THE UNIVERSITY OF AKRON INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

APPLICANT MANUAL

GUIDELINES FOR SUBMISSION OF PROTOCOLS AND PROCEDURES FOR REVIEW

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I. WHAT IS THE INSTITUTIONAL REVIEW BOARD?

The University of Akron Institutional Review Board for the Protection of Human Subjects (the IRB) is an administrative body established to protect the rights and welfare of individuals recruited for participation in research conducted under the auspices of the university or its affiliates. Its mission is to advance an organizational culture and infrastructure that supports the highest ethical standards in the review and implementation of research with human participants. The University of Akron gives the IRB ultimate authority for approval of research with human participants.

To accomplish its mission, the IRB:

- ensures adherence to the principles of ethical research promulgated in the *Belmont Report*
- implements the regulations found in the Code of Federal Regulations, Title 45, Part 46 (§45CFR46**)**
- educates and mentors the university research community on human subjects protections
- monitors the behaviors of university investigators through its ongoing review of research utilizing human research participants

The IRB operates under an approved Federal Wide Assurance from the U.S. Department of Health and Human Service's Office of Human Research Protections. In this assurance the IRB states that all research on human subjects conducted by university employees or students will meet the regulatory requirements in §45CFR46 and the ethical guidelines found in the Belmont Report.

II. INVESTIGATOR CERTIFICATION

Requirement for Researchers and Faculty Research Advisors

Beginning with fall semester 2008, the university affiliated with the Collaborative Institutional Training Initiative (CITI) to provide investigator training for research involving human subjects. The training consists of on-line courses, created and managed by Miami University. We have customized the course requirements for our use.

The CITI certification is good for 3 years. After 3 years, researchers must take the CITI refresher training to maintain their active status. The CITI certification is used by many institutions, and transferable to other affiliated institutions, which may require additional training modules. Once a training module is completed at any affiliated institution, it does not need to be repeated.

All researchers (both faculty and students) who are conducting independent research projects involving human subjects, and their research staff, are required to take the on-line CITI training. This applies both to researchers submitting applications for IRB review and to those submitting IRB exemption requests.

All research staff who will be involved in data collection or who will work with individually identifiable data which have been collected must also take the CITI training. In addition, faculty submitting classroom-based protocols and faculty advisors on student protocols must complete the

basic course. Approval of an IRB application will be withheld until all required training modules have been completed.

Taking the Training

The Core Training includes 8 modules covering the following topics:

1. The Belmont Report - the core ethical principles that guide human subjects research
2. History of abuses and the ethical principles spelled out in the Belmont Report
3. How the federal regulations define "research" and "human subjects"
4. The federal regulations as they apply to social & behavioral research
5. Assessing risks to human subjects in social and behavioral research
6. The basic elements of informed consent
7. Protecting the privacy of participants and the confidentiality of their data
8. Links to additional resources available to researchers (University of Akron page)

In addition to the Core Training modules listed above, researchers who conduct research involving certain vulnerable populations, sensitive topics, or methodologies are required to take additional modules addressing these specialized topics. These include studies involving prisoners, children, internet surveys, access to identifiable private data, or collection of data from international sites.

Each training module is followed by a brief quiz that must be taken in order to move on to the subsequent module. An overall grade of 75% is required to pass. You may review any module and retake the quiz in order to improve your score. Once all required modules are completed, your scores cannot be adjusted.

Estimated time to complete each of the modules is 15-20 minutes and modules can be completed in multiple sessions. When all required modules are completed with a passing grade, The IRB office will be sent an electronic completion report listing all modules taken. You may also print off a completion report for your personal records.

The CITI Training site can be accessed at http://www.citiprogram.org.

1. You will register as a new user and select your institution from a drop down list. We are in the CITI database alphabetically under the name, "The University of Akron."
2. Next, select a username and password and provide your name and email address.
3. Once on The University of Akron site, follow the instructions for selecting the appropriate learner group that will allow you access to the modules which meet your particular research needs.

Note that the university also uses this site for training for researchers using lab animal and for the responsible conduct of research and financial conflict of interest. Make sure you select the Human Subjects course for the purpose of fulfilling the IRB training requirement.

Optional Training for Students in Research Methods Courses

The IRB has created a special Learner Group on our CITI site for use by instructors who teach research methods and other courses that require students to take training in human subjects protection. The Student Learner Group provides access to all training modules related to social and behavioral research. Instructors can choose which modules and how many their students must take. This group is for educational purposes only.

