THE UNIVERSITY OF AKRON
INSTITUTIONAL REVIEW BOARD

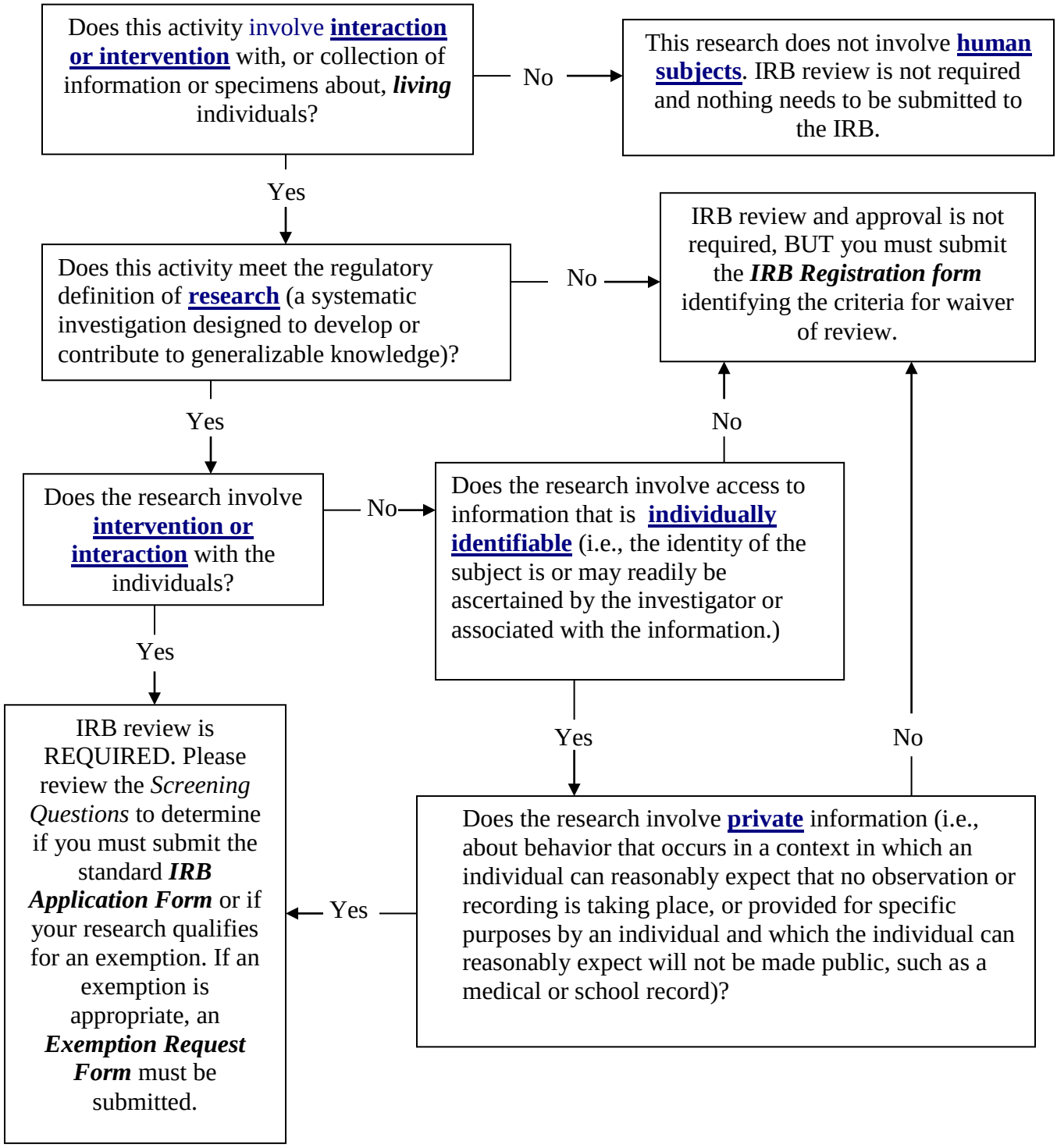
STANDARD OPERATING PROCEDURES MANUAL

January 2019

TABLE OF CONTENTS

I. WHAT TYPE OF PROJECT REQUIRES IRB REVIEW AND APPROVAL?

The first determination a researcher must make is whether or not the proposed research falls under the federal regulations for research on human subjects. Use this decision tree and the definitions on the following pages to make this determination (Definitions are provided for all underlines words.)



