Fetal Tissue Research Policy

1. Fetal tissue research is permissible when in compliance with institutional requirements.

2. The Einstein IRB requires a research consent document for the use of fetal tissue in research.
   a. If the tissue is not being destroyed, the Einstein IRB ‘Future Use’ language is required in the consent document. The storage and distribution of the samples must be described in the protocol. Distribution of collected samples requires a Material Transfer Agreement and must be approved by the IRB as an amendment to the fetal tissue collection protocol. Use of the samples by the new PI must be approved by the IRB under a separate protocol.
   b. Consent Process: induced abortion
      i. The consent process for an induced abortion, and the consent process to use the fetal tissue for research, are two distinct decisions and are required to be conducted by separate people. The person obtaining the research consent may not be involved in the clinical care of the patient.
      ii. Consent for the use of the tissue for research must be obtained after the consent for abortion has been obtained.
      iii. Only the consent of the mother is required.
   c. Consent Process: early pregnancy loss and fetal demise (less than 24 weeks estimated gestational age)
      i. A separate research consent is not required for the use of anonymous fetal tissue from early pregnancy loss, as this is considered left over tissue. If any identifiers are saved or a link is maintained to the mother’s or fetus’ identity (even if the link is maintained in a separate document), consent must be obtained.

3. Einstein IRB Review
   a. All research utilizing fetal tissue requires review by representation 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 and makes the recommendation if the protocol should be reviewed by one or more Committee members and designates which members of the Committee are responsible for the review.

4. Monetary payment to the provider and/or the woman for obtaining fetal tissue is prohibited. Reimbursement for time or travel or other expenses may be considered by the IRB for approval.

5. Commercial Use
   a. Use of fetal tissue for the development of cell lines for potential commercial purpose (e.g. diagnostic or therapeutic uses) is permissible, if in accordance with this Policy and with prior institutional approval.

6. All use of fetal tissue for transplantation into humans is considered experimental and requires full board review.