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

D1.000 GENERAL POLICIES

In addition to the requirements at the *series of standards* at B1.500, all referral arrangements with organ procurement organizations, *donor referral sources* and other *tissue banks shall* be documented.

(LD) Except for a *reproductive tissue bank*, written *procedures* for interacting with operating room staff, the patient's physician, or other sources/facilities *shall* be *established*.

D1.100 Monetary Compensation or Other Valuable Consideration

Monetary compensation or other valuable consideration, including goods or services, *shall* not be offered to a *donor, authorizing person*, the *donor's* estate, or any other third party acting on behalf of the *donor*, except in the following instances:

1) the *tissue bank may* reimburse responsible third parties for costs directly associated with a donation; or

2) the *tissue bank may* reimburse *living donors* for costs associated with an acceptable donation, including compensation for restoration of lost earnings when directly attributable to donation, if and as authorized by law.

(R) The *reproductive tissue bank may* provide monetary compensation to *donors* of *reproductive tissue* if the compensation is compliant with professional standards of practice.

Donors or their families *should* not be responsible for any expenses related to the *recovery* of *allogeneic tissue*.

D1.200 Tissue for Research

Facilities providing *tissue* for research and other non-*transplantation* purposes *shall* develop detailed relevant specific policies and *procedures*. *Informed consent* or *authorization* for research and/or education *shall* be obtained. See the *series of standards* at D2.000 and D3.000.

D1.210 Written Requests

All requests for human *tissue* intended for research use *shall* be submitted in writing. The request *shall* indicate the type of *tissue* requested and how it will be used as well as the name, address and affiliation of the principal investigator accepting responsibility for receipt of the *tissue*.

D1.220 Review and Approval

Tissue requests for research purposes *shall* be reviewed and approved based on legal, ethical, and technical considerations defined in the *SOPM*.

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D1.300 Consideration for the Donor *(Effective March 3, 2018)*

A policy shall be established requiring the donor always be treated with dignity and respect.

D2.000 AUTHORIZATION

D2.100 Requirements

Authorization to acquire *tissues* and make them available for *transplantation*, therapy, research or education *shall* be obtained from a *donor* or *authorizing person* in accordance with applicable anatomical gift acts and other laws or regulations. This *authorization shall* be expressed in a *document of gift/authorization*, the original or a copy of which *shall* be maintained in the *donor's record* at the *tissue bank* responsible for *recovery*, as well as in the *donor's record* at *the tissue bank* whose Medical Director is responsible for the *donor* eligibility determination. In the case of an electronic or voice recorded *document of gift/authorization*, the original recording *should* be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful authorization for donation of *tissues* for *transplantation*, therapy, research, or education.

D2.200 Conditions

Adequate information concerning the donation and *recovery* of *tissue shall* be presented in a language in which the *authorizing person* is conversant and in terms that are easily understandable by the *authorizing person*. The *donation coordinator should* be trained to appropriately answer the questions the *authorizing person may* have. Neither coercion nor inaccurate information *shall* be used in any manner to obtain *authorization.*

D2.300 Signatures and Documentation

D2.310 Document of Gift

In cases where a *donor* has executed a *document of gift* it *may* be acted upon (permits *recovery*) provided it meets applicable laws and regulations. Acceptable documentation *may* include a state driver's license, living will, advanced directive, state ID card, *donor* card, or photocopy thereof, and documentation that the *donor* registered in a *donor registry.*

D2.320 Document of Authorization

When a *document of authorization* is used it *must* contain the following *signatures* and related information:

1) the *authorizing person's signature* and:

   a) name;

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b) mailing address (NOTE: If requested by the *authorizing person*, only an email address *may* be documented as the address but, in such cases, the *authorizing person should* permit its use and *should* be informed that if the email address changes or if email communication is blocked, there *may* be no effective forwarding or receipt of information.);

c) phone number; and

d) relationship to the *donor*;

2) the *donation coordinator's signature* and:

a) the date; and

b) identity of their organization;

3) the *signature* of each *witness* if *witnessing* is required by law or regulation;

4) documentation that the Core Elements were used; and

5) a statement granting *authorization* for *tissue recovery.*

D2.330 Methods of Obtaining Authorization

Legal *authorization* can be obtained using different methods. When *authorization* is obtained:

1) **in person**, the *authorizing person must* read and *sign* the *document of authorization*.

