

INDIANA UNIVERSITY EAST INSTITUTIONAL REVIEW BOARD (IRB) REVIEW
DOCUMENTATION OF REVIEW AND APPROVAL (DRA)

IRB STUDY NUMBER: _____

(IRB Office will assign)

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator: _____

School: _____

(Last, First, Middle Initial-----must have faculty/staff status or faculty sponsor must sign)

Building/Room No.: _____

Phone: _____

E-Mail: _____

Contact Information:

Name: _____

Address: _____

Phone: _____

Fax: _____

E-Mail: _____

STUDENT PROTOCOLS ONLY: Name of the Student: _____

Phone: _____

Protocol Title: _____

E-Mail: _____

Sponsor/Funding Agency: _____

PI on Grant: _____

Sponsor Protocol #/Grant #: _____

Project Duration: From: _____ - _____

Sponsor Type: Federal; State; Industry*; Not-for-Profit; Unfunded; Internally Funded

Grant Title (if different from project title): _____

SECTION II: TYPE OF REVIEW

Exempt Review

Expedited Review

Full Board Review

SECTION III: SPECIAL SUBJECT POPULATIONS INVOLVED IN THE RESEARCH

Children

Human Fetuses (or Fetal Tissue) or Neonates

Cognitively Impaired

Pregnant Women

Economically/ Educationally Disadvantaged

Prisoners

SECTION IV: DOCUMENTS INCLUDED WITH RESEARCH SUBMISSION

Informed Consent Document(s), dated: _____

Assent Document(s), dated: _____

of consent document(s): _____

of assent document(s): _____

Summary Safeguard Statement (SSS), dated: _____

Recruitment Materials, dated: _____

Authorization(s), dated: _____

Advertisement(s), dated: _____

Protocol, dated: _____

Surveys, Questionnaires, dated: _____

Other, description: _____

You only need to list document dates if they are required by the investigator or sponsor.

SECTION V: INVESTIGATOR STATEMENT OF COMPLIANCE

By submitting this form, I assure the Board that all procedures performed under the project will be conducted in strict accordance with those federal regulations, Indiana University policies that govern research involving human subjects. I acknowledge that I have the resources required to conduct research in a way that will protect the rights and welfare of participants. I agree to submit *any* deviation from the project (e.g. change in principal investigator, research methodology, subject recruitment procedures, etc.) to the Board in the form of an amendment for IRB approval prior to implementation.

Signature of Investigator: _____

Date: _____

SECTION VI: IRB APPROVAL

This research project, including all documents included with the submission (e.g., informed consent statement, authorization, and/or waiver of authorization) has been reviewed and approved by the Indiana University East Institutional Review Board for a maximum of a one year period beyond the final approval date unless otherwise indicated as follows: _____

Authorized IRB Signature: _____ IRB Approval Date: _____

Recorded in the Minutes of: _____
