

Informed Consent  
Standard for  
Human Fetal  
Tissue Donation  
for Research



ISSCR

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# Informed Consent Standard for Human Fetal Tissue Donation

## PREFACE

*This preface provides background information for anyone who meets with women to discuss the possibility of donating tissue from fetal remains following a pregnancy termination.*

The International Society for Stem Cell Research (ISSCR) is an independent not-for-profit organization that fosters the exchange of information and ideas related to stem cells, including professional and public education regarding research standards, ethics, and the responsible translation of stem cell research to the clinic. The ISSCR supports the use of human fetal tissue in research because it is an important, non-replaceable resource for certain aspects of stem cell work. It is also vital for the advancement of other fields of biomedical research, including the study of infectious diseases and early human development. The ISSCR is providing this document to outline a professional consent standard for the donation of human fetal tissue for any field of research. The information described in this standard should be provided to any women who, after making a final decision to have a planned pregnancy termination, has expressed interest in donating tissue from the fetal remains.

Human fetal tissue has unique properties that other research materials cannot replicate. Human fetal tissue enables research on the complex interactions between different types of human cells over time and in the genesis of complicated organ systems. It is also helpful for studying infectious diseases that especially target humans such as HIV and Zika. Its

availability facilitates research on normal human development and the causes underlying congenital and inherited disorders such as those of the heart and nervous system, which in turn may provide unique insights into some adult disease states. While there have been some advances in recent years that have reduced the need for human fetal tissue in certain research areas, the continued use of fetal tissue is crucial for advancing scientific discovery and the development of new therapies.

The use of human fetal tissue in research and the consent process to donate tissue have come under scrutiny in some countries, placing promising biomedical research in jeopardy. The ISSCR hopes that by establishing an international standard for informed consent, this will promote uniformity and transparency for the entire process of tissue donation, collection and use, thereby providing confidence to everyone involved, as well as the public, that the entire process is being conducted in accordance with internationally agreed principles. Standardizing the consent process for human fetal tissue donation will also foster international research collaborations around this scarce resource that are helpful for the discovery of new treatments, as the tissue will be collected with the same ethical protections irrespective of where it is donated.

Some jurisdictions may require additional information and consent procedures, for both the pregnancy termination and any subsequent tissue donation and use. Regardless of what is in this ISSCR informed consent standard, any donation must also meet all applicable local legal requirements. For example, jurisdictions may require an ethics committee review of the donation process or the forms used to document the consent. Most jurisdictions will require documentation of the consent process; a sample informed consent template adapted for the United States is included in [Appendix I](#).

*\*This informed consent standard uses female pronouns to refer to the person donating human fetal tissue. Transgender men and nonbinary persons are also eligible donors. Informed consent materials and forms should be updated according to the donor's personal pronouns.*

## INFORMED CONSENT STANDARD FOR THE DONATION OF HUMAN FETAL TISSUE FOR RESEARCH

The information in this document outlines the essentials for an informed consent standard for fetal tissue donation. Consent for donation should be sought only after confirming that the potential donor is eligible under applicable local rules, policies, and practices to give consent. The woman must be provided with relevant information and time to read and understand it. The woman should also have an opportunity to discuss donation and to ask questions prior to giving consent.

### 1. Discussion of Fetal Tissue Donation May Not Occur Until After a Woman Has Made a Definitive Decision to Have a Planned Termination of Pregnancy

- a. The discussion of donation must be separate from and occur after the decision to have a planned termination. This separation ensures that the decision to terminate the pregnancy is not influenced by the opportunity to donate.
- b. Some jurisdictions may have additional requirements for the consent process to donate fetal tissue.

### 2. Voluntary Informed Consent

- a. Explain to the potential donor that the donation of fetal tissue is voluntary; a choice not to donate will not incur any penalty or loss of benefits or care to which the potential donor is otherwise entitled.
- b. Explain that the donor may withdraw her consent during the consent process, and that this can be done without penalty or change to medical care.
- c. Explain whether and up to which point the donor may withdraw her consent after the tissue has been donated.
- d. Explain whether any member of the medical care team has a potential financial or research interest in collection or use of the tissue that could be a conflict of interest.

### 3. Information Regarding Standard of Medical Care

- a. Explain that the medical care of the potential donor will always take priority over the collection and subsequent use of the donated tissue.
- b. Explain that the planned pregnancy termination will meet the same standard of medical care that would apply if she did not donate tissue.
- c. Describe whether the tissue donation may have additional medical implications for the donor, such as screening for pathogens (see below).

### 4. Donor Screening

- a. Explain the nature, purpose and risks (if any) of any additional screening (e.g., blood tests, donor survey) necessary for the donation of the fetal tissue.
- b. Explain whether the results of tests will be shared with the donor, and if so, how and when.
- c. If the tissue is donated for clinical transplantation research, explain why it may retain identifiers to link it to the donor for adverse event reporting.

### 5. Incidental Research Findings

- a. Disclose whether and how any incidental and secondary findings (e.g., genetic risks) will be returned to the tissue donor.

