR Determination Form for review.
There are two options for submitting this form:

- For those needing official determination letters, this form must be submitted via Ball State's online submission system,
- If the PI has informal questions on whether or not to submit, the form can be submitted via Ball State's online submission system or e-mail.

If the project is determined to be HSR, the PI will be responsible for submitting a full IRB application before they can begin their research.
Records of determinations including materials submitted and related correspondence, are retained by the ORI.

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Responsibilities of Investigators

1. **Responsibilities of Principal Investigator (PI)**

   The PI has the ultimate responsibility for ensuring the proper conduct of their study in a manner that minimizes risks, using sound research design and scientific scholarly standards.

   The PI must ensure research staff also is knowledgeable of issues related to the study.

   In addition to those duties, the principal investigator is also responsible for:

   - Ensuring proper IRB approval is obtained prior to the commencement of research;
   - Ensuring all research team members have completed applicable training on the basics of human research protections (e.g., completing training through BSU's online education system and for any research specific training that may be required to carry out the research);
   - Ensuring every research participant's rights, welfare, and safety are protected;
   - Developing a sound and ethical protocol design, that minimizes risks to participants while maximizing benefits;
   - Ensuring all members of the research team always comply with the findings, determinations, and requirements of the IRB;
   - Ensuring the adequacy of the informed consent process, regardless of which members of the research team are authorized to obtain and document consent;
   - Reviewing potentially reportable events and determine whether they require prompt reporting to the IRB; and
   - Requesting any changes by submitting modification in the appropriate and timely manner.

   Note: Eligibility of PI is defined in Eligibility of Principal Investigators (PIs) policy.

2. **Responsibilities of Co-PI, Investigators in Key Personnel**

   All Investigators in a research team are responsible for conducting the research in a manner that minimizes risks, using sound research design and scientific scholarly standards. They shall be aware of their responsibilities as investigators and fulfill them.

   All Investigators in a research team are responsible for completing initial and continuing required training.

   All investigators will not conduct research that has not been approved by the IRB or approved as exempt.

3. **Responsibilities of Faculty Advisor**

   For faculty acting as advisors for student research projects, responsibilities include, but are not limited to:

   - Serving as PI of record on the IRB application submitted after July 1, 2021.
   - Assisting students in developing proper research questions and methodologies;
   - Pre-reviewing all research materials before formal submission for IRB review;
   - If in agreement with materials submitted by the student researcher, electronically signing the package;
   - Working with the student on necessary revisions, modifications, continuing reviews, etc.;
   - Supervising in a continuous and on-going manner all student research activities associated with a project in which a faculty advisor has agreed to oversee;
   - Closing, modifying, and/or taking over the study protocol when a student graduates should the student not close the study at or before graduation; and
   - Completing and passing the appropriate online training for the type of research supervised before a protocol is submitted to the IRB.

The same expectations for faculty supervision are expected for master's level thesis research, doctoral dissertations, graduate research projects, undergraduate honors theses, all other faculty-student research collaborations, and class projects.

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Section 2. IRB administration and operation

IRB Organization and Composition

1. Overview

The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments, applicable laws and regulations, and standards of professional conduct.

The IRB shall be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

BSU will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

2. Composition of the IRB

The backgrounds of the regular members will be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB.
At a minimum, the IRB will be composed of at least five (5) voting members, including the following mandatory voting members:

- IRB Chairperson;
- Non-Affiliated (Community) Member;
- Scientific Member;
- Non-Scientific Member;
- Representative from Specialized Groups; and
    - Child Representative
    - Prisoner Representative

Note: If a Child or Prisoner rep are not required for a specific protocol, then 1 other person is needed and can be an additional Scientific, Non-scientific, or Community member. Additional voting members can include:

- Scientific member(s) that represent specific areas of research generally reviewed;
- Student representative- As BSU is an institution of higher education, the BSU IRB will make reasonable efforts to have a student rep on the committee as a regular member;
- Multiple community members;
- Physician(s); and
- Other persons that the IRB deems support the IRB's mission and BSU's research efforts

Note: The IRB also can invite special consultants (individuals with specialized training, credentials, etc.) to assist the IRB in protocol reviews.

- These individuals are not voting members and their presence or absence will not be used in establishing a quorum for a board meeting or contribute to a vote on the status of the protocol.
- Consultants will be used at the Chairperson's discretion, or if requested by the Full Board.
- All consultants will be asked to declare any known Conflicting Interests and will be asked to sign a Confidentiality Agreement prior to any board meeting or protocol review.

Note: The IRB will also maintain a pool of alternate members who can act as either a direct replacement for a specific voting member (e.g., Psychology Member and a Psychology Alternate Member).

- A general pool in order to fill the role of an absent, conflicted or otherwise absent voting member.
- Alternates will have all the same voting rights as the member they are replacing.
- In the case of a direct replacement, if both an alternate and a voting member are present, only the primary member's vote counts.

3. IRB Membership Selection Criteria

A. IRB Membership Selection Criteria

The members of the IRB shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of:

- Regulations;
- Applicable law;
- Standards of professional conduct and practice; and
- Institutional commitments.

The membership will be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, related experiences, and sensitivity to such issues as community attitudes to assess the research submitted for review.

B. The process of Joining the IRB

- A notice of interest should be sent in writing to the IRB Chairperson and ORI director;
- A copy of potential voting member's most current resume or Curriculum Vitae (CV) needs to be included with the notice of interest;
- The IRB Chairperson will then review the person's qualifications;
- If the person meets the appropriate qualification for a particular role or as a member in general, the Chairperson will present the person's resume/CV to the IRB membership at the next regularly scheduled Full Board meeting for review and consideration;
- If the Full Board approves of the person joining the IRB, the Chairperson will make a recommendation to the VP for Research to accept the potential member;
- If the VP for Research accepts the Chairperson's recommendation, the VP for Research will sign an appointment letter and send it to the potential member for their review and signature; and
- Once the appointment letter has been signed by the prospective member, they are now part of the IRB and able to attend the next regularly scheduled meeting.
    - If the person is filling a role that requires specialized credentials (e.g., Physician), then they need to provide a copy of that credential(s) for official records.
    - The ORI will maintain a record of all current Board Members' resumes/CVs and additional credentials.
    - For people wishing to join as Alternate Members, the process listed above will be the same.

4. Removal of IRB Members

A. Removal of IRB Membership

An IRB member may be removed for:

- Improper conduct;
- Failing to meet attendance requirements;
- Not disclosing conflicting interests; or
- Not maintaining confidentiality of official IRB proceedings.

B. The Process of removing IRB members

In the event a member is charged with violating any of the above, the IRB, at the next regularly scheduled Full Board meeting, will:

- Review the charges and collected evidence;
- Once discussions have concluded, the IRB will by a majority vote (not including the accused), vote on a recommendation to either retain or remove the member from the board;
- If the vote is to retain and the board requires any additional remedial action (e.g., retaking training) this needs to be noted in the meeting minutes;
    - The IRB Chairperson will notify the Director, ORI in writing of the results of the IRB recommendation before making a final decision as to the removal.
- The IRB Chairperson will notify the accused member in writing, and a copy will be submitted to the IRB.

C. Voluntary withdrawal

IRB Board members may also remove themselves from the committee for any reason (e.g., no longer able to attend meetings) and at any time.

- No Board action is required for this, though it should be noted in the meeting minutes.
- Voluntary withdrawal should be completed in writing and sent to the Chair and the Director, ORI.

5. Quorum Requirements and Voting

In order to properly conduct IRB related business, the committee must have a quorum present. For purposes of this policy, quorum is defined as ½ plus 1 of the voting memberships.

Alternate members can substitute for primary Board members that may be absent, conflicted out of the review, or otherwise unavailable.

6. Conflicting Interest of IRB members

No IRB member may participate in an initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
IRB members, including the Chairperson, who have conflicting interests are required to disclose such interests and to recuse themselves from deliberations, quorum counts, and votes on the relevant protocol prior the start of the review.
Such recusals will be recorded in the meeting's minutes as a recusal and not as an abstention.

Note: The IRB must maintain a quorum if votes are taken during absences.

7. Roles and Responsibility of IRB Chair, Vice Chair, and Members

See the Institutional Review Board (IRB).

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IRB Meeting Procedures

1. Meeting Schedules and Distribution of Materials

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive, is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

A. Exempt protocols

- The designated ORI staff member and/or IRB members or other qualified IRB experienced individual will review and determine what studies reviewed in the pre-review process should be considered Exempt.
- Such determinations will be recorded in BSU's online submission system and in the minutes for the next board meeting.
- Exempt protocols will be reviewed on a rolling basis.
- All materials will be available via BSU's online submission system. Materials will be available for review as soon as the pre-review process is completed.

B. Expedited protocols

- During the initial review of a protocol, if it is determined to be Expedited, the protocol will go through a pre-review process.
- Expedited review will be performed on a rolling basis by a fixed, primary reviewer and/or other IRB members based on the member's area of expertise. The meeting will be held only by requests from the primary Expedited reviewer and/or other designated IRB members.
- Once pre-review process is complete, it will be placed on the agenda of the next available Expedited Subcommittee meeting scheduled once a week.
- If a primary reviewer and/or other designated IRB members call for an expedited meeting, the meeting will be held next available meeting date. Meeting dates will be posted on the ORI website.
- A designated IRB reviewer or ORI staff may also call for additional Expedited meetings, if necessary. Additional meeting times may not be posted due to timing.
- All materials will be available via BSU's online submission system. Access to materials will be granted at least three (3) business days prior to a scheduled meeting.

C. Full Board protocols

- During the initial review of a protocol, if it is determined to be Full Board, or, during an Expedited meeting the subcommittee determines that the Full Board should review the protocol, the protocol will go through a pre-review process.
- Once the pre-review process is complete the protocol will be placed on the agenda of the next available meeting time of the Full Board Committee.
- The convened committee meets once per month, except on major holidays and other times as determined by the University. Meeting dates will be posted on the ORI website. The IRB Chairperson may also call for additional Full Board meetings to meet IRB or University needs or to conduct additional business (e.g., too many protocols to review for one meeting; review of an emergency protocol violation). Additional meeting times may not be posted due to timing.
- Material distribution:All materials will be available to board members via BSU's online submission system. Access to materials will be granted at least five (5) business days prior to a scheduled meeting.

