|  |  |  |
| --- | --- | --- |
| \_\_\_/\_\_\_\_/\_\_\_\_ | **Central Georgia Technical College** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Date Submitted** | **Institutional Review Board** | **File Number** |

**FULL IRB REVIEW PROTOCOL SUMMARY FORM**

|  |
| --- |
|  |

**Title of Research Project**

|  |
| --- |
|  |
| **College or University** |

**Principal Investigator/Project Director Department Phone Extension Email address**

|  |
| --- |
|  |

**Address (If not a CGTC Employee) City State Phone**

|  |
| --- |
|  |

**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

1. **Project Information:**
   1. **Project Activity Status:**

**New Project**

**Periodic Review of Continuing Project**

**Revision to Previously Approved Project**

**B. This project involves Central Georgia Technical College students or personnel**

**Students:**  **Yes Personnel:**  **Yes**

**No**  **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. Estimated 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.***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | \_\_/\_\_/\_\_ | |  | | | | \_\_/\_\_/\_\_ |
| Principal Investigator 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”? |
|  |  |  | 1. 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? |
|  |  |  | 1. If minors are included in the study, is provision made for obtaining parental consent? |
|  |  |  | 1. Does the consent form include each of the following basic elements of informed consent? |
|  |  |  | 1. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject’s participation. |
|  |  |  | 1. A description of the procedures to be followed. |
|  |  |  | 1. A description of any benefits to the subject or others. |
|  |  |  | 1. A description of any reasonably foreseeable risks or discomforts. |
|  |  |  | 1. A statement describing the extent to which confidentiality of records identifying the participant will be maintained. |
|  |  |  | 1. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights. |
|  |  |  | 1. 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. |
|  |  |  | 1. 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.

P:/Managing IE/IRB Process/IRB Request Form\_2014

See Also: Introduction on Home page of IE IRB site