Students are able to print a report of all modules taken for their personal records, but they will not receive a completion report nor will one be sent to the IRB.

The CITI database maintains a record of all modules taken by each individual. A student taking modules listed under this Learner Group will receive credit for all modules already taken if he joins the SBR Researcher group at a later date. Once all required modules for the Researcher Group are taken, a completion report will be sent to the IRB with the record of all completed modules.

The UA IRB website includes instructions for accessing and navigating within the CITI program.

III. DEVELOPMENT OF A PROTOCOL – WHAT YOU NEED TO CONSIDER

Research Design

The value of research depends upon the integrity of study results. One of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare. But if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study.

Investigators must provide a detailed description of the research question(s), design, and methodology of their project. This includes a description of the purpose and significance of the research, a description of all procedures that will be used, the characteristics of the study population, and, where applicable, the measurement instruments.

Points to consider:

1. Is the scientific design adequate to answer the question posed? Is the sample size adequate? Is the method proposed for selecting and assigning participants to treatment groups unbiased?
2. Is any of the information to be collected sensitive (related to sexual practices, substance abuse, HIV status, or illegal behavior)?
3. Are there adequate plans to protect participants from the risks of breach of confidentiality and invasion of privacy?

Selection of Participants

Defining the appropriate group of participants for a research project involves a variety of considerations – requirements of scientific design, susceptibility to risk, likelihood of benefit,

practicability, and considerations of fairness. The selection of participants must be equitable to ensure that the risks and benefits of research are fairly distributed.

Points to consider:

1. Is there a credible rationale for the selection of participants? Does the nature of the research require or justify using the proposed subject population?
2. Will the risks of participating in the research fall on those most likely to benefit from the research?
3. Will any special physiological, psychological, or social characteristics of the subject group pose special risks for them?
4. Does the recruitment process protect participants from being coerced or unduly influenced to participate? Are any payments or incentives to participants reasonable in relation to the risks, discomfort, or inconvenience to which they will be exposed?
5. If the participants are susceptible to pressures, are there mechanisms that might be used to reduce the pressures or minimize their impact?

Risks and Benefits to Participants

The IRB reviews applications to ensure that risks to subjects are minimized. According to the regulations, minimal risk means that 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.

Points to consider:

1. What are the risks to participants? Has the researcher selected a research design and included precautions and safeguards that minimize the risks to the extent possible?
2. Are the risks greater than minimal risk? Has the researcher taken into account any special vulnerabilities among prospective participants that might be relevant to evaluating the risk?
3. Are the risks reasonable in relation to the anticipated benefits either accruing directly to the participant or to society in general? Has due care been used to minimize risks and maximize the likelihood of benefits?
4. Are both risks and anticipated benefits accurately identified, evaluated, and described?

Privacy and Confidentiality of Research Participants

Researchers must maintain strict protection of participant privacy and confidentiality of data. Whenever possible, the IRB recommends that researchers obtain data from subjects anonymously.

Points to consider:

1. Are participants anonymous (no identifiers are collected that could link respondents to their data)?
2. Are data collected in a manner that respects the privacy of participants and their right to refuse?
3. If collecting sensitive information about individuals, have you made provisions to protect the confidentiality of the data through coding, destruction of identifying information, separate storage, and/or limiting access to data?

4. Are disclosures to participants about confidentiality adequate? Should a waiver of documentation of consent be requested to further protect confidentiality or ensure anonymity?
5. How and when will data be disposed of once the research project is complete?

Informed Consent

Researchers have an ethical responsibility to fully inform research participants of the purpose, risks, benefits, and procedures involved in participation. Consent is only meaningful if prospective participants are fully informed. Consent must also be voluntarily given.

Participants under the age of 18, and subjects with legal guardians, cannot provide legally effective informed consent to participate in research. Researchers must obtain informed consent from a parent or legal guardian of these participants. Nevertheless, in most cases, subjects between the ages of 7 and 18, as well as subjects with legal guardians, can provide **assent** to participate. Once written informed consent is obtained from a parent or legal guardian, the researcher should also provide the minor subjects with an assent form that explains the research. The assent form should be written with the age, cognitive ability and educational level of the participant in mind. The goal is to ensure that subjects truly understand their role in the project.

