CGTC IRB Home Page

Introduction

PROTECTING HUMAN SUBJECTS THROUGH INSTITUTIONAL REVIEW BOARDS

All institutions applying for federal funds must have Institutional Review Boards (IRBs) with clearly defined policies and procedures to ensure that grant-funded research activities protect human subjects. Principal investigators and/or project directors upon being awarded federal funds and whose activities involve research and human subjects must complete required forms and submit the project for IRB review and approval before any research on human subjects is to commence.

Institutional Review Board (IRB)

The Institutional Review Board (IRB) is a committee established to protect the rights and welfare of human research subjects involved in research activities.

CGTC IRB

The CGTC IRB assures both in advance and by periodic review that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. To accomplish this purpose, the IRB uses a group process to review research proposals and related materials (e.g. informed consent documents) to ensure protection of the rights and welfare of human subjects of research. The IRB follows FDA regulations and is authorized to approve, require modifications in (to secure approval), or disapprove research.

Contact Us:

Deborah Josey Burks, Ph.D., Vice President for Institutional Effectiveness, 3300 Macon Tech Drive, Macon, GA 31206; 478-757-3424; dburks@centralgatech.edu.

RESEARCH WITH HUMAN SUBJECTS

All research and experimental activities in which human beings participate as subjects must be approved by the Institutional Review Board (IRB) of Central Georgia Technical College. Approval must be obtained prior to involving subjects and prior to distributing any information or written materials to subjects that would require approval. This applies to all research sponsored by external funding agencies, to unsponsored research, and to continuing education and instructional projects and activities conducted by college students, staff, and faculty. This applies to all research conducted under college auspices or as a part of an investigator's professional activities as an employee of the college. It does not apply to research entirely unrelated to the college or to an employee's professional activities (e.g., conducting research for an external agency) unrelated to his or her college responsibilities, though employees may choose to submit such research for IRB review.

CGTC's human subjects procedure was developed in accordance with the Federal Policy for the Protection of Human Subjects, published in the Federal Register as a final common rule for participating federal agencies. The policy is designed to safeguard the rights and wellbeing of human subjects, and to ensure that the principles of respect for persons, beneficence, and justice are met by proposed activities involving human subjects.

See also: IRB Administrative Procedures

Getting Started:

As a principal investigator or project director, it is critical that you share our concern for human subjects. We know that you want your protocol reviewed in a timely fashion. To ensure this occurs, please review your protocol for completeness prior to submission.

Completed documents entail all required forms being complete and correctly filled out. If surveys are involved, the committee must review the actual instrument(s) you are going to use (current, up-to-date copies must be included with your submission); the process of obtaining informed consent must be fully and clearly described and you must ensure that the subjects are aware that this is research, the purpose of the research, clearly state any risk to participants, any benefits, any cost(s), etc.; and the curriculum vitae of the Principal Investigator/Project Director (the individual orchestrating/conducting the survey or research)

Complete and clearly written applications are reviewed more quickly. Every time a question is asked or a revision made, the process will be delayed. If you have questions, please consult with the IRB Chair (Office of Institutional Effectiveness, Vice President) before making your submission.

IRBs must adhere to federal regulations found in the Code of Federal Regulations (Title 45 Part 46, Protection of Human Subjects). Learning about these regulations begins with some basic definitions listed below.

Is my project considered research? Does my project involve human subjects? Does my project involve only minimal risk? Why is risk level important? According to federal regulations, principal investigators have an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Informed consent helps assure that prospective human subjects will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. Consent forms tell subjects they are free to withdraw from participation at any time, as well as convey other critical information; see informed consent guidelines listed below.

For More Assistance

The Office for Human Research Protections of the Department of Health and Human Services provides a **decision tree** **https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html** to help you decide: Does my research activity have to be reviewed

by the IRB? Can the review go through the expedited process? Can informed consent be waived?

Definitions

Published in the Code of Federal Regulations, Title 45

Public Welfare Department of Health and Human Services

Part 46 Protection of Human Subjects

Research: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Human Subject: "Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Informed Consent Guidelines

The regulations regarding informed consent are complex. Generally speaking, research subjects need to have sufficient information in the project in which they are being asked to become involved, and should voluntary agree to participate. The information given to the prospective subjects or the representatives needs to be in language they can understand. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardians.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.