D. Incomplete Submissions

- Incomplete applications will not be accepted for review until the PI has provided all necessary materials as determined by the person conducting the initial review or pre-review.
- Once all required materials are received, the protocol will be reviewed at the next available time slot as outlined above.
- If the PI does not submit the materials within 60 days of receiving their pre-review notice, their project will be withdrawn.

2. Convened IRB Meeting

A. IRB Member expectation

During a meeting in which research is being reviewed, the IRB and its members are expected to:

- Disclose any conflicting interests prior to the start of a protocol review;
- Conduct an in-depth review of all submissions, including ethical considerations;

- Document questions, concerns, suggestions, etc. in BSU's online submission system for the committee to review and discuss;
- Be prepared for discussion at the meeting;
- Be knowledgeable about the local research context in terms of where it is proposed that the research will be conducted, in order to make appropriate determinations;
- Be knowledgeable of the community from which the participants are drawn to ensure the protection of participants' rights and the appropriateness of the informed consent process; and
- Be ready to offer recommendation for promoting, enhancing or otherwise improving the protections of participants.

The IRB may request additional information from the PIs or consult with other individuals, if necessary, at any time during the review process.

- These individuals may be contacted directly;
- Attend the IRB meeting; or
- Provide written information to the IRB for consideration in their review.

B. Quorum Requirements and Voting

- In order to properly conduct IRB related business, the committee must have a quorum present.
- For purposes of this policy, quorum is defined as ½ plus 1 of the voting memberships.
- Alternate members can substitute for primary Board members that may be absent, conflicted out of the review, or otherwise unavailable.

C. Non-member Attendance at IRB Meetings

At the discretion and consent of the IRB Chairperson, non-members may attend a regularly scheduled meeting or part of a meeting. This includes, but not limited to:

- Special consultants assisting the IRB
- PIs asked to attend to help provide clarification on their proposed research
- Students learning about the IRB process
- Potential new Board members (recruiting)

Note: ORI staff will always be in attendance at Board meetings, supporting the IRB's efforts.

3. IRB Meeting Attendance Via a Virtual or Telecommunications Process

The IRB may utilize a virtual meeting process in case that IRB meeting cannot be physically held (e.g., the pandemic situation) or for those members, guests, PIs, etc. who cannot be physically present at a regularly scheduled meeting unless otherwise restricted by:

- Law;
- Regulation; or
- Grant/Funder Requirement.

Note: Use of this process is at the Chairperson's discretion.

The regulatory requirements (e.g. quorum) for a virtual IRB meeting are the same as an in-person meeting. In order for this process to constitute proper IRB Board Member attendance at a convened meeting, conduct of IRB business and allow for a proper protocol review, all of the following elements must be met:

- Conversations and discussions need to happen in real time allowing for real time verbal interactions;
- All Board members attending virtually must have real time access to all materials being reviewed (all materials found in BSU's online submission system);

- The meeting minutes need to note if the meeting is in virtual or which Board member(s) is/are in virtual attendance;
- When a vote is called for, any voting Board Member may cast their votes verbally or via the on-screen chat function.
- For all other non-members, the minutes should reflect who is in attendance virtually and what their role/purpose is at the meeting.
- To allow for appropriate discussion, all members must be connected simultaneously for a teleconference to take place

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IRB Documentations and Records

1. Meeting Minutes

Based on the joint guidance issued by OHRP and the FDA in 2017, the following items are mandatory in IRB Full Board meeting minutes:

- Attendance at the meetings;
    - Voting members present
        - Include the full name and representative capacity (e.g., scientist, nonscientist, unaffiliated) of each IRB member present at the convened meeting.
        - When an alternate member replaces a primary member at a convened meeting, the minutes must include the name of the alternate member in attendance.
        - When an alternate member substitutes for a primary member due to a conflicting interest, the minutes should identify the name of the primary member for whom the alternate member is substituting, and state that this is the reason for the substitution.
    - Names and titles of Non-voting members present
    - Consultants
        - Must include the name of the consultant and should include a brief description of the consultant's expertise.
    - Name and titles of Guest, PIs, etc. present
    - For all points above, if they are participating via a remote/teleconferencing process, the minutes need to note who is in attendance via this method.
    - Documentation of the point at which quorum is met, lost and/or regained.

- Actions taken by the IRB;
    - Minutes must show sufficient detail to identify the research activities being reviewed and voted on by the IRB at the meeting.
    - Any IRB action to approve, require modifications (to secure approval), or disapprove proposed research activities that occurs at a convened meeting must be documented in the minutes. Documentation of who moved and seconded the decision should also be noted.
    - If the IRB takes an action to require modifications or disapprove the proposed research, the minutes must be in sufficient detail to show the action taken by the IRB and the basis for said action.
    - Suspension or Termination of IRB Approval
        - Any IRB action to suspend or terminate IRB approval that occurs at a convened meeting must be documented.
        - Any suspension or termination of approval must include a statement of the reasons for the IRB's action.
        - Any decision to suspend or terminate the study that occurs outside of a convened IRB meeting (e.g., as determined by the IRB Chair, IO, or Director, ORI for participant safety reasons) should be reported to the convened IRB at the next regularly scheduled meeting and the discussion summarized in the minutes.

- Unanticipated Problems, Serious or Continuing Noncompliance, Suspension or Termination of IRB Approval
  - If at a convened meeting, the IRB reviews an issue that requires prompt reporting to the IRB under 45 CFR 46.103(b)(5) or 21 CFR 56.108(b) (e.g., an unanticipated problem involving risk to human participants or others), the minutes should summarize the report and must document the IRB's action, if any, resulting from that review.
- Special/protected populations
  - If the research involves any of the regulatory protected population groups, the meeting minutes must document the reviews, recommendations, and needed requirements of the applicable representative (e.g., Child rep; Prisoner rep.), review category (if applicable), and any requirement for additional review by federal authorities.
- Expedited reviews
  - The Full IRB will be notified of actions taken via the Expedited review process and provided an opportunity to ask questions.
  - A report of expedited actions may be appended to the minutes for reference and in fulfillment of this requirement.
  - Any questions, concerns or other requests concerning Expedited reviews need to be documented in the meeting minutes.
- Informed consent
  - The IRB must determine that informed consent will be appropriately documented in accordance with the applicable regulations.
  - The minutes should indicate that, as part of its review and approval of a study, the IRB reviewed the informed consent form(s) and determined that the form(s) meet the applicable regulatory requirements.
  - Any waivers or alternations to the informed consent process or form must be documented.
  - Requested changes and/or revisions to the informed consent form or process can be documented by the inclusion of the updated form or process.

- The vote on these actions, including the number of members voting for, against, and abstaining;
  - Total Voting = X; Vote: For = Y, Opposed = Z, Abstained = A
  - The minutes should identify any member who has a conflicting interest in a research study, and as such, is excluded (recused) from participation in the IRB's review of that particular research including the reason for the recusal.
  - IRB member(s) who participate in a convened meeting via a remote of teleconferencing process conferencing may vote and be counted towards the quorum. The IRB must ensure that the votes of such members are recorded in the minutes.

- The basis for requiring changes in or disapproving research
  - If the IRB requires that the investigator make specified changes to the research protocol or informed consent document(s) and resubmit such documents to the convened IRB for subsequent review, the IRB's action, along with the basis for requiring changes must be documented in the minutes.
  - If the IRB disapproves a research activity:
    - The IRB must include a statement of the reasons for its decision in the written notification to the investigator and the institution, and provide the investigator an opportunity to respond in person or in writing; and
    - The minutes must document the IRB's action along with the basis for disapproving the research.
- A written summary of the discussion of controverted issues and their resolution (e.g., disagreements on a protocol decision, dissenting opinions, ethical disagreements on policies)

2. IRB Documentation and Record Retention

BSU's IRB/ORI will maintain a system of records that accurately document the activities of the IRB and are in compliance with various federal regulations.

A. Retention

Unless otherwise specified by an applicable law or regulations, IRB records will be retained for at least 3 years after the completion of the research, and all other records are retained for at least 3 years.

Records maintained via BSU's online submission system may be retained indefinitely. BSU's current online submission system, IRBNet, is compliant with 21CFR11 and electronic signatures are in accordance with Subpart C of that instruction.

B. Access

Access to IRB records for inspection or copying is limited to the Director, ORI, the IRB Chairperson, IRB members, ORI staff, authorized BSU representatives, accreditation organizations, or parties contracted by the University.

The purpose of access by those permissible is to provide direct support to the IRB/ORI, and officials of Federal and state regulatory agencies, including the Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA).

Research investigators are provided reasonable access to files related to their research.

All other access to IRB records for inspection or copying is limited to those who have legitimate need for them, as determined by the Director, ORI. Appropriate accreditation bodies are provided access as needed.

Note: Department of Defense (DoD)-sponsored research may require submitting records to DoD for archiving.

C. IRB Records

The following is a list of some of the IRB records maintained**:**

- Written operating procedures
- IRB membership rosters
- IRB correspondence
- IRB research application (protocol) files and supporting documents
- Research (protocol) tracking system
- Documentation of Exempt reviews
- Documentation of Expedited reviews
- Documentation of convened IRB meetings (e.g., IRB meeting minutes)
- Documentation of review by outside consultants when appropriate
- Federalwide Assurances (FWA)
- Serious Adverse Event (SAE) reports
- Project tracking documents from automated system
- Documentation of cooperative review agreements, e.g., Reliance Agreement
- Sample forms
- Continuing Reviews of Full Board Protocols and other protocols requiring continued review
- Reports of injuries to participants
- Statements of significant new findings provided to participants (if applicable)
- Protocol violations submitted to the IRB
- A resume/CV for each IRB member plus any applicable credential(s)
- Unexpected adverse events submitted to the IRB

- Educational records for IRB Board members, PIs, and their research staff

D. IRB Membership Rosters

The Director, ORI (or their designee) ensures that current IRB membership roster is maintained and that any changes in IRB membership are reported to OHRP.

