Clark Atlanta University
IRB Application

Cover Sheet

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☐ **If Requesting Exempt Status Check Box and Complete Cover Sheet, Part I and Part II**
☐ **If Requesting Non-Exempt Status Check Box and Complete Cover Sheet and Part II**

Please check off or provide details on the following (**if not applicable, please enter N/A**)

Principal Investigator Name: _____ ☐Faculty/Staff ☐Graduate Student

Department _____ Campus Address: _____

Phone: _____ Fax: _____ E-mail: _____

Name of Research Advisor/Committee Chair if Graduate Student: _____

Department: _____ Campus Address: _____ Phone: _____

Project Title: _____

Funding Agency: _____

Objective Estimate of Risk to Subject: ☐ None ☐ Low ☐ Moderate ☐ High

☐ Existing Documents ☐ Existing Specimens Total Number of Participants (Est.) _____

Gender of subjects: ☐ Female ☐ Male ☐ Both Age (Range) _____

Source of Research Subjects:

- ☐ Subject Pool (_____)
- ☐ AUC Students
- ☐ Community
- ☐ Prisons
- ☐ School Teacher/Administrator
- ☐ Other Please Specify _____

Subject Recruitment:

- ☐ Person to Person Contact
- ☐ Telephone Solicitation (Attach a phone scrip)
- ☐ Newspaper Ad (Attach a copy)
- ☐ Posted Notices (Attach a copy)
- ☐ Letter (Attach a copy)
- ☐ Other (Describe)

Compensation Yes ☐ No ☐ (Attach payment schedule with dollar amounts)
Research/Course Credit Yes ☐ No ☐ Deception Credit Yes ☐ No ☐ (Attach debriefing form if yes)

Will Video ☐ or Audio tapes ☐ be used?
If yes, answer the following:
Retained Yes ☐ No ☐
Length of Time Retained _____
Destroy/Erase Yes ☐ No ☐
Other (**explain**)_____
Use specified in consent form? Yes ☐ No ☐
Designate who will use or have access to tapes: _____

Provisions for Confidentiality/Anonymity I

- ☐ Replies Coded
- ☐ Secure Storage
- ☐ Anonymous Response OR
- ☐ Confidential Response

(Cannot be both anonymous & confidential)

Invasive or Sensitive Procedures: Yes ☐ No ☐

- ☐ Blood Samples
- ☐ Physical Measurements (electrodes, etc.)
- ☐ Other (Specify)_____
- ☐ Urine Samples
- ☐ Stress Exercise
- ☐ Review of Medical/Pysch. Records
- ☐ rDNA

Sensitive Subject Matter: Yes ☐ No ☐

- ☐ Alcohol, Drugs
- ☐ Depression/Suicide
- ☐ Learning Disability
- ☐ Abortion, AIDS/HIV, Sex
- ☐ Psychological Inventory
- ☐ Other **please specify** _____

Location Where Signed Consent Forms Will be Filed:_____
(Consent forms must be kept on file for three (3) years after the successful close-out of the project). ***(It is best to keep the forms in a campus office in a locked file cabinet.)***

Do you have any relationship with any or all of the subjects, other than your investigator role? Yes ☐ No ☐
If "Yes," you must explain in the source of subjects section; explain how you will avoid any type of coercion.

Do not write in this area.
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PART I: CERTIFICATION OF EXEMPTION

Researcher and Faculty Sponsor (for student researchers)

Department _____ **Phone #** _____

Project Title _____

This is a Request for Exemption from the full review by the Institutional Review Board (IRB). (Check and initial all applicable conditions, sign below and provide protocol of research design.)

