CLARK ATLANTA UNIVERSITY
Research and Sponsored Programs

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

Guidance Manual Revised 5.1.2026

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I. FEDERAL ASSURANCE

Clark Atlanta University (CAU) affirms its enduring commitment to the ethical conduct of research and the protection of human participants through its Federal Wide Assurance (FWA00029428; expiration date: May 17, 2028) with the U.S. Department of Health and Human Services (HHS).

By entering into this assurance, the University pledges to uphold all applicable federal regulations designed to safeguard individuals who contribute to research knowledge. This commitment applies to all research supported by federal agencies that have adopted the human subjects protection regulations codified at Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46), including the "Common Rule" and Subparts B, C, and D, as overseen by the Office for Human Research Protections (OHRP).

Beyond federally funded research, Clark Atlanta University extends these same ethical principles to all human subjects research conducted under its auspices. Research that is not supported by federal agencies is governed by the institutional policies and procedures of the University, the Office of Research and Sponsored Programs, and the Institutional Review Board (IRB), and this guidance manual. These policies reflect CAU's belief that respect for persons, beneficence, and justice are fundamental obligations in all research endeavors, and they provide protections equivalent to those required by federal standards.

The Policies and Procedures of Clark Atlanta University's Institutional Review Board (IRB00004949) for the Protection of Human Participants (also referred to as "subjects") are rooted in the University's longstanding mission to serve as a responsible steward of knowledge and a trusted member of the communities it engages.

The CAU IRB exists to protect the rights, dignity, and welfare of individuals who participate in research and to ensure that their contributions are honored with care, transparency, and respect.

The University is committed to complying with all applicable federal regulations governing the establishment and operation of Institutional Review Boards (IRBs) and the protection of human research participants. Accordingly, the University conducts its human subjects research oversight activities in accordance with the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR Part 46 (Protection of Human Subjects) and, when applicable, the U.S. Food and Drug Administration (FDA) regulations at 21 CFR Part 50 (Protection of Human Subjects/Informed Consent) and 21 CFR Part 56 (Institutional Review Boards).

REGULATORY REFERENCES

- HHS / OHRP – 45 CFR Part 46, Protection of Human Subjects (Common Rule): https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46
- FDA – 21 CFR Part 50, Protection of Human Subjects (Informed Consent): https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50
- FDA – 21 CFR Part 56, Institutional Review Boards: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56

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 and 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.

For collaborative research studies reviewed and approved by an external or sponsoring institution's IRB, investigators should provide a copy of the IRB approval letter and related review documents as part of the submission package.

The University supports the use of Reliance Agreements, also known as Institutional Authorization Agreements (IAAs), and is willing to serve either as the reviewing IRB or as a relying institution, as appropriate for the research project and applicable regulatory requirements.

A Reliance Agreement is a formal written agreement between collaborating institutions that allows one institution to rely on the IRB review and oversight conducted by another qualified IRB. Reliance agreements are commonly used in multi-site or cooperative research studies to facilitate a single IRB (sIRB) review process, reduce duplicative reviews, and promote consistent protections for research participants.

The University will consider requests to enter into reliance agreements on a case-by-case basis, considering the nature of the research, the qualifications and capabilities of the reviewing IRB, sponsor requirements, and applicable federal, state, and institutional requirements. Any reliance arrangement must clearly define the roles and responsibilities of the reviewing IRB and each participating institution, including requirements for regulatory compliance, investigator oversight, reporting, communication, and recordkeeping.

Reliance agreements typically include:

- Identification of all participating institutions;
- The purpose and scope of the reliance arrangement;
- Designation of the reviewing IRB and relying institution(s);
- Responsibilities and obligations of each party;
- Requirements for communication, reporting, and regulatory compliance;

- Terms governing the duration, amendment, and termination of the agreement; and
- Signatures of authorized institutional officials and IRB representatives.

By participating in reliance agreements, the University seeks to promote efficient and effective IRB review while maintaining its commitment to the protection of human research participants and compliance with all applicable regulatory requirements.

Investigators wishing to establish a Reliance Agreement should contact the IRB as early as possible in the study planning process. The University will review proposed reliance arrangements on a case-by-case basis to determine whether reliance on an external IRB, or service as the reviewing IRB, is appropriate for the research project.

To initiate a Reliance Agreement, investigators should:

- Notify the IRB Office of the proposed collaborative or multi-site research study and indicate whether a reliance arrangement is being requested.
- Provide study documentation, including the research protocol, funding information (if applicable), and identification of all participating institutions.
- Identify the proposed reviewing IRB and submit any available reliance or single-IRB documentation.
- Submit supporting materials requested by the IRB, which may include approval letters, investigator qualifications, study-specific agreements, and local context information.
- Coordinate with collaborating institutions to ensure all parties agree to the proposed reliance arrangement and understand their respective responsibilities.
- Obtain institutional approval and execution of the Reliance Agreement before initiating any human subjects research activities covered by the agreement.
- Comply with all ongoing reporting and oversight requirements established by the reviewing IRB and the University.

The IRB will evaluate the proposed arrangement to ensure that appropriate protections for research participants are maintained and that all applicable federal, state, sponsor, and institutional requirements are met. Research activities conducted under a reliance agreement may not begin until the agreement has been fully executed and all required approvals have been obtained.

For studies that have already received approval from an external IRB, investigators should provide a copy of the IRB approval letter and any associated review documentation as part of the reliance review process.

Research Activities Requiring IRB Review

Federal regulations define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102). Any research involving human participants that meets this definition may require review and approval by the Institutional Review Board (IRB) prior to initiation.

The following research activities require IRB review and approval:

- Research involving children or other vulnerable populations as defined by applicable federal regulations and institutional policies.
- All master's theses, doctoral dissertations, and other graduate research projects involving human participants.
- Research submitted for external funding or support, including proposals submitted to federal, state, private, corporate, or nonprofit sponsors.
- Research involving more than minimal risk to participants, including studies that may expose individuals to physical, psychological, social, legal, or economic risks.
- Research conducted by investigators or organizations external to Clark Atlanta University that involves Clark Atlanta University students, faculty, staff, facilities, records, or other institutional resources.
- Research involving human participants that falls outside established academic, departmental, or programmatic activities and is not covered by approved written school or departmental guidelines.
- Any human subjects research for which the IRB determines that review and approval are required, including studies for which the IRB has notified the investigator, department, or school that it is exercising its oversight authority.

Important: No human subjects research activities may begin until the investigator has received written notification from the IRB that the study has been approved, determined to be exempt, or otherwise does not require IRB review. This prohibition includes, but is not limited to, participant recruitment, advertising, screening activities, distribution of study materials, initiation of the informed consent process, data collection, or any other research-related procedures.

IRB Determination of Research Involving Human Subjects

The Institutional Review Board (IRB) is responsible for making an independent determination as to whether a proposed activity meets the federal definition of research and involves human subjects, as defined in 45 CFR 46.102. This review helps ensure that all applicable ethical principles, institutional policies, and federal regulatory requirements are appropriately applied before any research activities begin.

The IRB's determination establishes whether IRB review and approval are required and ensures that the rights, welfare, and privacy of research participants are adequately protected. Investigators are encouraged to consult with the IRB whenever there is uncertainty regarding whether a project constitutes human subjects research or requires IRB oversight.

