

**Institutional Review Board (IRB)
for the Protection of Human Participants in Research**

Policies and Procedures

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I. FEDERAL ASSURANCE

Clark Atlanta University has entered into a Federal Wide Assurance (# FWA00008920; expiration 06/30/14) with the Department of Health and Human Services committing CAU to abide by Federal regulations applicable to human research subjects protection. This assurance is provided to all research funded by Federal agencies that have adopted Title 45 CFR 46 U.S. Department of Health and Human Services (DHHS) / Office for Human Research Protections (OHRP) Regulations, including the "Common Rule" regulations and Subparts B, C, and D of the U.S. Code of Federal Regulations (CFR). Research that is not funded by these Federal agencies is covered by internal policies and procedures of CAU, the Office of Research and Sponsored Programs and the IRB. These policies and procedures provide equivalent review and human research subjects protections.

The Policies and Procedures of Clark Atlanta University's Institutional Review Board (# IRB00004949) for the Protection of Human Participants (also referred to as "subjects") in research are grounded in the University's self-imposed commitment to safeguard the

rights and welfare of human participants in all research under its sponsorship and to serve as their protector on behalf of the community of persons of which the University is a part. The University seeks to comply with all federal regulations requiring the establishment and operation of such a board. (See Office for Human Research Protections, "Code of Federal Regulations," [45 CFR 46](#) and the Food and Drug Administration, [21 CFR 50](#) and [21 CFR 56](#). Links to further information on ethical standards and regulation may be found on our [links page](#).)

II. INSTITUTIONAL REVIEW AND APPROVAL

Forms of research involving human participants, as defined in this document, and conducted at Clark Atlanta University, by students, staff or administration, or conducted under its sponsorship at another location, must be reviewed and approved by the Institutional Review Board for the Protection of Human Participants (IRB).

All master's/doctoral dissertation research applications involving human subjects must be reviewed by the IRB, regardless of the research type (Full, Exempt or Expedited). Review is also required of research carried out under the sponsorship of an institution other than Clark Atlanta University, but which is performed on the premises of Clark Atlanta University, even if the research has already been approved by the IRB at the sponsoring institution or elsewhere.

- *[When submitting a collaborative research application that has already been approved by the IRB at the sponsoring institution, please attach a copy of the IRB review from that institution].*

Research Activities Which Require IRB Review:

Research is defined as "a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)].

1. Any research involving children.
2. All master's/doctoral dissertation research.
3. Any research proposal that is to be submitted for extramural funding or support.
4. Any research involving more than minimal risk to human participants.
5. Any research involving human participants carried out by an individual or agency outside of but involving Clark Atlanta University.
6. Any research involving human participants, which do not fall within the approved, written school or departmental guidelines.
7. Any research involving human participants for which the IRB provides notice to the investigator, school or department that the IRB is exercising its oversight responsibility and requires IRB review and approval.

The IRB is to provide an independent determination concerning:

1. The safeguarding of the rights and welfare of individual research participants.
2. Whether these participants are placed at risk; and, *if* risk is involved, whether:
 - a) the risks to the participant are so outweighed by the sum of the benefit to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept such risks;
 - b) the rights and welfare of participants are protected;
 - c) informed consent will be obtained by adequate and appropriate means;
 - d) the conduct of the activity will be reviewed at timely intervals.

Research covered by this policy that has been approved by the IRB may be subject to further review and approval or disapproval by officials of the institution. However, those officials may not approve the research without prior IRB approval.

- ***NOTE: Research may not be initiated until written notification of exemption is received. This includes recruitment of subjects, advertising, mailing or initiating the informed consent process, data gathering, etc.***

III. IRB ADMINISTRATION

1. Membership

Members of the IRB are appointed by Clark Atlanta University's VicePresident for Sponsored Programs to represent the interests of the University and the community. IRB members are ordinarily appointed for a three-year term and may be reappointed when this initial term expires.

All IRB members shall be appropriately qualified by education and/or professional experience to serve in their particular IRB role. *One member may satisfy more than one membership category.* There is at least one member whose primary concerns are in a scientific area, one member whose primary concerns are in a nonscientific area.

