THE UNIVERSITY OF AKRON
HUMAN RESEARCH PROTECTIONS PROGRAM

STANDARD OPERATING PROCEDURES MANUAL

June 2024

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I. PURPOSE AND BACKGROUND

This manual describes how the University of Akron implements its Human Research Protections Program (HRPP), which ensures the ethical treatment of human participants in human subjects research. The University of Akron (UA) has a Federalwide Assurance (FWA) on file with the United States Federal Government, which states it follows the ethical principles enumerated in the Belmont Report. The Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Report describes the ethical principles and guidelines that the Federal government expects to underlie research conducted with human participants.

Further, this manual is provided to ensure compliance with the University of Akron's FWA, which applies the Federal regulations governing human subjects research, codified at 45 C.F.R. 46 (also known as "the Common Rule"), to all human subjects research. These regulations require each institution accepting Federal funding have written policies and procedures describing how the institution ensures the ethical treatment of human participants, how it conducts oversight of research subject to the Common Rule, how it maintains records, and the make-up of the Institutional Review Board (IRB) tasked with such review. Note that the Common Rule was revised in 2018. Some Federal Agencies have not signed on to the revisions (e.g. the Department of Justice). If a project is funded by a Federal Agency or sponsor that has not signed on to the revised Common Rule, the pre-2018 regulations will be used by the IRB. Differences between the pre-2018 Common Rule and the revised Common Rule include changes in: exemption categories, criteria for approval, informed consent criteria, and continuing review requirements.

This manual is intended for a broad audience, including Federal regulators, institutional officials, HRPP staff, IRB members, and investigators. Links within the document are provided for additional information. Further, the University of Akron Research Compliance and Integrity webpages contain additional guidance for each specific audience category (e.g. investigators, IRB members) regarding the process, timelines, and resources for ensuring an ethical work with human subjects.

As of November 15, 2023, the UA HRPP utilizes a cloud-based protocol system. This system is the repository for protocol related records. Email communications necessary for compliance purposes are uploaded into the Cayuse Human Ethics module (Cayuse HE) to the appropriate study container. More information regarding Cayuse HE is available through UA's Research Compliance and Integrity webpages and internal resources (e.g. MS Teams). Protocols that were approved prior to the Cayuse HE implementation date under Expedited and Full-Board procedures, and still active, are also maintained in Cayuse HE. Investigators should provide information regarding these Legacy protocols through the Cayuse HE system. Applications that were submitted to the UA IRB prior to November 15, 2023, and determined as exempt from the Common Rule are maintained separate from Cayuse HE. Instead, these applications and documents are maintained on local UA electronic resources.

The HRPP is overseen by UA's Signatory Official (SO), who ensures adequate staffing, appoints IRB members, designates staff, and is responsible for communication with Federal agencies. The SO may designate an IRB Administrator to undertake some of the activities. The IRB Administrator serves in a support role to the HRPP, providing regulatory guidance and compliance oversight of the general program. The HRPP may also include administrative

staffing for support for IRB functions. Such personnel will be identified in internal communications, rather than specifically in this document. Duties, and IRB composition, are described later in this document.

Note the term “human subjects” in the Federal regulations. Thus, the term participant and subject may be used interchangeably in this manual.

II. What Type of Project Requires University and/or IRB Review and Approval or Certification prior to the project being initiated?

All research projects involving humans as participants or subjects require review by the University prior to it being conducted on the University of Akron campus, with University of Akron personnel or students, or prior to the project being conducted by or on behalf of University of Akron (UA) personnel (including students). Further, some non-research projects involving humans as participants or subjects require review by the University prior to the project being conducted by UA personnel, and some research projects, which do not involve human subjects (as defined by the Federal regulations) also require review and approval prior to initiation. There are several categories of such projects, some of which require differing levels of review. Additionally, some such projects require review and approval or certification by the UA Institutional Review Board, in addition to the University level approval.

A. Research projects involving human subjects: All research projects involving human subjects require review by the IRB, even those which are ultimately exempt from the Federal regulations. These projects should select the "Non-Clinical" option on the basic information page of the IRB application, or a subsequent option (e.g. clinical trial, single patient, etc.), as appropriate. Use these decision trees to determine whether the Investigator's project is research and whether it involves human subjects. In making this determination, the first question that should be asked is whether the project is research. The second question that should be asked is whether the research project involves human subjects (as defined by the Federal regulations). Some examples of research projects involving human subjects projects include research dissertations or theses, classroom research projects designed or intended to contribute to generalizable knowledge, fundamental (e.g. basic or foundational) research utilizing surveys, and many more.

B. Non-research projects involving human subjects. If a project does not meet the Federal definition of research (45 C.F.R. 46.102(l)), even if it involves human subjects, the Federal regulations are not applicable. Investigators wishing to have a letter certifying that such a project does not require IRB review may request the documentation by submitting a Not Human Subjects Research (NHSR) protocol in Cayuse HE. Such a protocol **must be requested prior to initiation of the project.** A letter will not be provided for projects that were conducted before the request was initiated. Some examples of such projects include clinical case studies of one or two individuals, classroom projects not designed to contribute to generalizable knowledge, quality improvement projects, and assessment projects. Note that the research and quality improvement projects lie on a continuum. If there is a question whether a project qualifies as research, investigators should contact the IRB to make a final determination. For more information on what constitutes research, see the Federal guidance on quality improvement activities. To request an NHSR determination, investigators should select the option "**Activities Without a Plan to Conduct Research**" on the basic information page of the application.

The following generally fall outside the Federal definition of research:

1. Normal educational activities that are designed to train students in research techniques and methods or to qualify students as investigators when those activities

are conducted as part of courses or in regular classroom settings and without the intent to share the results of the project outside of the course personnel. These classroom projects are not permitted to be presented publicly in senior theses, websites, social media sites, blogs, conference presentations, or journal articles. For such coursework, the class instructor should submit an IRB protocol requesting an NHSR determination, which describes the general nature of student projects.

a. Note that it is the responsibility of the instructor to ensure the class projects are conducted ethically. This includes ensuring:
    i. That students, who provide data to other students, cannot be identified, directly or indirectly;
    ii. Student (or other person's) participation as a subject of the data collection must be voluntary, and the student participants must be told the project is being conducted to meet a course requirement and that data collected will not be made public beyond the course instructor or teaching assistants.;
    iii. The project is no more than minimal risk to the participants;
    iv. The project is limited to surveys/questionnaires/interview procedures, observation of public behavior, or standard educational exercises directly related to the topic being studied;
    v. Surveys/questionnaires, if used, may only contain sensitive personal questions (e.g. about drug/alcohol use, sexual behavior/attitude, criminal activity, medical history, grades/test scores) or other personal information only if the survey/questionnaire is completely anonymous; and
    vi. The data are not archived or saved in any way for future use.
b. Instructors must ensure that any individual student class project, which involves vulnerable populations (children, mentally impaired, prisoners or individuals on probation) or collection of identifiable, sensitive, private information, be submitted to the IRB for review prior to the project being implemented. The course instructor must review all proposed student research and ensure that any student whose research project involves a vulnerable population or sensitive information submits an individual IRB application for review.
c. **The following academic projects require IRB review or determination of NHSR if they involve human participants:** Doctoral dissertations, including any Doctor of Nursing Practice projects that involve human subjects, funded research, research conducted through collaborations external to the University of Akron, Master's theses, and honors theses.

2. Contractual research such as organizational evaluations that involve surveying/interviewing individuals, if not to be disseminated beyond the organization, is not considered research subject to the regulations. Examples include Quality Assurance assessments or surveys exclusively designed to capture information for quality improvement purposes (e.g. course evaluations).

3. Projects designed to improve practice or process at an institution, especially if it is adaptive and/or iterative. Examples include Quality Improvement and Quality Assessment projects. While these types of projects are not research, the UA IRB

still requires review of the protection. NOTE: The UA IRB must still review this type of project in advance of the investigator initiating it, to certify it meets the Quality Improvement criteria.