Points to consider:

1. Who will seek consent and where will it take place? Is the process adequately described in the protocol?
2. Is the language and presentation of the information in the consent document appropriate to the participant population?
3. Is the identity of the researcher disclosed and the purpose of the research adequately described? Is contact information for the researcher provided?
4. Are all reasonably foreseeable risks and anticipated benefits to the participants or others adequately disclosed?
5. Are participants informed of all procedures to be followed and the expected duration of their involvement?
6. Are participants informed that participation is voluntary, that refusal to participate will not negatively impact them in any way, and that they may discontinue participation at any time?
7. Is contact information for questions about the rights of research participants provided?
8. Is a statement included describing the extent to which confidentiality of records identifying the participant will be maintained and when they will be destroyed?

Waiver of Documentation of Consent

In studies where the subjects are anonymous, or when a signed consent form would be the only identifying information received, the researcher may request the IRB waive the requirement to collect a signed consent. This is particularly appropriate with mail and on-line surveys. In these cases, a statement that fully informs the subjects of the purpose and procedures is provided, which includes a statement that their voluntary participation (return of survey, participation in interview, etc.) will serve as their consent.

The UA IRB website contains samples of consent statements and forms.

Waiver of Written Informed Consent

The researcher may also request the IRB waive the requirement for all or some of the elements of informed consent under special circumstances. The IRB may waive written consent if the:

- research involves no more than minimal risk;
- waiver will not adversely affect the rights and welfare of the subjects;
- research could not be practicably carried out without the waiver; **and**
- subjects will be provided with pertinent information after participation, if applicable.

Research Involving Children

Protocols involving children must be reviewed according to the additional protections for this vulnerable population found in Subpart D of 45CFR46. Researchers must acquire parental consent or meet the criteria for waiver of parental consent as set forth in the regulations.

Research Involving Prisoners

Protocols utilizing prisoners as subjects, or an at-risk population that could enter prisoner status during the research project (for example at follow-up data collection points), must address the additional items under Subpart C of 45CFR46. The IRB must find that the project meets the additional protections outlined under this Subpart.

IV. OTHER REGULATIONS AFFECTING RESEARCH WITH HUMAN SUBJECTS

A. 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 proposes accessing PHI from a covered entity, 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:
   - The use involves no more than minimal risk to the privacy of the individuals
   - The research could not be practicably conducted without the waiver
   - 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.

B. Conflict of Interest

Applicants are asked to indicate if they have any potential conflict of interest related to the conduct of the research to be reviewed by the IRB. A potential conflict of interest may arise if you anticipate financial rewards such as additional employment/salary, gifts, consultant agreements, stock options, ownership or equity in a company, royalties, etc. to be offered, based on the research outlined in the application.

C. International Projects

If you intend to perform human subjects research internationally (outside the U.S.), special provisions may apply to your project.

Per guidance from the Office of Human Research Protections (OHRP), the IRB must obtain an understanding of the local context where the research will be performed. Therefore, an individual who is familiar with the local context (aside from the researcher) must review the research project. The researcher can provide reviewer names to the IRB to facilitate this review. The local context review is in addition to the regular IRB review process outlined in the next section of these Guidelines.

The researcher must also tell the IRB if the government of the international site requires special permits or licenses before the research may be performed. If permits, approvals or licenses are required, the researcher must provide the IRB with a copy of them as part of the IRB application process.

If the researcher intends to work with an organization or agency at the international site, a research authorization letter from the agency should also be provided to the IRB. The letter must be on agency letterhead.

