Aurora University

INSTITUTIONAL REVIEW BOARD (IRB) MANUAL

This manual is intended to communicate basic information pertaining to the Institutional Review Board (IRB) at Aurora University. It provides details on IRB purposes and procedures, guidelines for levels of review, information about informed consent, and guidelines for commonly encountered topics. Please note that there are additional materials on the IRB webpage that can be accessed separately to provide researchers with more details. If you have questions, please email or call the IRB Chair (this can be found on the IRB webpage). These IRB standards are in compliance with Protection of Human Subjects Federal Regulations 45 CFR 46, 2018.

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Levels of Review

Review of human subjects research falls into three different categories: 1) full review, 2) expedited review, 3) exempt. This section discusses each of these levels of review and provides guidelines for applicants to consider with each.

FULL REVIEW

Full reviews of applications are those that involve specific types of research procedures, involve greater than minimal risk to participants, and/or involve protected classes of participants. The difference between a full review and other types of review is that it requires review at a convened meeting of IRB members. The deadlines for submission of a full review application are posted on the IRB website. Convened meetings for full review typically occur one week after the deadline for each specific month.

Applicants for full review research proposals should complete the IRB application (on the IRB website) and include all the additional documentation requested in the application. This includes:

- copies of informed consent forms,
- copies of study instruments that will be used,
- a certificate of completion of the CITI ethics training (see IRB website for details),
- and site permission from the setting where research will be conducted, if applicable.
- Where appropriate, applicants should also include recruitment materials (e.g. flyers or social media posts requesting participants).

The application asks researchers to answer questions about their proposed study related to the nature of the study procedures, the anticipated pool of study participants, how participants will be recruited, what foreseeable risks are involved and how they will be minimized, how confidentiality and security of data will be maintained, and how participants will be informed of the voluntary nature of the study. **In these applications, it is important for applicants to be as detailed as possible on these subjects and to communicate clearly and effectively on each question**.

EXPEDITED REVIEW

Expedited review applies to applications that present no more than minimal risk to participants AND fit within one of the categories of expedited review defined by federal regulations. Please refer to the following link for a list of these categories: Expedited Categories.

The difference between expedited review and full review is that these may be reviewed solely by the IRB Chair or another IRB member(s) designated by the chair. Applications that meet expedited review do not have a deadline and may be submitted to the IRB Chair at any time. Ultimately, the determination of expedited or full review is up to the IRB. If it is deemed that the study involves more than minimal risk or does not fit an expedited category, it will be sent to full review at the closest deadline.

Applicants that believe their study meets expedited categories will follow the same process of application as for full review in completing the IRB application and including all requested documents/materials. Applicants, however, should check the Expedited box in the application, which will allow the IRB Chair to determine its status.

EXEMPT

Federal regulations also identify several types of research that fit into exempt categories. It is important to note that "exempt" does not necessarily mean free from any sort of review. **Ultimately, it is the IRB that determines whether any human subjects research meets exempt criteria**.

Exempt research falls into a variety of categories that are laid out under federal regulations (see link below). However, some of the most common forms of exempt research that occur at AU are those involving de-identified data or anonymous survey research. Even with projects that only use these methods, they must also meet the threshold of minimal risk. So, for example, surveys that ask participants about topics such as drug use, mental health, sexual activity, etc. would not be considered exempt.

Exempt review typically involves review of the Human Subjects Determination Form (on IRB website) by the IRB Chair. The chair will then review the form to determine if the proposed research meets exemption categories and this form will be signed and sent back to the applicant. Even when the research is deemed to be exempt, the IRB may still require the applicant to provide additional materials (e.g. permissions from an organization or school to distribute a survey if applicable) or require that the applicant engage in best practices, such as providing a consent section prior to a survey or maintaining confidentiality and security of records.

