

INSTITUTIONAL REVIEW BOARD APPLICATION FORM

Oklahoma City University

I. THE RESEARCH PROPOSAL

Title:

Does this IRB application replace and/or continue an existing IRB approved study?

Yes _____ No _____ If Yes, provide the IRB number of the existing study: _____

Primary Investigator (PI) _____ Degree _____

College/Department _____ Title _____

Campus Address _____

Phone _____ Fax _____

Co-PI _____ Degree _____

College/Department _____

Title _____

Campus Address _____

Phone _____ Fax _____

Attach certificate(s) of completion of Protecting Human Research Participants (PHRP) course for each Project Director and Co-Project director participating in the proposed study. Website for training is at: <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html>

For the purposes of student research at OCU: Certificates from Lessons 1, 2, and 3 are the minimum requirements to accompany an IRB application, although faculty may require all 5 modules as a part of coursework. Students and faculty with Human Subjects Certificates that are less than 5 years since certification will be considered valid until the five year renewal date or 2029 (whichever comes first).

Certification from other certificate-granting bodies (example: CITI) will be honored until renewal date or 2029 (whichever comes first).

Collaborating Investigators (indicate Colleges and Departments for each):

Sponsor (funding agency or department):

Study Sites (specify OCU Bldg./Rm.):

Off-campus sites (specify all non-OCU locations):

The following issues are relevant only if study sites are locations not covered by the OCU IRB. Please check your procedures & guidelines handbook or with the IRB if you are unsure of the status of a particular facility.

Is IRB approval required at other outside sites? Y____ N____

If so, has it been obtained? Y____ N____

II. STUDY POPULATION

Age Range: _____ to _____ (include low/high age)

Gender: Males: _____ Females: _____ Both: _____

Special Qualifications: _____

Source of Subjects: _____

Number of Healthy Volunteers: _____

III. PROTECTED GROUPS (check any protected groups included in the study):

Children (under 18)** _____ Pregnant Women _____ Fetuses _____

Mentally Disturbed _____ Elderly (65 & older) _____ Prisoners _____

**With few exceptions, the Consent of both parents and the assent of the child are required if the research involves greater than minimal risk and will not directly benefit the individual child research subject. If both parents' consent is not going to be obtained, please explain why:

IV. PROTOCOL/CONSENT FORM REFERENCES

Indicate page numbers within the protocol and consent form(s) which address the following:

PROTOCOL

Inclusion/Exclusion Criteria _____

Duration of Participation _____

Early Termination Criteria _____

Drugs and Dosages _____

Devices _____

Surgical Procedures _____

Data Collection _____

Data Analysis _____

Confidentiality of Data _____

CONSENT FORM

Purpose _____

Status of Drug/Device Procedure _____

Description of Study _____

Costs _____

Risks _____

Benefits _____

Alternative to Participation _____

Compensation and Injury _____

Subjects Assurances _____

Contact for questions about _____

Rights as a research project _____

V. REQUEST FOR EXEMPT STATUS OR EXPEDITED REVIEW

I request this application be considered for:

Exempt # _____ Expedited# _____

Please refer to the list of Exempt/Expedited Categories and indicate the specific number which you feel applies to your study. The IRB Chair may grant exempt or expedited approval but reserves the right to require full Board review of any IRB application.

VI. CERTIFICATION/SIGNATURES

I certify that the information contained herein (application, research protocol and consent form, if required) is true and correct, and that I have received approval to conduct this research project from all persons named as collaborating investigators and from officials of the project sites.

Include Original Signatures (No Reproductions) and Dates In the Spaces Below

Project Director _____ Date _____

Co-Project Director _____ Date _____

Co-Project Director _____ Date _____

Department Chair or Program Director _____
Date _____