4. Case studies describing one or a small number of individuals (no more than three). **NOTE: Journals often require documentation of consent from the individual prior to publishing such a study. Investigators should review the anticipated journal requirements prior to accessing the individual or their data.** Individuals seeking a letter from the IRB certifying the project as not research MUST contact the IRB for such a letter PRIOR to initiating the project. No letters will be provided after the case study is initiated. Additionally, if these projects are submitted for publication, the narrative should not refer to the project as "research."

C. Research projects not involving human subjects: If a research project does not involve human subjects, as defined by the Federal government, the Federal regulations are not applicable. However, if such research project involves data derived from human subjects, it requires review by the UA HRPP to certify the projects does not meet the Federal definition of human subjects research (Not Human Subjects Research or NHSR). Further, the HRPP review also examines whether other laws or regulations are being followed in the conduct of the research, and whether there are institutional risks that need mitigating. Some examples of such projects include use of decedent data, use of publicly available data, and receipt of de-identified data. These projects should select the "**Activities Without a Plan to Conduct Research**" option on the basic information page of the application.

The following are typically considered interactions or interventions with human subjects:

1. Accessing, recording, or collecting identifiable data, documents, records, pathological specimens, or diagnostic specimens (even if these are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified).
2. Asking people to complete a survey, questionnaire, or be interviewed.
3. Answering questions from potential subjects about a research project.
4. Obtaining a subject's informed consent for the project.

The following are typically NOT considered interactions or interventions with human subjects:

1. Analysis of data that are de-identified (unless the data include a key, which could be used to re-identify the individuals).
2. Obtaining tissue from a third-party (i.e. not the patient or subject of the research), as long as 1) the tissue is anonymous and not linkable to the individual from which it was obtained or 2) coded in such a way the investigator cannot determine to whom it belongs **and** documentation assures that the investigator will not be able to access or be provided with the key to the code.

3. Obtaining tissue from a deceased individual. **NOTE: This type of project still requires compliance with applicable regulatory requirements, such as the Health Insurance Portability and Accountability Act (HIPAA).**
4. Use of identifiable data from a deceased individual. **NOTE: This type of project still requires compliance with applicable regulatory requirements, such as HIPAA.**

D. Projects not conducted by UA personnel, but accessing UA employees, students, visiting scholars, and other UA affiliated persons as subjects. Other than surveys sent to publicly available UA emails, these types of projects require review and approval by UA prior to these individuals receiving access to the participant population at UA, or prior to recruitment materials being distributed to the participant population at UA. University level review is conducted by the Research Compliance Officer (RCO), or the Vice-President for Research and Business Engagements Designee. Review typically includes whether the project has received IRB approval from another institution, whether the project is permissible according to the associated colleges or unit's supervisor (e.g. Dean, Director), and whether sensitive information may be collected. Other aspects of the project may additionally be reviewed. These projects do not require submission of a UA IRB protocol application in the Cayuse HE. Rather, these projects require submission of the IRB approved protocol and approval documentation by email to irb@uakron.edu.

DEFINITIONS

Research is defined as a ***systematic investigation*** designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or to ***contribute to generalizable knowledge*** in a particular field of study. Generalizable knowledge is knowledge that has implications for a broader group of people or that will be used to influence policy or practice. It is usually described in a formal protocol utilizing scientific methods that sets forth an objective and a set of procedures to reach that objective.

Human Subject means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) individually identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, drawing blood, dispensing drugs, administering other treatments) and manipulations of the subject or the subject's environment (controlling environmental light or sound, presenting sensory stimuli, making voice, digital or image recordings) that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject through surveys, interviews, focus group meetings, etc.

Data that are **Individually Identifiable** includes, but are not limited to, names, social security numbers, medical record numbers, addresses, phone and fax numbers, email addresses, account numbers, license or certificate numbers, vehicle identifiers, codes which the

investigator could reasonably use to identify a living individual, or combinations of information from which a person's identity could easily be determined.

Data are considered to be not individually identifiable if it has been stripped (by someone external to the research project) of all identifiers including, but not limited to, names, social security numbers, medical record numbers, student numbers, codes which the investigator could reasonably use to identify a living individual, or combinations of information from which a person's identity could easily be determined. Data could be from previously conducted surveys or interviews, or medical, educational or financial records.

Private data includes biological specimens and information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information or specimens provided for specific purposes which the individual can reasonably expect will not be made public (e.g., a medical or student record). Private data must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information, either directly or through a coded link) in order for obtaining the data to constitute involvement of human subjects.

III. PROCEDURES FOR CONDUCTING INITIAL REVIEWS

PURPOSE: This section describes the procedures the Investigator must follow to submit a protocol. It also describes the procedures and criteria the IRB or University uses to conduct initial review of submissions. A voting member of the IRB reviews all initial research submissions. A voting member of the IRB, or an individual designated by the IRB Chair, who has sufficient expertise, may review Not Human Subjects Research (NHSR) submissions. Types of submissions include the Initial protocol, Modifications to an already approved protocol, Incident reports, and Closures.

A. TYPES OF SUBMISSIONS

NHSR SUBMISSIONS

To submit this type of request, Investigators should choose the selecting "**Activities Without a Plan to Conduct Research**" radio button under the Project Type section.
IRB Process: These types of projects are reviewed by the Chair or Chair's designee. The Chair's designee need not be a voting member of the IRB, though must be a person with sufficient expertise to make an NHSR determination. If the documentation is appropriate, the submitter will be notified in writing within 2-4 weeks of submission. No further action by the IRB is required, however the IRB will be notified at their monthly meetings when such a project is approved.

ALL OTHER SUBMISSIONS

To submit a research protocol, the Investigator should determine the appropriate category the research falls under. Options are 118 Determination (when research with human subjects is planned for at a later stage in funded project), Fundamental (non-clinical) research, Clinical research, Single Patient, or Emergency Use. For further guidance on these categories, see the UA HRPP FAQs.

B. IRB REVIEW PROCESS

These Submissions are first pre-reviewed by the IRB Administrator and IRB Chair to determine appropriate review category and whether the Submission is sufficiently detailed to make such a determination. Submissions, which are insufficiently detailed, vague, or confusing will be returned to the PI prior to the Submission receiving substantive review by the IRB.

An initial review is completed upon receipt of a Submission and supporting materials (a description of the project, informed consent documents, oral scripts, surveys, etc.), a designated person ("Assistant") reviews the application for completeness, appropriate attachments, and also verifies that all personnel on the protocol have completed the required CITI certification. A more substantive review is completed by the IRB Administrator, who makes a preliminary determination of the category of review (e.g. exempt, expedited) and shares the Submission with the Chair. The Chair makes the final determination whether the protocol is exempt from review, requires expedited review, or must go to full board review.

C. CLASSIFICATION OF REVIEWS

Exempt and Limited Review [1]Determinations

A submission is exempt from the Federal regulations if the research poses minimal risk to subjects and matches one of the Federal exemption categories. The IRB reviews projects categorized as exempt, to certify these two criteria. For protocols classified as "limited review," the IRB uses an additional criteria to certify the Submission is exempt: whether there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. A Submission that is exempt from review does not require continuing review. Exempt Submissions will be considered active for 3 years from the certification of exemption date. The IRB may administratively check-in with the investigator as to whether the project is still active beyond the 3-year date. If no longer active, a Closure Submission will be requested, but not required.

Modifications to Exempt Protocols If an investigator conducting an exempt project wishes to make any changes or modifications that increase risk to the study's design or procedures (e.g. including minors as participants, when only adults were included previously) or change the category of exemption (e.g. adding benign behavioral interventions to a survey study), these changes must be submitted to the IRB prior to implementing the changes. In this case of a Modification Submission, the IRB Administrator may examine the changes to determine that there is no increase in risk, nor change in category of exemption. In that case, the IRB Administrator may approve the Modification Submission. In the case where the IRB Administrator determines there is an increased risk to subjects or include activities that do not fall within one of the categories exempted from the regulations, the IRB Administrator will forward the Modification Submission to the Chair for final determination of the appropriate level of review. Other changes to exempt submissions (e.g. increasing the number of participants) do not need to be submitted to the IRB.

Note: Exempt studies submitted prior to the transition to Cayuse HE simply require an email describing the modification requested. No form is required.

