

**INVESTIGATOR ATTESTATION I:  
REVIEW OF HUMAN FETAL TISSUE RESEARCH AT NIH  
BY THE OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS (OHSRP)**

I, \_\_\_\_\_, attest that:

- *I will be conducting research that uses human fetal tissue as described in the attached OHSRP Determination form, 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 the expectation of consent for use of tissues in research (but not limited to):*

**\*NOTE:** If research on transplantation of human fetal tissue for therapeutic purposes is being proposed, additional requirements apply. <http://www.hhs.gov/ohrp/policy/publiclaw103-43.htm.html>

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.*

\_\_\_\_\_ IC: \_\_\_\_\_ Date \_\_\_\_\_

This space is reserved for OHSRP use:

OHSRP Project ID#: \_\_\_\_\_

Determination: \_\_\_\_\_

Certified by: \_\_\_\_\_