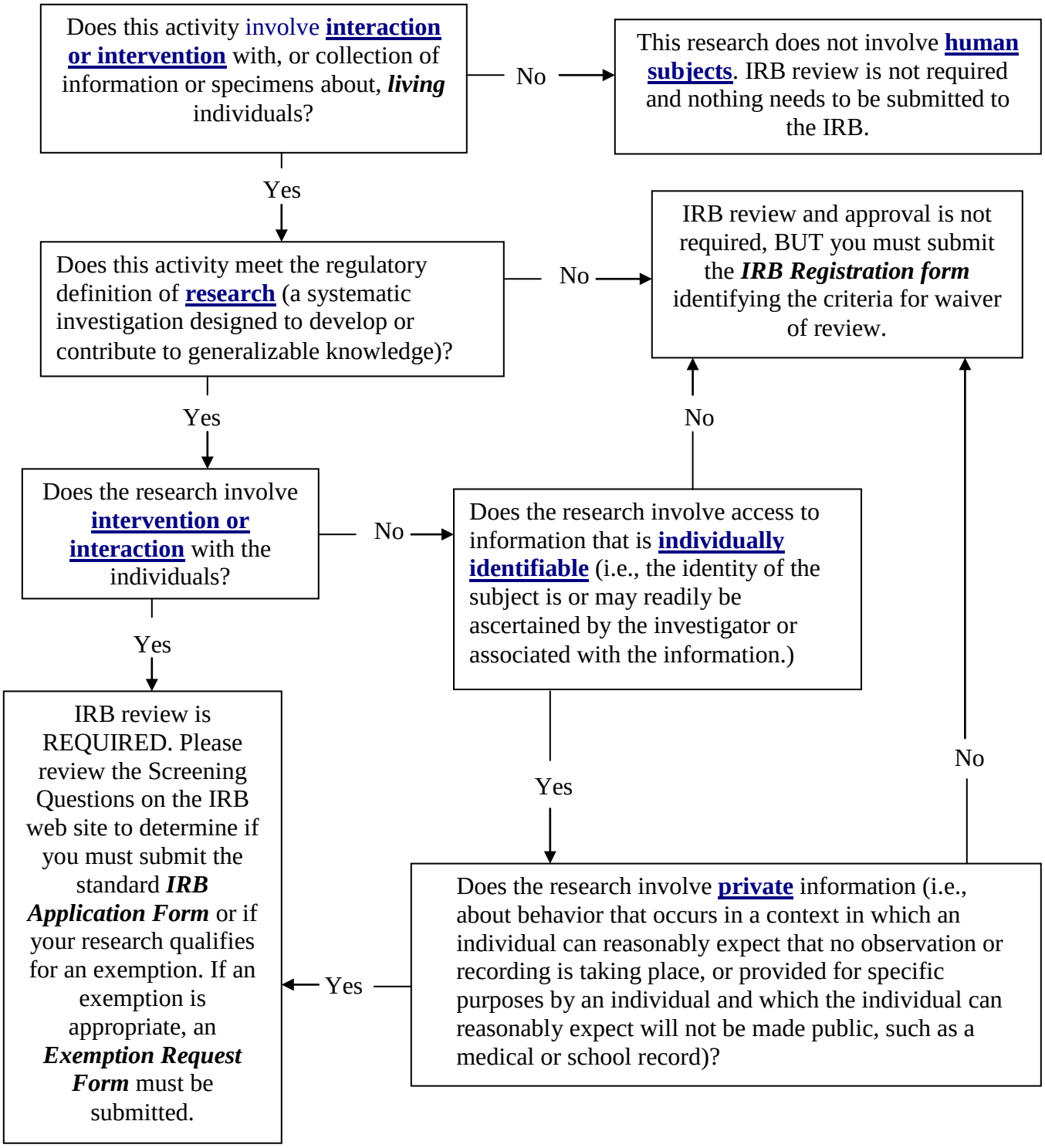
Finally, the protections afforded to human research participants in the U.S apply to human research participants internationally. The same rules and guidance for research design, informed consent, risks and benefits, privacy, and conflict of interest should be observed. Special consideration must be given to differences in culture and values. In addition, differences in educational attainment should be recognized in the creation of informed consent and informational documents. Subjects should be able to read about the project and consent to participate by viewing documents that are written in their language. If subjects cannot read, oral scripts should be created in the subject's language to ensure informed consent. See the OHRP Guidance on International Research at:

http://www.hhs.gov/ohrp/international/index.html#

The researcher should provide to the IRB copies of all documents provided to the subjects, in both English and the subjects' language.

V. 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 underlined 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.

WHAT IF MY PROJECT DOES NOT INVOLVE RESEARCH ON HUMAN SUBJECTS?

If the proposed project involves interaction with or collection of data about living individuals, but does not meet the definition of research, you must submit an **IRB Registration Form** to the IRB. The IRB Administrator reviews these forms. If the Registration Form is appropriate, the researcher will be notified in writing within one week of submission. No further action is required.

WHAT IF MY PROJECT DOES REPRESENT RESEARCH ON HUMAN SUBJECTS?

If you determine that your project does represent research on human subjects, the next step is to determine if it qualifies for exemption from IRB review.

VI. RESEARCH THAT QUALIFIES FOR EXEMPTION FROM IRB REVIEW

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 §46.101(b):

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 the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5. Research and demonstration projects which are conducted by or subject to the approval of 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.