There are at least seven members of the IRB, with various backgrounds and fields of expertise, which enables the IRB to evaluate a range of research. The professional preparation of IRB members includes:

- expertise in a range of research areas (Biomedical, behavioral/social),
- familiarity with applicable laws and regulations with relevant standards of professional conduct and practice, and
- knowledge of vulnerable or special populations such as children, prisoners, pregnant women, and disabled persons.
- knowledge of and sensitivity to such issues as local community attitudes to promote respect of its advice and counsel on safeguarding the right and welfare of ***Human Subjects.***

Not all constituent groups may be routinely represented on the IRB but if the IRB reviews ***Research*** that involves especially, a ***Vulnerable Population*** (e.g., ***Children, Prisoners, Pregnant Women***, or handicapped or mentally disabled persons), consideration will be

given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects. These ad hoc IRB consultants may not vote with the IRB.

2. Members

[Institutional Review Board Committee Members](#)

3. Meetings

The IRB meets once a month in formal session during the academic year. Meetings are also held during the summer sessions, as needed. The times of these monthly meetings are announced on the [IRB Meeting Schedule](#). Changes in time or date of the meetings or cancellation of the meeting are communicated to all concerned. At the discretion of the chairperson, the Board may conduct business via telephone, e-mail or campus mail.

4. Required Sponsorship

A review and approval of research activities will be made by the IRB only for studies sponsored by members of the faculty, staff, or administration of Clark Atlanta University. When individuals from an institution other than Clark Atlanta University wish to conduct research on this campus, a CAU faculty member must sponsor the application to the IRB.

5. Student Research

Students attending Clark Atlanta University (undergraduate and graduate) are bound by the same procedures and policies as the faculty and staff. Any application to the IRB from either an undergraduate or graduate student must be reviewed and signed by a sponsoring faculty or staff member familiar with the student and the proposed activity. Applications not in compliance will not be reviewed by IRB. [Full discussion of Students/Faculty and Course research is presented here.](#)

6. Submission of Applications

Any investigator intending to conduct research involving human participants, whether or not the research is supported by a grant, contract, or fellowship from any public or private agency, has the responsibility to at least file an application for exemption from formal review (discussed below), in order to determine whether the activities proposed require formal IRB review. If a grant or contract application is involved, this application should be sent directly to the IRB, in advance of the due date of the application in order to allow time for the review, should it be necessary. All research involving more than minimal risk (as defined below) must be reviewed by the IRB. All doctoral dissertation research and all research involving children must be submitted to the IRB.

7. Deadline for Submission of Applications

All applications to the IRB must be submitted at least 3 calendar weeks prior to the date of the IRB meeting. Applications received too late to permit proper review will be deferred until the next regularly scheduled meeting.

8. Approval of Research

IRB approval expires **one (1) year from the original approval date** or as stipulated by approval notification from the IRB Chair. Once approved, researchers will be sent a notification with the IRB Approval Code and the expiration date. All notifications will be sent electronically. Progress reports are due for all approved projects every six (6) months.

For all three categories of research (full, exempt and expedited), if research will continue beyond the one-year approval period, the researcher must reapply to the IRB *prior to the expiration date*. Renewal applications should be submitted on the same form as the original and should include all pertinent information about the study, particularly updates or changes (if applicable). Research that initially required a full review may be resubmitted as expedited if the research fits specific criteria for an expedited review (see Expedited Review, below). *Please note that while the IRB will make every effort to remind the researcher of the approval's expiration, **it is the responsibility of the researcher to know when his/her approval is set to expire, and to reapply.**

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to participants. A list of the reasons for any suspension or termination will be provided to the investigator and all appropriate supervisors/authorities.

IV. DEFINITIONS

Activities within the scope of the IRB's responsibilities include research, development, and related activities, which would normally be construed as biomedical or behavioral investigations involving human participants. Included are studies involving not only adults and children, but also investigations of prenatal life and deceased. Studies or procedures utilizing organs, tissues, or bodily fluids of a human being are also included, as are the use of graphic, written, or recorded information about individuals even when other institutions or investigators have collected this information.

For the purposes of IRB review, Clark Atlanta University stipulates the following definitions. Please see full list of definitions.

1. **Research** - Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to the well-being of participants and to generalizable knowledge. Activities that meet this definition constitute "research" for the IRB, whether or not they are considered research in other contexts.

Examples of systematic investigations include:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of educational or social programs
- cognitive and perceptual experiments
- medical chart review studies

Excluded from this definition are activities whose sole purpose is instructional; also excluded are activities whose purpose is related to routine course or program development. However, when such research involves students outside of the course, the investigator should submit the appropriate application.