In making its determination, the IRB considers whether the proposed research adequately protects the rights, welfare, and interests of research participants. Specifically, the IRB evaluates:

- The protection of the rights, welfare, privacy, and dignity of research participants.

- The risks associated with participation and whether those risks are reasonable in relation to the anticipated benefits, considering:

    - Whether the risks to participants are minimized and justified by the potential benefits to the participants and/or the importance of the knowledge expected to result from the research;
    - Whether appropriate safeguards are in place to protect the rights and welfare of participants;
    - Whether informed consent will be sought and documented through adequate and appropriate procedures; and
    - Whether the research will be subject to continuing oversight and review at intervals appropriate to the degree of risk and the nature of the study.

Research approved by the IRB may be subject to additional institutional review and approval or disapproval by authorized University officials. However, no institutional official may approve research involving human participants unless the research has first received IRB approval.

This policy ensures compliance with Federal regulations (45 CFR 46) and institutional standards for the protection of human subjects. Failure to obtain IRB approval or exemption prior to initiating research activities may result in the following consequences:

Failure to obtain IRB approval or exemption prior to initiating research activities may result in the following consequences:

- Suspension or termination of the research project
- Invalidation of collected data, which may not be used for publication, presentation, or academic credit
- Loss of current or future funding from internal or external sources
- Institutional disciplinary action, which may include academic sanctions or employment consequences
- Mandatory reporting to federal oversight agencies (e.g., OHRP), which may affect the researcher's professional standing and future research eligibility

Researchers are responsible for ensuring that no aspect of their study begins until formal IRB clearance is received.

III. IRB ADMINISTRATION

Members of the Institutional Review Board (IRB) are appointed by the University's Vice President for Sponsored Programs to represent the interests of both Clark Atlanta University and the broader community. IRB members are typically appointed for three-year terms and may be reappointed upon the expiration of their initial term.

All IRB members must be appropriately qualified through their education, training, experience, and professional expertise to fulfill their respective roles and responsibilities. An individual member may satisfy more than one required membership category.

The IRB is composed of at least five members with diverse backgrounds, perspectives, and areas of expertise to ensure a thorough and balanced review of the wide range of research conducted under the University's auspices. Consistent with applicable federal regulations, the IRB includes at least one member whose primary concerns are in a scientific area and at least one member whose primary concerns are in a nonscientific area.

The collective expertise of the IRB is intended to provide comprehensive review of research involving human participants and includes:

- Expertise in a variety of research disciplines, including biomedical, behavioral, and social science research;
- Familiarity with applicable laws, regulations, ethical principles, and standards of professional conduct and practice;
- Knowledge of the ethical and regulatory considerations associated with vulnerable and special populations, including children, prisoners, pregnant women, individuals with disabilities, and persons with impaired decision-making capacity; and
- Awareness of and sensitivity to local community values, attitudes, and cultural considerations to help safeguard the rights and welfare of research participants.

While not all constituent groups or areas of expertise may be represented on the IRB at all times, the IRB will ensure that appropriate expertise is available when reviewing research involving vulnerable populations or other specialized subject groups. When necessary, the IRB

may invite individuals with specific knowledge and experience relevant to the research under review to serve as consultants.

These consultants may provide advice and recommendations to the IRB regarding scientific, ethical, legal, cultural, or community considerations; however, they shall not participate in IRB deliberations as voting members and shall not vote on the approval, modification, or disapproval of research.

Current IRB Members

Scheduled Full-Board Meetings

The IRB meets on a **quarterly basis** during the academic year, with additional **monthly meeting dates scheduled as needed** to accommodate study submissions, time-sensitive reviews, and institutional needs. A current schedule of regularly planned meetings and supplemental review dates is maintained by the IRB Office and made available to investigators and the University community.

Any changes to scheduled meeting dates or times, including cancellations, will be communicated to investigators, IRB members, and other affected parties in a timely manner.

At the discretion of the IRB Chair, and in accordance with applicable regulations and institutional policies, certain IRB business may be conducted through alternative means, including teleconference, videoconference, electronic communication, or other approved methods. However, all convened IRB reviews requiring a quorum will be conducted in a manner that satisfies applicable regulatory requirements for IRB review and documentation.

A quorum, as defined by 45 CFR §46.108(b) and 21 CFR §56.108(c), must be present for the IRB to conduct official business. A quorum includes, a majority of IRB member, and at least one member whose primary concerns are in nonscientific areas.

The IRB Chair may call an emergency meeting when immediate review is necessary to protect the rights and welfare of research participants.

Sponsorship of Research Conducted by External Investigators

The Clark Atlanta University Institutional Review Board (CAU IRB) reviews research involving human participants that is sponsored by members of the University's faculty, staff, or administration. Investigators affiliated with institutions other than Clark Atlanta University who wish to conduct research involving CAU students, faculty, staff, facilities, records, or other University resources must obtain sponsorship from a CAU faculty member prior to applying to the IRB.

The CAU faculty sponsor serves as the University's representative for the proposed research and is responsible for ensuring that the study is conducted in accordance with University policies, ethical standards, and applicable federal regulations. The sponsor also acts as the primary liaison between the external investigator and the IRB throughout the review and conduct of the study.

Responsibilities of the CAU Sponsor

The CAU faculty sponsor is responsible for:

- Reviewing and endorsing the research application prior to IRB submission;
- Ensuring that the proposed research is consistent with the University's mission, policies, and ethical standards;
- Facilitating communication between the external investigator and the IRB;
- Monitoring research activities conducted at Clark Atlanta University, as appropriate;
- Ensuring compliance with applicable University policies and federal regulations; and
- Promptly communicating any significant study changes, concerns, or compliance issues to the IRB.

Responsibilities of the External Investigator

External investigators conducting research at Clark Atlanta University are responsible for:

- Complying with all CAU IRB requirements, institutional policies, and applicable federal regulations;
- Working collaboratively with the CAU faculty sponsor throughout the study;
- Obtaining all required approvals before initiating research activities; and
- Ensuring that all research activities are conducted in accordance with the approved protocol.

Application Procedures

To request IRB review, external investigators must:

- Identify and secure a CAU faculty sponsor before submitting an IRB application.
- Include documentation of the sponsor's endorsement with the IRB submission.
- Obtain the sponsor's signature on all required application materials.
- Submit all required study documentation in accordance with CAU IRB procedures.

Applications submitted without a CAU faculty sponsor will be considered incomplete and will not be reviewed by the IRB. No research activities involving Clark Atlanta University participants or resources may begin until all required approvals have been obtained.

Student Research

Students enrolled at Clark Atlanta University, including both undergraduate and graduate students, are subject to the same IRB policies, procedures, and ethical standards that apply to faculty and staff engaged in human subjects research.

All research applications submitted by students must be reviewed and endorsed by a faculty or staff advisor who is knowledgeable about the proposed research and willing to oversee the conduct of the study. The faculty or staff sponsor assumes responsibility for providing appropriate guidance, ensuring compliance with applicable University policies and federal regulations, and overseeing the student's research activities.

The faculty or staff sponsor must review and sign the IRB application before submission. The sponsor's signature confirms support for the project and acknowledgment of their oversight responsibilities.

IRB applications submitted by students without the required faculty or staff sponsorship and signature will be considered incomplete and will not be reviewed by the IRB. No research activities involving human participants may begin until all required approvals have been obtained.

