SMG 9001.3

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

GENERAL OR MULTIDISCIPLINE

RESEARCH INVOLVING HUMAN FETAL TISSUE

Effective Date: February 11, 2016

1. PURPOSE

The purpose of this Staff Manual Guide ("SMG") is to provide policies, requirements, and procedures for FDA-funded or conducted research involving human fetal tissue.

2. POLICY

The Food and Drug Administration (FDA) is committed to ensuring that research involving human fetal tissue is conducted responsibly and meets the highest ethical standards. FDA-funded or conducted research involving human fetal tissue must be in compliance with all applicable federal, state, and local laws and regulations (45 CFR §46.206). Current federal laws and regulations require informed consent from the donor for research involving the transplantation of human fetal tissue (42 U.S.C. 289g-1) and for research with human fetal tissue if information associated with the tissue can identify a living individual (45 CFR §46.206). Most states require informed consent for the use of fetal tissue in research.

This policy does not apply to secondary sources of tissue such as the acquisition of established cell lines or established animal models containing human fetal tissue.

3. PROCEDURES

A. Research conducted at FDA

1. Because of the biosafety risk associated with research involving human fetal tissue, such research conducted at FDA must be described in an application that is submitted by the researcher to the FDA Institutional Biosafety Committee (IBC)[1] for review and when appropriate, approval with respect to biosafety risk mitigation prior to initiation of the research activities.

2. When researchers submit their research protocols that involve human fetal tissue to the IBC, they must also submit an attestation form (see Appendix 1) to affirm that they will:

   - comply with the relevant legal and policy requirements regarding the conduct of research with human fetal tissue;

   - obtain human fetal tissue from a source that has provided assurances to the FDA that it has complied with the relevant legal and policy requirements; and

   - recognize that additional prohibitions apply regarding acquiring, receiving, or otherwise transferring any human fetal tissue for valuable consideration (42 U.S.C 289g–2).

B. Contracts, Grants, and Assistance Agreements

Program Officials must ensure that awardees who receive a contract, grant, or assistance agreement to conduct research involving human fetal tissue agree, as a term and condition of the contract, grant, or assistance agreement, to the following requirements:

- comply with the relevant legal and policy requirements regarding the conduct of research with human fetal tissue;

- procure human fetal tissue from sources that have complied with the relevant legal and policy requirements; and

- recognize that additional prohibitions apply regarding acquiring, receiving, or otherwise transferring any human fetal tissue for valuable consideration.

[1] For more information on the IBC, please visit: http://inside.fda.gov:9003/policyprocedures/laboratories/laboratorysafety/ucm369257.htm.

Awardees are expected to document that appropriate informed consent for use in research was obtained at the time of tissue collection, if the awardee was engaged in the direct collection of the tissue.

4. DEFINITION

A. FDA Centers/Offices

FDA Centers/Offices promote the public health through the evaluation, surveillance, and review of FDA regulated products and the enforcement of the applicable statutes and regulations.

B. Human Fetal Tissue

The term “human fetal tissue” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth. 42 USC 289g-1(g)

C. Institutional Biosafety Committee (IBC)

The IBC promotes biosafety in research and facilitates agency compliance with applicable federal, state and local regulations and guidelines and Agency policy. The Committee is composed of members nominated by the Directors of the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) and appointed by the Chief Operating Officer.

D. Office of Acquisitions and Grants Services

As part of the Office of Finance, Budget, and Acquisitions in the Office of Operations, the Office of Acquisitions and Grants Services negotiates, awards, and manages all contracts, grants, and assistance agreements.

E. Office of Scientific Integrity

The Office of Scientific Integrity (OSI) reports to the Chief Scientist and works with others in the Office of the Commissioner and FDA's Centers/Offices to promote FDA’s public health mission by strengthening the credibility of the agency’s science and science-based decision-making.

F. Program Official (PO)

A Program Official is the designated or authorized Contracting Officer’s Representative, Project Manager, Program Subject Matter Expert, or

Program Representative or Signatory for any given contract, grant, or assistance agreement.

G. Senior Science Council

The Senior Science Council provides an agency forum where cross-cutting regulatory science issues can be discussed by senior science representatives from FDA Centers and component offices of the Office of the Commissioner. The Senior Science Council provides advice and guidance to the agency and Center/Office leadership on cross-cutting regulatory science planning, reporting, programs, policies, and communication.

H. Valuable Consideration

The term does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue. 42 USC 289g-2(e)(3).

5. RESPONSIBILITIES

A. Institutional Biosafety Committee (IBC)

The IBC is responsible for reviewing, and when appropriate, approving research protocols with respect to biosafety risk mitigation prior to initiation of research at FDA. The IBC is also responsible for maintaining the database of research protocols and associated attestations of investigators for research at FDA with human fetal tissue, if applicable. The IBC will consider research involving human fetal tissue only if an attestation has been signed and accompanies the submission.

B. Office of Scientific Integrity

OSI provides assistance to Centers/Offices to implement this SMG.

C. Senior Science Council

In conjunction with the Office of Scientific Integrity, the Senior Science Council advises and assists Centers/Offices to implement this SMG.

D. Office of Acquisitions and Grants Services

The Office of Acquisitions and Grants Services negotiates, awards, and manages all contracts, grants, and assistance agreements, ensuring that contracts, grants, or assistance agreements follow this SMG.

E. Program Official (PO)

The PO is responsible for ensuring that the requirements described in this SMG are clearly set forth in the Statement of Work, Funding Opportunity Announcement, or any similar document that describes the requirements of the research that is to be performed. If this SMG is applicable to any contract, grant, or assistance agreement, it is the responsibility of the program official to identify this in their request for contract package/memorandum of need or request for funding announcement. The PO is also responsible for ensuring that the awardee meets the requirements described in this SMG by the delivery date(s) and/or within the period of performance.

F. FDA Centers/Offices

The Centers/Offices are primarily responsible for the conduct and funding of agency scientific research. Center Directors and the Associate Commissioner for Regulatory Affairs (ACRA) ensure such research complies with all applicable federal, state, and local laws and regulations through oversight of research staff and Program Officials.

6. EFFECTIVE DATE

The effective date of this staff manual guide is February 11, 2016.

7. Document History – SMG 9001.3, Research Involving Human Fetal Tissue

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	02/10/2016	N/a	OC/OSI	Luciana Borio, Chief Scientist

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