I certify that the project identified above, which involves the use of human subjects, qualifies as exempt from full IRB review and approval because it meets the criteria (ion) specified below:*

_____ Initials	(1) The research will be conducted in established or commonly established settings, involving normal education practices. For example: (a) Research on regular and special educational instructional strategies; (b) Research on effectiveness of instructional techniques, curricula or classroom management techniques.
_____ Initials	(2) The research involves use of education tests (☐cognitive, ☐diagnostic, ☐aptitude, ☐achievement), and the subject cannot be identified directly or through identifiers with the information.
_____ Initials	(3) The research involves survey or interview procedures, in which: (a) Subjects cannot be identified directly or through identifiers with the information; (b) Subject's responses, if known, will not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; (c) The research does not deal with sensitive aspects of subject's own behavior (illegal conduct, drug use, sexual behavior or alcohol use);
_____ Initials	(4) The research involves the observation of public behavior, in which: (a) The subjects cannot be identified directly or through identifiers; (b) The observations recorded about an individual could not put the subject at risk of criminal or civil liability or be damaging to the subjects financial standing or employability; (c) The research does not deal with sensitive aspects of the subject's behavior (illegal conduct, drug use, sexual behavior or use of alcohol). (d) The research involves survey or interview procedures with elected or appointed public officials, or candidates for public office.
_____ Initials	(5) The research involves collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, or which: (a) The sources are publicly available; or (b) The information is recorded such that the subject cannot be identified directly or indirectly through identifiers

I certify that the project will not be changed to increase the risk or exceed the exempt condition(s) without filing an additional or application for approval by the IRB.

_____ _____

Signature: Researcher Date Signature: Faculty Sponsor (if researcher is a student) Date

_____

Signature: Department Chair Date

Do not write below this line.

Approval: _____ Approval Date: _____

Begin Date _____ Expiration Date: _____

IRB Approval Number: _____ Agency Number: _____

Pending: _____ IRB Review Date: _____

Earliest Resubmittal Date: _____ Internal Control No. _____

Disapproved: _____ Disapproved Date: _____

Explanation: _____

_____

NOTE: Any research conducted before the approval date or after the end of data collection date shown above is not covered by IRB approval, and cannot be retroactively approved. All approved protocols must be evaluated on a yearly basis. Submit your protocol in time to be approved before the anniversary of your expiration date.

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PART II: PROTOCOL

I have read the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains. In light of this Declaration, I present for the Board's consideration the following information, which will be explained to the subject about the proposed research:

Principal Investigator Name: _____ ☐Faculty/Staff ☐Graduate Student
CAU Internal Control No: _____

Department _____ Campus Address: _____

Phone: _____ Fax: _____ E-mail: _____

Name of Research Advisor/Committee Chair if Graduate Student: _____
Department: _____ Campus Address: _____ Phone: _____
Project Title: _____
Funding Agency: _____
Funding Agency Mailing Address: _____
Funding Agency Contact Name: _____ Funding Agency Telephone: _____
Funding Agency Contact Fax: _____ Funding Agency E-mail: _____

1. SELECTION AND SOURCES OF SUBJECTS

2. EXPERIMENTAL PROCEDURE

3. RISKS AND BENEFITS TO SUBJECTS

4. SIGNATURE ASSURANCE:

Principal Investigator/Graduate Student Assurance Statement:

I understand Clark Atlanta University's policy concerning research involving human subjects and I agree:

1. To accept responsibility for the scientific and ethical conduct of this research study;
2. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form:
3. To immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;
4. To complete, on request by the IRB, the Continuation/Final Review Forms.

SIGNATURE: _____ DATE: _____

TYPED NAME: _____

=Faculty/Research Advisor's Assurance Statement:

I certify that I have read and agree with this proposal, that the PI has received adequate training to perform this research, and will receive adequate supervision while performing this research.

SIGNATURE: _____ DATE: _____

TYPED NAME: _____

=If the principal investigator is completing this project to meet the requirements of a Clark Atlanta University academic program, both the student's faculty/research advisor and the departmental head should sign the Signature Assurance Sheet.

***Department Head**

This is to certify that I have reviewed this research protocol and agree that the research activity is within the mission of the Department and appropriate for the responsibilities and assigned duties of the principal investigator.

SIGNATURE: _____ DATE: _____

TYPED NAME:_____

***If the principal investigator is also the Head of the department, the Dean of the School or equivalent should sign the Signature Assurance Sheet.**