The membership rosters include the following information**:**

- Names of IRB members
- List of Alternate Members
    - If an alternate member is meant to replace a corresponding regular member(s), the roster needs to reflect this.
- Earned degrees of each member and alternate, where applicable
- The department of that member
- Representative status (e.g., Scientific, Non-scientific, Community member, etc.)
- Affiliation status

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Section 3. IRB Submission and Review

Submission and Pre-review

1. Submission Requirements (all categories of research)

A. New Study

When submitting a new protocol for review, PIs will need to submit the following information at a minimum:

- IRB application;
- Data collection instruments, including surveys, questionnaires, interview questions, etc.;
- Recruitment materials, including flyers, advertisements, letters, email/phone scripts, etc.; and
- A standard informed consent form
- If minors are involved, then a Parental Consent and a Child Assent form will be required.
- If the research is being conducted in different languages, then an informed consent form(s) translated into the applicable languages needs to be included.
- If the research is potentially Exempt, PIs can submit an Information Sheet (see Exempt Review)
- If deception is involved, then a debriefing form/script needs to be included.
- Other forms/materials as needed for the research. Examples include, but not limited to:
    - FERPA Authorization form
- Media Permission form (for media used in research)
- Letters of Support (for research being conducted at non-BSU/non-IRB covered sites)
- Training certificate for any personnel who are not affiliated with BSU.

B. Modification

When submitting a modification for review, PIs will need to submit the following information:

- IRB amendment/ modification form;
- Any applicable documents that have been added or changed;
- If primary elements (study purpose, research design, or PI) of study have been changed, IRB application revised should be submitted.

2. **Pre-review Procedures**
When a protocol has been submitted, ORI staff pre-reviews the materials to verify whether the application is complete as described above.

ORI staff also verify all investigators in the key personnel meet education requirements and additional requirement such as conflict of interest disclosure.

If an application is incomplete or clarifications are required, ORI staff will notify the PI.

Submissions are not considered complete and are not forwarded for IRB or administrative review until the investigator has met all requirements for submission.

If no response is received within 60 days, the PI is notified that the submission will be withdrawn. If withdrawn, all materials and any related correspondence are retained by the ORI in accordance with HRPP policy.

3. **Review Assignment**
Once a protocol is submitted, ORI staff determines whether the submission requires review by IRB (Full or Expedited), qualifies for exempt, or qualifies for administrative review.

For protocols requiring full or expedited IRB review, ORI staff will place the protocol on the agenda of the next available IRB meeting.

For protocols qualifying exempt and administrative review, they will be confirmed and processed by ORI staff.

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Exempt Review

1. **Overview**
Research that meets the one or more of the categories for research exemption will be considered exempt from full IRB or subcommittee review once the pre-review process is complete.

The IRB will be notified of all Exempt determinations at the next regularly convened Full Board Meeting.

Exempt protocols will be reviewed by the ORI staff and/or a designated IRB Reviewer for ethical considerations, sound research design, and applicable participant protections.

2. **Exempt Categories**
   A. **Category 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.

   B. **Category 2**
   Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior

and online behavior (including visual or auditory recording) if at least one of the following criterium is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
- Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

C. Category 3

Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least one of the following criteria is met**:**

- The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
- Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- For the purpose of this provision, benign behavioral interventions are brief in duration (brief will be defined relative to the intervention being performed), harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing.
- Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Note: If the research involves deceiving the participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that they will be unaware of or misled regarding the nature or purposes of the research.

D. Category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms

are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

- The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

E. Category 5

Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human participants.

F. Category 6

Taste and food quality evaluation and consumer acceptance studies:

- If wholesome foods without additives are consumed, or
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, 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.

G. Category 7

Storage or maintenance for secondary research for which broad consent is required:

- Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

H. Category 8

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

- Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
- An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to participants as part of the study plan.

Note: This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

3. Responsibility for Determining Exempt Status

The ORI staff and/or an experienced IRB Member will review all submissions and will make an initial determination of Exempt status based on information and materials submitted for review.

Investigators are not permitted to make their own determinations of exemption.

The IRB Chairperson and/or the Director, ORI (or their designees) are responsible for providing consultation in the review of potential Exempt research.

4. Exempt Review Considerations

The activities listed should not be deemed to be of minimal risk simply because they are included on this list.

Inclusion on this list merely means that the activity is eligible for review through the exempt review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

The categories in this list apply regardless of the age of participants, except category 2. Subparts 1 and 2 can be applied to minors only if the researcher(s) do not participate in the activities being observed. Subpart 3 cannot be applied to minors.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

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Expedited Review

1. Overview

The IRB may review some types of research, utilizing an expedited review process, when that research:

- Presents no more than minimal risks to human participants; and
- Involves only procedures listed in one or more of the Expedited Research Categories.
- Has been reviewed by the Full Board, and the Full Board requests that changes be made and confirmed by the Expedited Board.

The fixed, primary Expedited reviewer, IRB Chair or other designated IRB members may use expedited review procedures to approve a limited class of research activities involving human subjects.

2. Expedited Categories

A. Category 1

Clinical studies of drugs and medical devices only when either condition below is met:

- Research on drugs for which an investigational new drug application (21 CFR 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

- Research on medical devices for which:
    - An investigational device exemption application (21 CFR 812) is not required; or
    - The medical device is cleared /approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

B. Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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
- From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

C. Category 3

Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- Un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base, wax, or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- 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;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or
- Sputum collected after saline mist nebulization.

D. Category 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 include:

- 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 participant or an invasion of the participants privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; or

- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

E. Category 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 participants. This listing refers only to research that is not exempt.

F. Category 6

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

Note: Not all research involving these items will require Expedited review. Reviews are still handled on a case-by-case basis and will factor in research design, risk, protections provided, anonymous v. identifiable, etc.

G. Category 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 participants. This listing refers only to research that is not exempt.

3. Expedited Review Considerations

The categories in this list apply regardless of the age of participants, except as noted.

The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human participants.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

Note: The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

4. Expedited Review Procedure

In order to approve research covered by this policy the IRB, though the Expedited Subcommittee (Subcommittee) will determine that all of the following requirements are satisfied:

- Risks to participants are minimized:
    - By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
    - Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
    - In evaluating risks and benefits, the Subcommittee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research).
    - The Subcommittee should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of participants is equitable.
    - In making this assessment the Subcommittee should take into account the purposes of the research and the setting in which the research will be conducted.
    - The Subcommittee should be particularly cognizant of the special problems of research that involves a category of participants who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by §46.116.
- Informed consent will be appropriately documented, or appropriately waived in accordance with, and to the extent required by §46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of Common Rule, and shall make the following determinations:
    - Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);
    - Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with §46.117; and
    - If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

5. Expedited Review Subcommittee Meeting

The Expedited review will be performed on a rolling basis by a fixed, primary reviewer and/or other IRB members based on the member's area of expertise. The meeting will be held only by requests from the primary Expedited reviewer and/or other designated IRB members.

The Subcommittee will consist of one fixed, primary reviewer and/or other IRB members.

Upon review, the Subcommittee will make one of the following determinations:

- Approve;
- Approve with Conditions (see note below);
- Information/modifications required (and tabled until issues are addressed);
- Study is greater than minimal risk and forwarded for Full Committee review;
- Study qualifies for Exempt review; or
- Not HSR.

In reviewing the research, the Subcommittee may exercise all of the authorities of the IRB except that the Subcommittee may not disapprove the research.

- A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in the Common Rule.

- Should the Subcommittee wish a protocol be considered for disapproval, it must forward the protocol to the Full Committee for review at its next regularly scheduled meeting.
- A research proposal may be disapproved only after review by the full IRB.

Due to the nature of how BSU's online submission system operates, the Subcommittee can make all of the standard review determinations, except if the subcommittee determines protocol is Conditional Approval (Approval with Conditions), it is handled administratively as follows:

- Conditional Approval pending minor revisions and clarifications: These revisions have no impact on the risk review or Subcommittee determinations and are generally handled administratively.
- Some examples include:
  - Adding additional contact information
  - Change non-substantive verbiage
  - Correcting amount of time spent in the study (e.g., in one place it states one hour and in another it states 45 minutes)
- If these types of minor revisions are requested, the ORI will unlock the PI's protocol, allow them to make the changes, the protocol is relocked by the PI, an administrative review is done and then the protocol approval process is finished. All of this is tracked electronically. If the PI does not submit the required changes within 30 days, the project will not be approved.
- These types of minor revisions can be administratively reviewed to ensure that they have been completed, by the IRB Chairperson, the Director, ORI, by a designee assigned by the IRB Chairperson, or by a member of the ORI.

6. Expedited Continuing Review

The primary expedited reviewer may request that a continuing review be implemented at the time of approval by consulting with the IRB chair or director, ORI. If a continuing review of an approvable Expedited protocol is requested, the meeting minutes must reflect:

- A clear and justifiable reason for the request;
- Requested timeframe (1 year is the standard default); and
- Any conditions or situations that could result in the continuing review period being dropped.
- Note: Expedited protocols do not require a continuing review unless requested by the sub-committee.

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Convened IRB Review

1. Required Criteria for IRB Approval (Full Board)

The Full Board will review all protocols that are deemed greater than minimal risk and those that are referred for review from the Expedited Subcommittee.

Based on the IRB's review of information provided by the PI, and in accordance with appropriate regulations and BSU policies, the IRB may grant approval of research, including:

- Initial review;
- Continuing review; and
- Review of modification to previously approved research.

Approval may be granted if the Board determines all of the following requirements are satisfied:

- Risks to participants are minimized by using procedures that:
  - Are consistent with sound research design and do not unnecessarily expose participants to risk.
  - Whenever appropriate are already being performed on the participants for diagnostic or treatment purposes.

- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
    - In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies/ treatments/procedures/activities participants would receive even if not participating in the research).
    - The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within its purview of its responsibility.
- Participant selection is equitable.
    - In making this assessment, the IRB should consider the selection (inclusion/exclusion) criteria and take into account the purposes of the research and the setting in which the research will be conducted.
    - Considerations should also focus on the special problems of research involving vulnerable populations.
    - The IRB should evaluate the influence of payments on equitable selection and assure the method and timing of disbursement is neither coercive nor presents undue influence on participants.
    - When applicable, the IRB should determine completion bonuses, incentives, etc. are reasonable and do not unduly influence participants to remain in research when they otherwise would have withdrawn.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative and documented in accordance with, and to the extent required by, the regulations, unless the IRB has waived or altered this requirement.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
    - The IRB will review the adequacy of the PI's proposed monitoring plan regarding data monitoring and participant safety.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
    - Utilized privacy and confidentiality measures/safeguards need to be documented in the PI application and reviewed by the IRB.
    - Summary of measures needs to be included in the informed consent.
- When some or all the participants are likely to be vulnerable to coercion or undue influence (e.g. children, prisoners, individuals with impaired decision-making capacity impacting their ability to consent, or economically or educationally disadvantaged persons) adequate safeguards have been included in the research proposal to protect the rights and welfare of these participants.
- The proposed participant recruitment methods, advertising materials, and incentives are fair, honest, and appropriate.