The categories for research that meet exemption according to federal regulations can be found at the following link, under section 46.104: Exempt Categories. Applicants that feel their research is exempt should complete the Human Subjects Determination Form and submit it to the IRB Chair, who reviews these applications on a rolling basis.

If you have questions about whether or not your project may be considered exempt, you may also complete the standard application or contact the IRB Chair with questions.

Procedures and Decisions

According to federal regulation 45 CFR 46.109(a), an IRB shall review, and has the authority to approve, require modifications in order to secure approval, or disapprove, human subjects research activities. The decision to approve, require modifications, or disapprove research will be communicated in writing by the IRB.

TIMELINE FOR REVIEW

For expedited and full review applications, either 1-2 IRB committee members (expedited) or the full IRB committee (full review) will review the research proposal submitted by the researcher(s) and make a determination on its approval, disapproval, or need for modifications within a roughly 2-3 week period from the time of submission.

For full applications, the IRB committee typically convenes for review 1 week after the monthly application deadline (posted on IRB webpage). Communication of decisions is made to applicants, typically from the IRB Chair, approximately 1 week after the convened meeting.

For expedited applications, once it is determined that the research proposal meets expedited review criteria, the application will be reviewed by 1-2 IRB committee members, who will submit their decisions within approximately 1 week.

Communication of decisions to applicants is made approximately 1 week after decisions are submitted. Please note that these timelines are typical, but can change due to a variety of factors, such as the amount of applications currently under review by the IRB. It is appropriate to request the status of review of your application by emailing the IRB Chair. It is recommended, however, that you do not request about the status of your review unless you have not received communication from the IRB in over 3 weeks since the time of submission.

COMMUNICATION OF DECISIONS

When decisions on submitted applications are made, the following categories will be communicated to applicants:

A. Approve: The IRB has reviewed and approved the research as proposed without modifications. The applicant will then receive an electronic approval letter, along with stamped consent forms (if applicable), within a few days. The IRB may approve the project as submitted without any changes noted for a maximum period of 12 months.

- If the project extends beyond 12 months, the application will need to be submitted for continual review.
- If the project is modified during the approval period, the applicant will also need to submit a continual review form detailing the changes.
- If the modifications require further IRB review, these will be reviewed and communicated to applicants. Applicants may only implement research activities that have been reviewed and approved by the IRB.

B. Modifications Requested: The IRB has reviewed the research as proposed and requires particular modifications to the proposal in order for approval to be obtained. Requests for modifications can be numerous, ranging from the minor (e.g. correcting typos and grammar to ensure clarity) to the major (e.g. asking for debriefing activities with participants to minimize study risks).

Upon communication of the requested revisions, applicants should make revisions within the originally submitted proposal, highlight the changes made, and re-submit the revised proposal to the IRB chair, including ALL of the materials in the originally submitted proposal (e.g. copies of data collection instruments, site permissions, etc.).

If the revisions are relatively minor, the IRB chair will review the revised application until the requested modifications are satisfied. If the revisions requested are numerous and substantial (especially those concerning perceived risks to research participants), the revised application will be reviewed once again by the whole IRB committee (full application) or original reviewer(s) (expedited).

Revised applications typically do not have to wait until the next month's full application deadline. Exceptions are made if the proposal is complex enough or represents potential risks to participants that the IRB deems it necessary to review modifications at the next convened meeting. The revised application will be immediately sent out to the IRB committee for review and decisions will be submitted in approximately 1 week. This process will be followed until the IRB determines that modifications have been made to secure approval of the research proposal.

C. Disapprove: The IRB may also disapprove research proposals. These typically involve instances where the nature of the proposed research includes risks to participants that exceed any perceived benefit regardless of any reasonable modifications that might be made. According to 45 CFR 46.109(d), if the IRB disapproves any research, it will include in its communication to the researcher(s) a statement of the reasons for the decision and provide an opportunity for the researcher(s) to respond, either in person or in writing.