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.

The following are typically considered research:

1. Any project, including student projects, conducted with intent to contribute to generalizable knowledge through publication and/or public presentation within an academic discipline. Presentation of a class assignment to the class and/or the writing of a class paper do not in themselves constitute public presentation or publication.

2. Graduate theses and dissertations are clearly understood as "research" and fall within IRB jurisdiction when "human subjects" are involved.

The following generally fall outside the federal definition of research under 45CFR46:

1. Normal educational activities that are designed to train students in research techniques and methods or to qualify students as researchers, when those activities are conducted as part of courses or in regular classroom settings. For such coursework, the class instructor should submit a Classroom Based Protocol application describing the general nature of student projects.

   However, individual student class projects involving vulnerable populations (children, mentally impaired, prisoners or individuals on probation) or collecting identifiable, sensitive, private information will require individual IRB review. The course instructor must review all proposed student research and insure that any student whose research project involves a vulnerable population or sensitive information submits an individual IRB application for review.

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.

3. Medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, fiscal or program audits, journalism, biography, oral history.

Human Subject means a living individual about whom and 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 is **Individually Identifiable** includes, but is 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 researcher could reasonably use to identify a living individual, or combinations of information from which a persons identity could easily be determined.

Data is 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 researcher could reasonably use to identify a living individual, or combinations of information from which a persons 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.

[end of definitions]

If the proposed project involves interaction with or collection of private, individually identifiable data about living individuals, but does not meet the definition of research, you must submit an IRB Registration Form to the IRB. If the project meets the definition of human subjects research, it may still be exempt from review. To assist in making this determination, the IRB has created a set of screening questions. If, after going through the questions, a researcher believes his/her project falls under one of the exemption categories, an Exemption Request Form may be submitted to the IRB. The exemption request will be reviewed by the IRB Administrator. If exemption is appropriate, the researcher will be notified. If exemption is not appropriate, the researcher will be asked to submit the standard IRB Application Form.

The IRB Registration Form, Screening Questions, and Exemption Request Form can be found on the ORA Website:

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

II. PROCEDURES FOR CONDUCTING INITIAL REVIEWS

REVIEW OF IRB REGISTRATION FORM

IRB Registration forms are reviewed by the IRB Administrator. If the registration form is appropriate, the researcher will be notified in writing within 1 week of submission. No further action is required.

REVIEW OF EXEMPTION REQUEST FORM

Exemption requests are reviewed by the IRB Administrator or the IRB Chair. If the exemption is appropriate, the researcher will be notified in writing within 1-2 weeks of submission. No further action is required. If exemption is not appropriate, the researcher will be instructed to submit an IRB Application Form.

A protocol is exempt from IRB review if the research poses minimal risk to subjects and matches one of the following federal exemption categories found at §46.104(d):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recordings.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, bio-specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food

ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage and maintenance of identifiable private information or bio-specimens for which broad consent for storage and maintenance will be requested for potential secondary research use.

8. The use of identifiable private information or bio-specimens for which broad consent will be requested for potential secondary research use.

Exceptions:

(a) Survey/Interview Exemption 2 does not apply to research involving **children (under 18)**
(b) Observation of Public Behavior Exemption 2 does not apply to research involving **children** except when investigator does not participate in activities being observed
(c) Exemption 3 – benign behavioral interventions – does not apply to research with **children.**

A protocol that is exempt from review does not require annual renewal. A final report will be requested, but not required. Exempted protocols will be kept for 3 years from the approval date. To continue a research protocol beyond 3 years, a new exemption request must be submitted.