2. Full Board Protocol Approvals and Continuing Review

All Full Board protocols can be approved for up to 1 year and they require a Continuing Review approval at least annually.

All PIs must submit a Continuing Review (CR) form for IRB review prior to the anniversary date (expiration date) of their protocol in order to receive consideration for continued approval.

Note: Failure to submit the CR in a timely manner or before approval has ended can result in the immediate termination of approval to continue conducting HSR and possible grounds for non-compliance.

Full Board protocols that have progressed to the point where they only involve one or both of the following, which are part of the IRB-approved study, will no longer require IRB Continuing Review:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

Note: This determination is made by the Full Board at a regularly convened meeting.

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Post IRB Approval Modifications

1. **Overview**

   It is a well understood premise that research is fluid and elements of a research project can change once a principal investigator (PI) starts conducting their research.

   These changes can be minor or major. The primary purpose of this policy is to address how these changes are to be handled both by the researcher and the IRB.

   The overall goal, however, is still to protect the rights and welfare of human research participants.

   Note: Unless otherwise restricted by law, regulation, or grant/funder requirement, the IRB will utilize the following process for reviewing Expedited and Full Board post-approval protocol modifications:

2. **Major Modifications**

   Any change to an approved protocol where the risk/benefit assessment changes, participant rights are altered, health/welfare benefits and protections are altered, etc. These changes reflect a significant alteration to the approved research.

   Major modifications include, but are not limited to:

   - Changes in personnel, including PI
   - Changes to the research methodology
   - Any change that alters the risk level up or down
   - Addition/change to participant rights, protections and/or welfare
   - Adding/removing deception use in research
   - Adding/revising questions to the survey or interview documents
   - Addition of a new participant pool not originally presented in the protocol (e.g., protocol was approved for adults with diabetes now you want to add normal/healthy adults)
   - Addition or removal of a protected population pool (e.g., minors, prisoners, etc.)
   - Changing the research's identification status (e.g., use of identifiable information to de-identifiable information)
   - Changing the use of data/information protected by another regulation or law (e.g., HIPAA and FERPA)
   - Participant increase by 20% or more from the originally approved number for protocols requiring full board review
   - Adding or changing participant compensation or incentive

3. **Minor Modifications**

   Any change to an approved protocol where the risk/benefit assessment does not change, participant rights are not altered, health/welfare benefits and protections are not altered, etc. These changes reflect a non-substantial alteration to the approved research.

   Minor modifications include, but are not limited to:

   - Correction of typos
   - Minor wording clarifications (in informed consent forms, surveys, etc.) that do not change/alter any rights, protections, etc.

- Participant increases that involve minimal risk protocols (Exempt and Expedited)
- Adding an additional (previously approved) recruitment notification round (e.g., approved for 2 e-mail notices going out and then adding 1 more)
- Addition of a participant pool similar to the one(s) already approved (e.g., protocol was approved for people with diabetes in town A and now you want to add the same type of group from town B.)
- Adding/changing dates of X (e.g., we stated X would be in Aug., but we had to move it to Oct.)
- Adding/changing room locations, testing sites, addresses, etc. unless there is a privacy/security issue or requires a letter of support
- Removal of survey/interview questions (excluding screening questions)

4. Responsibilities and Procedures

A. Principal Investigator (PI):

PIs are not required to submit minor modifications for IRB review, unless they are also part of a modification request involving major modifications.

It is the PIs' responsibility to submit any major modification for review by the IRB. Major modifications must be submitted for review and approved before the PI can act on the proposed modifications. Some major modifications may be handled by administrative review.

Minor modifications must be submitted with the next continuing review submission (for Full Board reviews) so that there is a complete and current record of the PI's proposed research. For example, if minor editorial changes were made to the informed consent form, these changes need to be included in the continuing review.

Minor modifications for exempt protocols only need to be submitted if the PI is also submitting a major modification for review.

B. IRB and ORI:

The ORI will review any major modification request to determine if the risk and/or review level have changed sufficiently to alter the review level. If the modification is sufficient to alter the review level, the ORI will assign it to the appropriate committee for review.

The IRB will review any proposed major modifications at the next available committee meeting (for Expedited and Full Board reviews).

C. ORI Administrative Review:

The IRB has determined that some modifications are more administrative in nature and not ones that impact risk, health/welfare, rights, and so forth.

As such the IRB has authorized the ORI to review these administrative and minor modifications, make applicable determinations and approve or send the modification(s) for further review by the IRB.

The list of items that fall into the administrative review category can change over time, reflect changes in regulations, and so forth.

Items that fall into the administrative review category include, but are not limited to:

- Change of PI (unless PI does not meet applicable requirements or ability to actually conduct the research)
- Personnel changes (research team, students, etc.)
- Closures
- Addition of research site(s) where a letter of support is needed (assumes no change to the research)

D. Exceptions

These procedures do not apply when

- Any administrative or regulatory body that has direct jurisdiction over the IRB process specifically requires that all modifications be reviewed and approved by the applicable IRB committee.
- Specifically required as part of the initial IRB review and made part of the formal approval.
- Modification(s) impacts and/or involves some other regulation, statute or applicable law (e.g., HIPAA or FERPA).
- Multi-site studies involving a single IRB. These will be handled on a case- by-case basis or as dictated by a reliance agreement.

5. Modifications to Exempt Research

Whenever a PI makes substantive changes to approved Exempt research, the PI may request proposed changes by submitting a modification request through BSU's online submission system.

The major modification(s) must be requested and approved prior to their initiation.

The PI is allowed to make minor modifications without review and approval.

These modifications are reviewed to ensure that the protocol is still Exempt and minimal risk. If the changes do not affect the Exempt status, the modification will be approved and the PI will be notified.

If the changes are determined to be significant enough to change the risk assessment to greater than minimal risk or the research no longer meets the criteria for Exemption, the PI will be notified accordingly, and the review transferred to the appropriate review committee (e.g., Expedited Review).

6. Modifications to Expedited and Full Board Research

Review of the modification request will be made by the appropriate committee at the next regularly scheduled meeting after the PI completes the pre-review process.

Minor modifications and modifications that can be approved administratively will be approved in the ORI and the Board will be notified at the next full board meeting.

PIs making a modification request must submit:

- A Modification form and
- Any materials that may be impacted by the modifications (e.g. if the informed consent is changed, the updated informed consent would need to be included)

Note: If a PI wishes to make any major modification to a currently approved protocol, a modification request must be submitted to the IRB for review and receive approval before the PI can implement any changes to an approved protocol.

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Cooperative Research and Reliance Agreements

1. Overview

Cooperative research projects are those projects covered by this policy that involve more than one institution (multisite). In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human participants and for complying with this policy.

2. **Single IRB**

Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the federal department or agency supporting the research.

The following research is not subject to this provision:

- Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
- Research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

For research not subject to this provision, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB (i.e., Reliance Agreement), or make similar arrangements for avoiding duplication of effort.

Note: Reliance Agreements will be required for multisite Expedited and Full Board Reviews regardless of funding or funding source. Multisite Exempt Reviews will not require a Reliance Agreement unless required by law, regulations or funder.

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Section 4. IRB Evaluation Criteria and Consideration

Informed Consent

1. **Overview**

One of the fundamental tenants of ethical HSR is that of informed consent.

Before a human participant is involved in a research study, the PI and/or a member of their research team MUST obtain legally effective informed consent (whether oral or written) from a prospective participant or a legally authorized representative unless the requirement has been waived by the IRB.

2. **Requirement for Informed Consent**

The prospective participant or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and a sufficient opportunity to discuss that information**.**

- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

Note: Exception to the two above rules can be found in the section below entitled “Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.”

No informed consent may include any exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The information that is given to the participant or the legally authorized representative shall be in language understandable to the participant or the legally authorized representative.

3. Reading and Comprehension Level

When developing an informed consent, PIs should write them at the 6th-8th grade reading level or to the reading level of the participant pool (e.g., 4th graders reading at the 4th grade level; people with diminished capacity may require a simpler reading level), whenever feasible.

For research that involves non-English speaking persons, PI must have the informed consent forms translated into the appropriate language(s) for the participant pool. While the translation may not be exact, it is expected to convey all of the information required to be in the informed consent and substantially mirror the English version submitted for review.
Note: Translated version and English version need to be included in the IRB submission package for review.

In some cases, an alternative to standard written informed consent documents may be used in the form of oral presentation of informed consent information. This process is typically used in situations where there is diminished capacity, illiteracy, and so forth. This process will follow the requirements outlined in the Documentation of Informed Consent section.

4. Elements of Informed Consent

(1) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's involvement, a description of the procedures to be followed, and identification of any procedures that are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the participant;
(3) A description of any benefits to the participant or to others that may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant;
- For research involving students in which extra credit is awarded, a statement of how a non-participating student can receive the same credit. The alternate process must be equivalent and equitable to the amount of time and involvement of a participating student.

(5) A statement describing the extent to which, if any, confidentiality of records identifying the participant will be maintained and how they will be protected;
- PIs must include basic information about the methods, technologies and/or process to be used.

(6) For research involving greater than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether 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 related to:
- Questions about the research- this can be the PI/Co-PI with appropriate knowledge;
- Research participants' rights- this is the ORI and/or IRB chairperson; and
- Whom to contact in the event of a research-related injury or discomfort to the participants-

- This can be the PI, or appropriate research team member, only if they have appropriate training to deal with the research-related injury or discomfort.
- This can also be an appropriate outside party or resource (e.g., local hospital, suicide hotline, primary care provider).

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or
- A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- If neither point above applies, include a statement that no identifiable private information or identifiable biospecimens will be collected.

5. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information will also be provided to each participant:

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

(2) Anticipated circumstances under which the participant's involvement may be terminated by the PI without regard to the participant's or the legally authorized representative's consent;

(3) Any additional costs to the participant that may result from participation in the research;

(4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

(5) A statement that significant new findings developed during the course of the research, that may relate to the participant's willingness to continue participation, will be provided to the participant;

(6) The approximate number of participants involved in the study;

(7) A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (e.g., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

6. Special Informed Consent Considerations and Requirements

Minors: For research involving minors, a Parental Consent and a Child Assent are required. The Child Assent process may vary based on age of the child, reading and comprehension level, risk to child, etc. The IRB may exercise flexibility in the use of oral Assent based on these factors. See also Vulnerable Populations.