Submission of Applications

Any investigator proposing to conduct research involving human participants, regardless of whether the research is supported by a grant, contract, fellowship, or other source of funding, is responsible for submitting the project to the IRB for determination. At a minimum, investigators must apply for exemption or other appropriate review so that the IRB can determine whether the proposed activity constitutes human subjects research and whether IRB review or approval is required.

When a grant or contract proposal involves human subjects research, investigators should submit the IRB application sufficiently in advance of the sponsor's deadline to allow adequate time for IRB review and determination, if required.

All research involving more than minimal risk to participants must be reviewed and approved by the IRB prior to the initiation of any research activities. In addition, all doctoral dissertation research involving human participants and all research involving children must be submitted to the IRB for review and determination, regardless of the level of risk.

Investigators may not begin participant recruitment, informed consent activities, data collection, or any other research-related procedures involving human participants until they have received the appropriate written determination or approval from the IRB.

Submission Deadlines

To ensure adequate time for review, all applications requiring review by the IRB must be submitted at least three (3) calendar weeks prior to the scheduled IRB meeting date.

Applications that are incomplete or received after the submission deadline may not allow sufficient time for thorough review and, therefore, may be deferred to the next scheduled IRB meeting. Investigators are encouraged to submit applications as early as possible to avoid delays in the review process and the initiation of research activities.

The IRB Office will notify investigators if a submission is incomplete or if review must be postponed to a subsequent meeting date. No research activities involving human participants may begin until all required IRB approvals have been obtained.

Approval, Continuing Review, and Renewal of Research

IRB approval is valid for a period of one (1) year from the date of approval, unless a different approval period is specified in the approval notification issued by the IRB Chair. Upon approval, investigators will receive electronic notification that includes the study's IRB approval number and approval expiration date.

To ensure appropriate oversight of ongoing research activities, progress reports must be submitted every six (6) months for all approved studies, as required by the IRB.

Progress Reports and Continuing Oversight

To ensure appropriate oversight of ongoing research activities, investigators are required to submit a Progress Report every six (6) months for all IRB-approved studies, unless otherwise directed by the IRB. Progress reports enable the IRB to monitor study conduct, evaluate participant protections, assess any changes in risk, and ensure continued compliance with applicable regulations and institutional requirements.

Failure to submit a required progress report may result in administrative action, including suspension of study activities, withholding of continuing approval, or other actions deemed appropriate by the IRB.

Progress reports should include the following information:

- Study Identification
- IRB protocol number;
- Study title;
- Principal Investigator (PI) name and contact information; and
- Department, school, or institutional affiliation.
- Approval Information
- Original IRB approval date;

- Current approval period, including approval and expiration dates; and
- A summary of any amendments or modifications approved since the initial review or most recent progress report.
- Study Status
- Current study status (e.g., Active, Completed, Suspended, or Terminated);
- Enrollment status (e.g., Open to Enrollment, Closed to Enrollment, or Enrollment Paused); and
- Anticipated completion date, if known.
- Participant Enrollment
- Number of participants approved for enrollment;
- Number of participants enrolled to date;
- Demographic characteristics of enrolled participants, when applicable;
- Number of participants who have withdrawn or been withdrawn from the study; and
- Reasons for participant withdrawals or dropouts, if known.
- Summary of Research Activities
- Progress made toward achieving the study objectives;
- Description of research activities conducted since the previous report;
- Summary of data collection activities;
- Status of data analysis, when applicable; and
- Description of any deviations from the IRB-approved protocol, including corrective actions taken.
- Adverse Events and Unanticipated Problems
- Description of any adverse events, whether serious or non-serious;
- Actions taken to address adverse events or participant concerns;
- Any unanticipated problems involving risks to participants or others; and
- Any reports submitted to sponsors, regulatory agencies, or institutional officials.
- Risk Assessment
- Current assessment of risks associated with the research;
- Comparison of current risks to those identified during the initial IRB review;
- Description of any newly identified risks or changes in the risk-benefit relationship; and
- Measures implemented to minimize or mitigate risks to participants.
- Additional Information
- Summary of any participant complaints;
- Description of any pending protocol modifications;
- Publications, presentations, or other dissemination activities resulting from the study, if applicable; and
- Any other information the investigator believes is relevant to the IRB's continuing oversight of the research.
- IRB Review of Progress Reports

The IRB will review submitted progress reports to determine whether:

- The study continues to satisfy the criteria for IRB approval;
- Risks to participants remain reasonable in relation to anticipated benefits;
- Appropriate safeguards remain in place to protect participants' rights and welfare;

- Any protocol deviations, adverse events, or unanticipated problems have been adequately addressed; and
- Continued approval or additional IRB action is warranted.

The IRB may request additional information, require modifications to the study, conduct further review, or take other actions necessary to ensure the continued protection of human research participants.

If a study will continue beyond its approval period, investigators must submit a renewal application to the IRB before the approval expires. Renewal applications are required for studies reviewed under full board, expedited, or exempt review categories, as applicable under University policy. The renewal submission should be completed using the current IRB renewal form and must include a summary of study progress, participant enrollment information, any adverse events or unanticipated problems, and any changes or updates to the approved research protocol.

Research originally approved through full board review may qualify for expedited review upon renewal if the study meets the applicable criteria for expedited review and the IRB determines that such review is appropriate.

Investigators are responsible for monitoring the approval status of their studies and ensuring that renewal applications are submitted in sufficient time to avoid a lapse in approval. Although the IRB Office may provide courtesy reminders regarding upcoming expiration dates, responsibility for maintaining continuous IRB approval rests solely with the investigator.

If IRB approval expires before renewal is granted, all research activities involving human participants must cease immediately unless continuation is necessary to eliminate an immediate hazard to participants.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements, applicable regulations, or approved study procedures, or when research has been associated with unexpected serious harm or increased risk to participants. In the event of a suspension or termination, the investigator will receive written notification outlining the reasons for the action, and appropriate institutional officials and regulatory authorities will be notified as required.

Study Closure and Termination of Approval Report

When a research study is completed, terminated, suspended, or otherwise closed, the Principal Investigator (PI) must submit a Termination of Approval (Study Closure) Report to the IRB. This report enables the IRB to document the final disposition of the study, verify that all research activities have concluded appropriately, and ensure that participant protections and regulatory obligations have been satisfied.

A Termination of Approval Report should be submitted when:

- All participant recruitment and enrollment activities have ended;
- All study interventions and interactions with participants have been completed;
- Collection of identifiable private information or identifiable biospecimens has ceased;
- Data analysis involving identifiable participant information has been completed; or
- The study is otherwise being closed, terminated, or discontinued.

The IRB may not consider a study closed until all required information has been submitted and accepted.