Expedited or Full Board Initial Reviews

All reviews are conducted pursuant to the regulations, as described below. The IRB must review to determine that the Federal criteria for approval are met for either Expedited or Full Board protocols. These are briefly summarized here.

Federal criteria for approval[2]

(a) Risks to subjects are minimized;

(b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Reviewers will

[1] If a project is funded by a Federal Agency or sponsor that has not signed on to the revised Common Rule, the pre-2018 exemption categories will be used by the IRB. Under this schema, there is no "limited review" procedure.
[2] If a project is funded by a Federal Agency or sponsor that has not signed on to the revised Common Rule, the pre-2018 criteria for approval will be used by the IRB.

not consider possible long-range effects of application of the knowledge gained (e.g. public policy implications);

(c) Selection of subjects is equitable. Reviewers will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons;

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with the applicable regulation, or criteria are met for approval of waiver or alteration of informed consent;

(e) Informed consent will be appropriately documented;

(f) Data monitoring plans, when necessary, are appropriate. Data monitoring is essential when the risks of the research are unknown, data monitoring to assess subject safety is critical;

(g) Subject privacy and confidentiality are protected. For example, if subjects are asked to provide sensitive personal information orally in a public location, procedures to reduce the possibility of their responses being overheard should be included in the Submission.

(h) For purposes of conducting the limited IRB review, the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained;
ii. Broad consent is appropriately documented or waiver of documentation is appropriate; and
iii. 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 subjects and to maintain the confidentiality of data.

(i) Additionally, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

The IRB Administrator conducts a pre-review and makes a recommendation to the Chair as to whether the Submission qualifies for Expedited Review or requires Full Board Review. The Chair makes the final decision as to the type of review.

D. EXPEDITED REVIEW PROCEDURES

A protocol may receive expedited approval if the research poses no greater than minimal risk to subjects and involves:

1. Procedures listed in one of the Federal categories eligible for expedited review,
2. Minor changes in previously approved research, or
3. Research for which limited IRB review is a condition of exemption under certain categories.

If the Chair determines that the project is appropriate for Expedited Review, the Chair assigns a primary reviewer for the initial submission. The Chair may determine that a second reviewer is necessary, in which case a secondary reviewer is also assigned. Submissions are assigned to a member within the same discipline as the investigator, whenever possible. Review and revision, when necessary, follows the procedures listed below:

1. The reviewer(s) who determine the review status and may take one of three actions:
    a. Approve as Expedited
    b. Contingent Approval as Expedited – revisions required
    c. Recommend Full Board Review
2. When a Submission requires revisions, the reviewer notes and the Submission are returned to the PI. The PI addresses the reviewer comments directly in their Submission.
    a. When a Submission requires Full Board Review, the PI is notified and the Submission is put on the Agenda for the next appropriate convened meeting. Procedures for this type of review are described below.
3. Revisions received by the HRPP staff are sent back to the reviewer(s).
4. This process of review and return to PI continues until the reviewer comments are addressed to the point where the reviewer can attest to all the required criteria for approval, or the PI requests full board review, or the reviewer(s) send the Submission to the full board for review.
5. Expedited Approval does not require continuing review.[3] Reviewer(s) may determine continuing review *is* required, in which case the rational for the continuing review must be fully documented.
6. When the study is completed a Closure is submitted and reviewed. The Closure is reviewed using the above process and if appropriate, the protocol is closed.
7. The expedited approval date is the date that all revisions are approved by the reviewer(s).
8. Where continuing review for expedited protocols is required, it is conducted using the expedited procedures, unless the Chair determines Full Board review is required.

Expedited Approval Categories:

1.) Clinical studies of drugs and medical devices for which either an investigational new drug application is not required; or for which (i) an investigation device exemption application is not required or (ii) the medical device is cleared/approved for marketing and the device is being used in accordance with its cleared/approved labeling.

2.) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as permitted per expedited review procedures.

3.) Prospective collection of biological specimens for research purposes by noninvasive means.

4.) Collection of data through noninvasive procedures routinely employed in clinical practice.

[3] If a project is funded by a Federal Agency or sponsor that has not signed on to the revised Common Rule, the pre-2018 regulations will be used by the IRB. Under the pre-2018 regulations, expedited review projects still require continuing review.

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).

6.) Collection of voice, video, digital, or image recordings made for research purposes.

7.) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8.) Continuing review of research previously approved by the convened IRB where: 1) the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects, 2) no subjects have been enrolled and no additional risks have been identified, or 3) remaining research activities are limited to data analysis.

9.) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

E. FULL BOARD REVIEW PROCEDURES

If the protocol is not eligible for expedited review, the protocol must be reviewed by the full board at a convened meeting. Unless expedited reviewer(s) call for full board review, the Chair determines when full IRB review is warranted. The PI will be notified of the need for full board review and the date and time of the meeting, in which the Submission will be reviewed. The PI may also be invited to attend the board meeting in order to provide needed clarification and address any questions.

Full board review is required for all protocols that represent greater than minimal risk. Protocols that involve vulnerable populations and/or sensitive subject matter may also warrant full board review.

- Review must be conducted at a convened meeting where quorum is achieved;
- A majority of members must be present for quorum;
- At least one member who is a non-scientist must be present for quorum;
- For research to be approved, it must receive approval from a majority of members present at a properly convened meeting with quorum;
- IRB members who have conflicting interests cannot participate in the review except to provide information. Such members must not be present during IRB deliberation and do not count towards quorum when/if the Submission is voted on at the meeting.

A Primary Reviewer (PR) will be assigned for each Submission requiring full board review. The PR will be a member with expertise in the subject area of the protocol. A Secondary Reviewer may be appointed. At least ten business days prior to the meeting, the board will receive the complete application, as well as all instruments, consent forms, and associated grant proposal if applicable. If the application is for continuing review, the board will also receive the initial application summary, the last board minutes where the project was reviewed, and any substantive

modifications that have been approved. The PR will contact the investigator for any required clarification or additional information before the meeting.

All members will receive the complete application, all consent forms, and any other information relevant to the protocol. For continuation applications, the most recent board minutes where the project was discussed will also be provided. Continuation materials will be provided to Board members at least one week prior to the meeting.

The IRB may conduct convened meetings by telephone or video conferencing as long as IRB member(s) have received a copy of all of the documents under review at the meeting, a quorum as defined above is present, and discussion occurs in real time. Such members count as part of the quorum and may vote. "Telephone polling" (where IRB staff or others contact IRB members individually by telephone) does not qualify as a convened meeting. To allow for appropriate discussion, all members must be connected simultaneously for a teleconference to take place.

The IRB must discuss and determine at a convened meeting that all of the Federal criteria for approval are satisfied (previously described under "Federal criteria for approval"). Upon review of a protocol at a convened meeting, the IRB will vote on the protocol. Action taken by the Board will fall into one of the following 4 categories:

1. **Disapproval of Protocol** - If a protocol is disapproved, the applicant will be notified in writing within two business days of the meeting and will be provided the opportunity to respond within seven business days of notification of the disapproval. If the protocol is not approved and the applicant is not satisfied with the IRB's decision after appeal, he or she may appeal to the Vice President for Research and Business Engagement (VPR).

   The VPR will review material provided by the subcommittee as well as any information provided by the investigator. While the signatory official (the VPR) may not approve human subjects research that the IRB has not approved, the VPR may convene a meeting with the full IRB to re-review the protocol if the investigator provides additional information or revisions that were not provided as part of the original review or the appeal to the IRB Chair or committee. The decision of this meeting, if convened, will be final.

2. **Deferred Protocol** – When the IRB determines that required revisions or unresolved issues are substantive, the Submission will be deferred and reconsidered at the next convened meeting, if revisions are received in time. Substantive revisions include changes that require more than simple concurrence by the investigator, such as protocol modifications, revision of research instruments, major revisions to consent forms, or the presentation of new material. Within two business days of the meeting, investigators will be told of the required revisions and will receive a written outline of materials to be submitted. Revised materials must be submitted in the protocol application system at least 14 business days prior to the next convened meeting for distribution to members.