Prisoners: For research involving prisoners, PI must include a statement that participation will not impact any legal proceedings, eligibility for parole or impact any of their rights or standings while in lawful custody within any Lawful Detention Center, Penal Facility or Correctional Facility. See also Vulnerable Populations.

Research involving students and student records subject to FERPA: For research in these situations, PI must include a statement that participation (or not) in the proposed research will not impact their grade, eligibility to graduate or their standing within the applicable educational system. **Note:** Reference external policy on Faculty Recruitment of Students in Research and Use of FERPA Protected Information.

Federal Agencies: Some federal agencies (e.g., DoD) require specific language in the informed consent. These will be decided by each agency and the PI must include this required language.

Visually Impaired: For groups that may have vision impairments or difficultly with reading small fonts, PIs are required to increase font sizes to an appropriate level.

Compensation/Incentives: When research involves any form of compensation or incentive to participate, PI must include a statement/explanation:

- How this will be handled;
- Conditions for receiving the compensation/incentive;
- The amount of compensation;
- If pro-rated, how this will be determined; and
- If required, that personal information may be collected for tax purposes

Participants Who Are Unable to Read the Consent Document: Participants that can understand and comprehend spoken English but are unable to read the informed consent document for any reason (e.g. illiteracy, blindness or diminished vision, dyslexia, unable to obtain a copy of the consent document for review, etc.) may be enrolled in research; however, special care must be taken to ensure the individual is able to understand the concepts of the research and evaluate the risks and benefits of being in the study when it is explained orally.
The research team must present the information orally and document the circumstances.
An impartial witness must observe the entire consent process and sign the consent document.
Although not required, a video recording of the consent interview is recommended.

Informed Consent Procedures Via Telephone and Video Conference Tool (or similar technologies): In some situations, or types of research, informed consent may be allowed to be conducted over the telephone, video conference platform, and/or over other similar technologies. In these situations, the person obtaining consent must document that the informed consent process took place by making appropriate notation regarding the process in the proper files.

- If a waiver of documentation of informed consent has not been approved by the IRB, the person discussing the research study with the potential participant must sign and date the consent document prior to sending it to the potential participant.
- Once the participant receives, signs, and returns the informed consent document to the study site, the document should again be signed and dated by the appropriate member of the research team who receives the document.
- Research-related activities may not begin until the signed informed consent document is received by the study team.
- If participants give their verbal consent via telephone and/or video conference platform, it should be properly audio or video recorded.

Online Informed Consent: The IRB recognizes that much research is conducted online and that physical signatures may not always be possible.

- For research that includes telecommunication or video conference processes, the PI will follow the process for telephones and video conference tool above.
- For research such as online surveys, PI will be required to post the informed consent form before any potential participant is allowed to access the survey and agree via some type affirmative process (e.g., “I agree” or “I disagree”).

- In general, the IRB considers this a standard alteration of the informed consent process routinely granted, it does not, however, guarantee that this will always be allowed.

7. Requirement for a Concise Summary

For research that involves a long informed consent form (more than 4 pages) or is overly complex, informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

- This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- In general, this is a summary sheet of the informed consent, not a replacement for, and must include in an easy to understand format:
  - The purpose of the study;
  - Duration of participation;
  - The major requirements (procedures) for the study;
  - Any potential benefits of participation; and
  - Any significant risks of participating in the study.

Note: A Concise Summary is not required for Exempt research, unless requested by the initial review/IRB.

8. Broad Consent

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in “Elements of Informed Consent” and “Additional Elements of Informed Consent.”

If the participant or the legally authorized representative is asked to provide broad consent, the following will be provided to each participant or the participant’s legally authorized representative:

- The information required in points 7 and 9 in the “Additional Elements of Informed Consent” section;
- A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
- Unless the participant or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the participant’s identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the participant in all circumstances, a statement that such results may not be disclosed to the participant; and

- An explanation of whom to contact for answers to questions about the participant's rights and about storage and use of the participant's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

9. General Waiver or Alteration of Informed Consent

The IRB may waive the requirement to obtain informed consent for research provided the IRB satisfies the requirements of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Alteration: The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth provided the IRB satisfies the requirements. An IRB may not omit or alter any of the requirements described. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required.

Requirements for waiver and alteration: In order for the IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - Public benefit or service programs;
    - Procedures for obtaining benefits or services under those programs;
    - Possible changes in or alternatives to those programs or procedures; or
    - Possible changes in methods or levels of payment for benefits or services under those programs; and
- The research could not practicably be carried out without the waiver or alteration.

10. Screening, Recruiting, or Determining Eligibility

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant or the participant's legally authorized representative, **if either of the following conditions are met:**

- The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

11. Posting of Clinical Trial Consent Form

For each clinical trial conducted or supported by a federal department or agency, one IRB-approved informed consent form used to enroll participants must be posted by the awardee or the federal department or agency component conducting the trial on a publicly available federal website that will be established as a repository for such informed consent forms.

If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal website (e.g. confidential commercial information), such federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on a publicly available federal website (ex. Clinicaltrials.gov) after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any participant, as required by the protocol.
For a multi-site study, only a single consent form from the entire study is required to satisfy the posting requirement and not a consent form from each participating site.

Preemption: The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

Emergency medical care: Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

12. Documentation of Informed Consent

(1) Except as provided in paragraph (3) of this section, informed consent will be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the participant or the participant's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

(2) Except as provided in paragraph (3) of this section, the informed consent form may be either of the following:
- A written informed consent form that meets the requirements of §46.116 (found in "General Requirements for Informed Consent"). The investigator shall give either the participant or the participant's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the participant or the participant's legally authorized representative.
- A short form written informed consent form stating that the elements of informed consent required by §46.116 (found in "General Requirements for Informed Consent") have been presented orally to the participant or the participant's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the participant, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the participant or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the participant or the participant's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the participant's legally authorized representative, in addition to a copy of the short form.

(3) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all participants if it finds any of the following:
- That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern;
- That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context or;
- If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(4) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants or legally authorized representatives with a written statement regarding the research.

13. Child Assent and Parental Permission

Parent permission must be obtained before child assent. Parent permission, when required, cannot assume that no response implies permission (i.e. opt out consent) unless

- No identifiable data (including video or audio recording) about students is being collected
- The procedures of the study are commonly accepted educational practices that will occur regardless of the research

Note: Any participant under the age of 18 must have a child assent form that is commensurate with their age and their legal guardian must give permission for them to participate in the study.

Exception: Students enrolled at Ball State University that are 17 years of age do not require parental consent for purposes of participating in HSR conducted at Ball State University. A standard adult informed consent process and form can be used for these students.

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Vulnerable Populations

1. Overview

When research involves vulnerable populations, the IRB must determine that specific requirements are satisfied in order to approve research with human participants.
In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations.

2. Vulnerable Populations

Vulnerable populations are those groups that historically have been subject to abuses, are in situations where undue influence can be applied and/or are particularly susceptible for a variety of reasons.
Vulnerable populations include, but may not be limited to:

- Children
- Prisoners
- Pregnant women (except when pregnancy is incidental to the research)
- Students
- Individuals lacking consent capacity
- Economically or educationally disadvantaged persons,
- Persons with limited treatment options, and
- Persons with increased susceptibility to harm including economic, social, or legal consequences from the study

Note: Because of the special vulnerability of these populations, the federal regulations, state and local laws, and institutional policies require additional protections for these individuals**.**

3. General Requirements

The IRB must carefully consider the following specific elements of the research protocol when reviewing research involving vulnerable participants:

- Strategic issues include: inclusion and exclusion criteria for selecting and recruiting participants, informed consent and willingness to volunteer, coercion and undue influence, and confidentiality of data.
- Group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards for vulnerable participants.
- Investigators are not permitted to over-select or exclude certain groups based on perceived limitations or complexities associated with those groups. For example, it is not appropriate to

target prisoners as research participants merely because they are a readily available "captive" population.
- Applicable state or local laws that bear on the decision-making abilities of potentially vulnerable populations. State statutes often address issues related to competency to consent for research, emancipated minors, legally authorized representatives, the age of majority for research consent, and the waiver of parental permission for research.
- Adequate procedures in place for assessing and ensuring participants' capacity, understanding, and informed consent or assent. When weighing the decision whether to approve or disapprove research involving vulnerable participants, the IRB ensures and requires that such procedures are a part of the research plan. It may be possible for researchers to enhance the understanding for potentially vulnerable participants.

Examples include:
- Having someone not involved in the research to obtain the consent;
- The inclusion of a consent monitor;
- A participant advocate;
- Interpreter for hearing-impaired participants;
- Translation of informed consent forms into languages the participants understand;
- Reading the consent form to participants slowly and ensuring their understanding paragraph by paragraph; and
- Additional safeguards. For instance, the IRB may require that the investigator submit each signed informed consent form to the IRB, that someone from the IRB oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time for family discussion and questions.

4. Additional Protections for Pregnant Women, Human Fetuses, and Neonates (Subpart B)

Research involving women who are or may become pregnant should receive special attention from the IRB because women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus.

Further, in the case of a pregnant women, the IRB must determine when informed consent of the father is required for the research.

Special attention is justified because of the need to prevent harm or injury to future members of society.

Note: The policies that follow only apply in instances where the research directly impacts women who are pregnant or may become pregnant, the fetus, or the neonate. These policies do not apply when research is unrelated to pregnant participants (e.g., online survey).

Research in which Pregnancy Is Coincidental to Participant Involvement
- Special care should be taken with any research in which women (of childbearing potential) are possible research participants and/or may inadvertently include women already pregnant or women who may become pregnant during the research.
- When applicable, DHHS regulations require that the informed consent document include a statement that the particular treatment, procedure, or research intervention may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable.
- The IRB must judge whether participation by the pregnant woman would pose any risk to the fetus or nursing infant.
- In some studies, the IRB may need to ensure that non-pregnant participants are advised to avoid pregnancy or nursing for a time during or following the research.
- Furthermore, where appropriate, participants should be advised to notify the investigator immediately should they become pregnant.

- In some instances, there may be potential risk sufficient to justify requiring that pregnant women either be specifically excluded from the research or studied separately.