If an investigator conducting an exempt study makes any changes or modifications to the study's design or procedures that either increase the risk to subjects or include activities that do not fall within one of the categories exempted from the regulations, a standard IRB application will need to be submitted for review.

REVIEW OF A STANDARD IRB APPLICATION

Initial Review

The review of a protocol that is not exempt begins with the submission of the IRB Application Form by the researcher. Upon submission of an application and supporting materials (a description of the project, informed consent documents, oral scripts, surveys, etc.), the IRB Administrator reviews the application for signatures, appended materials, etc. The IRB office also verifies that the principal investigator and co-investigators have completed the required CITI certification.

The IRB Administrator forwards the protocol to an IRB member representing the college of the principal investigator noted on the application. Protocols may also be reviewed by the IRB Chair.

IRB Member Review

Protocols are given to members within the same discipline as the researcher, whenever possible. The member has an understanding of professional codes and ethics appropriate for his or her academic specialty that may not be apparent to individuals outside the field. Additionally, the member has a better understanding of research methods appropriate for the field. This

information is invaluable for risk/benefit analysis. The member may also more easily call on resources at hand within the college to facilitate review of protocols for which he or she may have limited expertise. This professional, academic review is the best approach to ensure the protection of human subjects and is best accomplished by a reviewer within the same discipline.

The reviewer determines the review status and may take one of three actions:

1. Approve as Expedited
2. Contingent Approval as Expedited – revisions required
3. Recommend Full Board Review

All required review criteria are detailed on the IRB Reviewer Sheet distributed to the reviewer. This sheet is completed and returned to the IRB office indicating either the approval category for which the protocol qualifies or the recommendation for review at a convened board meeting. All required revisions are also noted on the form.

The reviewer cannot disapprove a protocol. If he/she feels the protocol should be disapproved, it must come before the full board for review.

EXPEDITED REVIEW

All reviews are conducted pursuant to the regulations outlined in §46.111 as noted below:

1. In order to approve any research under expedited review, the following requirements must be satisfied:

   (a) Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

   (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. In evaluating risks and benefits, the reviewer should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies or interventions subjects would receive even if not participating in the research). The reviewer should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of the IRB's responsibility.

   (c) Selection of subjects is equitable. In making this assessment the reviewer should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, 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, and to the extent required by §46.116, or criteria is met for approval of waiver or alteration of informed consent, as permitted under §46.116(d).

(e) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117, or criteria is met for waiver of documentation, as permitted under §46.117(c).

(f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(g) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(h) If the study proposes storage, maintenance or use of collected data or biospecimens for future use, broad consent is obtained and appropriately documented.

2. 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.

If the reviewer determines that the project is appropriate for expedited approval she/he completes the review following the procedures listed below:

1. All questions or requests for clarifications should be directed to the researcher, preferably in writing (e-mail). The regulations stipulate that all correspondence between the IRB and researcher be maintained in the records, so the IRB Administrator is to be copied on all communications.

2. Once the researcher has answered all questions and/or agreed to provide requested clarification/documentation, the reviewer completes the reviewer sheet, checking all boxes as applicable and including detail on any requested revisions that are still outstanding (if not already conveyed to the IRB office).

3. The reviewer signs and dates the reviewer sheet and returns it to ORA by any of the following means: fax - (330)972-4850; e-mail - sm48@uakron.edu; or mail - +2102.

4. When all revisions are received, the IRB Administrator will verify with the reviewer that the revisions satisfy the reviewer's request. The expedited approval date entered into the system will be the date that all revisions are received and approved.

Expedited Approval Categories: A protocol may receive expedited approval if the research poses minimal risk to subjects and involves only procedures listed in one of the following federal categories (§46.110(b)(1):

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

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

A protocol may also receive expedited review for minor changes that occur to already approved research during the period for which approval has been authorized (§46.110(b)(2)).

Expedited Approval is granted for the life of the project. Annual continuing review is not required. When the study is completed a Final Report is submitted and the protocol closed. Protocols are kept for 3 years after close and then destroyed.