Required Termination of Approval Report Information:

- Study Identification
- IRB protocol number;
- Study title;
- Principal Investigator (PI) name and contact information; and
- Department, school, or institutional affiliation.
- Approval Information
- Original IRB approval date;
- Most recent approval and expiration dates;
- Date study activities ended; and
- Summary of any approved amendments made during the course of the study.
- Study Status
- Final study status (Completed, Terminated, Suspended, or Withdrawn);
- Date participant enrollment was closed;
- Date all research activities were completed; and
- Reason for study termination, if terminated prior to completion.
- Participant Enrollment Summary
- Total number of participants approved for enrollment;
- Total number of participants enrolled;
- Number of participants who completed the study;
- Number of participants who withdrew or were withdrawn; and
- Summary of reasons for participant withdrawal or discontinuation, when applicable.
- Summary of Research Activities
- Brief description of the research conducted;
- Summary of progress toward study objectives;
- Status of data collection and analysis;
- Description of any protocol deviations or noncompliance events that occurred during the study; and
- Summary of study findings, if available.
- Adverse Events and Unanticipated Problems
- Summary of all adverse events reported during the study;
- Description of any serious adverse events;
- Summary of any unanticipated problems involving risks to participants or others;
- Actions taken to address identified issues; and
- Confirmation that all required reporting obligations have been fulfilled.

- Risk Assessment and Participant Protection
- Description of any ongoing risks to participants;
- Confirmation that no further participant contact or data collection will occur, if applicable;
- Plans for handling participant inquiries following study closure; and
- Confirmation that participant confidentiality protections remain in place.
- Data and Records Management
- Status of study records and research data;
- Location and method of records storage;
- Retention period in accordance with sponsor, regulatory, and institutional requirements;
- Procedures for maintaining confidentiality and security of records; and
- Plans for data destruction, if applicable.
- Study Outcomes and Dissemination
- Publications, presentations, dissertations, theses, or reports resulting from the study;
- Anticipated scholarly products still in preparation; and
- Any significant findings that may affect participant welfare or future research.
- Investigator Certification

<u>The Principal Investigator must certify that:</u>

- All study activities have been completed or appropriately terminated;
- All required reports have been submitted to the IRB and other oversight entities, as applicable;
- Participant rights, welfare, and confidentiality have been protected throughout the study; and
- Study records will be retained in accordance with applicable regulatory, sponsor, and institutional requirements.
- IRB Review of Termination Reports

The IRB will review the Termination of Approval Report to verify that the study has been appropriately closed and that all outstanding regulatory and ethical obligations have been satisfied. The IRB may request additional information or clarification before officially closing the study record.

Once the report has been accepted, the IRB will notify the investigator that the study has been formally closed. Investigators should note that closure of a study does not relieve them of their responsibility to maintain study records for the required retention period or to comply with any continuing obligations related to confidentiality, data security, or sponsor requirements.

IV. DEFINITIONS

The activities within the scope of the Institutional Review Board's (IRB) responsibilities include research, development, and related activities that are ordinarily considered biomedical, behavioral, educational, or social science investigations involving human participants. Such activities may involve adults, children, prenatal life, deceased individuals, human organs, tissues,

bodily fluids, or identifiable graphic, written, electronic, or recorded information about individuals, regardless of whether the information was collected by the investigator or obtained from another source.

For purposes of IRB review and oversight, Clark Atlanta University adopts the following definitions:

Research

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge and to advance understanding for the benefit of individuals, communities, or society.

Activities that meet this definition constitute research for purposes of IRB review, regardless of whether they are considered research in other contexts.

Examples of systematic investigations include, but are not limited to:

- Surveys and questionnaires;
- Interviews and focus groups;
- Analyses of existing data sets or biological specimens;
- Epidemiological studies;
- Educational, social, or program evaluations;
- Cognitive, behavioral, and perceptual experiments;
- Medical record or chart review studies; and
- Observational studies involving human participants.

The following activities are generally excluded from this definition when their sole purpose is instructional or administrative rather than research:

- Classroom exercises conducted exclusively for teaching purposes;
- Routine course development or curriculum assessment activities;
- Internal program improvement activities that are not intended to contribute to generalizable knowledge.

However, when such activities involve dissemination outside the classroom, publication, presentation, or the collection of data for research purposes beyond normal instructional activities, investigators should consult the IRB to determine whether review is required.

Research activities requiring IRB consideration typically include:

- Projects seeking external funding or support from federal, state, private, corporate, or nonprofit sponsors.
- Research conducted by faculty, staff, or administrators as part of their professional responsibilities.
- Graduate, master's, and doctoral research projects, including theses and dissertations.

- Student research conducted as part of independent study, honors, capstone, or similar academic programs.
- Research conducted by individuals external to the University that involves Clark Atlanta University participants, facilities, records, or resources.
- Human Participant (Human Subject)

A **Human Participant (or Human Subject)** is a living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual; and/or
- Identifiable private information or identifiable biospecimens.

- Intervention includes both physical procedures by which data are collected (such as blood draws, specimen collection, or other clinical procedures) and manipulations of the participant or the participant's environment performed for research purposes.

- Interaction includes communication or interpersonal contact between the investigator and the participant, including interviews, surveys, focus groups, observations, and electronic communications.

- Private Information includes information about behavior occurring in circumstances where an individual reasonably expects privacy, as well as information provided for specific purposes that an individual reasonably expects will not be made public, such as medical, educational, employment, or counseling records.

- Private information is considered identifiable when the identity of the individual is known, may reasonably be determined, or can readily be associated with the information obtained by the investigator.

Minimal Risk

Minimal Risk means that the probability and magnitude of anticipated harm or discomfort associated with participation in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical, psychological, educational, or diagnostic examinations or tests.

Investigators are encouraged to consult the IRB whenever there is uncertainty regarding whether a proposed activity exceeds the threshold of minimal risk.

IRB Approval

IRB Approval means the determination of the Institutional Review Board that a research study has been reviewed and may be conducted in accordance with applicable federal regulations, ethical principles, institutional policies, and any conditions imposed by the IRB.

IRB approval signifies that the Board has concluded that appropriate protections are in place for research participants and that the research satisfies the criteria for approval. IRB approval does not constitute endorsement of the scientific merit, sponsor, objectives, or conclusions of the

research beyond the Board's responsibility for protecting the rights and welfare of human participants.

Investigator

An Investigator is any individual responsible for the design, conduct, oversight, or reporting of research involving human participants. This includes principal investigators, co-investigators, faculty advisors, students, research staff, and external collaborators engaged in the research activity.

Vulnerable Populations

Vulnerable Populations are groups of individuals who may be at increased risk of coercion or undue influence or who may require additional protections under federal regulations. These populations may include, but are not limited to:

- Children;
- Prisoners;
- Pregnant women;
- Individuals with impaired decision-making capacity;
- Economically or educationally disadvantaged persons;
- Individuals with disabilities; and
- Other populations requiring additional safeguards based on the nature of the research.

The IRB may require additional protections when reviewing research involving vulnerable populations.

Informed Consent

Informed Consent is the process through which a prospective participant voluntarily confirms a willingness to participate in research after receiving sufficient information regarding the study's purpose, procedures, risks, benefits, alternatives, confidentiality protections, and participant rights. Informed consent must be obtained under circumstances that provide adequate opportunity for consideration and minimize the possibility of coercion or undue influence.

Exempt Research

Exempt Research refers to specific categories of human subjects research that meet federal exemption criteria and are determined by the IRB or its designee to be exempt from certain regulatory requirements. Investigators may not independently determine that their research is exempt; an official IRB determination is required.

Expedited Review

Expedited Review is a review procedure used for certain categories of research involving no more than minimal risk and for minor changes to previously approved research. Expedited review is conducted by the IRB Chair or designated experienced reviewer(s) rather than by the convened IRB.

