Aurora University
INSTITUTIONAL REVIEW BOARD (IRB)
MANUAL

Please find information regarding the IRB procedures, process, and sample information in this document. If you have questions, please email or call the chair of the committee (this can be found on the IRB webpage). These IRB standards are in compliance with Protection of Human Subjects Federal Regulations 45 CFR 46, 2009.

Aurora University
INSTITUTIONAL REVIEW BOARD
Procedures and Results

A university-wide Institutional Review Board has been formed. When an application is received, the review process will continue dependent on the type of review that is necessary. The Review Board will meet each month as needed. At those meetings, the reviewers will discuss the applications and take one of the following actions:

A. Approve without Revisions: The IRB may approve the project as submitted without any changes noted for a maximum period of 12 months.

B. Approve with Revisions: The IRB may approve a project contingent upon modifications to be completed by the principal investigator. When the IRB Chair receives the changes, he/she will compare the modifications received with the actions requested. If the modifications are in compliance, the Chair will approve the project for a maximum period of 12 months.

C. Disapprove Pending Resubmission: If the IRB deems that the proposal and/or informed consent as submitted require major revisions, they will require the Researcher to resubmit the application and attachments with all of the changes required.

D. Disapprove: The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. The Committee will notify the principal investigator and the advisor/committee chair (if the Principal Investigator is a student). Notification will include all of the reasons and rationale behind the disapproval. Upon disapproval, the principal investigator has the option of: revising and resubmitting the project, reducing the risks to the subjects.

GUIDELINES FOR USE OF A STANDARD / FULL APPLICATION

Research activities present no more than minimal risk to human subjects (minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests):

- applies regardless of age of subjects, except where noted
- may not be used where identification of the subjects and / or their responses would place them at risk of criminal, or civil liability or be damaging to subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- may not be used for classified research involving humans
- must use an informed consent

If your research meets the definition of minimal risk and cannot meet the requirements for an expedited or exempt review then you must complete the standard / full IRB documentation.

***Special additional protections are required for research on pregnant women, human fetuses, and neonates, biomedical and behavior research involving prisoners, elderly, or for children involved as subjects in research.

Please select the "standard/full" application when completing the IRB application.

GUIDELINES FOR USE OF AN EXPEDITED APPLICATION

Research activities present no more than minimal risk to human subjects (minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests):

- applies regardless of age of subjects, except where noted
- may not be used where identification of the subjects and / or their responses would place them at risk of criminal, or civil liability or be damaging to subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- may not be used for classified research involving humans
- must use an informed consent

If your research meets the definition of minimal risk and involves only procedures listed in one or more of the categories below it may be reviewed by expedited procedures.

1. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as for medical treatment or diagnosis).

2. Collection of data from voice, video, digital, or image recording made for research

3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

4. Continuing review of research previously approved by the convened IRB as follows:
   - Where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects; **or**
   - Where no subjects have been enrolled and no additional risks have been identified; **or**
   - Where the remaining research activities are limited to data analysis

5. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the IRB has determined and documented at a convened meeting that the research involves greater than minimal risk and no additional risks have been identified.

6. Clinical studies of drugs and medical devices that do not require investigational new drug or investigational exemption application

7. Collection of blood samples by finger stick, heel stick, or venipuncture

8. Collection of biological specimens for research purposes by noninvasive means (eg. hair and nail clippings, etc. to name a few)

9. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves (e.g., body weight, electrocardiograph, ultrasound, moderate exercise when appropriate).

Please select the "expedited" application when completing the IRB application.