Informed Consent

One of the central elements of ethical treatment of participants in human subjects research is that of informed consent. Requiring researchers to obtain informed consent from participants in research studies allows participants to understand the purposes of the research, the activities in which they will be involved, and the overall risks and benefits associated with participation, among other elements. In this section, there is a summary of important elements of informed consent, as well as some helpful guidelines to consider when addressing each of these elements in an informed consent document.

According to federal regulations, the following are basic elements of informed consent that must be presented to each potential participant (or their legally authorized representative) in a research study[1]:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

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

When appropriate, the following elements should also be provided to participants as part of informed consent:

[1] There are some additional elements specifically for research involving biospecimens or the use of identifiable private information. For the full list of federal regulations of informed consent, see 46.116 in the following link: Federal Regulations

1) A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

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

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

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

(6) The approximate number of subjects involved in the study

The IRB website includes a sample consent form, which is also included below on the following page. This is a template that the IRB recommends that all researchers use for their applications, as it includes the broad elements of informed consent as headings. Under each heading, there is a description of important features to include in the consent form, as well as references to other documents when more specific information may be needed (e.g. data storage and confidentiality of electronic data).

Waiver of Documentation of Informed Consent

Finally, there are circumstances when the requirement to have documented informed consent from participants may be waived. According to federal regulations, IRBs may waive the requirement for a signed informed consent form under the following circumstances:

1) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If any of the circumstances apply and the researcher(s) wants to waive the documentation of informed consent, they should complete the "Waiver of Documentation of Informed Consent" form on the IRB website and include it with their application. It is important to note that this simply waives the requirement of having documentation of informed consent (e.g. a signed form). When documentation is waived by the IRB, there will still typically be a requirement to include an informed consent section that does not require signing.

Aurora University
Institutional Review Board

SAMPLE INFORMED CONSENT FORM*
(Include the following information)

INFORMED CONSENT STATEMENT
[List title of project here]

INTRODUCTION
State that participants are invited to participate in a research study. **This is a letter to the participant, so remember to address them here** (e.g. "You are invited to participate…). 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 important 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. When appropriate, state the amount of participants included in the study.

If audio-taping, video-taping, or film procedures are going to be used, provide information about the use of these procedures.

RISKS
List all reasonably foreseeable risks of each of the procedures to be used in the study. All research consists of some element of risk as it interferes with daily living and these must be described here (i.e. Do not state that the study has no risks). Measures for minimizing these risks should also be mentioned in this section.

It is advisable NOT to state that the research includes only minimal risk. The IRB will make that determination. In this section, simply articulate what the foreseeable risks are, how they will be minimized, and that there could be unforeseeable risks associated with participation.

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 and how they will be kept this way (at least two locks/password should be described). Data will be stored securely (for 3 years) 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.

Additional information and measures of data storage, security, and confidentiality should be included here if using virtual/electronic platforms, such as Zoom or with electronic survey platforms. See the "Electronic/Virtual Data Collection" section in this manual and the Electronic Surveys guidelines on the IRB website for more specific information to discuss here.

CONTACT INFORMATION
The following is a template that can be generally used for the section on 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 or email], and [Phone Number]. If you have questions about your rights as a participant, contact Chair [Current IRB Chair Name], Institutional Review Board, Aurora University, [Current IRB Chair email and phone number]. If you have need of a counselor as a result of participation, please contact the AU Counseling Center at 630-844-4932 (when more appropriate, such as with studies in local school settings, other counseling resources should be included here, rather than the AU Counseling Center).

PARTICIPATION
The following is a template that can be generally used for the section on voluntary 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 any time 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 _____

If applicable, provide an additional signature and date line that allows participants to consent to audio/video recording

*This sample serves as a template to help applicants construct informed consents. However, the IRB reviews each consent form in the context of the proposed research and may require additional elements and information in the consent form beyond what is included here.

