Changes to (R) Standards + (with amendments)

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D4.357 Archived Samples

A serum or plasma sample from each donor shall be archived if any sample remains after testing. A policy shall be established to collect and archive serum, plasma, or hematopoietic tissue samples from donors. Samples shall be retained for ten years after the *Recovery* or *Collection* date. If a donor is determined to be unsuitable, archived serum, plasma, or hematopoietic tissue samples should still be retained for use for possible unforeseen future investigational purposes (e.g., emerging infectious diseases, medical/legal, blood borne pathogen exposure, etc.).

(DM) Appropriate brain tissue specimens (i.e., formalin-fixed brain tissue, histological sections from examination of brain, donor serum) from each donor of *Dura Mater* shall be archived under appropriate storage conditions, and for the appropriate duration.

(R) Archived serum or plasma from reproductive donors whose tissue has been stored but subsequently destroyed and never distributed does not require retention.

D5.200 Donor Identification

Each donor shall be assigned a unique donor identifier to facilitate tracing of the tissue from the donor and to final *Disposition* of each tissue.

~~(R) At the time of *Collection*, the collection container shall be labeled with the date and time of *Collection* and the donor's identification or, in the case of *Client Depositors*, the name.~~

D5.300 Tissue Recovery and Collection — General

D5.310 Recovery

Recovery shall be performed using aseptic or clean techniques appropriate to the specific tissue recovered and intended use of the tissue. The *SOPM* shall specify the time limits for the postmortem *Recovery* of tissue consistent with tissue-specific standards, where applicable. If *Recovery* is to be delayed for a deceased donor, the body should be refrigerated/cooled as specified in the tissue-specific standards. To prevent cross-contamination or mix-ups, *Recovery* from one donor shall be the exclusive activity taking place at one time at a *Recovery Site*. Other activities (e.g., embalming, autopsy, another tissue donor recovery) cannot occur simultaneously in the

same room as *Recovery*. Tissue recovery shall not occur after embalming procedures have begun (i.e., injection of embalming fluid, application of drying agents either internally or topically).

(LD) Methods for *Recovery* of perioperative tissue shall be safe, aseptic, and ensure accurate identification of tissue.

D5.31*2*0 Collection

(R) *Collection* of ~~anonymous~~ donor ~~*Semen* specimens~~ *Reproductive Tissue* shall be made at the ~~*Semen Bank*~~. *Reproductive Tissue Bank* *using a sterile collection container. The collection container shall be labeled with the date of Collection and the donor's identification or, in the case of Client Depositors, the name. The time of Collection shall also be recorded. If the tissue requires transportation to the Processing laboratory, it should be transported within a reasonable time period as specified in the SOPM, so as to maintain the utility of the tissue.*

~~**D5.800 Post Collection Packaging**~~

~~(R) Semen shall be collected into a pre-labeled sterile collection container. The collection container shall be labeled with the donor or client depositor identification, date, and time of collection. Oocytes shall be collected into a primary collection receptacle pre-labeled with the donor or client depositor identification. If the tissue requires transportation to the *Processing* laboratory, it should be transported within a reasonable time period as defined by the *SOPM*, so as to maintain the functional integrity of the tissue.~~

D5.9*8*00 Transportation of Tissue Following Recovery

D6*5*.0*9*00 Post-Recovery Reconstruction of a Deceased Donor

SECTION E - PROCESSING, PRESERVATION, QUARANTINE, AND STORAGE

E3.200 Situations Requiring Quarantine

Human tissue shall be *Quarantined* until the tissue is either determined to be suitable for transplantation or appropriate *Disposition* is accomplished. All tissue shall be *Quarantined* until the following criteria for donor suitability are satisfied:

1) All required infectious disease testing has been completed, reviewed by the *Responsible Person*, and found to be negative or non-reactive; and

2) Donor screening has been completed, reviewed by the *Responsible Person*, and determined to indicate freedom from risk factors for and clinical evidence of HIV, hepatitis B, and/or hepatitis C infection.

(R) *Cryopreserved Reproductive Tissues from untested Client Depositors shall be stored in a physically separate area clearly defined from those of tested Client Depositors*. Tissues from *Client Depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, ~~anti-HTLV-I, anti-HTLV-II,~~ anti-HCV, or HBsAg *or any other test excluding CMV without subsequent negative confirmatory testing as approved by the Reproductive Tissue Bank's Medical Director* shall be stored in a physically separated area clearly identified from tissue of seronegative *Client Depositors*. *See F2.200 for documentation required for release.* ~~Release of such tissues shall require the *Informed Consent* of the *Recipient* and her physician. *Cryopreserved Reproductive Tissues* from untested *Client Depositors* shall be stored in a physically separate area clearly defined from those of tested *Client Depositors*.~~

Tissue shall be *Quarantined* at any phase of the operation when its release could affect the *Safety*, effectiveness, or quality of the tissue, and subsequently, the health of the *Recipient*. The following tissue shall be *Quarantined*:

1) Tissue that is pending completion of *Processing*, packaging, *Preservation*, or labeling and final-release-approval signature;

2) Tissue collected from donors not meeting established donor suitability criteria, including unacceptable test results;

3) Tissue involved in a *Recall* pending investigation, documentation, and *Resolution*;

4) Tissue failing to meet technical or *Quality Assurance* specifications;

5) Tissue pending discard as medical waste; and

6) Tissue returned by a *Consignee*, pending evaluation.