FULL BOARD REVIEW

If the protocol is not eligible for expedited review, the protocol must be reviewed by the full board at a convened meeting. The initial reviewer will indicate if full IRB review is warranted on the IRB Reviewer sheet and send it to the IRB Administrator for placement on the agenda for the next board meeting. The PI will be notified of the need for full board review and the date and time that the protocol will be reviewed. The PI is also invited to attend the board meeting in order to provide needed clarification and address any questions.

The initial reviewer may be asked to serve as Primary Reviewer at the meeting, or another IRB member may be selected based on a particular expertise (children, prisoners). In the event that the reviewer believes a protocol should be disapproved, the full IRB must be convened to review the research.

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
- A majority of members must be present
- At least one member who is a non-scientist must be present
- For research to be approved, it must receive approval from a majority of members present
- IRB members who have conflicting interests cannot participate in the review except to provide information.

A Primary Reviewer (PR) will be assigned for each protocol requiring full board review. The PR will be a member with expertise in the subject area of the protocol. At least ten days prior to the meeting, the PR 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 PR 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 should contact the researcher for any required clarification or additional information before the meeting, and relay any additional information to the IRB office for distribution to all board members.

All members will be able to access the complete application, all consent forms, and any other information given to participants on Springboard. For continuation applications, the most recent board minutes where the project was discussed will also be available. Materials will be accessible 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 following requirements (from § 46.111) are satisfied:

1. Risks to subjects are minimized, (i) by using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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

3. Selection of subjects is equitable. Take into account the purpose of the research and the setting in which it will be conducted.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116, or criteria is met for approval of waiver or alteration of informed consent, as permitted under §46.116(d).

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117, or criteria is met for waiver of documentation as permitted under §46.117(c).

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. If the study proposes storage, maintenance or use of collected data or biospecimens for future use, broad consent is obtained and appropriately documented.

9. 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.

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 days of the meeting and will be provided the opportunity to respond within seven days of notification of the disapproval. The IRB will convene a subcommittee to review the response. If the subcommittee decides that the project is approvable, it will be placed on the agenda for the next full board meeting. 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 Assistant Vice President for Research (AVPR).

   The AVPR will review material provided by the subcommittee as well as any information provided by the researcher. Per 46.112, Review by Institution, the institutional official (the AVPR) may not approve human subjects research that the IRB has not approved. Nevertheless, the AVPR may convene a meeting with the full IRB to re-review the protocol if the researcher 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.

2. **Deferred Protocol** – When the Board decides that required revisions or unresolved issues are substantive, the protocol will be deferred and reconsidered at the next convened meeting. Substantive revisions include changes that require more than simple concurrence by the researcher, such as protocol modifications, revision of research instruments, major revisions to consent forms, or the presentation of new material. Researchers will be told of the required revisions at the meeting and will receive a written outline of materials to be submitted within two days of the meeting. Revised materials must be submitted to the IRB office at least 2 weeks prior to the next convened meeting for distribution to members.

3. **Contingent Approval of Protocol** – A protocol 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 will be the date of the convened meeting at which the protocol was reviewed.

If the Chair or the Primary Reviewer does not feel the revisions are responsive to the Board's request, the researcher 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.

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

Contingent Approval Guidelines
Protocol revisions/corrections that meet the definition of "non-substantive" and therefore are able to receive contingent approval:

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 researcher 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 is discussed and approved at the meeting, revision of the application to reflect this approval

***Other**:*

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

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III. PROCEDURES FOR CONDUCTING CONTINUING REVIEW OF RESEARCH

Requesting a Change in Protocol

Frequently, researchers wish to modify a protocol after they begin to collect data. Any modifications to an approved Expedited or Full Board protocol must be presented to, and approved by, the IRB prior to implementation. This is done by submitting the Request for Change in Approved Protocol form.

Researchers planning to modify an Exempt protocol are not required to submit anything unless the planned modification will result in increased risk to participants or the change means that the protocol now falls outside of the approved categories for exemption found in §46.101(b). Researchers who have been granted an exemption must contact the IRB in writing (e-mail) to present the change. The researcher will receive a written response indicating that either the protocol still qualifies for exemption or the standard IRB Application Form must be submitted.