Research involving pregnant women, human fetuses, and neonates

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
- One of the following is true:
    - The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.
    - The risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
- Any risk is the least possible for achieving the objectives of the research.
- For children who are pregnant, assent and permission are obtained in accordance with the regulations.
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- Individuals engaged in the research have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- Individuals engaged in the research have no part in determining the viability of a neonate.
- Where scientifically appropriate, preclinical and clinical studies have been conducted and provided data for assessing potential risks to neonates.
- Individuals engaged in the research have no part in determining the viability of a neonate.
- One of the following is true:
    - The research held out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective.
    - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there is no added risk to the neonate resulting from the research.

The IRB determines whether the approval criteria for consent and permission are met when research involves pregnant women or fetuses. The IRB Chair will have the IRB determine and document that:

- The consent of the pregnant woman is obtained in accordance with the regulations.
- If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the father is also obtained in accordance with the regulations, except that the father's consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

The IRB determines whether the criteria for approval of research are met when research involves nonviable neonates. The IRB Chair will have the IRB determine and document that:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provided data for assessing potential risks to neonates.
- Individuals engaged in the research have no part in determining the viability of a neonate.
- Vital functions of the neonate are not artificially maintained.
- The research will not terminate the heartbeat or respiration of the neonate.
- There is no added risk to the neonate resulting from the research.
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

The IRB determines whether the approval criteria for consent and permission are met when research involves neonates of uncertain viability. The IRB Chair will have the IRB determine and document that:

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The legally effective consent of either parent of the neonate is obtained in accordance with the regulations.
    - If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is obtained.
    - The consent of the father or his legally authorized representative does not have to be obtained if the pregnancy resulted from rape or incest.

The IRB determines whether the approval criteria for consent and permission are met when research involves nonviable neonates. The IRB Chair will have IRB determine and document that:

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The legally effective consent of both parents of the neonate is obtained in accordance with the regulations.
    - If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent of a nonviable neonate is sufficient, except that the consent of the father does not has to be obtained if the pregnancy resulted from rape or incest.
    - The consent of a legally authorized representative of either or both of the parents of a nonviable neonate is not allowed.
- The waiver and alteration provisions are not applied.

When following DHHS regulations the following applies:

- When research involves pregnant women, the IRB determines that the consent of the pregnant women is required if the research holds out:
    - The prospect of direct benefit to the pregnant woman.
    - The prospect of direct benefit both to the pregnant woman and the fetus.
    - No prospect of benefit for the woman or the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
- When research involves pregnant women, the IRB determines that the consent of the pregnant woman and the father is required, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest if the research holds out the prospect of direct benefit solely to the fetus.
- When the research involves neonates of uncertain viability, the IRB determines that the consent of either parent of the neonate is required or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is required, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- When the research involves non-viable neonates, the IRB determines that the consent of both parents is required, except:
    - If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent is required.
    - If the pregnancy resulted from rape or incest the consent of the father need not be obtained.

Note: When the research involves non-viable neonates, the IRB is not allowed to approve the consent of a legally authorized representative.

5. Additional Protections for Prisoners (Subpart C)

For the review of research involving prisoners:

- A majority of the IRB membership (exclusive of prisoner members) must have no association with the prison involved, apart from their membership on the IRB.
- At least one IRB member who is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity is present at the meeting.
- For prisoners, “minimal risk” means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- The Exempt procedure cannot be used for research involving prisoners.

The IRB determines whether the criteria for approval of research are met when research involves prisoners. The IRB determines and documents that:

- The research represents one of the following categories:
    - 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 participants.
    - 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 participants.
    - 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).
        - For DHHS-funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.
    - Research on practices, both innovative and accepted that has the intent and reasonable probability of improving the health or well-being of the participant.
        - For DHHS-funded research which 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 after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.
    - Epidemiologic studies that meet the following criteria:
        - The sole purposes are one of the following:
            - To describe the prevalence or incidence of a disease by identifying all cases.
            - To study potential risk factor associations for a disease.
        - The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants, and
        - Prisoners are not a particular focus of the research.
- Any possible advantages accruing to the prisoner through 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 the prisoner’s ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
- Unless the principal investigator provides justification in writing for following some other procedures, control participants are selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
- Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole.

- When there is a need for follow-up examination or care of participants after the end of their participation, adequate provisions are made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.
- For DHHS-funded research, indicate the individual (by title of position) who certifies to OHRP the duties of the IRB have been fulfilled.

For research involving prisoners reviewed by the convened (Full) IRB:

- The prisoner representative must be a voting member of the IRB.
    - The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
- The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections.
    - The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer).
- The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
    - The prisoner representative may attend the meeting via the Virtual or Telecommunications Process.
- The prisoner representative must present their review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
- Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.
- Modifications involving more than a minor change reviewed by the convened IRB – must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).
- Continuing review (Full Board)– must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described above).

For research involving interaction with prisoners reviewed by the expedited procedure:

- Research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
    - The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
- The prisoner representative must review the research as a reviewer, designated by the chair, or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
- Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.

For research that does not involve interaction with prisoners (e.g., existing data, record review) reviewed by the expedited procedure:

- Research that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
- Review by a prisoner representative is not required.
- The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.
- Review of modifications must use the same procedures as initial review.

If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C:

- When Subpart C applies (DHHS Supported research):
  - Confirm that the participant meets the definition of a prisoner.
  - Terminate enrollment or review the research study under Subpart C if it feasible for the participant to remain in the study.
  - Before terminating the enrollment of the incarcerated participant, the IRB should consider the risks associated with terminating participation in the study.
  - If the participant cannot be terminated for health or safety reasons:
    - Keep the participant enrolled in the study and review the research under Subpart C.
    - If some the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain in the study, keep the participant enrolled and inform OHRP of the decision along with the justification.
    - Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.
- When Subpart C does not apply:
  - Confirm that the participant meets the definition of a prisoner.
  - Decide whether it is in the best interests of the participant to remain in the study or to terminate enrollment.
  - Also decide whether it is feasible for the participant to remain in the study.
  - If it is in the best interests of the participant to remain in the study, keep the participant in the study and review the research at next meeting of the convened IRB.

Note: If a participant is incarcerated temporarily while enrolled in a study:

- If the temporary incarceration has no effect on the study, keep the participant enrolled.
- If the temporary incarceration has an effect on the study, handle according to the above guidance.

6. Additional Protections for Children (Subpart D)

The IRB determines whether the criteria for approval of research are met when research involves children. The IRB Chair will have the IRB determine and document that:

- **Category 1:**
  - No greater than minimal risk to children is presented
- **Category 2:**
  - More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual participant, or by a monitoring procedure that is likely to contribute to the participant's well-being.
  - The risk is justified by the anticipated benefit to the participants.
  - The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
- **Category 3:**
  - 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 participant, or by a monitoring procedure which is not likely to contribute to the well-being of the participant.
  - The risk represents a minor increase over minimal risk.
  - The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
  - The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition.
- **Category 4:**
  - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

    - The federal agency, 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, determined either:
        - That the research fell into categories 1 through 3; or
        - 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 the research will be conducted in accordance with sound ethical principles.

The IRB determines whether the criteria for approval of research are met when research in Category 3 or 4 involves wards of the state or any other agency. The IRB Chair will have the IRB determine and document that:

- The research is:
    - Related to their status as wards; or
    - Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.
- The IRB requires 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.
    - The advocate is 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.
    - The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigators, or the guardian.

When following DHHS regulations involving children the following applies:

- The IRB must follow the requirements in Subpart D pertaining to obtaining assent of children and permission of the parents or guardian (Parental Consent).
- For research that involves no more than minimal risk or more than minimal risk with the prospect of direct benefit to the individual children, the IRB determines whether:
    - The permission of both parents is required 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, or the permission of one parent is sufficient.
    - For research that involves more than minimal risk without the prospect of direct benefit to the individual children, the IRB determines that the permission of both parents is required 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.
- The IRB determines and documents that assent is a requirement of:
    - All children.
    - Some children.
    - None of the children.
- When the IRB determines that assent is not a requirement of some children, the IRB determines and documents which children are not required to assent.
- When the IRB determines that assent is not a requirement for some or all children, the IRB determines and documents one or more of the following:
    - The children are not capable of providing assent based on the age, maturity, or psychological state.
    - The capability of the children is so limited that they cannot reasonably be consulted.
    - 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 child and is available only in the context of the research.
    - Assent can be waived using the criteria for waiver of the consent process.
- When the IRB determines that assent is a requirement, the IRB determines whether:
    - Assent will be documented; and
    - If so, the process to document assent.

7. Waiver of Parental or Guardian Permission

- The IRB may waive the requirement for obtaining parental or guardian permission if it determines and documents the findings under either §46.116(c) or §46.116(d) and that the research is not FDA regulated.
- In addition and pursuant to 45 CFR 46.408(c), if the IRB determines that a research study is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), it may waive the parental permission requirements provided an appropriate mechanism is in place to protect the children, and provided further that the waiver is not inconsistent with federal, state, or local law.
- The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.
- In addition, the IRB may waive the parental permission requirements in cases involving older adolescents who, under applicable law, may consent on their own behalf for selected treatments (for example, for venereal disease, drug abuse, or emotional disorders).

Note: The investigator can prospectively request a waiver of parental/guardian permission in the IRB submission. It is the PI's responsibility, however, to explain why the waiver is being requested.

Disagreement between a child and the child's parents about research participation

- If a child is capable of assent and the IRB requires that assent be sought, it must be obtained before the child can participate in the research activity.
- Thus, if the child dissents from participating in research, even if the parents or guardian have granted permission, the child's decision prevails, unless the IRB has waived the assent requirement under §46.408(a).
- Conversely, if a child assents to participate in research and parental permission has not been waived by the IRB, the permission of the parents or guardian is required before the child can be enrolled in the research.

Note: To be clear: <u>If the child says no to participation, the PI cannot compel the child in any way to participate even if the parent(s)/guardian said yes.</u>

When a child reaches the legal age of consent while enrolled in a research study

- When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in ongoing research, the participant's involvement in the research is no longer regulated by the requirements of §46.408 regarding parental or guardian permission and participant assent.
- As such, unless the IRB determines that the requirements for obtaining informed consent can be waived, the investigators should seek and obtain the legally effective informed consent, as described in §46.116, for the now adult participant for any ongoing interactions or interventions with the participants.
- This is because the prior parental permission and child assent are not equivalent to legally effective informed consent for the now adult participant.
- The IRB could, however, approve a waiver of informed consent under §46.116(d), if it finds and documents that the required conditions are met.
- Similarly, if the research does not involve any ongoing interactions or interventions with the participants, but continues to meet the regulatory definition of human participants research (for example, it involves the continued analysis of specimens or data for which the participant's identity is readily identifiable to the investigator(s)), then it would be necessary for the investigator(s) to seek and obtain the legally effective informed consent of the now adult participant.