Electronic/Virtual Data Collection

The collection of data electronically or through virtual platforms has become much more common in recent years. The COVID-19 pandemic has also made use of electronic/virtual data collection a necessity in some cases as well. In this section, some general guidelines for common types of electronic/virtual data are discussed.

Virtual Interviewing/Focus Groups

A common method of data collection for researchers in a virtual setting is to conduct interviews and/or focus groups with participants via a virtual meeting platform. While this is an acceptable form of human subjects research, there are some elements to consider that are particular to the use of these platforms. **In most cases, it is required that researchers use their Aurora University Zoom account (NOT a personal or work Zoom account) to conduct approved human subjects research**.

In addition to using your AU Zoom account, AU IT has provided the following information for using AU Zoom meetings in a secure way:

- Please use scheduled meetings whenever possible. These create unique IDs that are more difficult to guess. In addition, ensure that the meeting ID has a passcode on it.
- Ensure that if you are using a personal meeting ID (PMI), that it is secured with a PIN or Passcode.
- Disable the setting "Allow participants to rename themselves" in the in meeting basic settings
- Please be careful when you receive a Zoom invite and make sure that the link to any AU Zoom meeting has "aurora.zoom.us" in the meeting link.
- Please do not share your passcodes to the public. The meeting code is for only authorized participants of Zoom meetings.
- We recommend that you store any recordings in the Zoom cloud so it is not open and exposed on the internet for malicious entities to find. Faculty, staff and students will now be able to save cloud recordings.
- Zoom recordings are not the only thing malicious entities are out there looking for. Please make sure if you are saving documents to OneDrive or Google, that documents are only available to specific people or that they are set to be private.

In addition to these IT guidelines for the security of Zoom meetings, the IRB has adopted the following policies for security and storage of data collected in this virtual setting:

1) Study participants must consent to the study AND being audio/video recorded on Zoom. Consent forms should have additional signature lines for audio/video recordings.

2) There are two options for storing Zoom recordings of data collection activities:
   a) stored to an externally secured device that has multiple layers of password-protection (in some instances, such as if the data is especially sensitive, the IRB may request additional layers of protection), or

b) stored to the Zoom cloud within your password-protected Zoom account. If option b is selected, the AU IRB requires, in most cases, that recordings only be held in the cloud account until a transcript is produced, after which the recording should be destroyed.

If you have additional questions about securely using Zoom platforms, please contact AU ITS. It is expected that you will address your use of Zoom in human subjects research, including security and storage of data in your IRB application.

Electronic Surveys

The collection of survey data via digital survey platforms is an extremely common form of data collection in human subjects research. Depending upon the nature of the study, studies that solely use these methods may even meet exempt or expedited categories. While this is a common and acceptable form of data collection in human subjects research, there are some elements to consider that are particular to the use of these platforms. **In most cases, the use of Qualtrics[2] or Survey Monkey[3] are acceptable platforms that are approved by the AU IRB**. The following are additional important guidelines for the use of electronic survey data. For additional details, please refer to the separate document on "Electronic Survey Research Guidelines" on the IRB website:

- The use of AU students for human subjects research in electronic surveys is not recommended by AU administration (with the exception of classroom research activities). Researchers seeking to use AU students as participants in human subjects research using electronic surveys should consult with their appropriate Dean and seek approval from AU administration.

- Researchers utilizing electronic surveys in their human subjects research should address storage, security, and anonymity/confidentiality of data in their IRB application and consent forms. Collecting surveys that are anonymous (no personally identifiable information, including IP addresses) are recommended. When identifiable information is collected in surveys, researchers should address how they will maintain confidentiality and security of data (refer to Electronic Surveys document on IRB website for best practices) in their application and consent forms.

- Often, it may be difficult, unnecessary, or risky to have participants provide a signature on an informed consent document for electronic survey research. When this is the case, researchers should complete the Waiver of Documentation of Informed Consent form (on IRB website). Researchers will still be required to provide a consent section prior to electronic survey, but signatures from participants would not be collected in these cases.