Full Board Review

Full Board Review refers to the review of research by a convened meeting of the IRB at which a quorum is present. Research that presents greater than minimal risk or otherwise does not qualify for exempt or expedited review generally requires full board review.

V. MANDATORY TRAINING

Human Research Protection Training

Clark Atlanta University is committed to ensuring that all individuals involved in human subjects research possess the knowledge and skills necessary to protect the rights, welfare, and privacy of research participants. Accordingly, the University requires human research protections training for investigators, research personnel, study sponsors, Institutional Review Board (IRB) members, and IRB administrative staff who are engaged in or support human subjects research.

All individuals subject to this requirement must complete the appropriate training before participating in human subjects research activities or IRB review processes and must maintain current certification as required by University policy.

Clark Atlanta University utilizes the Collaborative Institutional Training Initiative (CITI) Program as its primary source of online human research protections training. Additional training requirements and renewal expectations are described in the University's Mandatory Training policy and related IRB guidance documents.

Completion of required training may be verified by the IRB prior to the review, approval, or continuation of a research project. Failure to maintain current training certification may result in delays in IRB approval or suspension of research-related activities until training requirements have been satisfied.

VI. GENERAL APPLICATION PROCEDURES

All research involving human participants must be submitted to the Institutional Review Board (IRB) for review and determination prior to the initiation of any research activities. Investigators are responsible for ensuring that all application materials are complete and submitted in accordance with IRB requirements and established deadlines.

Submission Requirements

Investigators must submit a complete IRB application package, which may include, as applicable:

- IRB Application Form;
- Informed Consent Form(s);
- Recruitment materials (e.g., advertisements, flyers, emails, social media postings);
- Data collection instruments (e.g., surveys, questionnaires, interview guides, focus group protocols);

- Letters of cooperation or site authorization;
- Research protocol or study description;
- Evidence of required CITI Human Subjects Protection Training;
- Grant proposals or funding documentation, if applicable; and
- Any additional materials requested by the IRB.

Incomplete applications may be returned to the investigator and will not be reviewed until all required documents have been received.

Submission Process Through September 30, 2026

Until September 30, 2026, investigators must submit all IRB application materials electronically to the IRB Office at:

irb@cau.edu

Applications should be submitted as a single electronic package whenever possible and must be received by the applicable submission deadline for consideration at the next scheduled IRB review meeting.

Cayuse Human Ethics Submission Process Beginning October 1, 2026

Effective October 1, 2026, all IRB applications, amendments, progress reports, renewals, and study closure submissions must be submitted through Cayuse Human Ethics.

Cayuse Human Ethics is Clark Atlanta University's electronic research compliance system used to manage the submission, review, approval, and oversight of research involving human participants. The system provides a centralized platform through which investigators can prepare and submit IRB applications, track the status of submissions, respond to IRB requests, and maintain required study documentation throughout the life of a research project.

Through Cayuse Human Ethics, investigators can:

- Submit new IRB applications;
- Request amendments or modifications to approved studies;
- Submit continuing review, progress, and renewal reports;
- Submit study closure or termination reports;
- Upload and maintain research-related documents;
- Track the status of IRB submissions and approvals; and
- Communicate electronically with the IRB throughout the review process.

By automating and centralizing research compliance activities, Cayuse Human Ethics helps streamline IRB administration, improve recordkeeping, and support compliance with institutional, sponsor, and federal requirements governing human subjects research.

Prior to applying in Cayuse Human Ethics, investigators must ensure that all required human subjects research training has been completed and that they have appropriate system access.

Student Access to Cayuse Human Ethics

For undergraduate, graduate, master's, and doctoral students, the first step in using Cayuse Human Ethics is to complete and submit a Cayuse Human Ethics Request for Access Form. Access must be granted before a student can create or submit an IRB application within the system.

Students are encouraged to obtain access early in the research planning process to avoid delays in submission and review.

Faculty Advisor and Sponsor Review

Student applications must be reviewed and approved by the student's faculty advisor or designated faculty sponsor prior to IRB submission. The faculty advisor is responsible for providing oversight of the proposed research and ensuring that the submission is complete and scientifically and ethically appropriate for review.

IRB Review

Upon receipt, the IRB Office will conduct an administrative review to determine whether the submission is complete and whether additional materials are required. Complete applications will be assigned to the appropriate review category (Exempt, Expedited, or Full Board Review) and processed according to IRB procedures.

Investigators may not begin participant recruitment, informed consent activities, data collection, or any other research-related activities involving human participants until they have received the appropriate written determination or approval from the IRB.

VII. THE REVIEW PROCESS

IRB Review Procedures and Categories of Review

All research involving human participants conducted under the auspices of Clark Atlanta University (CAU) must be submitted to the Institutional Review Board (IRB) for review and determination prior to the initiation of any research activities. The IRB is responsible for ensuring that research is conducted in accordance with applicable federal regulations, ethical principles, and University policies designed to protect the rights, welfare, privacy, and safety of research participants.

The IRB reviews proposed research by evaluating the risks and potential benefits of participation, the adequacy of participant protections, and the appropriateness of the informed consent process. The Board seeks to ensure that risks to participants are minimized, are

reasonable in relation to anticipated benefits, and are clearly communicated to prospective participants.

As part of its review, the IRB may require investigators to revise study procedures, recruitment materials, consent documents, data collection methods, or other aspects of the research protocol. Investigators are responsible for responding to all requested modifications before final approval can be granted. Depending on the nature and complexity of the study, multiple rounds of review may be necessary.

No research activities may begin until the investigator has received written IRB approval or a formal written determination of exemption. This requirement includes, but is not limited to:

- Participant recruitment;
- Advertising or distribution of recruitment materials;
- Screening activities;
- Obtaining informed consent or assent;
- Collection of data or biospecimens; and
- Any other research-related interaction with participants or identifiable data.

All IRB determinations and decisions are communicated to investigators in writing.

Categories of IRB Review

Federal regulations provide several categories of IRB review based on the level of risk involved and the nature of the research activities. The appropriate review category is determined solely by the IRB; investigators may request a review category but may not make the final determination themselves.

The primary categories of review are:

1. Exempt Review

Certain categories of human subjects research may qualify for exemption from some federal regulatory requirements. Although exempt research is not subject to ongoing IRB review requirements, it is not exempt from IRB review and determination.

Investigators may not self-determine that a study is exempt. All research believed to qualify for exempt review must be submitted to the IRB, which will determine whether the project meets the applicable exemption criteria.

To request an exemption determination, investigators must submit a complete IRB application and all supporting materials. The IRB or its designee will review the submission and issue a written determination regarding the study's status.

Examples of research that may qualify for exempt review include:

- Certain educational research conducted in established educational settings;
- Certain survey, interview, or observational studies involving minimal risk;
- Research involving the analysis of publicly available information or data;
- Certain public benefit or service program evaluations; and
- Certain taste testing and food quality evaluation studies.

The IRB reserves the right to require additional oversight or review of research that may otherwise appear to qualify for exemption when warranted by the characteristics of the study, participant population, or potential risks involved.

2. **Expedited Review**

Research that presents no more than minimal risk to participants and falls within categories established by federal regulations may qualify for expedited review.

Expedited review is conducted by the IRB Chair or by one or more experienced reviewers designated by the Chair rather than by the convened IRB. This review process allows eligible studies to be reviewed more efficiently while maintaining the same ethical and regulatory standards required for all human subjects research.