8. Specific Responsibilities Involved in Child Research

A. Investigators

- Investigators may not screen for, recruit into, or enroll any child to a research study without prior IRB approval.
- The investigator can make the initial determination regarding the appropriate category in which the research falls, including justification as to why that category was selected. The IRB, however, will make the final determination. In addition, an explanation regarding how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of each parent or guardian must be provided.
- If the IRB grants a waiver of child assent, the investigator must still obtain parental/guardian permission (consent), unless a waiver of parental/guardian permission has also been granted.
- The investigator may only approach a child subject to obtain assent to participate in the research after the parents/guardian have given written permission (Parental Consent).

B. IRB during a review

- In evaluating the inclusion of children in research, the IRB will consider the protocol specific findings provided by the investigator in the Parental Consent and Child Assent Process.
- When the convened IRB reviews research involving children, an individual who is knowledgeable about and experienced in working with this population must be present at the meeting.

9. Additional Protections for Individuals Lacking Consent Capacity or with Diminished Capacity

In the absence of evidence to the contrary, it is assumed that adults have the capacity to provide informed consent to participate in research.

- However, certain groups of individuals may be suspected of lacking consent capacity such that they cannot provide informed consent for themselves and consent from a legally authorized representative is needed.
- These include persons under the influence of drugs or alcohol, sedated or unresponsive, suffering from a clinical illness or traumatic brain disorder or dementia, or who have evidence of history of psychiatric illness or disorder or a recent psychotic event, among others.

Consent capacity is demonstrated by the individual's ability to:

- Understand the nature of the research and of participation;
- Appreciate the consequences of the participation;
- Show the ability to consider alternatives, including the option not to participate; and
- Show the ability to make a reasoned choice.

When research proposes involving individuals who may lack consent capacity, potential participants should be assessed prior to obtaining informed consent to ensure consent capacity exists.

- Investigators should propose an appropriate plan for assessing consent capacity of potential participants, as well as a plan for obtaining consent from the individual's legally authorized representative and assent from the potential participant, when appropriate.

When the IRB reviews research involving persons lacking consent capacity or with diminished capacity, the IRB should:

- Include a person who has specialized training or knowledge applicable to the situation or consult with a trained professional on the matter.
- Ensure that appropriate provisions are made for assessing the potential participant's consent capacity, including the process for ongoing assessment of consent capacity and willingness to participate.
- The consent procedures should describe a plan for assessing and protecting individuals who may lose consent capacity while participating in research activities.
- The IRB may waive consent requirements pursuant to §46.116 of Subpart A, General requirements for informed consent.

- Review any additional protections and safeguards needed to make sure that the participants rights and welfare are not violated.

10. Additional Protections for Students

See BSU policy on faculty recruitment of students in research and use of FERPA protected information.docx

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Section 5. Quality Assurance, Research Compliance, and Reporting Unanticipated Problems

Quality Assurance/Quality Improvement (QA/QI)

1. Human Research Protection Program (HRPP)

The goal of BSU's QA/QI process is to increase the quality and performance of the HRPP as well as to ensure compliance with federal regulations.

The Quality Assurance portion of this program will assess the strengths and weaknesses of the HRPP, and the Quality Improvement portion of the program will continually improve the performance of the HRPP.

The BSU HRPP Quality Assurance process will periodically perform self-assessments and audits of research activities.

The Quality Assurance approach includes the systematic collection and analysis of available metrics, review of adverse events and outcomes, resolution of individual problems, and the review of current regulations and guidance.

The QA program covers the utilization of self-assessment tools (e.g., OHRP's Self-Assessment Tool), the review of these policies/SOPs, and other available monitoring tools to assess the performance in relation to the federal guidelines and ethical standards.

The IRB evaluates effectiveness and conducts quality improvement activities on a continual basis. Any problems identified are addressed and appropriate corrective action (e.g., change policy, procedure, communication, education or other such intervention) is taken to improve the process. The effects of the corrective action are then assessed within a reasonable timeframe to assure the action taken was effective.

Any changes to the research activity, SAEs, safety reports, protocol violations and non-compliance issues are reported and discussed at the IRB monthly meeting.

Any urgent concerns are discussed immediately with the IRB Chairperson and the Director, ORI for their immediate attention.

BSU's online submission system will help track the information and maintains the electronic records in accordance with federal guidelines.

Note: Internal review of the entire HRPP program should take place at least once every 3 years. Changes to the HRPP affected by changing regulations, new tools, better process, etc. will take place on an as-needed basis.

2. IRB Policies

The Director, ORI (or their designee) and HRPP manager will monitor new regulations, guidance, etc. and in conjunction with the IRB Chairperson (or their designee) update the appropriate IRB policy(s) accordingly.

New policies will be submitted to the Full IRB at the next regularly scheduled meeting for final review and adoption.

3. Responsibilities

The IRB Chairperson and the Director, ORI are jointly responsible for taking an active leadership role in performance improvement of the HRPP. They are responsible for:

- Developing an effective and systematic approach to assessing and improving the HRPP performance
- Planning, developing, conducting, validating, and reporting of the outcomes of the quality improvement program for the BSU HRPP including the education and orientation of the staff
- Evaluating performance and adherence to applicable federal regulations, state laws, and accreditation standards, which govern human research
- Conducting an annual review of the organization's participant outreach activities and considering any changes that may be needed

Note: IRB Members, ORI staff, and PIs and their research staff are responsible for identifying opportunities for improvement and for participating in performance improvement activities.

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Complaints, Non-Compliance, and Research Misconduct

1. Overview

As one of the mechanisms for ensuring ethical conduct of research and the protection of research participants, BSU has established a process for responding to complaints, issues of non-compliance, and research misconduct.

2. Responsibilities

A. The Director, Office of Research Integrity (ORI)

- The director, ORI will be responsible for investigating all non-compliance issues as well as any improprieties involving IRB members, investigators, or their staff. These issues will be handled in a timely manner, assuring protection of human participants is of prime importance, and holding any violators accountable to the applicable regulation.
- The Director, ORI will be responsible for providing written documentation of the resolution of the violation and will make a determination for every allegation of non-compliance as to whether the allegation has a basis in fact.
- All non-compliance, no matter how minor, will be evaluated by the Director, ORI to determine whether it is serious or continuing.
- The Director, ORI will evaluate all non-compliance that is neither serious nor continuing to determine whether a management plan is appropriate.
- The Director, ORI will report serious or continuing non-compliance to the IRB Chair, the Institutional Official (IO), and any applicable regulatory agencies.

B. The IRB Chairperson and IRB Members

- The IRB chairperson will be responsible for investigating all human participants' complaints, for finding a suitable resolution, and for providing a response to the complaints in a timely manner.
- The Chairperson and the IRB members are responsible for adhering to all applicable federal regulations, especially in conflict of interest situations.
- The Chairperson and the IRB members are responsible for making investigators aware of their responsibilities of taking human participants' complaints seriously and responding to them in a timely manner.
- The Chairperson and the IRB members are also responsible for making investigators aware of the repercussions of non-compliance and improprieties. The IRB Chair person may request assistance from the Director, ORI as part of the investigation.
- IRB members will be expected to immediately report any instances of undue influence to the Director, ORI.

C. The Principal Investigators (PIs) and all investigators

- The PIs and all investigators in the research teams will be responsible for complying with all federal regulations concerning their research and their research participants.
- Investigators and research staff must promptly report all non-compliance to the IRB.
- Investigators and research staff are responsible for the safety of all human participants enrolled in their studies.
- The investigators will hear complaints and try to resolve them prior to the complaint being filed with the IRB Chairperson.

D. The Responsible Conduct of Research (RCR) Officer

- The RCR officer will be responsible for reviewing any charges of misconduct that meet the federal definition of research misconduct (fabrication of data, falsification of data, or plagiarism). For more information on this process, see the Research Misconduct Policy.

3. Procedures

A. Complaints

- A research participant may lodge a complaint with the PI, the ORI or the IRB Chairperson. Each complaint will be reviewed to determine if possible non-compliance exists.
- If the complaint is received by the IRB Chairperson, the Chairperson will pass along ORI contact information to the complainant and/or pass the complaint along to the Director, ORI.
- If the PI receives the complaint first, they will make every effort to resolve the complaint prior to contacting the ORI.
- If the research participant wants to address the complaint or inquiries about a research project by telephone, in writing, or in person directly with the ORI, then the ORI staff person receiving the complaint or allegation will establish a complaint file, including the following information:
    - Participant's name, address, and phone number, but only if they are willing to provide this information. A caller can report an incident anonymously; however, the caller must be advised that a thorough review may not be possible, and that, without this information, follow-up responses to the participant are not feasible.
    - Study protocol title (or acronym) and Principal Investigator's name.
    - Date(s) of the incident.
    - An explanation of the complaint.
- The participant will be reassured that all means will be taken to inquire into the circumstances and appropriate measures will be taken to address the issue. Furthermore, the participant will be informed that a response to their complaint will be forthcoming as rapidly as possible (providing that contact information is given) but no later than 14 business days from the receipt of the complaint)
- A copy of the complaint is then forwarded to the IRB Chairperson. Within three (3) business days after receipt, the Chairperson will explore the allegation with the Director ORI and, if warranted, identify an IRB member(s) most appropriate to review the allegations or

concerns. If an IRB member review is warranted, the identified IRB member(s) will investigate the allegation(s) and prepare a written report addressing the allegation and making recommendation(s) for resolution or remedial action. The final report will be submitted to both the IRB Chairperson and Director ORI within 10 business days after receiving the assignment, which will ensure that an appropriate response to each complaint or allegation is prepared. The Chairperson will report at the following IRB meeting the action(s) taken and, if necessary, submit a report to the appropriate officials and agencies. The Director, ORI will make every effort to contact the individual who submitted the complaint or allegation to determine the level of satisfaction achieved and allow additional comments. If applicable, the Director will report these findings to the IRB.