2. Short description of methodology and duration of participant involvement.

3. Statement of risks/benefits to the participants.

4. Statement of data confidentiality.

5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators, and also contact information for your IRB (if graduate studies, use your university's IRB contact)

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be deceived, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, after the study is complete, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

__/__/__ **Central Georgia Technical College** _____

Date Submitted **Institutional Review Board** **File Number**

FULL IRB REVIEW PROTOCOL SUMMARY FORM

Title of Research Project

Principal Investigator/Project Director	**Department**	**Phone Extension**	**Email address**
Co-investigator/Student Investigator	**Department**	**Phone Extension**	**Email address**
Co-investigator/Student Investigator	**Department**	**Phone Extension**	**Email address**

Anticipated Funding Source: _____

Projected Duration of Research: _____ **months** **Projected Starting Date:** _____

Other organizations and/or agencies, if any, involved in the study: _____

Please answer the questions below and return this form with:

- A memo that briefly describes the intent of the project
- A completed copy of the Consent Form Checklist
- A copy of the Consent Form that will be provided to the participants
- A copy of any survey instrument to be utilized in the proposed research

I. Project Information:

A. Project Activity Status:

☐ **New Project**
☐ **Periodic Review of Continuing Project**
☐ **Revision to Previously Approved Project**

B. This project involves Central Georgia Technical College students

☐ **Yes** ☐ **No**

C. Human Subjects from the following populations will be involved in this study

☐ **Minors** ☐ **High School Students**
☐ **Mentally Disabled** ☐ **Prisoners**
☐ **Elderly** ☐ **Other**_____
☐ **None of the above**

D. Total number of subjects to be studied:_____

II. Abstract Describing Project and Purpose (Include a description of all experimental methods to be used and design and program activities; what measures or observations will be taken in the study? If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument.)

III. Protocol (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document; How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary)

IV. Precautions (What steps will be taken to insure that each subject's participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?)

V. Confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc.)

VI. Consent (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject)

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

I certify that the protocol and method of obtaining informed consent as approved by the Central Georgia Tech Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

_____ __/__/__ _____ __/__/__

Investigator/Project Director Signature — Co-Investigator/Student Signature (if appropriate)

Signature of IRB Chair:				**Date:** __/__/__
IRB Chair: Check 1 box:	☐ **Approved**	☐ **Approved with Restrictions**	☐ **Tabled**	☐ **Disapproved**

Central Georgia Technical College
Human Subjects Research Project
Consent Form Checklist

N/A	YES	NO	
			1. Is the consent form written in "lay language"?
			2. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
			3. If minors are included in the study, is provision made for obtaining parental consent?
			4. Does the consent form include each of the following basic elements of informed consent?
			a. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject's participation.
			b. A description of the procedures to be followed.
			c. A description of any benefits to the subject or others.
			d. A description of any reasonably foreseeable risks or discomforts.
			e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
			f. Information regarding whom to contact for answers to questions about the research study and the research subject's rights.
			g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.
			h. Appropriate FERPA notice and waivers (if appropriate).

If there was a "NO" response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why is it appropriate as submitted.

Central Georgia Technical College
Institutional Review Board

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.

2. Short description of methodology and duration of participant involvement.

3. Statement of risks/benefits to the participants.

4. Statement of data confidentiality.

5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators, and also contact information for Research University Institutional Review Board if study is part of graduate work as well as the CGTC IRB Chair (Vice President for IE).

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete,** each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

Central Georgia Technical College

SAMPLE **INFORMED CONSENT**
(go to the IE intranet site to obtain the editable forms necessary for submission)

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving ***informed consent.*** (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine _____. In this study, you (your child/ward) will be asked to _____. Your participation should take about _____ minutes.

There are no risks to you (your child/ward).

or

The only risks to you (your child/ward) include _____.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply _____.

Please feel free to contact _____ (names(s), title(s) of principal researchers) at _____ phone) if you have any questions about the study. Or, for other questions, contact the office of Institutional Effectiveness at 478-757-3424).