[2] Students in the EdD program are required to use the EdD Qualtrics account for electronic survey collection.
[3] MTurk is another platform that has become common in the use of survey research in recent years. However, there are some particular risks to confidentiality when using this platform due to its link to Amazon accounts. The IRB reviews the use of this platform on a case-by-case basis.

Use of Educational Records

It is common for researchers in disciplines such as education and social work to propose research projects that may seek to analyze educational data. Sometimes, it is expedient for researchers to analyze larger data sets of secondary educational data. While secondary data (i.e. data records, grades, etc.) itself often meets exempt categories according to regulations which govern IRBs, it is important for researchers interested in accessing and analyzing educational records to understand that personally identifiable educational records are governed and protected by other federal regulations.

Federal law [34 CFR 99, 99.03 through 99.37], often known as FERPA, governs the privacy and access to 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). Thus, if you are performing research that involves the collection of personally identifiable educational records or student data from an educational institution, you will likely need to request written consent from the institution AND permission from students and students' parents for disclosure of educational records.

Exceptions to General Rule of Parental/Student Consent

It is often not feasible for researchers or educational institutions to obtain written permission from parents and/or students to collect their personally identifiable educational records. It is also often not necessary for researchers to have access to personally identifiable information, as they may not necessarily need to link it to any particular person. FERPA does provide exceptions to the general requirement for written permission from parents and/or students that allow for the obtainment of de-identified records.

De-Identified Data

According to federal regulations, an educational agency or institution may release educational records without prior parental/student consent ***after the removal of all personally identifiable information*** provided that the educational agency or institution party has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information. According to these regulations, "personally identifiable information" includes, but is not limited to, the following:

(a) The student's name;
(b) The name of the student's parent or other family members;
(c) The address of the student or student's family;
(d) A personal identifier, such as the student's social security number, student number, or biometric record;
(e) Other indirect identifiers, such as the student's date of birth, place of birth, and mother's maiden name;
(f) Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty; or
(g) Information requested by a person who the educational agency or institution reasonably believes knows the identity of the student to whom the education record relates.

It is important to note that this list includes direct identifiers (e.g. names, addresses, student id numbers, etc.) and possible indirect identifiers. It is important that the data does not include information that could indirectly identify a student (e.g. race/ethnicity if there are very few students in a particular race/ethnic category in the school). According to this exception, an educational official with professional access to educational records (other than the researcher) may strip the data of any personally identifiable information and provide the de-identified data set to the researcher.

Coded Data

Sometimes, researchers may not need to identify any particular student in the records, but may need to have some way of matching de-identified data for analysis purposes. According to federal regulations, an educational agency or institution may release de-identified student level data from education records for the purpose of education research by attaching a code to each record that may allow the recipient to match information received from the same source, provided that: 1) The educational agency or institution does not disclose any information about how it generates and assigns a record code, or that would allow a recipient to identify a student based on a record code, 2) The record code is used for no purpose other than identifying a de-identified record for purposes of education research and cannot be used to ascertain personally identifiable information about a student, and (3) The record code is not based on a student's social security number or other personal information. According to this exception, an educational official with professional access to education records (other than the researcher) may strip the data of any personally identifiable information, attach a random number code (not a student id number used by the school) for each educational record, and provide this de-identified data set to the researcher.