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. It meets one of the 7 categories of expedited review; or
2. It represents a minor change to the approved protocol as allowed under §46.110(b)(2). 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).

ANNUAL REVIEW OF FULL BOARD PROTOCOLS

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. Unless the Board has voted as such, the protocol must be reviewed annually by the convened Board before the expiration date. The IRB office notifies all principal investigators two months prior to the annual expiration date

that a continuation application must be submitted. If a continuation application 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.

IV. PROCEDURES FOR REPORTING FINDINGS AND ACTIONS TO INVESTIGATORS AND THE INSTITUTION

REPORTING REVIEW OUTCOMES TO INVESTIGATORS

1. Exempt and Expedited Reviews – Except in unusual circumstances, reviews are completed with two weeks. Once the reviewer notifies the IRB office of approval, an email notification and letter is sent to the principal investigator (PI). If the PI is a student, the faculty advisor is copied on the email notification. The letter contains the following information:

a. Approval date
b. IRB application number
c. Regulatory approval category
d. Statement of the requirement for IRB review and approval of any protocol modifications prior to implementation
e. If applicable, a statement that waiver or alteration of consent, or waiver of consent documentation, has been approved
f. If applicable, a copy of the approved consent document(s), with the approval date stamp, is sent with the letter.

2. Full Board Reviews – The PI is 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 within two 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 agreed upon at the meeting within one day of the meeting. 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 two days of receipt of all materials. The approval date is the date of the convened meeting. 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 at the meeting that the application is deferred until the next regularly scheduled meting. The IRB Administrator sends an email outlining the revisions discussed at the meeting within one day of the meeting. All materials 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 at the meeting that the application has been disapproved. A letter outlining the rationale for disapproval will be sent to the PI within two days of the meeting. The PI will have seven days to appeal the decision. The PI will be notified within 1 week of any subsequent action taken.

REPORTING REVIEW OUTCOMES TO THE INSTITUTION

1. Faculty advisors receive copies of all IRB approval letters for their students.
2. Quarterly reports of all IRB reviews by College are sent to Deans.
3. Annual reports of IRB reviews by department are sent to the Assistant Vice President for Research.
4. Monthly reports of exempt and expedited approvals are presented to the IRB for the previous month at every monthly meeting.
5. 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.

V. PROCEDURES FOR DETERMINING WHICH PROJECTS REQUIRE REVIEW MORE OFTEN THAN ANNUALLY

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.

1. The project must represent greater than minimum risk 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. The project was narrowly approved (more than 3 no votes recorded)
4. Complex projects involving multiples sites and personnel

VI. PROCEDURES FOR DETERMINING WHICH PROJECTS NEED VERIFICATION FROM SOURCES OTHER THAN THE INVESTIGATORS THAT NO MATERIAL CHANGES HAVE OCCURRED SINCE PREVIOUS IRB REVIEW

The following criteria will be used to determine if a project requires independent verification.

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.

VII. PROCEDURES FOR ENSURING PROMPT REPORTING TO THE IRB OF PROPOSED CHANGES IN A RESEARCH ACTIVITY

The IRB notifies principal investigators of the regulations on continuing review in several ways. The approval letter for all protocols indicates that changes to a protocol require a Continuation Application and approval by the IRB.

In addition, the IRB Applicant Manual indicates that continuing review is required for all protocols. Finally, the IRB provides training through its Investigator Responsibility Certification and through on going workshops, meetings and training sessions to alert researchers to this requirement.

VIII. 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

UNANTICIPATED EVENTS – Sometimes during the course of a research project, the researcher is made aware of information that may indicate an unanticipated risk to a subject or someone else. If the approved protocol does not allow for a response to this risk, the researcher is to bring the information to the attention of the IRB Chair and Administrator.

Initial Review by Chair - The IRB Chair will review the information and, at his/her discretion, will either approve a revision to the protocol in order to remove or minimize the risk or will convene a subcommittee of IRB members to review the information and determine the correct course of action.