3. **Contingent Approval of Protocol** – A Submission may be approved on a contingent basis. Such contingent approval may occur only if the required revisions are not substantive and require only simple concurrence by the investigator. Upon submission of the non-substantive contingency revisions by the applicant, the Chair or Primary Reviewer can approve the changes to the protocol via an expedited review procedure. Written

notification of approval will be sent within one week of receipt of all requested materials. The approval date is the date the Chair or Primary Reviewer concurs that the changes were made in accordance with the IRB's requirements.

If the Chair or the Primary Reviewer does not feel the revisions are responsive to the Board's request, the investigator will be notified that the project is deferred until the next convened meeting. Any additional materials requested must be submitted at least 2 weeks prior to the next convened meeting for distribution to members.

Contingent Approval Guidelines

Protocol revisions/corrections that meet the definition of "non-substantive" and therefore are able to receive contingent approval generally include the following types of changes (note this list is not all inclusive):

Consent forms:

1. corrections to IRB contact information, change in PI contact number from home phone to office phone, copy of consent on University letterhead
2. changes to eliminate inconsistencies with application
3. requests for clarifications – change in terminology (anonymous vs. confidential)
4. addition of statement informing subjects of disposition of audio and videotapes
5. addition of statement requesting consent to audio and/or videotape
6. addition of statement requesting consent to follow-up contact
7. when alteration/waiver of informed consent or waiver of documentation of consent is discussed and approved at the meeting, revision of the application to reflect this approval
8. additional consent forms requested for multiple classes of subjects, provided the same approved format and wording is used
9. simplification of consent language to increase comprehension by subjects
10. addition of specific required elements (compensation amounts, risks, confidentiality of data). The Board must provide the required language, and the investigator must provide a revision with the provided language

Additional Materials:

1. referral/resource lists
2. other institutional approvals if applicable – HIPAA authorizations or waivers, IRB approvals
3. letters of approval/permission from entities where research will be conducted or from which subjects will be recruited – even if these state approval is contingent on IRB approval

IRB Application:

1. corrections to application questions where additional risks should be noted
2. changes to eliminate inconsistencies with consent form(s)
3. additional information requested and provided at the meeting concerning research procedures and methods, protection of subject confidentiality, disposition of audio and videotapes

4. when alteration/waiver of informed consent or waiver of documentation of consent[4] is discussed and approved at the meeting, revision of the application to reflect this approval

Other: revisions to instruments, survey questions – if these have been discussed and the specific revisions agreed to at the convened meeting

4. **Approval of Protocol** - A Submission may also be approved with no revisions. The applicant will be notified in writing of the Board's decision within five business days of the meeting.

   Protocols approved by the full-board must be reviewed at least annually by the convened Board before the expiration date, except in the case described below. The full board determines an appropriate continuing review interval (termed a "Renewal Submission") as part of the initial review and approval process, and communicate this to the PI as part of the approval letter. Reminders to all principal investigators are sent at 90, 60 and 30 days prior to the annual expiration date that a Renewal Submission must be submitted. If a Renewal Submission is not submitted by the expiration date, an email and formal letter are sent to the investigator notifying him/her that the project is closed and that a final report must be filed. The one exception to at least annual continuing reviews is that the IRB can vote at a convened meeting that a protocol qualifies for expedited review if it determines that the research involves no more than minimal risk. In that case, continuing review is generally not required (but see the "PROCEDURES FOR CONDUCTING CONTINUING REVIEW OF RESEARCH" section for more information).

F. REVIEW OF PROJECTS NOT CONDUCTED BY UA PERSONNEL, BUT ACCESSING UA PERSONNEL AS SUBJECTS.

Other than surveys sent to publicly available UA emails, email requests from non-UA personnel to recruit UA personnel and students, distribute research interventions on campus, or which request human subjects or de-identified data from human subjects research projects, will be reviewed by the IRB Administrator for University concerns. Such requests must provide the IRB Administrator proof of IRB approval or exemption certification from another institution and the protocol documentation. Further, the appropriate College Dean, Director, or Designee must provide approval for the project to be advertised to the College personnel (employees and/or students). If the documentation is appropriate and the University concerns are satisfied, the submitter will be notified in writing within 2-4 weeks of submission.

[4] If a project is funded by a Federal Agency or sponsor that has not signed on to the revised Common Rule, the pre-2018 regulations will be used by the UA IRB. Under the pre-2018 regulations, informed consent and waiver and alteration to informed consent have different criteria than under the revised Common Rule.

IV. PROCEDURES FOR CONDUCTING CONTINUING REVIEW OF RESEARCH

PURPOSE: This section discusses modifications to already approved protocols and how the IRB conducts continuing review of approved studies.

A. MODIFICATIONS

Frequently, investigators wish to modify a protocol after they begin to collect data. Any modifications to an approved protocol (expedited or full board procedures), regardless of approval type, must be presented to, and approved by, the IRB prior to implementation. This is done by submitting a Modification request.

Depending on the nature of the modification, and the initial review level, the change may require full board review or may receive expedited approval under one of the following conditions:

1. The modification meets one of the 7 categories of expedited review; or
2. The modification represents a minor change to the protocol previously approved through full board procedures as allowed. Some examples of minor changes are:
    a. Revision of consent form to include reference to a Certificate of Confidentiality
    b. Corrections of spelling errors on consent forms, instruments, scripts
    c. Corrections to contact phone numbers
    d. Other minor changes that do not increase the level of risk
    e. Addition of another recruitment site or method – i.e. the addition of a mail survey in addition to a web based survey
    f. Addition or substitution of an instrument, if collected information is not of a more sensitive nature than the original(s).

B. CONTINUING REVIEW

Continuing review of certain projects is a Federal requirement. First, protocols that are greater than minimal risk, or do not fall into an expedited category of review, require continuing review at least annually. Additionally, Federal regulations provide guidance on when a full board review project requires continuing review more than annually. Finally, Federal regulations state that some expedited review projects may undergo continuing review, when the IRB determines such review is appropriate. This section describes the procedures for determining when continuing review is required and the continuing review interval.

The IRB notifies principal investigators of the requirement for continuing review in several ways. The approval letter for all protocols (except Exempt) indicates that changes to a protocol require continuing review and approval by the IRB. To initiate the continuing review process, the PI must apply for a "Renewal" submission.

Continuing Review of Full Board Studies (minimal requirement of annual continuing review)

1) The following criteria will be used to determine if a project requires review more often than annually. The presence of one or more of these conditions could trigger more frequent review.
    - The project is greater than minimum risk and involves vulnerable populations and/or sensitive subject matter;

- The project is conducted by investigators who have previously failed to comply with IRB or HHS requirements;
- The project was narrowly approved (more than 3 no votes recorded);
- Complex projects involving multiples sites and personnel

2) For research requiring continuing review by the full board, a properly convened IRB reviews the research at an interval appropriate to the degree of risk and at least once per year. The review procedures and criteria for approval are the same as that described in the "Full Board Review" section of this manual.

Continuing Review of Expedited Studies[5]

1) For research reviewed and approved by Expedited Review procedures on or after January 21, 2019, unless an Expedited Reviewer determines otherwise and documents the rationale as required continuing review of research is not required for the following:
   - Research eligible for expedited review
   - Research reviewed by the IRB in accordance with limited IRB review;
   - Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
2) For research requiring continuing review, which qualifies for review under expedited procedures (meets the criteria for expedited review described in 45 C.F.R. § 46.110 and is determined to require continuing review), the Renewal submission is assigned to the Chair or an IRB member following the expedited review procedures described in the "Expedited Review" section of this manual.

[5] Except in the case where the research is Federally funded by an agency that has not signed on to the revised common rule. In that case, Expedited projects require continuing review according to the "Full Board Review" section. That is, at least annually, and more where the reviewers determine it is appropriate. See the pre-2018 common rule.

V. PROCEDURES FOR REPORTING FINDINGS AND ACTIONS TO INVESTIGATORS AND THE UNIVERSITY

PURPOSE: This section describes timelines for reviews and how investigators will be notified of the outcome of a review. Further, this section describes how the IRB keeps the University appraised of IRB functions.