Other Important Considerations

Federal regulations do allow educational professionals (e.g. school officials/administrators) to disclose and use personally identifiable educational records for instructional purposes, to specified officials for audit and evaluation purposes, etc. However, it is important to recognize

that this is only for those educational purposes and access in those ways cannot be combined with generalizable research projects carried out as an AU student. For example:

- A teacher in a school district that could receive educational records for instructional purposes CANNOT also use this data for human subjects research as an AU student. For research purposes, they would need to either: a) obtain parental/student permission OR b) request de-identified data as described above

- A school social worker, either working at a particular school, or hired by another district to perform evaluative activities CANNOT also use data received in that setting for human subjects research as an AU student. For research purposes, they would need to either: a) obtain parental/student permission OR b) request de-identified data as described above

- A school administrator that typically has access to student records as part of their professional responsibilities CANNOT also use this identifiable data as part of their human subjects research as an AU student. For research purposes, they would need to either: a) obtain parental/student permission OR b) request de-identified data as described above

Researchers that intend to collect de-identified data as described in the "De-Identified Data" and "Coded Data" sections above should submit a Human Subjects Determination Form (on IRB website) and describe the type of data being requested, the process by which educational records will be received de-identified, and documentation of permission from the relevant educational institution to receive records.

Please use the following resources for further information on federal regulations governing the use of educational records:

https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

https://www2.ed.gov/policy/gen/guid/fpco/pdf/ferparegs.pdf

Classroom Research

The conduction of research projects to complete course requirements and/or teach about research practices/methods is common in a number of disciplines in higher education. Often, these projects are exempt from IRB review, as they may not meet the definitions of "research" or involve "human subjects" as defined by federal regulations. However, this is not universally true and there are a number of circumstances in which some level of IRB review is necessary for classroom research projects.

Generally, class projects that are solely for purposes of course assignments and are only communicated within a particular course AND do not involve protected human subjects (e.g. children) or collection of sensitive information are exempt. Class projects that extend to presentation or publication, however, often do meet the definitions of human subjects research and require some level of IRB review.

Additionally, many IRBs still require at least some review of projects if they involve participants that are in protected populations or involve the collection of sensitive information. Additionally, there are always a number of best practices and guidelines that students and faculty overseeing classroom research should implement with classroom projects that involve human participants. Please see the document "Classroom Research Guidelines" on the IRB website for more details on these issues.

It is always best to contact the Aurora University IRB with questions about classroom research projects and whether they may require IRB review.

Continuing Review of Research

Annual Review of Previously Approved Research

Federal regulations require IRBs to conduct continuing review of research not less than once per year. When an application is approved by the IRB, the approval letter will include a date of approval and state that this approval is valid for one year (in some cases, some approvals may be for shorter periods of time, related to associated risks of the study). If conduction of the study goes beyond the approval period, the researcher(s) will need to apply for continuing review of the project.

The researcher(s) should complete the **"Project Renewal Form"** on the IRB website and submit it to the IRB Chair for review. It is important for researcher(s) to state in as much detail any additional risks or modifications to the study, if any, that are expected to exist for the study as it goes past the original approval timeframe. Upon review, the researcher(s) will be notified if the study approval has been extended and for what time period. If the enrollment of new participants and involvement of participants in data collection methods has ceased, and data analysis is the only element left in the study, continuing review is not necessary.

If the study has concluded, researcher(s) should complete the **"Study Closure Form"** on the IRB website and submit it to the IRB Chair. This will notify the IRB that the study has been concluded and that it may be archived.

Modifications to Previously Approved Research

Sometimes, researcher(s) may recognize the need to make modifications to a study that was already approved by the IRB. In such circumstances, the researcher(s) should complete the **"Project Modification Form"** found on the IRB website and submit it to the IRB Chair. The applicant(s) should be clear and detailed in terms of what modifications are being made to the study and, specifically, what additional risks, if any, may be involved in these modifications. The applicant(s) should also include updated informed consent documents and study instruments/protocols if applicable. Depending upon the extent of the modifications, the IRB may approve, request revision, or deny these modifications. **Importantly, researcher(s) should not implement modifications to approved studies without prior IRB review.**

Reporting Adverse Events

Procedures must be established for researchers to report unanticipated problems, including adverse events and/or injuries, involving risks to participants in human subjects research or serious or continuing noncompliance with the requirements of the IRB. If any adverse events or unanticipated problems involving risks to participants occur during the conduction of human subjects research, the researcher(s) should promptly report this information to the IRB by submitting the **"Reporting Adverse Events"** form found on the IRB website. Upon review, the IRB will make recommendations to the researcher(s) about steps to follow to minimize risks. Suspension or termination of the research may be required depending upon the nature of the unexpected event or risk to participants.

