Institutional Review Board Protocol Review Application

Print Form

Reset Form

Use this form to request review & approval for a new research project involving human subjects *before* it is initiated. Applications are to be typed. Please *electronically* submit the **signed**, **completed** application including all four (4) application pages, checklist, and associated necessary attachments and documentation (i.e. letter of permission, questionnaires, interview schedules & questions, tests, sample consent forms, etc.) to the Institutional Review Board via the **SUBMIT** button, which will appear at the bottom of the application after no errors are found on the form via the **CHECK FORM** button. Other methods of submission will be accepted, but may take longer to process. Once a **completed** application is received, the review should take between 5 to 7 business days. If you have questions, please contact the board at *IRB@savannahstate.edu* .

I. PRINCIPAL INVESTIGATOR & BASIC PROJECT INFORMATION:

Name: Title:

Applicant Status & Affiliation: ◯ 1 - Faculty ◯ 2 - Student ◯ 3 - External

Department:

Major:

Institution:

Address: *Street or PO Box* *City* Alabama *State* *Zip Code*

Email Address(es):

Phone Numbers: *Office* *Cell* *Home*

Project Title:

Co-Investigator *(if applicable)*:

Faculty Mentor *(if applicable)*:

Faculty Mentor Email Address:

Grant Information *(if applicable)*: ◯ Planned ◯ Pending ◯ Funded

Supporting Agency:

Proposed Project Period: *Begin Date* to *End Date*

II. THE HUMAN SUBJECTS INVOLVED IN THIS RESEARCH:

1. Who are the subjects? (Age, sex, range, etc.)

2. How many subjects are involved?

3. How will you recruit or select the subjects?

4. How long will each subject be involved in the project? (Number of occasions & duration of time spent with subjects)

Number of Occasions Duration

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YES	NO	Please mark the appropriate column and provide details as necessary.
○	○	Will you advertise for subjects or post a notice for volunteers? If **YES**, attach a copy of the advertisement notice in the "Attachments" section of this application.
○	○	Will you pay your subjects? If **YES**, indicate how much & describe how you will pay the subjects whom withdraw before the project ends.
○	○	Are your subjects Savannah State University students?
○	○	Are your subjects students at an institution other than Savannah State University? If **YES**, indicate the institution(s) in which they are enrolled and attach an approval letter from the entity's equivalent of an IRB in the "Attachments" section is the application.
○	○	Do you ensure appropriate representation of women and minorities in your project?

YES	NO	Do your subjects include any of the following:
○	○	Infants and/or children younger than seven (7) years of age.
○	○	Institutionalized mentally impaired persons.
○	○	Students enrolled in your own classes.
○	○	Prisoners.
○	○	Other special populations. Please indicate:

III. THE RESEARCH PROCEDURE/PROTOCOL:

1. Describe in simple & concise terms what you will be doing to or with your subjects. Please include a lay summary of the project provide information included specific aims, background and signification, research design and method, etc. Please use a separate sheet and attach it in the "Attachments" section of this application, if necessary.

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YES	NO	Please mark the appropriate column and provide details as necessary.
◯	◯	Will you obtain information about your subjects' private behavior, economic status, sexual preferences, religious beliefs, or other matters which, if made public, might impair the subjects' self-esteem or reputation? If **YES**, describe how you will ensure that all of your data is kept secure and confidential.
◯	◯	Does your study involve deception of your subjects?* If **YES**, describe how you will debrief your subjects.
◯	◯	In cases of deceptive research*, are you willing to allow subjects to withdraw after debriefing and remove from your data all records of your subjects' involvement?
◯	◯	Will you be carrying out procedures or asking questions that might disturb your subjects emotionally or produce stress or anxiety? If **YES**, describe your plans for counseling and treating subjects.
◯	◯	Will you use a questionnaire, survey, or structured interview as part of your procedure? if **YES**, attach a copy of the questionnaire(s), survey and/or interview in the "Attachments" section of this application.

* The Savannah State University Institutional Review Board does not approve of deceit in research. It will review and *may* approve applications that involve limited deception with the proviso that subjects receive a comprehensive debriefing.