Research activity would normally include the following:

- Persons or programs requesting extramural (federal, state, or private) funds for research or training.
- Individual faculty members (as well as members of the staff and administration) engaged in research as part of their professional role within the University or as part of their job assignment.
- Graduate and doctoral students doing research, which is of the nature of a thesis or dissertation and is part of a degree program.
- Students performing research as part of an independent study or the Honors Program.
- Individuals (including students or persons from outside the University other than faculty, staff, or administration) conducting research at Clark Atlanta University.

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

- **Intervention** includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** includes communication or interpersonal contact between investigator and subject.
- **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the

information to constitute research involving human subjects.

3. **Minimal Risk** - The probability of 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. (Investigators have the obligation to request a clarification by the IRB regarding activities or procedures that are seen by the investigator as questionable in terms of their inclusion in this description.)
4. **IRB Approval** - Means that the IRB has reviewed the research and that the research will be conducted within the policies and procedures outlined in these policies and within the constraints of other institutional and federal requirements. IRB approval does not necessarily include approbation of the research itself.

Please refer to full list of [CAU IRB DEFINITIONS](#).

V. MANDATORY TRAINING

Clark Atlanta University has human protection training policy for investigators, sponsors, IRB members and IRB administrative personnel. See [Mandatory Training](#) for details and online training provided through the [Collaborative Institutional Training Initiative \(CITI\) program](#).

VI. GENERAL APPLICATION PROCEDURES

No research may begin, including recruiting subjects or initiating the informed consent process, until Human Protection Committee of the IRB approval has been granted!

Submit two (2) copies of the research protocol application to IRB Office. The application package should include the following items.

- Human Subjects Research Proposal Form
- Survey Instrument (questionnaire, test measures, etc.)
- Consent/Assent form(s), if applicable
- Letter of cooperation, if applicable
- Certificate of Completion of Mandatory Training program (CITI)
- Copy of full **Technical Proposal** (Agency Sponsored Research) if applicable
- Copy of Approved **Research Prospectus** (Graduate Degree Dissertation) if applicable.

Note: If copies or required application parts are missing, review may be delayed.

Completed forms and attachments should be submitted to:

IRB: Human Subjects Assurance Committee
Office of Research and Sponsored Program (ORSP)
2035 Research Center for Science and Technology
(Campus Mail Box #142)

VII. THE REVIEW PROCESS

All human studies research conducted at CAU must be reviewed by the CAU-IRB regardless of the level of risk. The IRB reviews a proposal by first assessing the risks and benefits of research participation. After determining that the research benefit outweighs the risks involved, the IRB turns to the consent process to ensure that subjects are fully aware of the risks and the benefits and that they participate in the project voluntarily. The consent form is a key element in this review.

After reviewing the application and its supporting materials, the IRB may require revisions in the protocol. When the investigator revises a project, the IRB reviews the project again to see whether its concerns have been adequately addressed. A project may undergo several reviews.

To fully protect subjects, the IRB must approve a project before investigators start to work on it -- even before they begin to recruit subjects, since recruitment strategies are part of the review. Although there are different types of review, many projects require "full" committee review. The initial full review will occur within two weeks of submission if the application is complete. All IRB actions are communicated in writing to the investigator by the IRB staff.

1. Primary types of review

Research projects are reviewed at one of three levels, according to the IRB's determination of the project's potential risk to the human subjects and the federal guidelines that define the categories of review, which are:

- exemption from full IRB review,
- expedited IRB review, and
- full convened IRB review.

The level of review is determined only by the IRB.

2. Screening for exempt status

Investigators do not have the authority to determine whether research involving human subjects is exempt from full review (45 CFR 46.101(b) and (c)). Hence, while research that involves only minimal risk to human subjects is sometimes exempt from the requirements of 45 CFR 46, it is still subject to IRB review. Researchers must file an application requesting that the IRB determine exempt status for a project. In general, the federal guidelines for research on human subjects allow a project to be exempt from full

review only if the research involves *no risk* to the subject and the procedures are limited to the following criteria:

3. FULL REVIEW - RESEARCH FOR FORMAL REVIEW

A researcher must apply for full review, unless he or she believes the proposed research meets the criteria for expedited review or exemption from formal review. The IRB application form may be found by accessing the following: [IRB application](#). A new application for review is required for each new research project even if procedures or subject populations differ only slightly from a previously approved application. IRB approval codes are linked to particular research titles. Small changes to approved research may be made via the "Changes to IRB Approved Research" form, also found by accessing the following: Changes to IRB Approved Research.