A. REPORTING OUTCOMES TO INVESTIGATORS

1. ***Exempt Determinations and NHSR Determinations***: These types of Submissions may take 2-3 weeks for initial determination. If clarifications are required, to ensure the Submission meets the criteria for exemption or to qualify as NHSR, the Submission will be returned to the PI in the Cayuse HE. Comments from the reviewer will be embedded in the Submission. Once the PI submits the application with any requested changes or clarifications, the Submission may take an additional 2-3 weeks to make a determination.

2. ***Expedited Reviews***: Expedited protocols may take 2-4 weeks for initial review. If clarifications are required to ensure the Submission meets the criteria for approval, the Submission will be returned to the PI in the Cayuse HE. Comments from the reviewer(s) will be embedded in the Submission. Once the PI submits the application with any requested changes or clarifications, the Submission may take an additional 2-4 weeks to review the changes. This process continues until the Submission is either approved or sent to full committee review.

a) Once the Submission is approved, an email notification and letter is sent to the principal investigator (PI). Co-PIs and Primary contacts are copied on the approval notice. The notice contains the following information:

a. The approval date;
b. The IRB application number;
c. The regulatory approval category;
d. A statement of the requirement for IRB review and approval of any protocol modifications prior to implementation; and
e. If applicable, a statement that waiver or alteration of consent, or waiver of consent documentation, has been approved.

3. ***Full Board Reviews*** – The PI may be invited to attend the board meeting at which his/her protocol is discussed to answer questions and provide clarification if needed. The PI is informed of the IRB decision following the vote at the meeting.

- Approved Applications – The approval letter is sent to the PI generally within two business days of the meeting. A copy is sent to the faculty advisor, if the PI is a student. The approval date is the date of the convened meeting. The approval letter contains everything that the expedited letter contains with the exception of the regulatory approval category.

- Applications Receiving Contingent Approval – The IRB Administrator sends an email outlining the revisions required as agreed upon at the meeting, generally within two business days of the meeting. The PI responds with revisions. Upon receipt of all requested revisions, the IRB Chair or Primary Reviewer will confirm compliance with board requests. The approval letter will be sent within five business days of receipt of the reviewer(s) confirmation. The approval date is the date of the confirmation of compliance with the changes required by the Board. If

revisions do not comply with board requests, the PI will be notified of the deficiencies and the project will be deferred until the next full board meeting.

- Deferred Applications – The PI is informed after the meeting that the application is deferred until the next regularly scheduled meeting. The list of revisions required is provided to the PI as soon as they are finalized by the Board. Any revisions made by the PI must be received within two weeks of the next meeting in order to be placed on the agenda. The full board will review the revised application at the next meeting.

- Disapproved Applications – The PI will be informed after the meeting that the application has been disapproved. A letter outlining the rationale for disapproval will be sent to the PI within five business days of the meeting. The PI will have seven days to appeal the decision. The PI will be notified within 7 business days of any subsequent action taken.

2. REPORTING REVIEW OUTCOMES TO THE INSTITUTION

This section describes how review outcomes are reported to the University.

1. Faculty advisors receive copies of all IRB approval letters for their students.
2. Annual reports of IRB actions are sent to the Vice President for Research.
3. Reports of exempt certifications and expedited approvals, incident reports received, and other IRB actions taken are presented to the IRB for the previous interval from the prior meeting at every monthly meeting.
4. The discussion and outcome of all full board reviews are recorded in the meeting minutes. Minutes are distributed to all board members prior to the next board meeting.

VI. PROCEDURES FOR DETERMINING WHICH PROJECTS NEED VERIFICATION FROM SOURCES OTHER THAN THE INVESTIGATORS THAT NO MATERIAL CHANGES HAVE OCCURRED SINCE PREVIOUS IRB REVIEW (45 C.F.R. § 46.108)

PURPOSE: This section describes how the IRB determines whether projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review. This section also describes the procedures for how the University conducts outside verification.

A. IRB Determination

The following criteria will be used to determine if a project requires independent verification. The IRB may make this determination at a convened meeting or if an incident report suggests one of these categories, the IRB Chair may make this determination.

1. The project must represent unusual levels or types of risks involving vulnerable populations and/or sensitive subject matter.
2. The project is conducted by investigators who have previously failed to comply with IRB or HHS requirements.
3. Projects where concerns about possible material changes occurring without IRB approval have been raised based upon information provided in continuing reports or from other sources.

The presence of one or more of these conditions could trigger requests for outside verification.

B. Procedures for outside verification

When the IRB determines outside verification is required, it will make a request to the Office of Research Administration (ORA). Personnel in the ORA will conduct post-approval monitoring (PAM) of the protocol. PAM may include a variety of means to make outside verification, including but not limited to: 1) in-person observation of the study facilities and/or interactions with participants, 2) review of records by ORA personnel, 3) contacting the external IRB charged with direct oversight, or 4) other means appropriate to gather sufficient information for the IRB.

VII. PROCEDURES FOR ENSURING PROMPT REPORTING OF: A) ANY UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS; B) ANY SERIOUS OR CONTINUING NONCOMPLIANCE; AND C) ANY SUSPENSION OR TERMINATION OF IRB APPROVAL (45 C.F.R. § 46.108)

PURPOSE: This section describes how Investigators report certain events to the IRB and how the University provides required reports to the required Federal agencies. The University is responsible for ensuring reporting of: 1) unanticipated problems involving risks to subjects or others, 2) any serious or continuing noncompliance with Federal regulations or the requirements or determinations of the UA IRB, or 3) any suspension or termination of IRB-approved human subjects research to the Federal government. Thus, Investigators must report such events to the UA IRB.

UA's assurance of compliance is applied to all research, regardless of funding source. Depending on the nature or the severity of the incident reported, the IRB reserves the right to voluntarily report incidents, which may not fall into the definitions described in this section, to the Office for Human Research Protections (OHRP). Note that exempt certified studies are not subject to incident reporting, but the PI is encouraged to report deviations from exempt-certified projects. The IRB will review and certify, when appropriate, that the change did not increase risk. Submission of incident reports for exempt certified studies is a form of quality improvement of the human research protections program.

A. REPORTING BY THE PI

Definitions

- **Unanticipated Problems** – A problem that is unanticipated in terms of nature, severity, or frequency, related or possibly related to the research, for which there is an increased risk to the participants or others must be reported as an Incident report.
- **Adverse Events** – Events that negatively affect the participants that are related or possibly related to the research (e.g. injury to the participant).
- **Breaches in Confidentiality**- Even potential breaches should be reported, for example if a computer where data files are stored is stolen.
- **Protocol Deviations or Non-Compliance With Approved Protocol or Study Materials** - A protocol deviation occurs when there is a variance in a research study between the protocol that has been reviewed and approved by the IRB and the actual activities performed by the research team.
- **Research Participant Complaints**- When a subject's complaints suggest their rights, welfare, or safety has been adversely affected, the PI must submit an Incident report for the IRB to review.
- **Suspension or Termination of the Research**- If a sponsor, an oversight agency, a reviewing IRB other than the UA IRB, or a study site suspends or terminates the research, the PI must submit an Incident report.
- **Incarceration of a Research Subject**- If a research subject becomes incarcerated during the course of the study, such an event must be submitted as an Incident report.
- **Misconduct by Research Personnel-** Alleged or actual misconduct by research personnel must be reported as an Incident report.

- **New Information Suggesting Increased Risk to Participants or Others-** New information, which suggests increased risk to the research participants or other persons must be reported.

The PI must report all study-related protocol violations and incidents to the UA IRB/HRPP **within 5 business days** of discovery of the violation or incident.

Reportable events are adverse events or other incidents that have the potential to be classified by the IRB as an unanticipated problem posing a risk to participants or others. Additionally, unanticipated actions or processes, which are departures from the approved study protocol, Federal regulations, or institutional policies must also be reported. Only the IRB determines whether the event is an unanticipated adverse event or a protocol deviation requiring reporting to OHRP.