Examples of research that may qualify for expedited review include:
- Collection of data through surveys, interviews, focus groups, or behavioral assessments that do not qualify for exemption;
- Collection of biological specimens through noninvasive procedures;
- Research involving existing records, data, documents, or specimens collected for non-research purposes;
- Collection of data from audio, video, digital, or image recordings for research purposes;
- Research involving individual or group behavior, cognition, communication, cultural beliefs, or social practices; and
- Minor modifications to previously approved research.

Expedited reviewers may:
- Approve research;
- Require modifications necessary for approval; or
- Refer the study to the convened IRB for further review.

Expedited reviewers may not disapprove research. Any protocol that raises significant concerns or exceeds expedited review criteria will be referred for convened IRB review.

3. **Full Board (Convened) Review**

Research that involves greater than minimal risk, vulnerable participant populations requiring additional protections, or activities that do not qualify for exempt or expedited review must undergo review by the convened IRB.

Full Board Review occurs at a convened meeting of the IRB where a quorum of voting members is present. The Board evaluates the scientific and ethical aspects of the proposed research to determine whether the criteria for approval have been satisfied.

Research commonly requiring Full Board Review includes:

- Studies involving more than minimal risk;
- Research involving sensitive topics that may expose participants to significant psychological, social, legal, or economic risks;
- Clinical interventions or procedures involving elevated risk;
- Research involving vulnerable populations when additional protections are required; and
- Studies that do not meet federal criteria for exempt or expedited review.

The IRB may:

- Approve the research as submitted;
- Require modifications prior to approval;
- Table the study pending additional information; or
- Disapprove the research.
- Application Requirements

Each new research project requires a separate IRB application, regardless of whether the proposed procedures are similar to those of a previously approved study.

A complete submission should include sufficient information to allow the IRB to evaluate the scientific and ethical conduct of the research. Applications should address the following areas, as applicable:

- Study Overview
- Purpose of the study;
- Research questions, hypotheses, or objectives;
- Background and significance; and
- Summary of relevant literature or prior research.
- Risks and Benefits
- Description of anticipated risks and discomforts;
- Expected benefits to participants and/or society;
- Measures to minimize risks; and
- Procedures for protecting participant safety and welfare.
- Participant Population
- Target participant population;
- Estimated enrollment;
- Estimated time commitment; and
- Plans for data analysis.
- Informed Consent Process
- Procedures for obtaining informed consent and assent;
- Documentation of consent, if applicable;
- Participant rights and withdrawal procedures;
- Confidentiality protections; and
- Investigator contact information.
- Privacy, Confidentiality, and Records Management
- Data security measures;
- Methods for maintaining confidentiality;
- Who will have access to study records;

- Inclusion and exclusion criteria;
- Vulnerable populations, if applicable; and
- Recruitment methods and materials
- Research Procedures
- Detailed description of study activities;
- Data collection methods;
- Research instruments and measures;
- Record retention period; and
- Procedures for secure storage and eventual destruction of records, if applicable.
- Protocol Modifications

Any changes to approved research must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate an immediate hazard to participants.

Proposed modifications may include changes to:

- Research procedures;
- Participant populations;
- Recruitment methods;
- Consent documents;
- Study personnel; or
- Data collection instruments.

The IRB will determine the appropriate level of review for proposed modifications.

Continuing Responsibility of Investigators

IRB approval is an ongoing process rather than a one-time event. Investigators are responsible for maintaining compliance with all approved procedures and reporting requirements throughout the life of the study, including:

- Submission of progress reports;
- Submission of amendments and modifications;
- Reporting adverse events and unanticipated problems;
- Submission of renewal applications when required; and
- Submission of a study closure or termination report at the conclusion of the research.

Failure to comply with IRB requirements may result in suspension or termination of IRB approval and other institutional actions as appropriate.

VIII. INFORMED CONSENT

Respect for persons requires that individuals be given the opportunity to make an informed and voluntary decision about whether to participate in research. Except where waived or altered by the IRB in accordance with applicable regulations, investigators must obtain and document

informed consent from each prospective participant before any research procedures are initiated.

When a prospective participant lacks the legal capacity to provide informed consent, consent must be obtained from a parent, legally authorized representative, or guardian, as permitted by law and institutional policy.

For research involving children who are capable of providing meaningful agreement, investigators must obtain the child's assent in addition to obtaining parental or guardian permission. Generally, assent should be obtained from children seven (7) years of age and older unless the IRB determines that assent is not required or is not feasible due to the age, maturity, psychological state, or health status of the child. Assent documents should be written in language appropriate to the age, reading level, and comprehension of the child.

All informed consent and assent documents must be reviewed and approved by the IRB before use in any research activity.

A copy of the signed consent form must be provided to the participant or the participant's legally authorized representative, and the investigator must retain the original signed document in accordance with applicable record retention requirements.

Required Elements of Informed Consent

Informed consent documents and consent discussions must be presented in language that is clear, understandable, and appropriate for the intended participant population. Technical, legal, and scientific terminology should be minimized whenever possible.

At a minimum, participants must be informed of the following:

- That the activity is research.
- The purpose of the research.
- The expected duration of participation.
- The procedures that will be followed during the study.
- Any reasonably foreseeable risks, discomforts, or inconveniences associated with participation.
- Any benefits that may reasonably be expected for participants or for society.
- Appropriate alternative procedures or courses of treatment, if applicable.
- The extent to which confidentiality and privacy will be maintained.
- For research involving more than minimal risk, whether compensation and/or medical treatment will be available in the event of a research-related injury.
- Whom to contact for questions regarding:
- The research study;
- Participant rights; and
- Research-related injuries or concerns.

- That participation is voluntary and that participants may refuse to participate or withdraw at any time without penalty, loss of benefits, or adverse consequences to which they are otherwise entitled.
- How research records and data will be managed, including:
- The length of time records will be retained;
- Who will have access to the records;
- How the records will be stored and protected; and
- Whether and when records or data will be destroyed.

The IRB may require additional information to be included in the consent process when necessary to protect participants or to satisfy regulatory requirements.

Methods of Obtaining Informed Consent

Written Consent

The standard method of obtaining consent is through a written informed consent document that contains all required elements of consent and is signed and dated by the participant or the participant's legally authorized representative.

Oral Consent with Documentation

In certain circumstances, consent information may be presented orally to participants. When oral consent procedures are used, the participant or legally authorized representative must sign documentation confirming that the study has been explained, that questions have been answered, and that participation is voluntary.

When oral consent is used, a witness must be present during the consent discussion, and a written summary of the information presented must be submitted to and approved by the IRB prior to use.

Waiver or Alteration of Informed Consent

The IRB recognizes that some research designs may not permit the use of standard written consent procedures or may require an alteration of certain consent elements. In such cases, investigators may request a waiver or alteration of informed consent.

Any waiver or alteration must be reviewed and approved by the IRB before implementation. Investigators may not independently modify consent requirements.

The IRB may approve a waiver or alteration of informed consent only when all applicable regulatory criteria are satisfied.

To qualify for a waiver or alteration of consent, the investigator must demonstrate that:

- The research involves no more than minimal risk to participants.
- The waiver or alteration will not adversely affect the rights or welfare of participants.
- The research could not practicably be carried out without the requested waiver or alteration.
- Whenever appropriate, participants will be provided with additional pertinent information after participation.

