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

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 grou( )-111((C2 B058004F()-7BT1 0 0 1 4F()-7BT1 0)-7BT1 0 man

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

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)

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

- 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:

a. Persons or programs requesting extramural (federal, state, or private) funds for research or training.
b. 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.
c. Graduate and doctoral students doing research, which is of the nature of a thesis or dissertation and is part of a degree program.
d. Students performing research as part of an independent study or the Honors Program.
e. 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 t33 Tm 0 BT1asrm d

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

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

(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 no

Categories for exemption from formal review:

Below is a description of research project categories that may qualify for exemption from

or interview research involving children.]

See also **Student Research**

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, 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 (u)-3(ld)-163(bNelus( )-21(g)6(iv)n-5(l).6(e)] T1163-87-21(IRB)6421

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-3(o374.31 Tm i4.- 1)-91(o)abyand tha33o374.31 Tm/sT

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):**

XIII. ADDENDUM

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