Reporting Outcome to Institution – The Assistant Vice President for Research will be notified of the outcome of any reported unanticipated event within one week of its resolution. The IRB Chair will present a summary of any unanticipated events at the next scheduled meeting of the full board.

PROTOCOL VIOLATIONS - A protocol violation 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. Protocol violations may be minor or major.

Minor protocol violations would include violations that:

- have no substantive effect on the risks to subjects
- have no substantive effect on the value of the data collected (scientific analysis of the results is not confounded)
- did not result from willful or knowing misconduct on the part of the researcher(s)

Major protocol violations would include:

- violations that have harmed or posed a significant risk of harm to subjects
- violations that have damaged the scientific integrity of the data collected for the study
- willful or knowing misconduct on the part of the researcher(s)
- serious or continuing noncompliance with federal, state or local research regulations

Initial Review by Chair -The IRB Chair will assess all information related to the potential violation, contrast the violation with the approved protocol, and make a conclusion regarding the seriousness of the violation. Consultation with experts in the particular area of research may be obtained as needed. Every attempt will be made to complete the initial review of a potential protocol violation within two weeks. However, if the violation puts subjects at risk, the protocol will be immediately suspended until the review is complete.

Minor Protocol Violation Procedure - If the findings of the Chair's initial review reveal that a minor protocol violation occurred, the Chair will issue a memo to the researcher(s) stating what must be done to bring the protocol into compliance. The Chair will provide the memo within two weeks of the completion of the initial review. Upon receipt of the principal investigator's response and completion of any requirements to bring the protocol into compliance, the Chair will notify the principal investigator that the protocol is in compliance. If a response from the principal investigator is non-compliant, the IRB Administrator will inform the PI to provide a compliant response by a deadline. If nothing is received by the deadline, or if the response is non-compliant, the IRB Chair will suspend the protocol until the PI provides the necessary revisions or information.

Major Protocol Violation Procedure - If the initial review by the Chair produces findings that indicate a potential major protocol violation, the Chair will convene an ad hoc committee to review the facts of the matter. The committee will convene within three weeks of the completion of the initial review by the Chair.

The committee shall consist of the IRB Chair, the IRB Administrator, the IRB representative(s) from the researcher's department or discipline, and others as necessary or required.

If the committee determines that a major protocol violation has occurred, the IRB Chair shall immediately suspend the research protocol. The Chair will provide a summary of the committee's findings to the principal investigator within two weeks of the committee's last meeting.

If suspension of the protocol would result in harm to subjects, the Chair will ask the researcher's supervisor to assign principal investigator duties to another qualified person. The newly assigned principal investigator will submit a Continuing Application outlining the change in researcher and any changes in the protocol (including suspension if required by the IRB Chair).

Any suspension of funded protocols will be reported to ORA. ORA shall notify sponsors as required.

If the findings of the committee indicate that academic misconduct may have occurred, the matter will be remanded to the Assistant Vice President of Research (AVPR) for disposition per university policies, along with any pertinent information.

Appeals - The principal investigator may appeal the findings of the review by the IRB Chair for minor protocol violations or the review of the committee for major protocol violations. The appeal must be forwarded to the IRB Chair within seven (7) days of receipt of the Chair's or committee's findings. The Chair or the committee will re-review the evidence and provide a summary report to the principal investigator within two weeks of the appeal review.

The principal investigator may appeal to the AVPR if the second review by either the IRB Chair or the committee has been completed and the results unfavorable to the PI. The researcher will have seven (7) days to prepare the appeal to the AVPR after receipt of the results of the IRB Chair's appeal procedure.

The AVPR will review material provided by the IRB Chair or committee as well as any information provided by the researcher. Per 46.112 Review by Institution, the institutional official (the AVPR) may not approve human subjects research that the IRB has not approved. Nevertheless, the AVPR may convene a meeting with the full IRB to re-review the protocol if the researcher 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.

The IRB Chair will present a summary of any protocol violations at the next scheduled meeting of the full board.