The IRB will carefully evaluate requests for waivers or alterations to ensure that participant autonomy and welfare remain adequately protected.

Waiver of Documentation of Consent

In certain minimal-risk studies, the IRB may approve a waiver of the requirement for a signed consent form when permitted under applicable regulations. A waiver of documentation does not eliminate the requirement to provide participants with relevant information about the study unless specifically approved by the IRB.

Investigators requesting a waiver of documentation must provide sufficient justification for the request and describe how participants will be informed about the research.

Assent and Parental Permission for Research Involving Children

When research involves children, the IRB will determine whether parental permission, child assent, or both are required.

Unless waived by the IRB, investigators should obtain:

- Permission from a parent or legal guardian; and
- Assent from children capable of providing meaningful agreement.

Assent materials should be written in age-appropriate language and should describe the study in a manner that can be understood by the child participant. The IRB may require different assent procedures depending on the age, maturity level, and circumstances of the participant population.

Passive ("Opt-Out") Consent

Clark Atlanta University does not recognize passive consent, sometimes referred to as "opt-out consent," as an acceptable consent procedure for human subjects research.

Consent may not be presumed based on a participant's or parent's failure to respond or decline participation. Investigators seeking to conduct research without obtaining affirmative consent must request a waiver or alteration of consent from the IRB and demonstrate that all applicable regulatory criteria have been met.

IRB Review of the Consent Process

The IRB reviews both the consent document and the process by which consent will be obtained. The Board evaluates whether:

- Information is presented in understandable language;
- Risks and benefits are accurately described;
- Participation is voluntary;
- Adequate protections are provided for privacy and confidentiality;
- Additional safeguards are included when vulnerable populations are involved; and
- The consent process allows prospective participants sufficient opportunity to consider participation and ask questions.

The informed consent process is an ongoing conversation between the investigator and participant and should continue throughout the conduct of the research whenever new information becomes available that may affect a participant's willingness to continue participation.

X RESPONSIBILITIES OF INVESTIGATORS

Investigators are responsible for conducting research involving human participants in accordance with applicable federal regulations, ethical principles, University policies, and the conditions of IRB approval. The Principal Investigator (PI) bears ultimate responsibility for ensuring the protection of research participants and the integrity of the research process.

Investigators are expected to:

Understand and Comply with IRB Requirements

Investigators must familiarize themselves with the policies, procedures, and requirements of the Clark Atlanta University Institutional Review Board (IRB) and seek guidance from the IRB whenever questions arise regarding proposed research activities or compliance obligations.

Obtain IRB Approval Prior to Beginning Research

Investigators must submit a complete and accurate IRB application for each research project involving human participants and obtain the appropriate IRB determination or approval before initiating any research activities. No participant recruitment, informed consent, data collection, or other research-related activities may begin until written IRB approval or determination has been received.

Conduct Research in Accordance with the Approved Protocol

Investigators are responsible for conducting research exactly as approved by the IRB. Any proposed modifications to the research protocol, consent materials, recruitment methods, study

personnel, or research procedures must be submitted to and approved by the IRB prior to implementation, unless an immediate change is necessary to eliminate an apparent hazard to participants.

Protect the Rights, Welfare, Privacy, and Confidentiality of Participants

Investigators must implement appropriate safeguards to protect participant privacy and maintain the confidentiality and security of research records and data throughout the study. Access to identifiable research information should be limited to authorized personnel with a legitimate need to know.

Report Adverse Events and Unanticipated Problems

Investigators must promptly notify the IRB of any adverse event, unanticipated problem, protocol deviation, noncompliance, or other occurrence that may affect the rights, welfare, or safety of research participants. When appropriate, the investigator must also notify relevant University officials, sponsors, and regulatory authorities.

Submit Required Progress Reports

For ongoing studies, investigators must submit progress reports to the IRB every six (6) months, or at such intervals as required by the IRB. Progress reports provide information regarding study status, participant enrollment, adverse events, protocol deviations, and other matters relevant to the continued oversight of the research.

Complete Required Human Subjects Research Training

Investigators and research personnel must complete all required human subjects protection training and maintain current certification throughout the conduct of the study. Additional training may be required for certain categories of research, including research involving vulnerable populations, international research, internet-based research, or other specialized research activities.

Maintain Continuous IRB Approval

If research activities will continue beyond the approved study period, investigators must submit the required renewal or continuing review materials before the study's expiration date. Research activities may not continue beyond the expiration of IRB approval unless continuing approval has been granted.

Maintain Accurate Research Records

Investigators are responsible for maintaining complete, accurate, and secure research records, including consent documents, study data, correspondence, and regulatory documentation. Records must be retained for the period required by applicable federal regulations, sponsor

requirements, and University policies, generally for a minimum of three (3) years after study completion, unless a longer retention period applies.

Ensure Appropriate Oversight of Research Personnel

Principal Investigators are responsible for ensuring that all members of the research team are appropriately qualified, adequately trained, and aware of their responsibilities related to participant protections, confidentiality, and regulatory compliance.

Submit a Study Closure Report

Upon completion, termination, or discontinuation of a study, investigators must submit a Termination of Approval (Study Closure) Report to the IRB and obtain confirmation that the study has been officially closed.

Cooperate with IRB Oversight Activities

Investigators must cooperate with all IRB oversight activities, including requests for information, audits, monitoring activities, and reviews of research records. Failure to comply with IRB requirements may result in suspension or termination of IRB approval and other institutional actions as appropriate.

By accepting IRB approval, investigators acknowledge their responsibility to uphold the highest standards of ethical conduct and to ensure the protection of the rights, welfare, dignity, and privacy of all research participants.

XI. RECORDS RETENTION AND RESEARCH DOCUMENTATION

Federal regulations, sponsor requirements, and professional standards require investigators to retain research records not only during the conduct of a study, but also for a specified period after the research has been completed. Because multiple regulatory and contractual requirements may apply to a single study, investigators are responsible for maintaining research records for the longest applicable retention period.

Failure to maintain adequate research records may result in regulatory findings, audit deficiencies, loss of funding, or other institutional and sponsor actions.

General Record Retention Requirements

Investigators must retain all research records in a secure manner that protects participant privacy, confidentiality, and data integrity. Research records must remain accessible for monitoring, auditing, inspection, or review by authorized institutional officials, sponsors, and regulatory agencies.

The required retention period will depend on the nature of the research and the regulations governing the study.

Applicable Record Retention Requirements

Human Subjects Research Regulations

- Research records related to studies governed by federal human subjects protection regulations must be retained for at least three (3) years after completion of the research.

HIPAA Requirements

- Studies that involve the collection, use, or disclosure of protected health information (PHI) may be subject to the Health Insurance Portability and Accountability Act (HIPAA). In such cases, authorization forms and related documentation must generally be retained for at least six (6) years from the date of authorization or as otherwise required by law.

Sponsor and Funding Agency Requirements

- Research funded by federal agencies, private organizations, foundations, or industry sponsors may be subject to additional record retention requirements. Investigators are responsible for reviewing and complying with any retention requirements specified in grant agreements, contracts, cooperative agreements, or sponsor policies.

- In some cases, sponsors may require records to be retained for substantially longer periods, such as ten (10), fifteen (15), or more years following study completion.