The ultimate determination of whether participants are at risk can be made only by the IRB or the appropriate designee. If participants will be placed at more than MINIMAL RISK (as defined above), then the IRB must approve the research and the informed consent form to be used via a convened meeting. The IRB must approve both the form and the procedure by which consent is to be obtained. It is the policy of the IRB to require an informed consent, as well as assent, for any study involving children (under 18 years of age) and other vulnerable populations, no matter what the condition of risk. The procedures necessary for a proper informed consent are described below.

When reviewing research proposals, the IRB is primarily interested in safeguarding the rights and well-being of the human participants and in assessing the ethical implications of the proposed procedures. In this context, the IRB may pass judgment on "research design," but only to the extent that such design affects the rights or well-being of human participants. In analyzing the risk/benefit ratio of a research activity, both the stated goals and the scientific merit of the research will be considered.

Therefore, the research must be described to the IRB in a manner that allows adequate review of all these aspects of the research. The IRB recommends that research descriptions and applications adhere to the following narrative outline:

- **OVERVIEW:** Brief description of the research planned. Please include (a) most recent relevant research in the area of inquiry, and (b) purpose of the study. Be sure to specify your research question(s) or hypothesis(es).
- **BENEFITS/RISKS:** Expected benefits and risks of the study. Benefits do not include payment for participation. No research is void of any risk. Risks should be minimized and should be reasonable when compared to the benefits available to the participants. Describe what procedures (e.g., proper screening of risk-prone individuals, availability of psychological or medical aid, methods for detecting illness, securing personal data, etc.) will be taken to safeguard the welfare of the

participants.

- **PARTICIPANTS:** Subject pool. Please specify (a) the expected number of participants; (b) characteristics of the participants, e.g. age, minority population, special group whose ability to give consent is compromised, pregnant women, fetuses, prisoners; and (c) methods of recruitment. If using flyers or other advertisements, please attach a copy with your application. If a cooperating institution/agency is providing access to participants, include a permission letter, on the institution/agency's letterhead, stating that they are aware of the research and grant access to participants.
- **PROCEDURES:** Description of the methods and procedures to be used with the participants of the research. What will they be asked to do; what tools will be used; what data/information will be collected and how? Please estimate how long the research will take. Include instruments and state reliability and validity. If an outdated instrument (>10 years) is used, provide the rationale for using it. If the instrument is researcher-developed, provide documentation that the instrument was piloted, pretested, or reviewed by three (3) colleagues knowledgeable in the field of inquiry.
- **INFORMED CONSENT:** (See [Consent Form template](#) and [Consent Process](#)). A signed consent form is not necessary for Exempt applications; instead, applicants may use a Participant Letter that addresses the same elements of a signed informed consent form. Include process of obtaining consent (i.e., written or oral), investigator contact information, voluntariness of participation, procedure for withdrawal, confidentiality of data, risks/benefits. Keep original and provide copy to participant.
- **RECORDS MANAGEMENT:** Records must be kept for as long as the applicable regulations require (at LEAST 3 years; See [Records Retention](#)). Please state the length of retention, that records will be kept in a locked file, and who will have access to the records. If records will not be destroyed, please state that in this section.

4. Exemption: Screening for exempt status

Investigators do not have the authority to determine whether research involving human subjects is exempt from full review ([45 CFR 46.101\(b\) and \(c\)](#)). Hence, while research that involves only minimal risk to human subjects is sometimes exempt from full IRB committee review, it is still subject to IRB review. Researchers must file an application requesting that the IRB determine exempt status for a project.

CATEGORIES OF RESEARCH EXEMPT FROM FORMAL REVIEW [45 CFR 46 101

(b)]

Some research involving only Minimal risk is exempt from full Committee review; the new federal guidelines allow for administrative review of six types of research activity. The administrative office of the IRB: Human Subjects Committee will screen applications for *exempt* status to determine eligibility for this classification.