IX. PROCEDURES FOR REVIEW OF RESEARCH INVOLVING CHILDREN

Protocols utilizing children as subjects will be reviewed by the IRB under 45 CRF 46 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 45 CFR46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research.

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

Research Category 1: (§46.404) 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 as set forth in §46.408;
2. Adequate provisions have been made for soliciting the permission of their parents or guardians as set forth in §46.408, or criteria is met for approval of waiver or alteration of informed consent, as permitted under §46.116(d). (Permission of one parent is sufficient if approved by the IRB)
3. permission by parents or guardians is documented in accordance with and to the extent required by §46.117 of Subpart A

Research Category 2: (§46.405) 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, as permitted under §46.116(d). (Permission of one parent is sufficient if approved by the IRB)
4. permission by parents or guardians is documented in accordance with and to the extent required by §46.117 of Subpart A

Research Category 3: (§46.406) 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, as permitted under §46.116(d). (Except under specific circumstances*, permission must be obtained from both parents)
5. permission by parents or guardians is documented in accordance with and to the extent required by §46.117 of Subpart A

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

Research Category 4: (§46.407) 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 (§46.409) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 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 in accord with §46.116 of Subpart A.

X. PROCEDURES FOR REVIEW OF RESEARCH INVOLVING PRISONERS

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 45 CRF 46 Subpart C.

The IRB must document in the Board minutes the seven additional findings detailed in 45 CFR 46.305 (and outlined below) and provide protocol specific detail:

1. The research represents one of the four permissible categories identified in 46.306 (and listed below.) The Board must make a determination as to 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 DHHS funded, before the study can proceed, the IRB must certify to the Secretary of DHHS that the duties of the Board under Section 46.305 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 under Section 46.305 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.

XI. HIPAA PRIVACY RULE

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 included provisions to protect the privacy of personally identifiable health information (PHI). To implement these protections, the U.S. Department of Health and Human Services issued a final Privacy Rule, which was to be implemented by April 14, 2003.

The Rule governs how health care providers use and disclose PHI on their patients, including use and disclosure for research purposes. Health plans, healthcare providers and healthcare clearinghouses are all "covered entities" under the Privacy Rule. Another category of "hybrid entities" includes organizations that are not covered as a whole but contain specific units that are covered. The University of Akron is a hybrid entity. At this time the only units within the university that fall under the Privacy Rule are the Audiology and Speech Center and the Benefits Administration Office.

Even researchers who don't qualify as "covered entities" under the Rule may be affected if their research protocols require the use of PHI obtained from a health care provider who is covered. Researchers who are accessing, using, and/or disclosing PHI from a covered entity will need to address HIPAA in their IRB application.

Personally identifiable health information (PHI) is 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).

If a project falls under HIPAA, the researcher 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 researcher. If developing your 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
    c. The research could not practicably be conducted without access to the PHI

When requesting a waiver, the researcher 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.

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

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

Application Files – All applications received are date stamped and given an IRB number that identifies it by year and month of initial submission. The application file contains the complete documentation of all communication between the P.I. and the primary reviewer, the IRB office, and the board.

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 when study is completed

All active protocols are filed alphabetically by PI in the IRB Office. Closed files are archived as space is needed for active files. 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, or 2) letter to the principal investigator from the IRB closing the study due to failure to file a continuation application. In all cases of closure initiated by the IRB, submission of a final report is requested from the principal investigator.

Exempt protocols are closed 3 years after the approval date, if no final report is received. Expedited protocols are closed 3 years after the latest continuation approval, if no final report is received.