Reportable events are submitted to the IRB as an "Incident" submission. The following types of incidents must be reported **within 5 business days**. If a PI is unsure of whether to submit an Incident report, err on the side of submitting. If the event is not reportable, the IRB will let the PI know after it has reviewed the Incident report.

B. REVIEW OF INCIDENT REPORTS BY THE IRB

Definitions

- **Noncompliance**-Failure to comply with the regulations, institutional policies, laws, or the requirements or determinations of the IRB.
- **Continuing Noncompliance**-Any noncompliance that occurs in a persistent or repeated manner.
- **Serious Noncompliance**-Any noncompliance that: 1) adversely affect the rights and welfare of the subjects, 2) increases risks to subjects or others or alter the risk/benefit ratio, 3) compromises the integrity or validity, or 4) results from the willful, knowing, or intentional misconduct on the part of the investigator or research staff.
- **Suspension**-IRB-approved research or some of the activities in the research are temporarily stopped in order to protect human subjects pending completion of an investigation. Once the investigation is complete, a determination is made as to: 1) lift the suspension and allow protocol activities to resume or 2) terminate the study or some activities of the protocol.
- **Termination**-IRB-approved research is permanently stopped. No further work may be done on this research.
- **Unanticipated Problem Involving Risks to Subjects or Others**-Any incident, experience or outcome that is: 1) unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and the informed consent document, and the characteristics of the subject population being studied, 2) related or possibly related to participation in the research, AND 3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

- **Adverse Event-**Any untoward or unfavorable physical or psychological occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.
- **Serious Adverse Event**-Any adverse event that: 1) results in death, 2) is life-threatening (places the subject at immediate risk of death from the event as it occurred), 3) results in inpatient hospitalization or prolongation of existing hospitalization, 4) results in a persistent or significant disability/incapacity, 5) results in a congenital anomaly/birth defect, or 6) based upon appropriate medical judgment may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.
- **Unexpected Adverse Event**-Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity or frequency of which is not consistent with either: 1) the known or foreseeable risk of adverse events associate with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts or 2) the expected natural progression of any underling disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
- **Unexpected Adverse Device Effect**-Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of the subjects

1) The IRB Administrator will review the information and make an initial determination whether the Incident reported meets the any of the definitions in this section, and determine whether the Incident report is complete.
2) The IRB Administrator forwards the Incident report to the IRB Chair for review.
3) The IRB Chair makes a determination whether the Incident meets one of the following definitions from this section:
   - Serious or continuing noncompliance;
   - Unanticipated problem involving risks to subjects or others; or
   - Suspension or Termination.
4) Type of Review for the incident report:
   - If the Incident does not meet one of the three definitions described above, the Chair conducts review to determine the appropriate follow-up. The Chair may ask for input from other HRPP personnel; or
   - If the Incident meets one of the three reportable events, the Chair convenes a subcommittee of at least one additional IRB member, the IRB Chair, and the IRB Administrator. In this case, a preliminary report to OHRP and the sponsor (if appropriate) is made by the Office of Research Administration prior to or during when the subcommittee is convened.
5) The reviewing person or body makes a written summary of the problem, the outcome, and any steps necessary to prevent recurrence. In the case of a subcommittee reviewing, the IRB Chair and additional IRB member must come to consensus on the review. The IRB Administrator

serves as a regulatory consultant, rather than a reviewing member. If no consensus is possible, the Incident must be sent for full committee review.

- The reviewing person or body has the full authority of the IRB to require modifications to the protocol, suspend or terminate the protocol, temporarily halt the protocol until the Incident report is reviewed, or any other action necessary to protect the participants or others.

6) Reviews of the Incident will be completed by the IRB/HRPP within seven business days of receipt of the Incident.
7) The findings of the review are reported to the PI, Primary Contact, and co-Is as an email letter.
8) Any follow-up required by the PI must be completed within the timeline identified, if any, in the email letter. Follow-up actions that may be required include:
   - Additional training of research personnel;
   - Notification of participants of the Incident (e.g. confidentiality breach, increased risk, etc.);
   - Modification of the study protocol;
   - Temporary halt of the study until modification(s) are approved by the IRB; and/or
   - Other actions as deemed necessary by the IRB
9) The VPR will be notified of the outcome of any Incident report within seven business days of its resolution. The IRB Chair will present a summary of any Incident report at the next scheduled meeting of the full board.
   - If the findings of the committee indicate that academic misconduct may have occurred, the matter will be remanded to the VPR for disposition per university policies, along with any pertinent information.
10) If the Incident was reported to OHRP as a preliminary report, the final report must be submitted within five business days of completion of the requirements.

C. APPEALS

1) The PI may appeal the follow-up requirements of the review. The appeal must be in writing and emailed to the IRB Chair within five business days of receipt of the Chair's or subcommittee's findings.
2) In the case of an appeal, the Incident report is sent to full committee review at the next convened meeting (even if the meeting is the next day). The convened IRB determines the follow-up requirements by a majority vote. The findings of this determination are sent to the PI within two business days of the meeting.
3) The principal investigator may appeal to the VPR if the second review by convened IRB is unsatisfactory to the PI. The investigator will have seven (7) days to prepare the appeal to the VPR after receipt of the results of the IRB Chair's appeal procedure.
4) The VPR will review material provided by the IRB as well as any information provided by the investigator. Per Federal regulations, the Signatory Official (the VPR) may not approve human subjects research that the IRB has not approved. Nevertheless, the VPR may convene a meeting with the full IRB to re-review the protocol if the investigator provides additional information or revisions that were not provided as part of the original review or the appeal to the IRB Chair or committee. The decision of this convened meeting will be final.

VIII. PROCEDURES FOR REVIEW OF RESEARCH INVOLVING CHILDREN

PURPOSE: Children are considered a vulnerable population, requiring special protections. The Federal regulations have codified the requirements for these protections in Subpart D of the Common Rule. This section describes the UA IRB's approach to ensuring the protections are met.

Protocols utilizing children as subjects will be reviewed by the IRB under Subpart D. The IRB policy is to require parental consent for studies involving minors. Waiver of parental consent will only be considered for studies that meet the guidelines established by the Protection of Pupil Rights Amendments (PPRA) and Subpart D - Additional Protections for Children Involved as Subjects in Research.

Procedures: The IRB will document consideration of additional protections and can approve only research that satisfies one of the conditions outlined below.

Research Category 1: Research not involving greater than 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.

The IRB must find that:

1. Adequate provisions have been made for soliciting the assent of the children;
2. Adequate provisions have been made for soliciting the permission of their parents or guardians, or criteria is met for approval of waiver or alteration of informed consent (permission of one parent is sufficient if approved by the IRB); and
3. Permission by parents or guardians is documented in accordance with and to the extent required.

Research Category 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects – more than minimal risk is acceptable if the intervention or procedure holds out the prospect of direct benefit for the individual subject.

The IRB must find that:

1. Risk is justified by anticipated benefit;
2. Relation of the benefit to the risk is at least as favorable to the subjects as that represented by available alternative approaches;
3. Adequate provisions have been made for soliciting the assent of the children and permission of their parents or guardians, or criteria is met for approval of waiver or alteration of informed consent (permission of one parent is sufficient if approved by the IRB); and
4. permission by parents or guardians is documented in accordance with and to the extent required.

Research Category 3: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

The IRB must find that:

1. Risk represents a minor increase over minimal risk;

2. The intervention or procedure presents experiences to the subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
3. The procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for understanding or amelioration of the subjects' disorder;
4. Adequate provisions have been made for soliciting the assent of the children and permission of their parents or guardians, or criteria is met for approval of waiver or alteration of informed consent (except under specific circumstances*, permission must be obtained from both parents); and
5. permission by parents or guardians is documented in accordance with and to the extent required.

*deceased, unknown, incompetent, not reasonably available, or when one parent has legal responsibility for child

Research Category 4: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children – the IRB may approve research that does not meet any of the conditions above only if:

1. IRB finding that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem;
2. * after consultation with a panel of experts in pertinent disciplines, the IRB has determined either:
   (a) that the research in fact meets one of the conditions outlined in 1-3 above, or;
   (b) 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
   (c) the research will be conducted in accordance with sound ethical principles.