2) **by telephone**, the person obtaining the *authorization shall* read to the *authorizing person* the *document of authorization* or, alternatively, *shall* present each of the Core Elements described in D2.400.

This telephone conversation *shall* be recorded. There *shall* be documentation that the *authorization* was obtained by telephone.

A sampling plan *must* be adopted that verifies that recordings match the content in the written *document of authorization*. This *verification must* be performed by someone other than the *donation coordinator* or *witness*. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means is feasible for documenting *authorization*, the conversation *should* be *witnessed* by a third person. Sampling plans and methods *must* be established, *must* be adequate for their intended use, and *must* be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

3) **using a facsimile transmission**, a copy of the *document of authorization* is provided to the *authorizing person*. The *authorizing person shall* return the *signed*

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document of authorization by facsimile transmission. A *donation coordinator shall* be available to respond to questions posed by the *authorizing person.*

A sampling plan *must* be adopted that *verifies signatures* received by facsimile. This *verification must* be performed by someone other than the *donation coordinator* or *witness*. Sampling plans and methods *must* be established, *must* be adequate for their intended use, and *must* be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

4) **using an electronic transmission**, a copy of the *document of authorization* is provided to the *authorizing person*. The *authorizing person shall* electronically respond (e.g., by e-mail) that he/she has read the *document of authorization*, is authorized to grant *authorization*, and is granting such *authorization*. A *donation coordinator shall* be available to respond to questions posed by the *authorizing person.*

   A *document of authorization* received by electronic transmission *should* be verified pursuant to the relevant law on electronic *signatures*, such as the Uniform Electronic Transactions Act of the relevant state. An electronically transmitted, read-only or otherwise protected *document of authorization may* be used.

D2.400 Core Elements for Authorization

The *document of authorization shall* contain *adequate information*. No *document of authorization* from an *authorizing person shall* be acted upon if it does not contain the following Core Elements. These Core Elements also apply to D2.500.

Core Elements:

1) the name of the *Donor*;

2) the name, mailing address, and telephone number of the *authorizing person*, and his/her relationship to the *donor* (NOTE: If requested by the *authorizing person*, only an email address *may* be documented as the address but, in such cases, the *authorizing person should* permit its use and *should* be informed that if the email address changes or if email communication is blocked, there *may* be no effective forwarding or receipt of information.);

3) an explanation that the *tissue* is a gift, and that neither the *donor's* estate nor the *authorizing person* will receive monetary compensation or valuable consideration for it;

4) a description of the general types of *tissue* to be *recovered*;

5) a description of the permitted use(s) of the *recovered tissues* (i.e., *transplant*, therapy, research, or education);

6) an explanation that *recovery* of *tissue* requires the following actions, and the *document of gift/authorization* thus specifically *authorizes*:

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a) access to, and required disclosure of, the *Donor's* medical and other relevant *records*;

b) testing and reporting for transmissible diseases;

c) the removal of specimens which *may* include, but are not limited to blood or *tissue* samples for the purposes of biopsy or other testing necessary for determination of *donor* eligibility;

d) the release to the *tissue bank* of any and all *records* and reports of a Medical Examiner, Coroner or Pathologist (e.g., autopsy report); and

e) such other requirements as may be applicable for the specific donation or *tissue bank*, such as transport of the *donor's* body, archiving of samples, photographic or other imaging, etc.

7) contact information for the organization represented by the *donation coordinator*; and

8) any additional information required by laws or regulations.

The following information *should* be provided to an *authorizing person*:

1) a general description of the *recovery* e.g., timing, relocation of *donor* if applicable, contact information, etc.;

2) an explanation that costs directly related to the evaluation, *recovery*, *preservation*, and placement of the *tissues* will not be charged to the family;

3) an explanation regarding the impact the donation process may have on burial arrangements and on appearance of the *donor's* body; and

4) an explanation that the *document of authorization* is available.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that *tissue* may be distributed internationally, *must* be included.

When an Organ Procurement Organization (OPO), or other entity (e.g., hospital), has initiated the process of obtaining *authorization* for a potential organ and *tissue* donation, the *tissue bank* for which the *authorization* is being obtained *shall* request that the OPO or other entity follow the *procedure* and utilize a *document of authorization* that satisfies the requirements of D2.000.

For a *donor* one month (28 days) of age or less, adequate consent pursuant to law *shall* be obtained for collection of blood from the birth mother that will be used for testing.