GUIDELINES FOR EXEMPT (free from applying)

This policy can apply to all research involving human subjects. **If your research involves ONLY one or more of the categories listed below you can use an exempt review process. Also, please see the "Human Subjects Form on the webpage to submit if you are unsure as to which category your project qualifies.**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. This category may include children.
    a. Research on regular and special education instructional strategies
    b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior for which subjects cannot be identified directly or through coded identifiers, or, if they can be identified, release of the information would not be harmful to the subject. (Harmful means that any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or can be damaging to the subjects' financial standing, employability, or reputation.)
    a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior **is not exempt** if the human subjects are elected or appointed officials or candidates for public office or if Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
    b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior for which subjects cannot be identified, or release of information would not be harmful to the subject. This category may include children.
    c. Research involving the use of survey procedures, interview procedures, or observation of public behavior for which subjects cannot be identified, or release of information would not be harmful to the subject. This category may not include children.

3. Research involving the collection or study of existing data (means the items exist before the research was proposed or was collected prior to the research for a purpose other than the proposed research), 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.

4. Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads, and which are designed to study or evaluate public benefits or services. (e.g. evaluation of public benefits programs: Medicare, Public Assistance). This category refers to projects under Federal Department or Agency Heads. This category may include children.

5. Taste and food quality evaluation and consumer acceptance studies. This category may include children.

Aurora University
Institutional Review Board
Special Considerations for the Protection of Children (or vulnerable populations)
Participating in AU-Sponsored Research

The information in this section is provided to clarify the preparation and review process for researchers who plan to include children (or vulnerable populations) as participants in their research projects. This information is intended to facilitate the compliance approval process.

General Information

Federal regulations require that the researchers explicitly address the measures taken to protect the welfare and rights of children participating in research projects. The IRB assesses the adequacy of these measures during the approval process. Because of the potential vulnerability of children, a higher standard of protection must be demonstrated for approval. **As a result, almost all research** involving children requires expedited or full review. The only exception to this rule (discussed in part 5 of this section) occurs when the research involves observation of public behavior. All other minimal risk projects that would normally be considered exempt from review are not exempt when children are involved.

Please note that you may not initiate contact with potential child-participants, or begin data collection, before you have received final approval from the Institutional Review Board. The following section addresses several significant areas of concern that commonly arise during reviews of research involving children.

1. Identifying and Recruiting Potential Child-Participants

Clearly describe the methods used to identify and recruit potential child-participants. Describe the measures taken to prevent potential concerns about coercion or breaches of confidentiality in the identification and contact stages of your research project. Copies of notices or advertisements that will be used should be included in your application.
Only after permission from the appropriate authorities has been granted in writing may potential child-participants' identities be obtained from school classrooms, care-giving programs, or other agencies. For example, researchers wishing to study students in public school systems must obtain written permission from the school board or its authorized representative before students can be contacted. This approval cannot be used to require teachers or students to participate. School board or institutional permission is often conditioned upon IRB approval of your project. If your project must receive approval prior to the granting of any institutional permission, please contact the IRB Chair.

2. Consent Procedures

Federal law recommends the **assent** of the child and requires the **permission** of the parent(s), or guardian(s), in place of consent of the child before a child may be involved in a research project. Research involving "mature" or emancipated minors may not need parental permission, but full IRB committee approval must be obtained to waive the parental permission requirement.

Note: A **guardian** is an individual who is authorized under applicable state or local law to give permission for a child. **Permission** is the explicit agreement of parent(s) or guardian to the participation of their child or ward in research.

Both parents must give their permission in any research that places the child-participant at greater than minimal risk, unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

The permission of one parent is sufficient for any research that places that child-participant at no more than minimal risk. The IRB may consider that the permission of one parent is sufficient for research involving greater than minimal risk, if there is a clear prospect of direct benefit to the child-participant.

Assent is a child's affirmative agreement to participate in research. Assent is an ethical concept. However, failure to object cannot be construed as assent. Researchers who include children in their research should be especially mindful of the rights of children participating in their research. Even when assent is not required, researchers are asked to demonstrate a good faith effort to enlist the cooperation of children who participate in their research.

