CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION F – RELEASE AND TRANSFER OF TISSUE

F2.000 OTHER RELEASE

Current (13th edition)
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 test for sexually transmitted diseases, excluding CMV;

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

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

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) A written statement to the attending physician disclosing the *Deviation(s)* from *Standards* and description of potential risks to the *Recipient*; and

4) A written, signed statement from the attending physician and the recipient indicating that:

   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 ample opportunity to discuss the implication with the Medical Director and other medical authorities;

   c) The implications have been fully explained to the *Recipient* and she has had ample opportunity to ask questions and consult with experts of her choice; and

   d) The attending physician has obtained documentation of *Informed Consent*.

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

(with amendments)
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.

(as amended)
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, HBsAg, or any other test, 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; 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 statement 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

2) Acknowledgement from the medical provider indicating he/she:

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

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

c) agrees to fully explain the implication*(*s*)* to the *Recipient* and provide her ample opportunity to ask questions and consult with experts of her choice; and

d) will document *Informed Consent* from the *Recipient*.

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.

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