Exceptions:

(a) Exemptions 1-6 do not apply to research involving **prisoners**

(b) Survey/Interview Exemption 2 does not apply to research involving **children (under 18)**
(c) Observation of Public Behavior Exemption 2 does not apply to research involving **children** except when investigator does not participate in activities being observed

Only the IRB can determine if a protocol is exempt. Investigators are not permitted by federal regulation to make this determination.

SCREENING QUESTIONS TO DETERMINE IF A PROJECT QUALIFIES FOR EXEMPTION

The following screening questions will help you to determine if your research project falls under one of the categories that are exempt from Federal Regulations and therefore not subject to IRB review. 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.

All of the activities that you will employ must fall into one or more of the exempt categories in order for the project to be exempt. Please contact the IRB at x7666 if you are unsure.

If you are only using existing data, and will have no contact with subjects, please skip to # 9.

1. Does this research involve the use of any drug, device or invasive procedure, place participants at risk for bodily injury or involve them in risky behavior?
☐ YES - submit the IRB application form ☐ NO - continue

2. Does your research target pregnant women or fetuses, prisoners, including individuals on probation or otherwise involved in the criminal justice system, or individuals with impaired decision-making capacity? ☐YES - submit the IRB application form ☐ NO - continue

3. Is the research conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.) ☐ YES - answer 3a ☐ NO - go to #4

3a. Does the research involve only normal education practices (such as research on regular or special education instructional strategies, research on effectiveness of or comparison among instructional techniques, curricula, or classroom management methods) and involve no extraordinary educational or non-educational activity?
☐ YES - submit a request for exemption under Exemption Category 1 **(NOTE – if your project involves surveys or interviews of minors under 18, conducted solely for the research, it cannot be exempt and you must submit an IRB Application Form.)**
☐ No –continue

4. Does your research involve only the administration of standard educational tests (cognitive, diagnostic, aptitude, achievement)?
☐ YES - submit a request for exemption under Exemption Category 2
☐ NO - continue

Research conducted in schools, even if exempted by the IRB under category 1 or 2, must follow any guidelines/restrictions imposed by the school(s) or district(s). You must submit evidence of approval from any school in which the research will take place. This approval should also state

whether or not the school requires or waives parental consent for the research. ***(Note that the UA IRB may require parental consent even if the school does not.)***

5. Does the research involve observation of public behavior in which the investigator does not participate in the activity being observed?
☐ YES - submit a request for exemption under Exemption Category 2
☐ NO - continue

6. Does your research involve the collection of data through surveys, questionnaires, interviews or focus groups, or observation of public behavior in which the investigator interacts with the subjects being observed, or? ☐ YES - answer 6a ☐ NO - go to #7

6a. Are any of your subjects under the age of 18?
☐ YES - submit the IRB application form ☐ NO - answer 6b

6b. Could the data collected reveal damaging or sensitive financial or personal information, or expose criminal activity about your subjects, or persons they know?
☐ NO - submit a request for exemption under Exemption Category 2
☐ YES - you must also answer YES to 6c, 6d or 6e to qualify for an exemption

6c. Are data collected anonymously so that no link ever exists between the research records and the participant's identity?
☐ YES - submit a request for exemption under Exemption Category 2 ☐ No-continue

6d. Are your subjects elected officials or candidates for public office?
☐ YES - submit a request for exemption under Exemption Category 3 ☐ No-continue

6e. Does any Federal statute require without exception that the confidentiality of the personally identifiable data will be maintained throughout the research and thereafter? ☐ YES - submit a request for exemption under Exemption Category 3 ☐ No-continue

If you did not answer "YES" to 6c, 6d OR 6e, you must submit the IRB application form.

7. Is the research conducted or approved by a Federal Department or Agency head and involve only the study, evaluation, or examination of a public benefit or service program?
☐ YES - submit a request for exemption under Exemption Category 5 (NOTE: This exemption is for Federally-supported projects and is most appropriately invoked with authorization or concurrence by the funding agency.)
☐ NO - go to #8

8. Is this a study of food preferences or quality assessment to determine consumer acceptance of wholesome foods containing either no additives or additives at levels found to be safe by the Food and Drug Administration or approved for consumption by the Environmental Protection Agency or the U.S. Department of Agriculture?
☐ YES - submit a request for exemption under Exemption Category 6
☐ NO - submit the IRB application form

Questions 9-10 are for studies involving only access to secondary data and no direct interaction or involvement with subjects.

