Fetal Tissue Research Policy

1. This policy applies to both fetal and placental tissue.
2. Fetal tissue research is permissible.
3. The reasonable person standard (traditionally used by the Einstein IRB when using left over surgical specimens for research) would not apply to fetal tissue research since reasonable people hold different points of view in this matter. Therefore, explicit consent is required.
4. The Einstein IRB requires a separate generic consent document for the use of fetal tissue in research.
   a. The Einstein IRB ‘Future Use of Specimens’ language is required in the consent document.
   b. Consent Process: Elective Abortion
      i. The consent process for an elective abortion, and the consent process to use the fetal tissue for research, are two distinct decisions and are required to be separate.
      ii. Consent for the use of the tissue for research must be obtained after the consent for abortion has been obtained.
   c. Consent Process: Spontaneous Abortion (Miscarriage)
      i. A separate generic consent is not required for the use of fetal tissue or placenta from a spontaneous abortion (miscarriage), as this is considered left over tissue.
5. Einstein IRB Review
   a. All research utilizing fetal tissue requires review by one member of the Einstein IRB Fetal Tissue Subcommittee to ensure that the use of fetal tissue is appropriate and scientifically justified. The chair of the Einstein IRB is a member of the Fetal Tissue Subcommittee.
   b. Expedited Review is acceptable.
   c. IRB approval from a collaborating researcher’s IRB is required, prior to submitting the protocol to the Einstein IRB for review.
   d. A facility not under the jurisdiction of an IRB, or not affiliated with an IRB, requires approval by the Einstein IRB on a case-by-case basis.
6. Monetary payment to the provider and/or the woman for obtaining fetal tissue is prohibited.
7. Diagnostic/Therapeutic and/or Commercial Use
   a. For research purposes and possible use by non-Einstein companies for diagnostic or therapeutic purposes, use of fetal tissue for the development of cell lines for potential commercial purpose is permissible.
   b. Through the informed consent process and document, women are given the right to choose whether or not their tissue can be used for unknown future research including possible commercial purposes.
8. At the present time, all use of pre-embryonic cells or fetal tissue for transplantation into humans is considered experimental and requires full board review.