Any investigator who intends to conduct research involving human participants at Clark Atlanta University, and who on the basis of the categories described below judges that research to be exempt from formal review, must file the application (form provided) for exemption from formal review with the IRB for approval **prior to initiation** of the research project. **Please note that only the IRB makes the final determination regarding whether a protocol is eligible for exemption.**

The term exempt does not mean exempt from review. An exempt review is not conducted by the entire Committee, but may be carried out by the IRB chairperson, or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

Exemption is determined only by IRB:

Determination of exemption is not made by the investigator but the IRB. *Exemption* waives the need for full Committee review of proposed research. It does not waive the need for consent of study subjects. In most cases written consent will be required.

If identifiers that can be linked directly to an individual research subject (*Name, Social Security Number, Hospital Admission Number, Specimen Number, Prison ID#, etc.*) are to be collected, the research project does not qualify for **Exemption** and the investigator must submit the project for **Expedited or Full Board** review.

Research involving vulnerable subject populations may not apply to the categories of exemption. (Vulnerable populations are defined in the federal regulations as: children, prisoners, pregnant women, handicapped, or mentally disabled persons, economically or educationally disadvantaged persons). The use of children as research subjects is strictly controlled by federal regulations. Some exempt categories may include children as subjects but only as indicated below.

Exempt applications should also follow the above narrative format.

All questions pertaining to the exemption claim must be completed; incomplete applications will not be processed, resulting in delays. (All attachments including consent and/or assent forms, interview schedules, questionnaires, recruitment information, etc.) must accompany the original application. Student researchers must include their advisor's signature on all applications (submit forms to IRB Office, RSCT).

Questions concerning exemptions or other aspects of human subjects research review should be referred to:

IRB Office: (404) 880-6979; or (404) 880-6829

Categories for exemption from formal review:

Below is a description of research project categories that may qualify for exemption from review by the full committee of the IRB. Research is defined as "a *systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.*" If an investigator believes that his/her project qualifies for exemption, the Exempt Application Form should be completed citing the appropriate category number and submitted to the IRB office.

These Exempt categories are identified in 45 CFR 46 101 (b). The category number preceding each description is the number to claim on question number 2 on the application form.

1. **Instructional Strategies In Educational Settings**

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.

See also [Student Research](#).

2. **Surveys/Interviews; Standardized Educational Tests; Observation of Public Behavior**

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
- iii. Information is damaging to the subject's financial standing, employability, or reputation.
 - [Surveys on sensitive or personal topics which may cause stress to study participants are not exempt from Committee review.]
 - [The section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey

or interview research involving children.]

See also [Student Research](#).

3. **Public Officials; Surveys/Interviews; Educational Tests; Observation of Public Behavior**

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 (2) of this section if:

- i) The human subjects are elected 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. **Existing Data; Records Review; Pathological Specimens**

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.

- [Records considered private based on federal and state statute, including medical records and education records, require written release by the study subject or by the *custodian of the record*. Researchers are cautioned that review of private records involving access to and/or recording of identifiable information is not exempt from Committee Review and **requires written consent** of the study subject. Existing public records do not require prior consent of subjects to review the record.]
- [Pathological or diagnostic specimens which are considered waste and are destined to be destroyed can be used in research and are considered exempt from Committee review if there are no patient identifiers linked to the specimen and if the data is not intended to be used in the diagnosis or treatment of a patient. (If either of these conditions applies, consent of the research subject is required and a higher level of Committee review is required.) Specimens retrieved as *extra* during a clinical procedure require review at a higher level and require written consent from the subject.]
- [Inclusion of fetal tissue in the pathological specimens category of exempt research is prohibited by regulation.]

See also [Research using waste tissues](#).

5 Public Service Programs; Demonstration Projects

Research and demonstration projects that 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 Testing and Food Quality Evaluation

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.
 - *[This category may be applied to research involving children; children, however, are considered a vulnerable population and therefore receive additional protections in the Federal regulations (Minors -Subpart D, 45 CFR 46.401-409). University policy requires written parental consent to include children in taste-testing studies. The only research activities involving children that may fall under exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. (Please see Subpart D of 45 CFR 46.)]*
 - *Other vulnerable populations, such as pregnant women and prisoners, also receive additional protections under various subparts of 45 CFR 46. (Please see Subparts B and C.)*

Right to Review Research That May Qualify as Exempt Research:

Based on the nature of the **Research** and of the **Human Subject** populations to be involved, the CAU IRB reserves the right to require initial and continuing review and oversight of **Human Subjects Research** that may otherwise qualify as **Exempt Research** per the **OHRP Regulations** and/or of protocols that may not otherwise require prior IRB **Full Committee** or **Expedited** review.