9. Does your research involve access to private data from archives, databases, private records or biological specimens? ☐ YES - go to #10

10. Are the subjects who provided the data individually identifiable?
☐NO - your research does not meet the federal definition of "research on human subjects". Please submit the IRB Registration Form ☐ YES - answer 10a

10a. Will all data, documents, records, or specimens be in existence before your research project begins?
☐ YES - answer 10b ☐ NO - submit the IRB application form

10b. Is the archive, database or record collection publicly available?
☐ YES - submit a request for exemption under Exemption Category 4
☐ NO - answer 10c

10c. Will any identifying information that may link your project data to individuals in the database/archive be included in your research records? For example, will you create a link list for follow-up purposes or to compare data from multiple sources?
☐ NO- submit a request for exemption under Exemption Category 4
☐ YES - submit the IRB application form

All exemption request forms are reviewed by the IRB Administrator or the IRB Chair. If exemption is appropriate, the researcher will be notified in writing within 1-2 weeks of submission. If exemption is not appropriate, the researcher will be instructed to submit the standard **IRB application form**.

A protocol that is exempt from review does not require annual renewal and a final report is not required. However, 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. Exempted protocols are kept for 3 years from approval date. Continuation beyond 3 years will require submission of a new exemption request.

The IRB Registration Form, Exemption Request Form, and IRB Application Form can be found in the IRB section of the ORA web site at:

http://www.uakron.edu/research/ora/irb/irbforms.dot

VII. PROCEDURES FOR REVIEW OF NEW IRB APPLICATIONS

An IRB Application Form must be submitted for review by the IRB for all research on human subjects that does not qualify for exemption. Two levels of review are possible – expedited review and full board review.

Initial Staff Review

The initial review of an IRB application is conducted by the IRB Administrator to ensure that the application is complete, signatures have been obtained and attachments provided as necessary. The CITI website is also checked to ensure all involved have their human subjects certification. The IRB Administrator next reviews the protocol to determine if it qualifies for an exemption. If it does, the Administrator may request clarifying information or suggest revisions. Once all requests are satisfied, the protocol is approved. If the protocol does not qualify for exemption, it is sent to one of the IRB members representing the college of the principal investigator noted on the application, or to the IRB Chair.

Member Review

Review of the protocol by a member within the investigator's college accomplishes several goals. First, a faculty member with a particular academic specialty is a more appropriate reviewer of protocols from his/her college than individuals with expertise in areas outside the fields represented within the college. 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 his/her 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.

The member conducts a review and determines the review status. The reviewer may take one of three actions:

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

EXPEDITED REVIEW

Expedited review is possible when a protocol represents minimal risk to participants and all procedures fall under one or more of the categories outlined in the Federal regulations. Review by the convened Board is not required and the review is conducted by the Chair or an appropriate member.

Expedited Approval Categories for New Protocols

1. clinical studies of drugs and medical devices for which either an investigational new drug application is not required; or for which (i) an investigational 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 nonresearch purposes (such as medical treatment or diagnosis);

6. collection of data from voice, video, digital, or image recordings made for research purposes; and

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.

Expedited Approval is granted for one year only, after which the approval expires. A Continuation Application must be submitted within 1 year of the initial or most recent annual continuing approval in order to continue the study into another year. No additional subjects can be recruited or data collected or analyzed beyond the expiration date, or during a period in which approval has lapsed.

Full Board Review

If the protocol represents greater than minimal risk to participants it is not eligible for expedited review and must be reviewed by the full Board at a convened meeting. In addition, if the reviewing member believes a protocol should be disapproved, the full Board must be convened to review the research. The University of Akron's IRB currently meets on a monthly basis to review all protocols submitted during the previous month that did not receive exemption or approval through expedited review.

Section 46.111 of the Federal regulation provides guidance on the parameters of discussion that should be undertaken by the IRB when it reviews a protocol. Particular care is taken to discuss the level of risk to subjects; research design; risks and benefits; equitable selection of subjects; informed consent and documentation thereof; and additional safeguards for vulnerable populations such as children, prisoners, cognitively disabled individuals, or economically disadvantaged persons.

Applicants are invited to attend the Board meeting. They are asked to provide a short, verbal description of the protocol as well as clarify any items necessary for the Board to complete its review. Attendance is strongly recommended as any unresolved issues may defer approval until the next convened meeting.

Upon review of a protocol at a convened meeting, the IRB votes to approve, approve with contingencies, defer approval, or disapprove the protocol.