If the participant is of age (18 years old or older), use:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

_____
Signature of Participant Date

If the participant is not of age, use:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

_____
Signature of Parent/Guardian Date

ASSENT format:

I understand what I must do in this study and I want to take part in the study.

_____
Signature of Child/Ward Date

Attach Consent Form that will be provided to the participants

IRB TRAINING

Federal regulations require IRB committee member training. IRB members can follow the links (below) to complete training at the time of their appointments. IRB members must then submit a copy of the certificate to the IRB Chair indicating they have completed human subjects training.

Other sources of IRB training and information:

Recommended: **Office for Human Research Protections**, http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp Department of Health and Human Services training

National Institute of Health http://ohsr.od.nih.gov/ training and information

National Cancer Institute http://phrp.nihtraining.com/users/login.php training and information

The Belmont Report

The Belmont Report sets forth three basic ethical principles for the conduct of human subject research:

- Respect for persons
  - Respect individual autonomy
  - Protect individuals with reduced autonomy
- Beneficence
  - Maximize benefits and minimize harms
- Justice
  - Equitable distribution of research burdens and benefits

Application of the general ethical principles to the conduct of human subjects' research leads to the following requirements:

Respect for Persons

- Informed consent
- Protecting privacy and maintaining confidentiality
- Additional safeguards for protection of subjects likely to be vulnerable to coercion or undue influence

Beneficence

- IRB assessment of risk/benefit analysis including study design
- Ensure that risks to subjects are minimized
- Risk justified by benefits of the research

Justice

- Ensure that selection of subjects is equitable.

Food and Drug Administration

The Food and Drug Administration (FDA) has a separate set of regulations governing human subjects research (21 CFR Part 56 — IRBs and 21 CFR Part 50 — Informed Consent). The basic requirements for IRBs and for informed consent are congruent between the HHS and FDA regulations.

Differences center on differences in applicability:

- HHS regulations at 45 CFR Part 46 applies to research conducted or supported by HHS.
- FDA regulations apply to clinical investigations of FDA regulated products: drugs, devices, or biologics.

This tutorial will focus on the HHS regulations at 45 CFR Part 46. Institutions conducting research regulated by FDA should contact FDA for detailed guidance.

HHS Regulations

HHS regulations include additional protections for vulnerable populations as subparts of 45 CFR Part 46:

Subpart B - Additional HHS Protections for Pregnant Women, Human Fetuses and Neonates involved in Research.

Subpart C - Additional HHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.

Subpart D - Additional HHS Protections for Children Involved as Subjects in Research.

Definitions

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of the HHS regulations, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject - A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Exempt Research

Certain research is exempt from the requirements of the HHS regulations.

A determination that research is exempt does not imply that investigators have no ethical responsibilities to subjects in such research; it means only that the regulatory requirements related to IRB review, informed consent, and assurance of compliance do not apply to the research.

OHRP recommends that Institutions adopt clear procedures under which the IRB, or some authority other than the investigator, determines whether proposed research is exempt from the HHS regulations for the protection of human subjects.

Basic Provisions of the HHS Regulations

The HHS regulations contain three basic provisions for the protection of human subjects:

- Institutional assurances of compliance
- IRB review
- Informed consent

Institutional Assurances of Compliance

- What is an Institutional Assurance of Compliance?
  Documentation of an institutional commitment to comply with HHS regulations for the protection of human subjects.

HHS will conduct or support non-exempt research covered by the regulations only if:

- the institution has an OHRP-approved Assurance,
- the institution has certified to the HHS that the research has been reviewed and approved by an IRB, and
- the research will be subject to continuing review by an IRB.

Institutional Review Board (IRB)

The Institutional Review Board (IRB) is a committee established to protect the rights and welfare of human research subjects involved in research activities.

IRB Membership

IRBs must have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of its members — including considerations of the race, gender, and cultural backgrounds and sensitivity to issues such as community attitudes — to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

Every nondiscriminatory effort must be made to ensure that the IRB does not consist entirely of men or entirely of women.

No IRB may consist entirely of members of one profession.

Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

No IRB member may have a member participate in the review of any project in which the member has a conflicting interest.

An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Except when an expedited review procedure is used, the IRB must review research at convened IRB meetings at which a majority of the IRB members are present, including one member whose primary concerns are in non-scientific areas.