*If the study is funded by DHHS, the IRB must submit this category of research to the Secretary of DHHS for review and approval. The Secretary will convene a panel of experts.

Wards- Children who are wards of the State or any other agency, institution, or entity can be included in research approved under Category 3 or Category 4 only if such research is:

1. related to their status as wards; or
2. conducted in schools, camps, hospitals, institutions, or other settings in which the majority of children involved are not wards.

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

Child Assent- The IRB will ensure that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all

children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. In general, the IRB considers children aged 8 and above to be capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

IX. PROCEDURES FOR REVIEW OF RESEARCH INVOLVING PRISONERS

PURPOSE: Prisoners are considered an additional population of persons requiring special protections when participating in research. The Federal regulations codify the required protections under Subpart C of the Common Rule. This section describes the UA IRB's approach to ensuring the rules of Subpart C are met.

Protocols utilizing prisoners as subjects, or an at-risk population that could enter prisoner status during the research (for example at follow-up data collection points), must be reviewed by the IRB under Subpart C. In these cases, a majority of the Board (exclusive of member satisfying the prisoner perspective) shall not be employed by, nor be a member of the governing board of, the prison(s) involved and at least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except where the research is reviewed by more than one Board (in that case, only one Board need satisfy this latter requirement).

Procedures: The IRB must document in the Board minutes the seven additional findings, outlined below, and provide protocol specific detail:

1. The research represents one of the four permissible categories identified in the Federal regulations (listed below). The Board must determine which category, i-iv, the research represents.

    i. Study of possible causes, effects, and processes of incarceration and of criminal behavior, provided it represents no more than minimal risk and no more than inconvenience to the subjects;

    ii. Study of prisons as institutional structures or prisoners as incarcerated persons, provided it represents no more than minimal risk and no more than inconvenience to the subjects;

    iii. Research on conditions particularly affecting prisoners as a class (vaccine trials, research on hepatitis which is much more prevalent in prisons, and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)

    iv. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving health or well-being of the subject.

2. Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, are not of such a magnitude that the ability to weigh the risks against the value of such advantages in the limited choice environment of the prison is impaired.

3. The risks are commensurate with risks that would be accepted by a non-prisoner volunteer.

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Control subjects must be selected randomly from all who meet the eligibility criteria unless the PI provides the Board in writing a justification for some other procedure.

5. The information is presented in language that is understandable to the subject population.

6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the study in making decisions regarding parole, and each prisoner is clearly informed in advance that participation will have no effect on his or her parole.

7. When the Board finds there may be the need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for the provision of such care.

If the study is Department of Health and Human Services (DHHS) funded, before the study can proceed, the IRB must certify to the Secretary of DHHS that the duties of the Board have been fulfilled. If the Board approves under category iii or iv, (with a control group comprised of prisoners), then the Secretary of DHHS must consult with a panel of experts and publish a notice in the Federal Register of his intent to approve the research. (This can take up to 6-8 months). The study cannot go forward until OHRP issues its approval in writing to the university on behalf of the Secretary.

If the study is not DHHS funded, the IRB will document in the meeting minutes that the additional protections specified by the Federal regulations are in place. If the research falls into category iii or iv (with control group), the IRB will convene a panel of experts to review.

X. ADDITIONAL PROTECTIONS FOR PREGNANT WOMEN, HUMAN FETUSES AND NEONATES INVOLVED IN RESEARCH.

PURPOSE: Pregnant women, human fetuses, neonates are considered additional populations requiring special protections when participating in research. The Federal regulations codify the required protections under Subpart B of the Common Rule. This section describes the UA IRB's approach to ensuring the rules of Subpart B are met.

Procedures: In addition to the criteria for IRB approval of research, the following additional protections must be met for research involving pregnant women, human fetuses, and neonates.

1. Pregnant women or fetuses may be involved in research if all of the following conditions are met:
    a. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
    b. 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; or, if there is no such prospect of benefit, 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;
    c. Any risk is the least possible for achieving the objectives of the research;
    d. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor 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, her consent is obtained in accord with the informed consent provisions;
    e. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions, 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.
    f. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
    g. For children who are pregnant, assent and permission are obtained;
    h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
    i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
    j. Individuals engaged in the research will have no part in determining the viability of a neonate.
2. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
    a. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

b. Each individual providing consent under paragraph (3)(2) or (4)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
c. Individuals engaged in the research will have no part in determining the viability of a neonate.
d. The requirements of paragraph (3) or (4) of this section have been met as applicable.

3. **Neonates of uncertain viability**. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:
    a. The IRB determines that:
        i. The research holds 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, or
        ii. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
    b. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
4. **Nonviable neonates.** After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:
    a. Vital functions of the neonate will not be artificially maintained;
    b. The research will not terminate the heartbeat or respiration of the neonate;
    c. There will be no added risk to the neonate resulting from the research;
    d. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
    e. The legally effective informed consent of both parents of the neonate is obtained, except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not 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 will not suffice to meet the requirements of this paragraph (c)(5).
5. **Viable neonates**. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of the Federal regulations.

XI. HIPAA PRIVACY RULE

PURPOSE: This section describes the Investigator's and University's obligations as it relates to the HIPAA privacy rule, when health information for research purposes is sought. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 included provisions to protect the privacy of protected health information (PHI). To implement these protections, the U.S. Department of Health and Human Services issued a final Privacy Rule. The Rule governs how health care providers use and disclose PHI on their patients, including use and disclosure for research purposes.

Definitions

Covered Entities-Health plans, healthcare providers and healthcare clearinghouses are all "covered entities" under the Privacy Rule.

Hybrid Entities-Another category covered entities are "hybrid entities." These include organizations that are not covered as a whole but contain specific units that are covered. The University of Akron is a hybrid entity, because its student health unit is a covered entity.

Protected Health Information (PHI)-information, including demographic data, that relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. PHI includes many common identifiers (e.g., name, address, birth date, social security number).

A. RESPONSIBILITY: Investigators who are accessing, using, and/or disclosing PHI from a covered or hybrid entity will need to address HIPAA in their IRB application.

If a project is subject to HIPAA, the investigator must do one of the following:

1. Request authorization to access PHI from each research participant. This can be accomplished by including a separate signature approving access on the consent form, or by the use of a separate HIPAA Authorization Form. The Authorization form may be provided by the covered entity or developed by the investigator. If developing an Investigator's own form, please contact the IRB office for assistance.

2. Request the IRB to waive the requirement to acquire authorization from research participants. Three criteria must be met to qualify for a waiver:
    a. The use involves no more than minimal risk to the privacy of the individuals;
    b. The research could not be practicably conducted without the waiver; and
    c. The research could not practicably be conducted without access to the PHI.

3. Propose the use of a limited data set. Specific identifiers must be removed to qualify as a limited data set. Contact the IRB office for information. Use of a limited data set will require a signed data use agreement between the investigator and the covered entity.

Please contact the Office of General Counsel for assistance in obtaining a signed data use agreement with an outside agency.

B. WAIVERS: When requesting a waiver, the investigator must provide the IRB with detailed information on the specific PHI that will be accessed, provide an adequate plan to protect the PHI from improper use and disclosure, have a plan for destroying all identifiers at the earliest opportunity, and provide adequate written assurance that the PHI will not be used or disclosed for any other purpose.

For additional guidance on The University of Akron's response to HIPAA, please see the Office of General Counsel website.

XII. IRB RECORDS AND DOCUMENTATION

PURPOSE: This section describes how the University of Akron keeps records and documentation related to the HRPP, as required by the Federal regulations.

1) **Application Files** – On November 15, 2023, the HRPP transitioned to a cloud-based application system. The following sections describe the records and documentation for applications submitted prior to November 15, 2023 and for those after.

2) **Studies submitted on or after November 15, 2023**
All new studies and submissions related to a particular study are created and maintained in the cloud-based IRB application system (i.e. Cayuse HE). Study submissions include the:
    1. Initial submission
    2. Modification submission (if any)
    3. Incident submission (if any)
    4. Renewal submission (if any)
    5. Closure (if any)

    Official communications related to these submissions are also created and maintained in the Cayuse HE. Communications or questions may be received through email to the IRB Chair, Administrator, or other HRPP staff. In these cases, the email file is uploaded to the Cayuse HE and stored with the other electronic documentation.