Approval

The applicant will receive notification soon after the meeting. The research can commence with no changes.

Approval with Contingencies
Protocols may be approved occasionally 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 may approve the changes to the protocol via the expedited review procedure.

Deferred Action
When the IRB requests substantive clarifications, protocol modifications, or substantive informed consent document revisions, IRB approval of the proposed research will be deferred, pending subsequent review of responsive material by the full Board at the next meeting. PI's are strongly encouraged to attend the meeting.

Disapproval
If a protocol is disapproved, the applicant will be notified promptly in writing and will be provided the opportunity to respond within seven days of notification of the disapproval. If the applicant is not satisfied with the IRB's decision after appeal, he or she may appeal to the Vice Provost for Research.

Institutional Disapproval
On rare occasions, the Vice Provost for Research may decide that a protocol, although recommended for approval by the IRB, does not conform to university policies. Accordingly, the Vice Provost for Research is authorized to disapprove the protocol.

VIII. CONTINUING REVIEW OF ONGOING RESEARCH

Federal regulations require IRBs to perform continuing review of research not less often than annually. The University of Akron's IRB reviews continuing applications as required by federal regulation and its Federal-Wide Assurance. The initial approval letter identifies the expiration date for the approval (usually one year from the approval date). As a courtesy, the IRB secretary sends reminder notices to all researchers at least one month prior to the expiration date. However, it is the responsibility of the researcher to submit for continuation before the approval expires. Any protocol not submitting an application for continuation prior to expiration will be considered closed. A letter is sent notifying the researcher that the project is closed and requesting a final report.

The continuation application form is available on the IRB website. A continuation application must be submitted to continue as long as any of the following conditions apply:

1. Additional subjects will be recruited or follow-up contact with existing subjects will take place in the coming year.
2. Data analysis involving individually identifiable data will continue.
3. Researcher expects to recruit additional subjects at some point in the future.

If all recruitment and data collection are complete, the data are stripped of identifiers, and the key to linking data to individual participants is destroyed, then a final report should be submitted and the protocol closed.

Submission Procedures

The procedure for submission and review of a continuing application is similar to that for a new application. The Chair or a member generally undertakes the initial review of the continuing application (after ORA review for signatures, attachments, etc.). Protocols initially receiving expedited approval will be reviewed by the Chair for continuation.

Continuation applications for protocols initially approved by the full IRB will either be reviewed once again by the convened Board, or may receive expedited approval under the following circumstances:

1. At the initial review meeting, the Board found that, upon further clarification or adoption of recommended revisions, the protocol represented no greater than minimal risk. The Board must have approved the future review by expedited means by majority vote at the convened meeting. Annual continuations may be approved under expedited review category 9.

2. The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and research remains open only for long-term follow-up. Annual continuations may be approved under expedited review category 8.
3. No subjects have been enrolled and no additional risks have been identified (expedited category 8).

4. The remaining research activities are limited to data analysis (expedited category 8).

Adverse Consequences

As part of the continuing review process, the researcher should report to the IRB all adverse consequences that may be related to the research project ***as they occur***. If the protocol is funded by a sponsor, adverse findings will be reported immediately to the agency funding the research (as applicable in accordance with university policies) and, at a minimum, the following will be reported: injuries or any other unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with the regulations or requirements of the IRB; and any suspension or termination of IRB approval. Such notification will be undertaken by ORA on behalf of the IRB. The research may be terminated by the IRB if such action is necessary.

Protocols Requiring Review More Often than Annually

On occasion, the IRB will require a protocol to be reviewed more often than annually. In general, the criteria that the IRB follows to make such a determination include the level of risk to subjects, the possible consequences of a breach of confidentiality, the type of intervention or action performed by a subject, and other areas of concern that may be particular to a protocol. If the IRB determines that a protocol requires review more often than annually, the schedule of review will be provided to the researcher as part of the approval letter.

IX. REQUESTING A CHANGE IN AN APPROVED PROTOCOL

Any changes to a protocol that has received expedited or full Board review and approval must be reviewed and approved by the IRB prior to implementation. Researchers must submit a request for change application, detailing the rationale for all changes and any impact on the risks to participants. If changes will require revisions to the informed consent document(s) or other materials given to participants, copies of all revised materials must also be submitted.

The IRB may use the expedited review procedure to review minor changes in previously approved full Board research during the period (of one year or less) for which approval is authorized, as allowed under § 46.110(b)(2) of the regulations.