D2.500 Notification of Gift

In cases where the gift is authorized by a *donor's* own *document of gift* (i.e., first person

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consent), including a *document of gift* recorded in a *donor registry* (i.e., *donor* designation), and where law mandates *notification*, such *notification shall* be made pursuant to law.

In all other cases, prior to transport of the *donor's* body or *recovery*, the *donation coordinator* ***should*** attempt to *notify* the person who would have been an *authorizing person* had no gift been made during the life of the *donor* or the person who is authorized to make arrangements for final disposition. The information to be provided in the *notification* ***should*** contain, at a minimum, Core Elements of *authorization* but at no time *shall* the *donation coordinator* indicate that the recipient of the information is empowered to revoke or amend the gift made by the *donor*.

The *donation coordinator* ***should*** inquire during the *notification* whether the notified person is aware of any revocation or refusal made by the *donor*.

Notification, if made, *shall* be documented.

Where good faith efforts to *notify* an appropriate person of the gift fail to result in actual *notification* within a time frame compatible with the successful *recovery* of the *tissue*, the attempt to notify *shall* be documented, and *recovery may* proceed.

D2.600 Services to Donor Families

Services to donor families or referral to a support system *must* be offered to the *authorizing person*. Subsequent communications and periodic evaluation of services *shall* be documented, maintained, and readily available. See AATB Guidance Document No. 4.

D3.000 INFORMED CONSENT

D3.100 Requirements

Except for autologous tissue, *informed consent* to acquire *tissues* and make them available for *transplantation*, therapy, research or education *shall* be obtained from a *living donor* or their legal representative, or from a *client depositor* in accordance with applicable laws or regulations. This *informed consent shall* be documented in a *record* of *informed consent*, the original or a copy of which *shall* be maintained in the *donor's* or *client depositor's record* at the *tissue bank* responsible for *recovery, collection* or *acquisition*, as well as in the *donor's record* at the *tissue bank* whose Medical Director is responsible for the *donor* eligibility determination. In the case of an electronic or voice recorded *record* of *informed consent*, the original recording *should* be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful informed consent for donation of *tissues* for *transplantation*, therapy, research, or education. *(last amended April 19, 2017*

D3.200 Conditions

Adequate information concerning the *recovery, collection,* or *acquisition* of *tissue shall* be presented in a language in which the *living donor* or their legal representative, or the *client depositor* is conversant, and in terms that are easily understandable by them. The *donation coordinator should* be trained to appropriately answer the questions the *living donor,* their legal

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representative, or the *client depositor* may have. Neither coercion nor inaccurate information *shall* be used in any manner to obtain *informed consent*.

The potential *donor* or their legal representative *shall* not be under the influence of anesthesia or any drug that could influence his/her ability to give *informed consent*.

Informed consent must be obtained prior to *recovery or acquisition*, or when not possible and *recovery* or acquisition has already occurred, as soon as practical before use of the *tissue*.

D3.300 Signatures and Documentation

The *record* of *informed consent must* comply with applicable laws and regulations. It *must* contain, at a minimum,

1) the *living donor's signature* or their legal representative's *signature*, or the *client depositor's signature* and:

   a) name;

   b) mailing address (NOTE: If requested by the *living donor,* their legal representative, or the *client depositor*, only an email address *may* be documented as the address but, in such cases, the *living donor,* their legal representative, or the *client depositor should* permit its use and *should* be informed that if the email address changes or if email communication is blocked, there may be no effective forwarding or receipt of information.);

   c) phone number;

2) the *donation coordinator's signature* and:

   a) the date; and

   b) identity of their organization;

3) the *signature* of each *witness* if *witnessing* is required by law or regulation;

4) documentation that the Core Elements for *informed consent* (see D3.400) were used;

5) a statement that the *living donor* or their legal representative, or the *client depositor* understands what has been read or explained and is granting *informed consent* for *tissue recovery, collection,* or *acquisition*; and

6) a statement that the *living donor* or their legal representative, or the *client depositor* has been informed that his/her name and address, as well as required *records*, *shall* be kept on file by the *tissue bank* or *reproductive tissue bank*.

D3.310 Methods of Obtaining Informed Consent

Informed consent can be obtained using different methods, if and as authorized by law or regulation. The methods below appear in preferential order. When *informed consent*

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is obtained:

1) **in person**, the *living donor,* their legal representative, or the *client depositor must* read and *sign* the *record* of *informed consent*.

2) **by telephone**, the person obtaining the *informed consent shall* read to the *living donor,* their legal representative, or the *client depositor* the *record* of *informed consent* or, alternatively, *shall* present each of the Core Elements described at D3.400.