It is the responsibility of the IRB to decide if researchers should seek a child's assent as part of a project's consent procedure. The determination of a child's capacity to provide assent is based on the nature of the research, and the child's age (typically the IRB requires assent from children age seven through seventeen), maturity, and psychological state of the population of children from whom participants will be drawn. The decision to require assent depends on the capacity of the children to appreciate the nature, extent, and probable consequences of their participation in a research project.

Assent is especially important in cases where there is no direct benefit to the child-participants. When assent is required, the procedure should include an explanation of the proposed research in language that is appropriate to the child's age and maturity. The investigator should indicate what the children will be told about the research and how the information will be conveyed. The investigator should discuss how the information provided might vary with the age, maturity, and level of experience of the children involved in the study. The assent process should be free from coercion and unfair inducements. All children who are capable of providing assent must be informed that they are free to withdraw from participation at any time.

____ Adequate provision must be made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent.

____ If it is determined that the capability of some or all of the children is so limited that they cannot be reasonably 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 research, the assent of the children is not a necessary condition for proceeding with the research.

____ Permission is to be obtained from a parent or guardian. If the research is of high risk, both parents must give their permission**,** unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

3. Risk and Benefit Assessment

Risk Assessment: Federal regulations require Review Committees to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the proposed research study. The categories of research involving children that may be approved, based on degree of risk and benefit to individual participants are as follows:

1) Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Examples of research in this category might include: research on children's attitudes about food preferences, surveys about play activities, etc.

2) Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant. Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the participant; and (b) the relationship of risk to benefit is at least favorable as any available alternative approach.

Examples of research in this category might include: research on the coping strategies of children living in foster care, or research on the effectiveness of drug-use intervention programs for children testing positive for drug use.

3) Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. Research in this category is approvable provided: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participant's disorder or condition.

Examples of research in this category might include: research using abused children that is designed to identify early warning signs of potential abuse in the general population of school-aged children; or research on the effectiveness of corporal punishment.

4) Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a

serious problem affecting the health or welfare of children. Research that is not approvable may be conducted provided that the IRB, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health or welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles.

No examples of research in this category are provided because projects in this category are unique and require federal approval.

Assessing probable risks is a central consideration of the IRB's approval process. The assessment of the probability and magnitude of the risk may differ depending on conditions child-participants may have. The issue of what is considered "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations" may vary depending on the circumstances or conditions of the population from which the children are drawn. The IRB considers the extent to which research procedures would be a burden to a child. Behavioral interventions likely to cause psychological stress may be considered to exceed minimal risk.

Benefit Assessment: Carefully identify and describe all reasonably anticipated benefits that may be received by child-participants. As noted in the risk assessment subsection, anticipated benefits to child-participants must exceed anticipated risks when research procedures expose child-participants to greater than minimal risk.

4. Use of Educational Records

Federal law [34 CFR 99, 99.03 through 99.37] governs the privacy and access to elementary and secondary school records. The primary rights of access to these records are given to parents, guardians, and to students (once they have reached 18 years of age). Except for administrative purposes, schools must withhold access to personally identifiable information from educational records except with the written permission of the students' parents, or students once they have reached 18 years of age. To be valid, a written consent for disclosure of educational records must include three items: a specification of the records to be disclosed, the purpose(s) of the disclosure, and the party or class of parties to whom the disclosure will be made.

The requirement for written permission applies to all research, except that conducted by or for educational agencies or institutions developing, validating, or administering predictive tests, administering student aid, or improving instruction (provided such studies will not permit the identification of individual students and that personally identifying data will be destroyed upon completion of the study).

5. Exempt Research Involving Children

At this time, the only research procedure involving child-participants exempt from review is observation of public behavior. The definition of observation of public behavior requires that researchers not interact in anyway with the children, record their identities (this includes the use of audio and videotaping procedures), or place the children at risk.

