

**GOVERNORS STATE UNIVERSITY**

**Research Subjects and Safety Review Form**

Please fill out the form completely. IRB Review cannot be accomplished unless all the sections are completed, a copy of the consent form is included, and appropriate signatures are obtained. Incomplete forms will be returned.

PROJECT DIRECTOR: (GSU faculty member who is coordinating the research project or thesis):

DATE:

STUDENT RESEARCHER: (if appropriate)

COLLEGE: DIVISION:

PROJECT TITLE:

PROPOSED PROJECT DATES:

FUNDING AGENCY OR RESEARCH SPONSOR:

FUNDING AGENCY IDENTIFICATION NUMBER:

PROJECT DIRECTOR'S MAILING ADDRESS:

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PROJECT DIRECTOR'S TELEPHONE NUMBER:

PROJECT DIRECTOR AND STUDENT RESEARCHER'S E-MAIL ADDRESS(ES):

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**I. PROJECT DESCRIPTION:**

A- This project will be conducted at the following SITE(S):

The Project Director is responsible for obtaining the appropriate site administrator's signature before submitting this form for administrative endorsements when **any external sites** are to be involved:

\_\_\_\_\_  
Signature of External Site Administrator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of External Site Administrator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Title of External Site Administrator

\_\_\_\_\_  
Mailing Address of External Site Administrator

B. This project involves the use of an INVESTIGATIONAL NEW DRUG (IND):

Yes\_\_\_\_\_ No\_\_\_\_\_

Drug name, IND number and company:

C. This project involves the use of an INVESTIGATIONAL MEDICAL DEVICE:

Yes\_\_\_\_\_ No\_\_\_\_\_

Device name, IDE number and company:

D. This project involves the use of RADIATION or RADIOISOTOPES:

Yes\_\_\_\_\_ No\_\_\_\_\_

E. This project involves the use of GOVERNORS STATE UNIVERSITY STUDENTS as subjects:

Yes\_\_\_\_\_ No\_\_\_\_\_

F. HUMAN SUBJECTS from the following population(s) would be involved in this study:

Minors          Fetuses          Neonates  
Abortuses      Pregnant Women      Prisoners  
Persons with cognitive impairments

G. ANIMAL SUBJECTS would be involved in this study:

Yes\_\_\_\_\_ No\_\_\_\_\_

Identify the animals:

H. TOTAL NUMBER OF SUBJECTS TO BE STUDIED: \_\_\_\_\_

II. **ABSTRACT:** (150 WORDS OR LESS) **Please attach separately.**

III. **PROTOCOL:** (Describe procedures to which humans will be subjected. Use additional pages if necessary) **Please attach separately.**

IV. **BENEFITS:** (Describe the benefits to the individual and/or humankind.) **Please attach separately.**

V. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes psychological and social risk.) **Please attach separately.**

VI. **ALTERNATIVE PROCEDURES:** (Describe any alternative procedure(s) available to the subject.) **Please attach separately.**

VII. **RESEARCH RELATED COSTS:** (Describe any costs which will be involved as a result of the research procedures which are over and above what would be incurred by standard treatment, e.g. additional diagnostic tests, additional hospitalization, drugs, devices, etc., and indicate who will be responsible for them.) **Please attach separately.**

VIII. **CONFIDENTIALITY OF DATA** (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.) **Please attach separately.**

IX. **CONSENT:** (**Please attach a copy** of the CONSENT FORM(S) to be signed by the subject and/or any STATEMENT(S) to be read to the subject, or INFORMATIONAL LETTER to be directed to the subject.)

X. **MANDATORY IRB TRAINING documentation:** **Please attach a copy** of your CITI investigator training certificate. Your application cannot be approved without evidence of completion of CITI training. **Please attach separately.**

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

Signatures required:

Project Director (GSU Faculty Member) \_\_\_\_\_ Date \_\_\_\_\_

Student Researcher (if appropriate) \_\_\_\_\_ Date \_\_\_\_\_

**INSTITUTIONAL ENDORSEMENTS**

Your endorsement is requested to assure the Institutional Review Board that your office is aware of the existence and status of this research activity.

Division Chair \_\_\_\_\_ Date \_\_\_\_\_

Dean \_\_\_\_\_ Date \_\_\_\_\_

Please return to:      Institutional Review Board  
   c/o Veronica Hunt  
   Office of the Provost  
   G 353

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IRB Chair or Representative \_\_\_\_\_ Date \_\_\_\_\_