**GUIDANCE: Additional Consent Language for Human Fetal Tissue Collection**

**Background:** On July 26, 2019 the National Institutes of Health (NIH) issued notice [NOT-OD-19-128](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html). This notice required that studies which sought to study human fetal tissues would have additional requirements. The notice defines a human fetal tissue study as “research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions…”

Among the additional requirements for investigators was a stipulation that all such proposals would be subject to review by an additional body called an “ethics advisory board.” This board will, among other things, “review and verify the core ethical principles and procedures used in the process for obtaining written voluntary informed consent for the donation of the tissue…”

**Requirement:** The same notice also requires that certain assurances be made by the institutions and PIs submitting proposals which will use human fetal tissue. Among these is a requirement that informed consent documents for obtaining human fetal tissues must:

* State that the informed consent was obtained by someone other than the person obtaining the informed consent for the elective abortion,
* State that the informed consent for the research occurred after the informed consent for the elective abortion,
* State that the research will not affect the method of the elective abortion,
* State that no enticements, benefits, or financial incentives were used to incentivize the elective abortion or the donation of the human fetal tissue for the research, and
* Be signed by both the individual having the elective abortion and the person obtaining the informed consent for the research.

**Guidance:** In light of the above, when a researcher is submitting a proposal for funding for a study which will involve the collection of human fetal tissue from elective abortions, the must use the signature block below in the research informed consent document.

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| **Participant** |
| *I have received a copy of this consent document and a copy of the “Experimental Participant's Bill of Rights” to keep. I agree to participate in the research described in this form.*  *Informed consent for donation of Human Fetal Tissue was obtained by someone other than the person who obtained the informed consent for my abortion, occurred after the informed consent for my abortion, and will not affect the method of my abortion.*  *Lastly, no enticements, benefits, or financial incentives were used at any level of the process to incentivize my abortion or the donation of Human Fetal Tissue.*  Printed Name of Participant  Signature of Participant Date |
| **Person Obtaining Consent** |
| *I document that:*   * *I (or another member of the research team) have fully explained this research to the participant.* * *I have personally evaluated the participant’s understanding of the research and obtained their voluntary agreement.* * *I was not the individual who obtained informed consent for the participant’s abortion.* * *I conducted the informed consent process after the informed consent for the participant’s abortion.* * *This informed consent will not affect the method of the participant’s abortion.* * *No enticements, benefits, or financial incentives were used at any level of the process to incentivize the participant’s abortion or the donation of Human Fetal Tissue.*   Printed Name of Person Obtaining Consent  Signature of Person Date  Obtaining Consent |
| **Witness (if applicable)** |
| *I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.*  *I document that informed consent for donation of Human Fetal Tissue was obtained by someone other than the person who obtained the informed consent for the abortive procedure, occurred after the informed consent for the abortion, and will not affect the method of the participant’s abortion.*  *Lastly, no enticements, benefits, or financial incentives were used at any level of the process to incentivize the participant’s abortion or the donation of Human Fetal Tissue.*  Printed Name of Witness  Signature of Witness Date |

**Questions:** For questions on the use of the above signature block, please write to the Office of IRB Administration at [irb@ucsd.edu](mailto:irb@ucsd.edu).