3) **Studies submitted prior to November 15, 2023**
Protocols submitted prior to November 15, 2023 will have at least some documentation kept external to Cayuse HE. The Application file includes the following documentation:

    Contents of Application File
    1. Initial application including all required attachments (summary statement, instruments, consent/assent forms, scripts, recruitment materials)
    2. All correspondence regarding the application
    3. Approved consent/assent forms – date stamped with approval date
    4. IRB approval letter
    5. Notification of annual renewal deadline
    6. Continuation applications – annual and change requests
    7. Copies of all approved revisions to protocol
    8. If full board reviewed, copies of meeting minutes at which the protocol was reviewed
    9. Any incident and event reports and documentation of action taken
    10. Final report, where required, when study is completed

All such protocols are stored electronically in SharePoint in a file folder with the protocol number. All protocol files are kept for 3 years after official closure of the study. Closure is evidenced by 1) filing of a final report by the principal investigator (where required), or 2) letter to the principal investigator from the IRB closing the study administratively because it is exempt or not human subjects research and requires no additional follow-up.

Exempt protocols and Not Human Subjects Research applications are administratively closed 3 years after the approval date, if no final report is received.

For protocols, which were approved by the UA IRB through expedited or full board review procedures, these protocols are input into Cayuse HE as "Legacy-[Protocol ID]." The Application file created outside of Cayuse HE is maintained as above, however no new documentation is stored in that Application file. Rather, any actions taken on or after November 15, 2023 are made in Cayuse HE and stored as described in the "Studies submitted on or after November 15, 2023" section.

4) IRB Meeting Minutes – During the academic year, the IRB meets monthly if needed, and at least once a semester, on a day determined by the Chair with the consensus of the Committee. Minutes of every meeting are distributed to all IRB members prior to the next meeting and members have the opportunity at each meeting to request revisions to the previous month's minutes. The minutes are voted on and placed on file as approved.

Contents of Meeting Minutes

1. List of members present and absent;
2. Approval of previous month's minutes;
3. Documentation of IRB actions taken through expedited or other non-full board procedures (e.g. NHSR, Exempt and Expedited approvals) from the previous month;
4. Separate review of each full-board protocol on the agenda that includes:
    a. Initial comments and questions from the Primary Reviewer;
    b. Presentation by Principal Investigator (if present);
    c. Discussion of controverted issues and their resolution;
    d. Listing of board recommendations;
    e. Type of Approval (approved, contingent, deferred, or disapproved) and vote tally indicating the number voting for, against, and abstaining;
    f. Vote tally on whether or not to allow expedited continuing review if the following conditions are met – (1) study involves no greater than minimal risk, and (2) at time of continuation submission no additional risks are identified and no adverse events are reported;
    g. For projects that receive approval for a waiver or alteration of consent, or waiver of documentation, the rational for approval;
    h. For projects involving minors, specification of the section of Subpart D under which the project is approved (Section 46.404 – 46.407); and
    i. For projects involving prisoners, the approval category is specified as well as documentation that the research meets the 7 additional criteria for approval.

5) Other Documentation

Other documentation related to the IRB functions or the HRPP more generally is stored in SharePoint by the Office of Research Administration. Such documentation includes:

- Federalwide Assurance Form/ OHRP IRB Registration Form;
- Board minutes;
- Board & Subcommittee reports;
- Annual reports of IRB reviews;
- IRB rosters;
- IRB appointment letters; and
- Correspondence not related to a specific IRB Study.

Materials that are updated periodically & are available on the ORA website:

- Sample consent / assent forms;
- Policies and Procedures Manual;
- Frequently Asked Questions; and
- Other Resources.

XIII. IRB STRUCTURE AND COMPOSITION (45 C.F.R. § 46.107)

PURPOSE: This section describes how the UA IRB is organized and composed. The organization of UA's IRB complies with Federal regulations and the University's Federalwide Assurance. The University maintains one active IRB. The UA IRB is made up of a chair, voting members, and non-voting consultants and/or support staff.

1) **IRB Members / Roles**:

- The Chair presides over convened IRB meetings; oversees the review functions of the members; transmits the IRB's conclusions with regard to reviewed applications; and represents the university and acts as a liaison with the Office of Human Research Protections. The Chair is appointed by the Vice President for Research. The Chair serves for a 3-year term which may be continued by mutual consent of the Chair and the VPR.

- Voting members are appointed for three-year terms. Appointments may be renewed for unlimited additional three-year terms. Voting Members of the IRB include representatives from the university as well as the community. Federal regulations require that each IRB include at least one community member with no ties to the institution and one member who is a non-scientist. The IRB also includes a prisoner advocate as a regular voting member.

  Voting members review IRB applications as appropriate and consistent with professional standards within the field. Upon review of an application, the member determines whether the research qualifies for expedited review or requires full board review. Members may also recommend revisions to protocols prior to approving under expedited review. Members may also provide the primary, in-depth review function for protocols that must undergo full board review. They vote to approve, approve contingent upon modifications, or disapprove protocols in full IRB meetings.

- Non-voting consultants may be called upon when their particular expertise is required. The Chair makes such requests, based upon input from the HRPP.

2) **Attendance:** Attendance of members at all convened meetings is expected. Three consecutive unexcused absences may disqualify a member from continuing IRB membership and the Chair may seek nominations for a replacement. If a member has missed three consecutive meetings without an excuse, the Chair will contact the member in writing to determine whether a replacement is appropriate.

3) **Membership Terms:** The IRB is structured around at least two cohorts, when possible. The terms of each cohort expire in different years. New IRB members may be self-nominated or nominated by other IRB members, Deans, Department Chairs, faculty, ORA, or other interested parties.

- Ex-officio members of the IRB include the IRB Administrator and other IRB support staff as determined necessary by the Signatory Official. This(ese) individuals provide support and advice as required by the IRB. In addition, the IRB Administrator has been delegated authority by the Chair of the IRB to sign IRB approval letters and other IRB correspondence.

The IRB Administrator also reviews NHSR applications and certifies them as NHSR (when appropriate).

4) **IRB Meeting Times:** The Board meets monthly if needed, and at least once a semester, during the academic year. Meetings are held at a time and day selected by the current Chair. Summer meetings are arranged as needed. The meeting schedule and deadline dates for the year is posted on the IRB website at the beginning of each academic year: http://www.uakron.edu/research/ora/compliance/irb/.

5) **IRB Deadlines:** Applications for review by the full IRB must be received by 5:00 p.m., 14 business days prior to the scheduled meeting. Applications for exemption and those requesting expedited review can be submitted at any time and will be reviewed as received. Exempt and expedited reviews are typically completed within two to three weeks.

XIV. MANDATORY EDUCATION REQUIREMENTS

PURPOSE: This section describes the mandatory training requirements for Investigators, the research team interacting with human participants, and IRB members.

1) **Investigators and Research Team:** All personnel conducting research involving human subjects, or their identifiable data or biological specimens, must complete the CITI Investigator Training ("SBR Investigators"), a web-based curriculum.

2) **IRB Members:** All IRB members must complete the CITI training for IRB Members.

The CITI certification is good for three years, after which investigators and IRB members must take the CITI Refresher training to maintain active status.

The CITI Website is https://about.citiprogram.org/en/homepage/

XV. HRPP CONTACT INFORMATION

Website: http://www.uakron.edu/research/ora/compliance/irb/

Mailing Address: 302 Buchtel Common, Akron, OH 44325-2102

Physical Location: Leigh Hall, 5th Floor

IRB Contact Information

Email: irb@uakron.edu
Phone: 330-972-7666
Fax: 330-972-4850

Approvals

IRB Chair	DocuSigned by: Susan Kushner Benson CBEC9B19A0F64AD... Susan Kushner Benson 6/12/2024 | 10:19 AM EDT
Signatory Official	DocuSigned by: Suzanne Bausch 366560CFCDEA45C... Suzanne Bausch 6/12/2024 | 12:11 PM EDT