Examples of Cases When the Exemption Involving Children Does Not Apply

The observation of public behavior exemption does **not** apply when a) the child-participants have a reasonable expectation of privacy (e.g., a private conversation in a public park); b) survey instruments are used (this would constitute an interaction, even if conducted by an independent third-party, such as a teacher); and c) the researcher rearranges or changes the setting/environment in which the public observation takes place.

Quick Checklist for Protocols Involving Children as Participants

1. Have you adequately described your methodology and procedures using nontechnical language?

2. Have you clearly identified your methods for identifying and recruiting children?

3. Do you intend to recruit children through schools, or conduct your research at schools? If so, you should include written permission to approach children and teachers from the school board and principals in the schools you are targeting.

4. Have you described your parental consent procedures and included a copy of the parental/guardian's informed consent form? If a waiver of parental permission is requested, provide justification.

5. Have you described your child assent procedures? Assent should be sought from children seven years-old and older. If a waiver of children's assent is requested, provide justification.

6. Have you included an assessment of the probable risks and benefits anticipated in your research?

7. Are you planning to use information from school records? If so, have you included a written consent for disclosure of educational records that specifies the records to be disclosed, the purpose(s) of the disclosure, and the party or class of parties to whom the disclosure will be made.

Institutional Review Board
Aurora University
Elements of Informed Consent

Informed Consent Considerations

Investigators should seek consent under circumstances that provide the prospective participants sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

Basic Elements of Informed Consent

As you develop your consent form or procedure, please include the following information.

1. State that the study involves research.
2. Explain the purposes of the research and the expected duration of the participants' participation.
3. Describe the procedures that directly involve human participants, and identify any procedures that are experimental.
4. Describe any foreseeable risks or discomforts to participants.
5. Describe any benefits to participants or to others that may reasonably be expected from the research.
6. Disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.
7. Describe the extent to which confidentiality of records identifying participants will be maintained, where the records will be stored, how long they will be stored (at least three years) and who will have access to the records.
8. For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs. If compensation or treatments are available, they should be described. The procedures for obtaining additional compensation/treatment information should be stated.
9. Identify the persons participants can contact for answers to pertinent questions about the research, and participants' rights.
10. State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

Additional Elements of Informed Consent (may be required):

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

Aurora University
Institutional Review Board
SAMPLE INFORMED CONSENT FORM

[List title of project here]

INTRODUCTION

State that participants are invited to participate in a research study. Briefly describe the study and state the purpose/objectives of the study.

INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

List all procedures, preferably in chronological order, that will be employed in the study. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using non-technical language. Explain all procedures using language that is appropriate for the expected reading level of your participants.

State the amount of time required of participants per session and for the total duration of study.

If audio-taping, video-taping, or film procedures are going to be used, provide information about the use of these procedures, including an additional audiotaping consent signature line at the bottom.

If you are planning to include children in your study, please review the document entitled Special Considerations for the Protection of Children Participating in AU-Sponsored Research.

RISKS

List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.

_____Participant's initials (place on the bottom front page if you have a two-sided consent form.

BENEFITS

List the benefits you anticipate will be achieved from this research, either to the participants, others, or the body of knowledge.

CONFIDENTIALITY

State that the information in the study records will be kept confidential for at least 3 years. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports that could link participants to the study.

CONTACT INFORMATION

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, [Name], at [Office Address], and [Office Phone Number]. If you have questions about your rights as a participant, contact Chair, Autumn McKeel, Institutional Review Board, Aurora University, amckeel@aurora.edu, (630) 844-6186.

PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide not to participate, you may withdraw from the study at anytime without penalty. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

CONSENT

I have read the above information. I have received a copy of this form. I agree to participate in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

Additional Notes to Investigators:

1. Be sure to follow the directions for preparing the signature lines. Separate forms should be prepared when minors are used; one for the minors and one for the parents.

2. If your form is more than one page, there should be a line at the bottom of each page for the subject's initials, except for the last page where the signature is obtained.

3. Be sure to include any elements of informed consent that are appropriate to your study. If they apply to your study, they must be included.