SECTION F - RELEASE AND TRANSFER OF TISSUE

F2.200 Special Circumstances in Release of Reproductive Tissues

(R) Release of reproductive tissue may be considered in the special cases of:

1) *Reproductive Tissues* from *Client Depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, ~~or~~ HBsAg, or any *other* test ~~for sexually transmitted diseases~~, excluding CMV, *without subsequent negative confirmative testing as approved by the Medical Director; or*

2) *Reproductive Tissues* from *Client Depositors* that have not been tested or do not meet current *Standards*; *or*

3) *Directed Donors* who have completed all required testing and screening according to *Standards* who had reactive test results on either initial or repeat tests or are determined ineligible according to screening criteria; ~~and~~ *or*

4) *Directed Donors* who have not completed the 180-day quarantine and re-testing requirement.

In the case of release for one of the four circumstances listed above, the following documentation is required (refer to G3.210 Summary of Records Content, and G3.220 Package Insert Content, for labeling requirements):

~~1) A written description that describes the *Deviation* from *Standards* and what risk(s) potentially exist;~~

~~2) Medical Director or licensed physician designee review of all relevant information present and approval of the exception;~~

~~3~~*1*) A written statement ~~to the attending physician~~ *signed by a Responsible Person at the Reproductive Tissue Bank* disclosing the *Deviation(s)* from *Standards* and description of potential risks to the *Recipient*; and

~~4~~*2*) ~~A written, signed statement~~ *Acknowledgement* from the ~~attending physician and the recipient~~ *medical provider* indicating ~~that~~ *he/she*:

a) ~~The attending physician~~ has received the written statement from the *Reproductive Tissue Bank* and acknowledges the *Deviation(s)* from *Standards*;

b) ~~There~~ has ~~been~~ *had* ample opportunity to discuss the implication*(s)* with ~~the Medical Director~~ *a Responsible Person at the Reproductive Tissue Bank* and other medical authorities;

c) ~~The~~ *agrees to fully explain the* implication*(*s*)* ~~have been fully explained~~ to the *Recipient* and ~~she has had~~ *provide her* ample opportunity to ask questions and consult with experts of her choice; and

d) ~~The attending physician has obtained documentation of~~ *will document Informed Consent from the Recipient.*

~~*The Reproductive Tissue Bank* shall release specimen only after completion of above steps and receipt of formal written approval from the attending physician.~~

F2.300 Shipping Reproductive Tissue in Quarantine

If donor Reproductive Tissue is to be released before completion of the donor suitability assessment, the tissue must be kept in quarantine during shipment. The labeling must include a statement that the donor suitability assessment has not yet been completed. It must also include a statement indicating the Reproductive Tissue must not be transplanted or transferred until the donor suitability assessment is complete.

SECTION H - DISTRIBUTION AND DISPENSING

H1.110 Client Depositor Authorization

(R) Cryobanked ~~samples of~~ ~~r~~*Reproductive* ~~t~~*Tissue* for potential therapeutic insemination, use in another *Assisted Reproductive Technology* procedure, or for other specified *Disposition* shall be released only upon written authorization of the *Client Depositor*, if of legal age or, if not, by that of parent, legal guardian, or his/her legally appointed designee.

Cryobanked ~~samples~~ *Reproductive Tissue* shall be released for ~~insemination only of~~ *use by the Client Depositor or* the *Client* Depositor's sexually intimate partner *only*. Prior to release of the specimens, a ~~signed~~ statement *containing a verified signature* from the *Client Depositor* shall be obtained ~~stating that a sexually intimate~~ *indicating the* relationship ~~exists~~ between ~~him and~~ the intended *Recipient and the Client Depositor*.

~~If *Semen* from a *Client Depositor* is to be released to a *Recipient* who is not his sexually intimate partner, he shall be evaluated as a donor, as required in D4.220, D4.310, and D4.360. Such *Semen* shall be released only if the results of medical history evaluation and laboratory testing conform to criteria established by the Medical Director and these *Standards* for donors.~~

H1.120 ~~Semen~~ *Reproductive Tissue* Distribution Restrictions

(R) A *Client Depositor* who requests that his*/her* cryobanked ~~*Semen*~~ *Reproductive Tissue* be distributed to a *Recipient, who is not the Client Depositor or who is not the sexually intimate partner of the Client Depositor,* shall be treated as a *Directed Donor(s)*. ~~The~~ *All Directed Donor(s)* must be fully tested ~~for sexually transmitted diseases~~ *and screened* in a manner consistent with donor protocols and these *Standards*. *Alternatively, the Client Depositor Reproductive Tissue may be distributed in Quarantine with proper labeling to clearly identify the donor suitability assessment is not yet complete. See F2.300.*

~~*Semen*~~ *Reproductive Tissue* shall not be distributed to private individuals unless the request is in the form of a physician's written order for such *Distribution*.