- The complaint(s) will be handled in a confidential manner. Access is limited to only those employees with a responsibility that requires knowledge of the complaint or unless access is required by federal or state law.
- All complaint(s) will be reviewed by the IRB Chair under the policy and procedures for unanticipated problems involving risks to participants or others for a determination as to whether the complaint is an unanticipated problem involving risks to participants or others, and if so, will require review by the convened IRB.

B. Compliance/Non-Compliance

- All Non-Compliance determined to be serious or continuing will be reviewed by the convened IRB. Each IRB member will receive access to the complete IRB study file for that particular study along with all correspondence related to the non-compliance.
- The ranges of actions that can be taken by the IRB are as follows:
    - Modification of the research protocol
    - Modification of the information disclosed during the consent process
    - Providing additional information to past participants
    - Notification of current participants when such information may relate to participants' willingness to continue to take part in the research
    - Requiring current participants to re-consent to participation
    - Modification of the continuing review schedule
    - Monitoring of the research
    - Monitoring of the consent
    - Suspension of the research
    - Termination of the research
    - Referral to other organizational entities
- The IRB will monitor performance of specific compliance issues and any non-compliance issues brought to the IRB’s attention. Periodic audits will be conducted through a random sampling of the specific compliance issue being monitored.
- When investigator non-compliance issues are identified, the Director, ORI will be notified and will receive a copy of the non-compliance allegation. The Director, or their designee, will promptly investigate the allegation of non-compliance and corrective action will be taken. The Director will make every effort to correct the issue(s) at the administrative level. Within three (3) business days after receipt, the Director, or their designee, will explore the allegation and identify the individual(s) most appropriate to respond to the allegations/concerns. The identified responsible individual(s) will investigate the allegation(s) and prepare a written report addressing the allegation(s) and making recommendation(s) for resolution/remedial action or disciplinary action, if appropriate. The final report will be submitted to the Director within 10 business days after receiving the assignment. The Director, or their designee, will ensure appropriate response to each complaint/allegation is taken. The Director will report at the following IRB meeting the action(s) taken and if necessary, submit a report to the appropriate officials and agencies.
- Allegations of serious or continued non-compliance will be reported immediately to the IRB Chairperson, to the Director ORI, and to the IO if not already informed.

C. Regulatory Improprieties in Research

- Research Misconduct (falsification, fabrication and plagiarism), will be reported to the Research Integrity Officer (see policy on research misconduct). Other instances of improprieties will be reported to the Director, ORI.
- Each instance of alleged impropriety will be evaluated on a case-by-case basis. All effort will be made to correct the impropriety at the administrative level.
- If the impropriety involves potential harm to others or significant property damage, the appropriate institution officials will be notified for immediate action pending formal inquiry.
    - If allegations of academic misconduct in research are involved, the Director will involve the appropriate institutional officials once the initial investigation has occurred and the merits of the claim can be established.

D. Further Actions

- The Director, ORI or their designee, as appropriate, will conduct an initial review to determine the nature of the complaint, non-compliance issue, or impropriety.
- During this review, every effort will be exercised to maintain the confidentiality of all parties involved. The Director will evaluate the facts gathered and take appropriate action. Dependent upon the nature of the event or circumstances, certain actions may occur:
- Further inquiry may be initiated.
- Administrative action may be taken (e.g., suspension or termination of the study).
- Details and recommendations forwarded to the appropriate committee Chairpersons (e.g., IRB, IACUC, Radiation Safety) for consideration in their committees, and action.
- Details and recommendations forwarded to the appropriate department Chairperson for action.
- Details and recommendations forwarded to the Vice Provost for Research (IO), Provost, University General Counsel, or the President for action.
- Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and follow-up, if applicable.
- Other actions as deemed appropriate.

E. Final Actions

- The final course of action is entirely dependent upon the nature, severity, and degree of seriousness of the findings. For example, the IRB may require special monitoring of the consent process by an impartial observer (consent monitor) to reduce the possibility of coercion and undue influence by an investigator or research team.

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Reporting of Unanticipated Problems and Adverse Events

1. Overview

Prompt reporting of unanticipated problems and adverse events is a key component in managing and mitigating impacts on research participants.

This procedure is followed whenever the IRB or the ORI learns a problem, regardless of whether the problem is reported by the investigator or the IRB/ORI learns about the problem by other mechanisms.

The PI is responsible for reporting to the IRB the any problems that require prompt reporting.

2. Problems and Events Descriptions

PI's must report to the IRB the following problems as soon as possible, but always within the described timeframes:

- Any harm experienced by a participant (including any adverse event) regardless of whether the event was internal (on-site) or external (off-site) and regardless of whether the event

meets the FDA definition of “serious adverse event”, which in the opinion of the principal investigator are both unexpected and related. Indicate that adverse events not meeting these criteria do not need to be reported.
    - A harm is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document.
    - A harm is “related to the research procedures” if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is likely the event affects the rights and welfare of current participants.
- Information that indicates a change to the risks or potential benefits of the research should be reported no later than 10 calendar days from occurrence or discovery. For example:
    - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
    - A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
- A breach of confidentiality should be reported no later than 10 calendar days from occurrence or discovery (including unauthorized use, loss, or disclosure of individually-identifiable participant information).
- Change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant should be reported no later than 10 calendar days from occurrence or discovery.
- Incarceration of a participant in a protocol not approved to enroll prisoners should be reported no later than 10 calendar days from occurrence or discovery.
- Event that requires prompt reporting to the sponsor should be reported no later than 10 calendar days from occurrence or discovery.
- Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team should be reported no later than 10 calendar days from occurrence or discovery.
- Protocol violation that caused harm to participants or others or indicates that participants or others are at increased risk of harm should be reported no later than 5 calendar days from occurrence or discovery.

Note: The listed items may not be unanticipated problems involving risks to participants or others. Once the PI has reported the problem, the IRB, not the investigator, decides which of the reported problems are unanticipated problems involving risks to participants or others.

3. Procedures

All reported problems will be reviewed by the IRB Chair and the Director, ORI or their designees. This review will determine and document whether the reported problem is an unanticipated problem involving new or increased risk of harm to participants or others based on whether the event is**:**

- Related (or possibly related) to the study
- Unexpected
- New or increased risk of harm

If the reviewers determine that the event is an unanticipated problem involving risk to participants or others that are greater than minimal risk, then the problem must be reviewed by the convened IRB.

If the reviewers determine that the event is an unanticipated problem involving risks to participants or others that are minimal risk, no full board actions are required and the report will be listed as informational on the agenda.

The reviewers must also determine if immediate action is warranted (e.g., suspension of activities; notification of participants) to prevent an immediate hazard or if no immediate action is warranted to prevent an immediate hazard prior to the IRB review.

The convened IRB will make a determination on referred unanticipated problems involving new or increased risk of harm to participants or others and the board action will be reflected in the minutes of the meeting.

If the convened IRB determines that the event is not an unanticipated problem involving new or increased risk of harm to participants or others, no further considerations or actions are required.

All IRB members will receive a copy of the IRB Adverse Event, any materials the investigator sent, the protocol and consent document (if applicable) and the reviewer's comments.

The range of actions to be considered by the convened IRB, include:

- Modification of the research protocol
- Modification of the information disclosed during the consent process
- Providing additional information to past participants
- Notification of current participants when such information may relate to participants' willingness to continue to take part in the research
- Requirement that current participants re-consent to participation
- Modification of the continuing review schedule
- Monitoring of the research
- Monitoring of the consent
- Suspension of the research
- Termination of the research
- Referral to other organizational entities

Note: The Director, ORI will report to the IO and, when applicable, regulatory agencies when the IRB determines that a problem is an unanticipated problem involving risks to participants or other.

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Education and Training

1. Overview

One of the core components of the strong HRPP is education and training. As such all IRB members, investigators (and their research staff), and students conducting HSR must complete the initial educational training material that constitutes certification.

This training serves as an orientation to their responsibilities under the HRPP.

In addition, recertification is required every 3 years in the form of a refresher course. Additional training may be identified and required on an as-needed basis throughout the year.

2. Education and Training Requirements

A. IRB Members

All IRB Board members are required to take and complete the online training for IRB Board Members. This must be completed no later than 60 days from the date of becoming a member or by the time of the second Full Board meeting, whichever is soonest.

B. Researchers (principal investigators, faculty advisors, and all key personnel)

An individual is considered certified after completion of the HRPP mandated educational orientation which includes:

- Belmont Report: All investigators are required to read the Belmont Report and be willing to abide by it; and

- Human Subject/Participant Training: All researchers and research team members must complete all required trainings as found in BSU's online training system. Access to the web-based Collaborative Institutional Training Initiative (CITI) Course can be found on the Educational/Training page of the ORI website (or at www.citiprogram.org). Registration instructions are located on the IRB website. The main menu on the CITI site contains access to all previously completed coursework and displays course title, score and completion/expiration dates. Most (not all) of the comprehensive modules within a required course are followed by a short quiz. An overall score of 80% or higher constitutes a passing score for the course. Upon achievement of the required modules, a copy of the completion report must be included in the protocol application for new investigators; and
- Standard Operating Procedures (SOPs) and other policies - IRB members and investigators may be required to review additional educational materials, policies, etc. as deemed required by the federal regulations, the university, the State and/or that may be required by the specifics of the proposed research (e.g., HIPAA training may be required for research involving protected health information).

3. Training Completion and Protocol Approval

No protocol sent for review will be approved until all training requirements are received and/or verified.

Protocols submitted without the educational component being completed or verified, may still be reviewed but approval will not be grated until all educational requirements are complete or verified.

4. Continuing Training

All IRB Members and persons conducting HSR must renew their training certificates every 3 years. This is completed by taking online CITI refresher modules before the expiration date of their prior certificate.

Other required trainings (e.g., HIPAA) may have a different renewal time frame.

5. Training for Key Personnel not Affiliated with BSU

Any key personnel who is not affiliated with BSU should take the required training for their institution and upload evidence of this training to the BSU online submission system for the project for which they are key personnel.

If there is no training required or the key personnel is not affiliated with another institution, the unaffiliated key personnel should take the training required by BSU if it does not present an undue burden (i.e. financially).

If this training is not available, the PI of record should document the training that the unaffiliated personnel has in the protection of human participants and will take responsibility for the unaffiliated personnel's ethical conduct in the research.

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