### 6. Potential Uses of Donated Fetal Tissue

- a. If the specific purpose of the research is known at the time of collection, provide the donor with available information and an opportunity to learn more by providing contact information for questions. If it is known, provide the potential donor with the following:
  - i. Purpose of the research.
  - ii. Uses of the fetal tissue, including the development of new products or transplantation into humans or animals.
  - iii. Source of the funding.
  - iv. The benefits of using human fetal tissue instead of alternative materials.

- v. Review and approval process for the project.
  - vi. If the tissue is being donated for unspecified research and therapeutic uses, discuss the types of research that use fetal tissue (e.g., research seeking to improve understanding of human development and the development of treatments for human diseases).
- c. Discuss whether the donated tissue and its derivatives may be shared with other researchers, including not-for-profit research institutions and for-profit companies, and used for the development of commercial medical or biological products, and whether it may be shared and used internationally.
  - d. If it is known, explain how the tissue will be stored before use (if this is to be the case), how long it may be stored, and how it will be disposed of, including if it is not used for research purposes.

#### **7. Statement of Benefits**

- a. Discuss that the potential donor will not benefit financially from the donation of human fetal tissue for research or from any ensuing commercial applications relating to that tissue.
- b. Explain that there are potential benefits of the research, including important knowledge that may be gained.

#### **8. Statement of Risks to the Donor (including Confidentiality)**

- a. Provide the donor with information about any risks from the donation, including the risk to the donor's confidentiality. Explain that the donor might be identified in the future due to genetic analysis that could link deidentified tissue to the donor and incidental findings of relevance to the donor.
- b. Discuss whether the donated fetal tissue will be deidentified and what deidentification means in terms of privacy protections. If it will not be deidentified, explain who will have access to the identifiable information.
- c. Explain that there are no additional medical risks from donating tissue outside those which are related to pregnancy termination.

#### **9. Contact Information for Questions**

Provide contact information for the donor to discuss questions related to the use of the donated fetal tissue. Some jurisdictions may require the disclosure of the researcher's contact information if the tissue is being provided to a specific researcher or specific project.

#### **10. If the Donation is for Transplantation Research**

- a. Explain that the donor will not be informed of the identity of the recipients.
- b. Explain that the donation must be made without any restriction regarding the identity or attributes of the recipient.

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# Appendix I

## DONATION OF HUMAN FETAL TISSUE INFORMED CONSENT TEMPLATE – U.S. ADAPTATION

### Statements and Acknowledgments from the Donor

Please carefully read the statements and sign below if each of the following topics was explicitly discussed before providing consent for the donation.

Statements and Acknowledgments from the Donor
I made a final decision to terminate my pregnancy before I was approached to discuss the possibility of donating tissue from the fetal remains.
I have been provided information on fetal tissue donation in writing and have had an opportunity to consider this information, ask questions, and discuss any concerns.
My decision to donate fetal tissue is completely voluntary, and I understand the limitations on when I can withdraw my consent to use the tissue.
I understand I will not be paid for the donation of human fetal tissue, and I will not receive any other direct benefits from the donation.
I understand that I will not receive any payment even if the tissue helps lead to a commercial product.
I have been informed of the risks of donating human fetal tissue, including the possibility that my identity may be linked to the tissue.
I have been informed on how the tissue might be used, stored and what will happen to the tissue after use or if it is not used.
I have been provided contact information to discuss any questions and report any concerns regarding the donation.

Signature of the Donor \_\_\_\_\_ Date \_\_\_\_\_

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# Appendix II

## STATEMENTS FROM DONOR AND ATTENDING PHYSICIAN FOR HUMAN FETAL TISSUE DONATION FOR TRANSPLANTATION RESEARCH

### Statements from the Donor of Human Fetal Tissue for Transplantation Research

If the human fetal tissue is being donated for transplantation research, please read the statements and sign below if each of the following topics was explicitly discussed before providing consent for the donation.

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#### Statements from the Donor of Human Fetal Tissue for Transplantation Research

The donated human fetal tissue may be used for therapeutic transplantation research without any restriction regarding the identity of the individuals who receive the transplantation and without the disclosure of the identity of the recipient(s).

The identity of the recipient(s) of donated tissue used for therapeutic transplantation research will not be disclosed to me.

Signature of the Donor \_\_\_\_\_ Date \_\_\_\_\_

#### Statement from the Attending Physician for Human Fetal Tissue for Transplantation Research

The donated fetal tissue was obtained in accordance with the donor's signed statement.

The consent process fully disclosed the possible uses of the tissue and the relationship of the person taking that consent to the possible research being done with that tissue.

The consent process disclosed any known risks to the donor, including risks to the donor's privacy.

The pregnancy termination was performed in accordance with the normal medical standard of care. The standard of care was not altered solely for the purpose of obtaining tissue from the fetal remains.

The donor's final decision to terminate the pregnancy was made before she was approached to discuss the possibility of fetal tissue donation.

The pregnancy termination will be performed in accordance with applicable state and local laws.

Signature of the Attending Physician: \_\_\_\_\_ Date \_\_\_\_\_

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# Acknowledgments

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