IRB Review of Research

An IRB must review all research activities covered by the HHS regulations, including proposed changes in previously approved human subjects research, and have the authority to approve, require modifications to secure approval, or disapprove any research activity.

An IRB must conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year.

An IRB has the authority to suspend or terminate approved research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects.

Any suspension or termination of approval must include a statement of the reason for the IRB action and must be reported promptly to the investigator, appropriate institutional officials, and HHS.

Research approved by the IRB may be subject to further review and approval or disapproval by institutional officials. However, institutional officials may not approve the conduct of human subjects research covered by HHS regulations that has not been approved by the IRB.

Informed Consent

Unless specifically authorized by the IRB, no investigator may involve a human being as a subject in research covered by HHS regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Informed consent is the voluntary choice of an individual to participate in research based on an accurate understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.

Unless specifically waived by the IRB, informed consent must be documented by a written consent form approved by the IRB and signed by the subject or by the subject's legally authorized representative.

Institutional Responsibilities

The responsibility for the protection of human subjects does not rest solely with the IRB. It is a shared responsibility between the Institutional Official, the IRB, and the investigator. Each has a crucial, yet distinct, role to play.

The Institution bears full responsibility for all research involving human subjects covered under its Assurance.

For all HHS-conducted or supported research, all of the requirements of the HHS Regulations at 45 CFR Part 46, Subpart A, as well as Subparts B through D, must be met.

Institutions are responsible for ensuring that all institutions and investigators engaged in its HHS supported human subject research operate under an appropriate OHRP-approved Assurance for the protection of human subjects. In some cases, one institution may operate under an Assurance issued to another institution with the approval of HHS and the institution holding the Assurance.

Institutional Official Responsibilities

The Institutional Official is the individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance.

Administratively, the Institutional Official is responsible for:

- Designating one or more IRBs that will review research covered by the institution's FWA.
- Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties.
- Providing training and educational opportunities for the IRB and investigators.
- Depending on the organizational structure at a given institution, other administrative arrangements may be appropriate.
- Setting the "tone" for an institutional culture of respect for human subjects;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities as detailed in Module 2;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Serving as a knowledgeable point of contact for OHRP, or delegating this responsibility to another appropriate individual.
- Developing policies and procedures for effective and efficient administration of the Human Research Protections Program (HRPP).
- Ensuring that Assurances are in place and certifications of IRB review are submitted to the appropriate authorities for all HHS-sponsored research, not only for themselves, but also for collaborating performance sites for which the institution has agreed to accept oversight responsibility.
- Implementing appropriate oversight mechanisms to ensure compliance with HHS regulations and effective administration of the HRPP.

Source:
Office for Human Research Protections, http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp Department of Health and Human Services training

IRB Record Keeping

An institution or when appropriate an IRB shall prepare and maintain adequate documentation of IRB activities, including the following: •Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by investigators; and reports of injuries to subjects.

•Minutes of IRB meetings.

•Records of continuing review activities.

•Copies of all correspondence between the IRB and the investigators;

•A list of IRB members.

•Written procedures for the IRB.

•Statements of significant new findings provided to subjects.

IRB Minutes

Minutes of IRB meetings must include:
•a list of attendees at the meeting;

•actions taken by the IRB;

•the vote on these actions, including the number of members voting for, against, and abstaining;

•the basis for requiring changes in or disapproving research;

•a written summary of the discussion of controverted issues and their resolution.

Continuing Review

An IRB must conduct continuing review of ongoing approved research at intervals appropriate to the degree of risk, but not less than once per year. For approved research, the IRB determines which activities require continuing review more frequently than every 12 months. Continuing IRB reviews are preceded by receipt of appropriate progress reports from the investigator, including available study-wide findings. Continuing review must be substantive and meaningful.

See OHRP Guidance at: http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm.

Relying on Another IRB

An institution relying on another IRB has the following responsibilities:

- To ensure that the reviewing IRB is in compliance with the IRB requirements in the Federal regulations;

To ensure that the particular characteristics of the institution's local research context are considered, either through knowledge of its local context by the reviewing IRB; or through subsequent review by appropriate designated institutional officials.