X. 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. The initial review of a potential protocol violation will be completed within two weeks.

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, IRB member(s) from the researcher's college, the IRB Administrator, representatives 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 Vice Provost for Research 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 Vice Provost for Research (VPR) 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 VPR after receipt of the results of the IRB Chair's appeal procedure.

The VPR 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 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 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.

XI. SPECIAL CATEGORIES OF STUDENT RESEARCH

CLASSROOM BASED RESEARCH

The IRB recognizes that many student research projects conducted to fulfill course requirements involve human subjects. Such research occasionally entails certain risks to the subjects involved. As students vary in expertise regarding research procedures designed to protect the rights of human subjects, the IRB has developed the following guidelines regarding classroom-based research projects. These guidelines are intended to provide clarification and simplify the process for obtaining IRB approval for classroom-based research projects.

For classroom-based projects for which the subjects are **not**:

- identifiable by name or description (i.e. completely anonymous);
- drawn from vulnerable populations;

and the subject matter is not sensitive; instructors should submit an **Application for Classroom-Based Research** to the IRB prior to the beginning of classes in order to obtain approval. This application is submitted on behalf of the entire class.

****Instructors submitting applications for classroom-based research must have completed the on-line CITI Training before approval will be given.**

The IRB will approve and file the classroom-based application and the instructor may then permit students to proceed with their research without further review, assuming all projects meet the Classroom-Based Research guidelines.

Please note that all human subjects must provide informed consent when participating in any protocol conducted under the approved Classroom-Based Research. To protect subject anonymity, the IRB recommends the use of passive informed consent procedures when developing protocols for use under this Guideline. Passive informed consent requires informing the prospective subject about the research to be performed, but waives the requirement to obtain a signed consent form from each participant.

Informed consent information can be provided to the subject verbally or in a descriptive information sheet. In addition, the prospective subject must be offered the opportunity to decline participation.

Classroom Projects Requiring Individual IRB Applications
Student researchers who want to investigate the opinions, behaviors, and/or experiences of human subjects in sensitive topic areas, even for a classroom-based project, must submit an individual IRB application. Sensitive topics include:

- sexual orientation

- AIDS or HIV
- incest, rape or date rape, sexual molestation
- substance use and/or abuse
- eating disorders or behaviors
- contraception, pregnancy or abortion
- questions dealing with subjects' mental health
- religious orientation and/or views
- veteran or wartime experiences
- illegal activities

Student researchers must also file an individual IRB application for any protocol that systematically selects human subjects from potentially vulnerable or sensitive groups and asks questions regarding their opinion, behavior or experiences. Vulnerable or sensitive groups include:

- children
- persons who abuse illegal substances
- cognitively impaired persons
- prisoners/arrestees
- traumatized or comatose patients
- persons seeking emergency treatment
- institutionalized persons
- persons geographically located outside the U.S.
- terminally ill persons

****Student researchers submitting individual applications must also complete the required CITI training modules.**

CONSORTIUM REVIEW OF STUDENT THESES AND DISSERTATIONS

Students who are enrolled in consortial programs such as the combined Masters of Social Work program with Cleveland State University; the Masters of Public Health program with Kent State University; the Ph.D. program in Audiology with Kent State University; the Ph.D. program in Nursing with Kent State University; and other combined programs as they are created, should submit protocols to the chair of the student's review committee for review and approval.

The IRB of the chair's home institution will have primary responsibility for review. The IRB chair or administrator will be responsible for forwarding copies of the proposal to the IRB of the student's home institution and soliciting input during the initial screening and review process, if requested.

XII. CLOSE OUT OF PROTOCOLS

When a protocol has been completed, the investigator is asked to submit a final report to the IRB. The final report should include a summary of the research findings, any adverse events or injuries to subjects, and any additional information that might be useful to the IRB's understanding of the

research. If the project was externally funded, the researcher may submit the abstract from the final report to the funding agency in place of the summary. The Final report form is available on the ORSSP IRB webpage. Submission of the final report allows the IRB to close the protocol file. Files are kept for three years following the close of the protocol, as required by Federal regulations.

XIII. IRB CONTACTS

Sharon McWhorter, IRB Administrator
Office of Research Administration
330-972-8311
sm48@uakron.edu
284 Polsky Building

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

Submit all applications and requests to:

Campus mail: The IRB
Office of Research Administration
+2102

Postal: The IRB
Office of Research Administration
The University of akron
302 Buchtel Common
Akron, OH 44325-2102