Additionally, if the IRB is made aware of any serious or continuing noncompliance with IRB requirements on the part of human subjects researchers, the IRB may suspend or terminate research upon investigation of the noncompliance. In such cases, a written statement will be submitted to the researcher(s) summarizing the reasons for the IRB's action

Research Involving Children

The information in this section is provided to clarify the preparation and review process for researchers who plan to include children as participants in their research projects. Children are considered a special population in need of additional protections according to federal regulations. There are other special populations, but research with children is the most common additionally protected population for projects conducted at AU (please be sure to consult the IRB should your research involve other protected populations, such as pregnant women and prisoners). This information is intended to facilitate the compliance approval process.

General Information

Federal regulations require that 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, much research involving children requires expedited or full review.** Exceptions to this include research conducted in commonly established educational settings involving normal educational procedures or the involvement of educational tests or public observation when researchers do not participate (surveys or interviews with children do not meet exempt categories).

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 district or its authorized representative before students can be contacted. This approval cannot be used to require teachers or students to participate. Consent and assent of individuals is always required. School permission is sometimes 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. 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, 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.

3. Risk and Benefit Assessment

What is Risk?

One of the key functions of the Institutional Review Board is to determine the level of risk to human participants involved in a research study. The IRB is typically concerned with whether or not the study includes research procedures that pose *minimal risk* or greater than minimal risk. According to the Department of Health and Human Service's Code of Federal Regulations 45.46.102 (i), *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" (p. 4). Many studies involving human participants only include minimal risks by this definition. For example, a research study involving a survey of student perspectives of cafeteria food would likely only involve minimal risk.

On occasion, there may be research studies that include greater than minimal risk. This does not mean that such studies cannot gain IRB approval. If research studies include greater than minimal risk, the IRB is tasked with determining if the benefits provided by the research are greater than the risks associated with the study procedures. An example of this provided by HHS Code of Federal Regulations is an instance where an intervention conducted with a child presents greater than minimal risks, but holds out the prospect of direct benefit for the child.

How Do You Articulate It?

There are specific places in the IRB application where researchers are asked to address the risks associated with study procedures. It is also a requirement that the risks in the study are communicated to possible participants in informed consent documents. Despite the fact that a large number of studies involve no more than minimal risk, this should not be assumed by researchers submitting for IRB approval. ***It is important to note that all research includes some risks. Therefore, you should not state that your study includes "no risks" to participants***. Rather, you should anticipate what possible risks might be associated with the research study and how such risks may be mitigated. For example, in a study involving student perspectives of cafeteria food, a researcher might state that it is possible that asking students to recall past experiences may evoke negative emotions and that participants will be reminded that all forms of participation are voluntary should such instances occur.

Despite the fact that this study may involve minimal risk, the risks that are identified should still be articulated in the application and consent forms. Additionally, if and when research may involve greater than minimal risk, researchers should simply address and describe the risks associated with the research procedures, along with the potential benefits. Ultimately, the decision as to whether the benefits outweigh the risks is subject to IRB determination and should not be assumed by the researchers in the application.

Policies regarding research with children

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.

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. Exempt Research Involving Children

Research procedures involving child-participants that meet exemption categories include observation of public behavior, research in commonly accepted educational settings involving normal educational procedures, and the use of educational tests. However, observations and use of educational tests must be done in a way where researchers are not involved in the activities, identities are not recorded, and activities do not place children at risk.

Examples of Cases When the Exemption Involving Children May 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 or interview procedures 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 (defined as persons who have not attained the legal age for consent under the laws of the relevant jurisdiction where research takes place). 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?