Professional and Licensing Requirements

- Certain disciplines, professional organizations, accrediting bodies, or licensing entities may establish additional record retention requirements. Investigators are responsible for ensuring compliance with any applicable professional standards governing their area of research.

Types of Records to Be Maintained

The Principal Investigator is responsible for maintaining complete and accurate records of all IRB-approved research activities. Investigator files should contain documentation sufficient to demonstrate compliance with regulatory, institutional, and sponsor requirements.

At a minimum, investigator records should include:

- Copies of all IRB applications and supporting materials submitted for review;
- Approved research protocols and study procedures;
- Approved informed consent, assent, and recruitment materials;
- IRB approval letters and determination notices;
- Copies of responses to IRB requests for modifications or additional information;

- Approved amendments and modification requests;
- Progress reports, continuing review submissions, and renewal materials;
- Adverse event and unanticipated problem reports;
- Study closure or termination reports;
- Correspondence with the IRB and other oversight bodies;
- Sponsor communications related to human subjects protections;
- Training documentation for research personnel, as applicable;
- Monitoring, auditing, inspection, or compliance reports; and
- Research data and study records generated during the conduct of the research.
- Storage of Consent Documents

Original signed consent and assent forms should be maintained in a secure location with appropriate safeguards to protect participant confidentiality. Whenever possible, consent documents should be stored separately from research data and other study records to reduce the risk of unauthorized disclosure of participant identities.

Consent records must remain readily available for review by authorized institutional officials, auditors, sponsors, and regulatory agencies, when required.

Security of Research Records

Investigators must implement appropriate administrative, physical, and technical safeguards to protect research records from unauthorized access, loss, alteration, theft, or destruction. Security measures should be commensurate with the sensitivity of the information being maintained and may include:

- Locked filing cabinets or secured office space for paper records;
- Password-protected computers and databases;
- Encrypted electronic storage systems;
- Restricted access to authorized research personnel; and
- Secure methods for transferring, sharing, or disposing of research data.
- Destruction of Research Records

At the conclusion of the applicable retention period, research records containing confidential or identifiable information should be destroyed in a manner that protects participant privacy and confidentiality, unless a longer retention period is required by law, sponsor agreement, institutional policy, or ongoing research needs.

Investigators who intend to maintain research records indefinitely should document the reason for continued retention and ensure that appropriate safeguards remain in place.

Access to Research Records

IRB records and investigator records may be subject to review, inspection, or audit by:

- Clark Atlanta University officials;
- Research sponsors and funding agencies;
- Federal and state regulatory agencies;
- Accrediting organizations; and
- Other authorized oversight entities.

Investigators are expected to cooperate fully with any authorized review or inspection of research records.

The Principal Investigator bears primary responsibility for ensuring that all research records are complete, accurate, secure, and retained for the required period. When multiple record retention requirements apply, records must be retained for the longest applicable period. Investigators should consult the IRB Office whenever questions arise regarding record retention requirements for a specific study.

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

Appendix A: Regulatory References

A summary of the federal regulations governing human subjects research, including:

- 45 CFR 46 – Protection of Human Subjects (Common Rule)
- Subpart B – Pregnant Women, Human Fetuses, and Neonates
- Subpart C – Prisoners
- Subpart D – Children
- Subpart E – IRB Registration Requirements
- 21 CFR Part 50 – FDA Informed Consent
- 21 CFR Part 56 – FDA Institutional Review Boards
- HIPAA Privacy Rule requirements related to research

Appendix B: IRB Submission Requirements Checklist

A checklist on what investigators must complete prior to submission:

- IRB application
- Research protocol
- Consent forms
- Assent forms
- Recruitment materials

- Surveys/questionnaires
- Interview guides
- Site permission letters
- Data collection instruments
- CITI certificates
- Faculty advisor approval (for students)
- Reliance agreement documentation (if applicable)

Appendix C: Application Types and Review Categories

Quick-reference guide describing:

- Exempt Review
- Expedited Review
- Full Board Review
- Modifications/Amendments
- Continuing Review
- Progress Reports
- Study Closure Reports
- Reliance Agreements

Appendix D: Informed Consent Templates

Current approved templates including:

- Adult Consent Form
- Parent Permission Form
- Child Assent Form
- Online Survey Consent Statement
- Verbal Consent Script
- Recruitment Script
- HIPAA Authorization Form (if applicable)

Appendix E: Investigator Forms

Links or copies of:

- New Study Application
- Amendment Request
- Progress Report Form
- Termination/Closure Report
- Reportable Event Form
- Protocol Deviation Form
- Reliance Agreement Request Form

- Cayuse Human Ethics Access Request Form

Appendix F: Vulnerable Populations Guidance

Special requirements for:

- Children
- Prisoners
- Pregnant women
- Developmentally impaired individuals
- Economically or educationally disadvantaged populations
- International research participants

Appendix G: Cayuse Human Ethics User Guide

Since CAU is transitioning to Cayuse Human Ethics, this should include:

- Overview of Cayuse Human Ethics
- Access procedures
- Student access request process
- Faculty certification process
- Submission workflow
- Amendment procedures
- Progress report submission instructions
- Closure report instructions

Appendix H: Reportable Events and Noncompliance

Definitions and procedures for:

- Adverse Events
- Serious Adverse Events
- Unanticipated Problems
- Protocol Deviations
- Protocol Violations
- Noncompliance
- Serious Noncompliance
- Continuing Noncompliance

- Include reporting timelines.

Appendix I: Records Retention Requirements

A table summarizing:

Record Type	Minimum Retention Period
Human Subjects Research Records	3 years after study completion
HIPAA Authorizations	6 years
Sponsored Research Records	Per sponsor requirements
FDA-Regulated Studies	Per FDA requirements
Student Research	Per University policy

Appendix J: IRM Membership Roster and Expertise

Rather than listing members by name (which changes frequently), include:

- Required membership categories
- Scientific member requirements
- Nonscientific member requirements
- Community member requirements
- Conflict of interest requirements

- Reference the current roster maintained by the IRB Office.

Appendix K: Continuing Review and Progress Reporting Requirements

Include:

- Six-month progress report requirements
- Renewal procedures
- Study status definitions
- Monitoring requirements
- Study closure requirements
- Appendix L: Reliance Agreements and Single IRB (sIRB)

Include:

- Reliance Agreement definitions
- Investigator responsibilities
- Request procedures
- External IRB review process
- NIH single IRB requirements
- Roles of reviewing and relying institutions

Appendix M: Training Requirements

Summarize required training for:

- Principal Investigators
- Faculty Advisors
- Research Coordinators
- Student Researchers
- IRB Members
- IRB Administrative Staff

Include:

- CITI course requirements
- Refresher timelines
- Specialized training requirements

Appendix N: IRB Contact Information

Maintain separately from policy language so it can be updated easily:

Clark Atlanta University IRB Office

Email: irb@cau.edu
Cayuse Human Ethics website
Office location
Telephone numbers
Business hours

Appendix O: Glossary of Human Subjects Research Terms

A comprehensive alphabetical glossary including:

- Adverse Event
- Assent
- Beneficence
- Confidentiality
- Exempt Research
- Human Subject
- Informed Consent
- Minimal Risk
- Principal Investigator
- Protocol Deviation
- Reliance Agreement
- Research

- Vulnerable Population