EXPEDITED REVIEW (also CONTINUING REVIEW)

The Institutional Review Board (IRB) uses an expedited review process to review studies

that involve no more than 'Minimal Risk,' but does not qualify for exemption (does not fit into one or more of the above exemption categories) or be a *minor* change in previously approved research that involves *no additional risk* to the research subject. Expedited review procedures allow the IRB to review and approve studies that meet the criteria stated below without convening a meeting of the full IRB (45 CFR 46.111, 45 CFR 46.110, 21 CFR 56.111, and 38 CFR 16.111) published by the Office for Human Research Protection (OHRP). Included may be 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) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101](#)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Expedited review may also be used for previously approved research that continues beyond one year, where:

- (a) (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
- (b) where no subjects have been enrolled and no additional risks have been identified; or
- (c) where the remaining research activities are limited to data analysis
- (d) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- (e) Prospective collection of biological specimens for research purposes by noninvasive means
- (f) Collection of data through noninvasive procedures
- (g) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
- (h) Collection of data from voice, video, digital, or image recordings made for research purposes
- (i) Research on individual or group characteristics or behavior
- (j) Continuing review of research previously approved by the convened IRB

Expedited review procedures are not to be used for research involving prisoners, cognitively impaired and mentally disabled participants.

The expedited review procedures may be used when informed consent is altered or waived as long as the regulations on informed consent are met ([45 CFR 46.116\(c\)](#)).

An expedited review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. The expedited reviewer(s) may exercise all of the authorities of the IRB ([45 CFR 46.111](#)) except that they may not disapprove the research. Reviewers may either approve, require “specific minor revisions,” or refer the research to the convened IRB for review in accordance with the nonexpedited review procedures set forth in [45 CFR 46.108](#).

If substantial changes in the protocol are to be made, the IRB must be notified in writing and approval sought for these changes. In the case of grant applications for which continuing applications must be submitted yearly, the application must be submitted to the IRB to conform with continuing research for expedited review policy.

Investigators requesting an expedited review must demonstrate in the application how the proposed project activities fall into one or more of these categories. To apply for expedited review, investigators complete the IRB Application Form and indicate that they are requesting expedited review in the appropriate section.

Expedited applications should also follow the above narrative format.



Are you unsure over which type of review to request? Please see the [Full, Expedited or Exempt Decision Charts](#). You may also contact our office for help in determining which form would be best to use.

VIII. INFORMED CONSENT

In most research activities the investigator must obtain informed consent from each of the participants; or, in the case of those not able to give informed consent (e.g., children, mentally challenged), informed consent must be obtained from their guardians or legal representatives. For research involving children aged seven (7) and over, an assent form should be used in addition to parental consent. The assent form should include age-appropriate language. Readability levels may be checked using some word-processing software. Please contact the IRB office for further information.

A copy of the informed consent form should be given to the person signing the form, and the researcher should retain the original. The IRB must approve all informed consent documents.

[Informed consent and assent templates](#) and [other information](#) may be found on the web.

In clear, nontechnical and age-appropriate language, participants must be informed of:

1. The fact that the study is research.

2. The purpose of the research.
3. The expected duration of the participant's participation.
4. The procedures to be followed.
5. Any reasonably foreseeable risks or discomforts.
6. The benefits to the subject or to others, which may reasonably be expected from the research.
7. Appropriate alternative procedures or course of treatment, if any that might be advantageous to the participant.
8. The extent, if any, to which confidentiality of data and privacy of participants will be maintained.
9. For research involving more than minimal risk, whether any compensation and whether any medical treatments are available if injury occurs.
10. Whom to contact for answers to pertinent questions about the research, participants' rights, and research related injury to the participant.
11. The fact that participation is voluntary and that the participant may withdraw his or her consent at any time without penalty or loss of benefits.
12. How long records will be maintained by the researcher (at least 3 years; See [Records Retention](#)), who will have access to the records, where records will be stored (i.e., locked file), and if and when data will be destroyed.

There are two procedures, which may be used to obtain informed consent:

1. The participant or a legal representative signs a written informed consent document, which embodies the elements above.
2. The participant or a legal representative signs a document indicating that the subject had the above elements explained to him/her orally and that he/she understand this oral description and he/she agrees to participate in the activity described.

