HUMAN FETAL TISSUE OBTAINED FROM ELECTIVE ABORTIONS JUSTIFICATION

Offerors shall address each of the following topic areas:

1. Indicate why the research goals cannot be accomplished using an alternative to Human Fetal Tissue (HFT) (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models).

2. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).

3. Describe results from a literature review used to provide justifications.

4. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.

5. Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.

6. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $0 if using donated or existing HFT. The line item cost shall also be included in the offeror's separate Business proposal.

7. HFT Compliance Assurance: Offeror shall provide a letter signed by the Program Director/Principal Investigator assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.