INVESTIGATOR ATTESTATION II:
REVIEW OF HUMAN FETAL TISSUE RESEARCH AT NIH BY
THE INSTITUTIONAL REVIEW BOARD (IRB)

I, Print Name of NIH Investigator **, attest that:**

- ***I will be conducting research that uses human fetal tissue as described in the attached protocol, and***
- ***I am aware of and will comply with the relevant legal and policy requirements regarding the conduct of research with human fetal tissue*, including consent for use of material for research (but not limited to):***

***NOTE: If research on transplantation of human fetal tissue for therapeutic purposes is being proposed, additional requirements apply.**

42 U.S.C. 289g-2: *"Prohibitions regarding human fetal tissue*

(a) Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:

§46.204 Research involving pregnant women or fetuses. ~ (a) – (g)

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

NIH Investigator Signature _____ **IC: _____ Date_____**

This space is reserved for IRB use:

Protocol #: _____

Approval Date: _____