In this case, however, an auditor witness to the oral presentation must be present. A written summary of the oral presentation must be submitted to and approved by the IRB. A copy of this presentation is to be retained by the IRB.

There may be cases in which the use of either of these procedures for obtaining informed consent may be considered inappropriate by the investigator because they would adversely affect the experimental design or procurement of valid results. Accordingly, modifications to the above informed consent procedures can be recommended to the IRB. However, all modifications must be approved prior to implementation of the proposed research. This approval must be recorded in the Board's minutes.

No such modification will be approved unless and until the IRB determines:

1. That the risk to any human participant is, in fact, minimal, justifying a less full disclosure in the informed consent procedures than would normally be required; or,
2. That the use of either informed consent procedure would, in fact, invalidate objectives of considerable immediate consequence, and that the use of any reasonable alternative means for attaining these objectives would be less advantageous to the participant.

A request to waive written informed consent must be accompanied by a complete explanation in response to the four statements below. All of the criteria must be met to

qualify for a waiver of consent:

- a. The proposed research presents no more than minimal risk of harm to subjects.
- b. The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
- c. The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
- d. The research could not practicably be carried out without the waiver or alteration.
- e. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Please note that passive consent, whereby consent is assumed unless a participant/guardian "opts out," is not an acceptable form of consent. Instead, a waiver of consent, meeting the above criteria, must be requested.

X. RESPONSIBILITIES OF INVESTIGATORS

1. Familiarize themselves with these guidelines and discuss with members of the IRB any questions regarding proposed research activities.
2. Submit an adequately prepared IRB application for each research project involving human participants.
3. Notify the IRB and the dean or departmental chairperson of any injury (physical, psychological, or social) suffered by a research participant because of his or her participation in a research activity.
4. Take proper measures to ensure confidentiality and security of all information obtained from the participants.
5. Submit status reports to the IRB in a timely manner (every 6 months). Forms may be found at the following: Status Reports
6. Participate in required [IRB training](#). Additional training may be required for specific types of research (international research, Internet research, etc.), or vulnerable populations (e.g., research with prisoners). Please contact the IRB office for details.
7. If research continues beyond one (1) year from the original approval date, reapply *prior to* the expiration.
8. Understand that all research is bound by Federal Regulations and must be kept for the longest applicable period (3 years or longer, see Records Retention, below).

XI. RECORDS RETENTION

Regulations require each investigator to retain research data not only while the research is being conducted, but also after the research is completed. How long must the investigator retain records after the completion of the research? Unfortunately, there are several different regulations, each of which has different requirements. As a result, researchers must retain their records for as long as the applicable regulations require.

- **OHRP Requirements:** 45 CFR 46 requires research records to be retained for at least 3 years after completion of the research.
- **HIPAA Requirements:** Any research that involves collecting identifiable health information is subject to HIPAA requirements. As a result, records must be retained for a minimum of 6 years after each subject signed an authorization.
- **Sponsor Requirements (Grant or Contract):** If your study is sponsored, you must ensure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 15 years.
- **Professional Association Requirements:** If your research falls within the guidelines of a particular profession (e.g., American Psychological Association), you may be required to retain records based on the association's practices.

Types of Records

The principal investigator's records should be a mirror image of the IRB's records: where the IRB holds an original, the principal investigator should hold a copy, and vice versa.

The documents that researchers should have on file include:

- a copy of the original application submitted to the IRB, including the consent form and the research protocol;
- the original of the IRB's response;
- a copy of responses to IRB stipulations or requests for additional information;
- the original notice of final approval;
- a copy of the "Certification of Approval" sent by the IRB to any funding agencies;
- copies or originals of all other correspondence with the IRB;
- copies of completed "Continuing Review" forms and attachments;
- the original notice of renewal of approval and certification, where applicable; and
- copies of any inspection or audit reports.

Original signed consent forms should be kept in a secure location separate from correspondence with the IRB but readily available to inspectors. IRB records are subject to inspection by federal authorities. Sanctions for incomplete or nonexistent records include suspension of funding, fines, exclusion from future funding, and suspension of laboratory access.

XII. REPORTING MISCONDUCT AND NONCOMPLIANCE

Research investigators are responsible for reporting to the IRB any instance of serious or continuing noncompliance with the IRB policies and procedures or the requirements or determinations of the IRB.

XIII. ADDENDUM

Direct comments to the IRB staff: IRB@cau.edu