2. Describe the *final disposition* of your data (i.e. notes, drafts, lists of subjects, photographic records, tapes, etc.) after you have completed and presented your research.

IV. REQUIREMENTS FOR INFORMED CONSENT:

The Code of Federal Regulations governing research on human subjects (45 CFR 56.116) states that, "...no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in the language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

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Unless the IRB issues a specific waiver, the written informed consent of subjects is required for ALL research project except those projects that qualify for certification of exempt status. Written informed consent of subjects may also be required in some projects that qualify for certification or exempt status.

Informed Consent for Minors

When research subjects will be under the age of eighteen (18), the written consent of one or both parents is required for projects for expedited or full board review, and for some projects that otherwise would qualify for exempt review. Assent of the child may be required if the child is capable of making an informed decision whether or not to participate.

Storage of Informed Consent Forms

Signed copies of informed consent forms must be maintained by the principal investigator and be stored in a secure manner. Furthermore, these files must be available for continuous review by the IRB. If the investigator leaves Savannah State University before the end of the designated period for storage of forms, the files must be submitted to the Office of Sponsored Research Administration for final review.

Consent Checklist

YES	NO	Please mark the appropriate column.
○	○	Is it clear to the subjects that their participation is fully voluntary?
○	○	Is it clear to the subjects that they may withdraw at any time?
○	○	Is it clear to the subjects that they may refuse to answer any specific question they may be asked?
○	○	I will obtain written informed consent & and I have attached a copy to be reviewed.
○	○	I understand if minors (individuals under the age of 18) are involved, parental consent will be required and included in the attached consent form.

V. ATTACHMENTS

1. Informed Consent Form

Add Attachment | Delete Attachment | View Attachment

2. Testing Instrument

Add Attachment | Delete Attachment | View Attachment

3. CITI Program Completion Report

Add Attachment | Delete Attachment | View Attachment

4. Collaborating Institutional Approval

Add Attachment | Delete Attachment | View Attachment

5. Recruitment Announcement/Advertisement

	Add Attachment	Delete Attachment	View Attachment

6. Other Attachments

	Add Attachment	Delete Attachment	View Attachment
	Add Attachment	Delete Attachment	View Attachment
	Add Attachment	Delete Attachment	View Attachment
	Add Attachment	Delete Attachment	View Attachment
	Add Attachment	Delete Attachment	View Attachment
	Add Attachment	Delete Attachment	View Attachment

VI. CHECKLIST FOR PROTOCOL APPLICATION:

- ☐ All questions have been addressed and/or answered fully.
- ☐ If a cooperating institution is involved, written permission is included in the "Attachments" section.
- ☐ The research design guarantees protection for research subjects' rights.
- ☐ The research design ensures confidentiality of the data collection.
- ☐ The research design ensures anonymity of participants, if appropriate.
- ☐ Each of the elements of informed consent is addressed.
- ☐ The informed consent statement is described in an understandable manner using appropriate terminology the potential subjects can understand.
- ☐ A copy of the informed consent statement is included in the "Attachments" section.
- ☐ A copy of the testing instrument (survey, questionnaire, interview questions, etc.) is included in the "Attachments" section.
- ☐ A copy of the Principal Investigator's CITI Program completion certificate/report is included in the "Attachments" section.
- ☐ A copy of the recruitment announcement or advertisement is included in the "Attachments" section, if applicable.

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VII. PRINCIPAL INVESTIGATOR CERTIFICATION OF APPLICATION:

Principal Investigator's Certification:
I certify that the information, statements, and all attachments provided in this request for IRB approval are accurate and complete, and if I receive IRB approval for this project, I fully understand my obligations to the human research subjects who will be used in my project. I agree to use only the protocols reviewed and approved by the IRB for my research. I also agree to submit the informed consent files for review every six months during the progress of the project. In the case of an occurrence of any unusual incidence or risk to the human subjects, I agree to inform the IRB immediately.

Principal Investigator's Name (Typed)

Principal Investigator's Signature

Date

Check Form

If "ERROR" is present, click to see the errors on the application.
If "COMPLETE" is present, you are ready for submission.

COMPLETE