IRB Meeting Minutes – The IRB meets monthly on a day determined annually by the Chair. 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. Discussion of Exempt and Expedited approvals for the previous month
4. Separate review of each 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)
    i. For projects involving prisoners, the approval category is specified as well as documentation that the research meets the 7 additional criteria for approval

Other Documentation

Federalwide Assurance Form/ OHRP IRB Registration Form
Board minutes
Board & Subcommittee reports
Annual and Quarterly reports of IRB reviews
Monthly reports of exempt and expedited approvals
IRB Nomination procedures /Nominating Subcommittee minutes
IRB rosters
IRB appointment letters
Correspondence

Materials that are updated periodically & are available on the ORA website:
Application forms
Sample consent / assent forms
Applicant Manual
Policies and Procedures Manual

XIII. IRB STRUCTURE AND COMPOSITION

The organization of The University of Akron's IRB complies with federal regulations and the university's Federal Wide Assurance. The university maintains one active IRB. The IRB is made up of a chair, voting members, and voting consultants. Staff support for the IRB consists of one half-time Administrator and one half-time graduate student.

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 Assistant Vice President for Research upon recommendation by the IRB. Candidates with sufficient experience are solicited from the current membership and selected based on a vote by members. The Chair serves for a 3-year term.

- Voting members are elected by a Nominating Subcommittee of the IRB to fill vacant positions. Members are appointed for three-year terms. Appointments may be automatically renewed for an additional three-year term. After serving two 3-year terms, a member may put his/her name in for nomination to an additional term. 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 from their college or department 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 revise, approve or disapprove protocols in full IRB meetings.

- Voting consultants are called upon when their particular expertise is required.

Attendance of members at all convened meetings is expected and absences must be excused by the Chair. 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.

The IRB is structured around three cohorts. Each year the terms of one cohort expire. Upcoming vacancies are filled through a university wide call for nominations during spring semester. New IRB members may be self nominated or nominated by other IRB members, Deans, Department Chairs, faculty, ORA, or other interested parties. A nominating subcommittee of the IRB reviews all nominations, including those of current members who apply for a third term. The Subcommittee recommendations are presented to the full board at the May meeting.

- Ex officio members of the IRB include the IRB Administrator and a student assistant, who are Office of Research Administration (ORA) staff. These 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 approve exemption requests and to sign IRB approval letters and other IRB correspondence.

IRB Administrator Duties:

- Initial review of protocols and assignment to primary reviewer
- Reviews and approves exemption requests
- Signs approval letters for expedited/exempt reviews
- Reviews and accepts final reports – brings to the attention of the Chair if any adverse events are reported
- Reviews and accepts Classroom Based applications
- Reviews and approves registration forms
- Updates/revises IRB guidelines and application forms as needed
- Assists with educational sessions for the university community
- Assists in development and refinement of IRB policies and procedures
- Assists with new member orientation
- Serves as liaison between the IRB and University Administration
- Provides ongoing educational resources for board members
- Develops IRB meeting agenda and compiles and mails monthly board meeting packets
- Takes the minutes at IRB meetings

IRB Student Assistant Duties:

- Logs in all applications
- Ensures all investigators have completed the CITI Certification
- Sends applications out for review
- Maintains IRB member files
- Maintains IRB office files
- Maintains IRB database and develops reports as needed
- Compiles and sends quarterly reports of IRB application submissions to Deans
- Sends reminders to principal investigators of active protocols of annual renewal dates - one month prior to expiration for expedited renewals, two months prior for full board renewals

IRB Meeting Times

The Board meets monthly during the academic year. Meetings are held at a time and day selected by the current Chair. Summer meetings are arranged as needed.

IRB Deadlines

Applications for review by the full IRB must be received by 5:00 p.m., 15 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.

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/

XIV. MANDATORY EDUCATION REQUIREMENTS

All investigators conducting research involving human subjects, or their identifiable data or biological specimens, must complete the CITI Investigator Training, a web-based curriculum.

All IRB members must complete the CITI training for IRB Members.

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

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

XV. IRB CONTACT INFORMATION

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

Physical Address: 284 Polsky Building

All forms must be submitted electronically to irb@uakron.edu.

IRB Administrator: **Katie Watkins**, Asst. Vice President, Research, ORA
Phone: 330-972-6764 / Fax: 330-972-4850
e-mail all correspondence to: irb@uakron.edu

IRB Chair: **Dawn Johnson**, Ph.D.
Professor, Psychology
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