   This telephone conversation *shall* be recorded and it *shall* be documented that the *informed consent* was obtained by telephone. A sampling plan *must* be adopted that *verifies* that recordings match the content in the written *record* of *informed consent*. This *verification must* be performed by someone other than the *donation coordinator* or *witness*. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means are feasible for documenting *informed consent*, the *informed consent may* be made telephonically and *should* be *witnessed* by a third person. Sampling plans and methods *must* be established, *must* be adequate for their intended use, and *must* be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

3) **using a facsimile transmission**, a copy of the *record* of *informed consent* is provided to the *living donor,* their legal representative, or the *client depositor.* The *living donor,* their legal representative, or the *client depositor shall* return the *signed record* of *informed consent* by facsimile transmission. A *donation coordinator shall* be available to respond to questions posed by the *living donor,* their legal representative, or the *client depositor.*

   A sampling plan *must* be adopted that *verifies signatures* received by facsimile. This *verification must* be performed by someone other than the *donation coordinator* or *witness*. Sampling plans and methods *must* be established, *must* be adequate for their intended use, and *must* be based on valid statistical rationale (e.g., such as the FDA Guide to Inspection of Quality Systems).

4) **using an electronic transmission**, a copy of the *record* of *informed consent* is provided to the *living donor,* their legal representative, or the *client depositor.* The *living donor,* their legal representative, or the *client depositor shall* electronically respond (e.g., by e-mail) that he/she has read the *record* of *informed consent,* and is granting such *informed consent.* A *donation coordinator shall* be available to respond to questions posed.

   A *record* of *informed consent* received by electronic transmission *should* be verified pursuant to the relevant law on electronic *signatures*, such as the Uniform Electronic Transactions Act, of the relevant state. An electronically transmitted, read-only or otherwise protected *record* of *informed consent may* be used.

D3.400 Core Elements for Informed Consent

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No *informed consent* from a *living donor,* their legal representative, or a *client depositor shall* be acted upon if it does not contain the following Core Elements.

Core Elements:

1) the name of the *living donor* or *client depositor*; or

2) the identity of the person authorized by law to consent on behalf of the *living donor* or *client depositor* and his/her relationship to the subject including name, address, and telephone number;

3) if applicable, an explanation that the *tissue* is a gift, and that the *living donor* or their legal representative will not receive monetary compensation or valuable consideration for it;

4) a description of the general types of *tissue* to be *recovered, collected*, or *acquired* and any information pertinent to the specific *recovery, collection,* or *acquisition* contemplated;

5) a description of the permitted use(s) of the *tissues* (i.e., *transplant,* therapy, research, or education);

6) a description of the general purposes for which the *tissue may* be used;

7) a legally adequate release of the *relevant medical records* of the *living donor*, their legal representative (when applicable), or of the *client;*
8) permission to test for disease, if applicable;

9) a statement that confirmed positive test results will be reported or disclosed if required by law or regulation (e.g., to the *living donor,* their legal representative, or the *client depositor*, to the attending physician, to appropriate health officials);

10) contact information for the organization represented by the *donation coordinator;*

11) information concerning possible risks and benefits to the *living donor,* their legal representative, or the *client depositor,* if applicable; and

12) any additional information required by laws or regulations.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that *tissue* may be *distributed* internationally, *must* be included.

(R) In the case of a *client depositor* the *record* of *informed consent shall* also include details about costs of *tissue cryopreservation*, *storage*, *distribution* and *disposition* options.

In the case of an *anonymous donor*, the *record* of *informed consent shall* also include details about monetary compensation. See D1.100.

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D3.500 Services Involving Living Donors

(BT) Services *shall* be developed that provide answers to questions posed by the birth mother after delivery.

D4.000 DONOR SCREENING AND TESTING

Current (14th Edition)

D4.100 Donor Screening

Donor eligibility criteria *shall* be established by the Medical Director and *shall* not conflict with these *Standards*. Each *donor shall* be evaluated according to *established* criteria.

(A) *Donor* eligibility *shall* be documented by a physician caring for the *autologous donor*. It is not necessary to document a *physical examination*, a *donor risk assessment interview*, or medical history and medical *record* review for *autologous tissue* in the *tissue bank records*.

(BT) Except for *autologous* donations, the health status of the infant(s) *shall* be assessed in regard to information that could affect the *quality* or *safety* of the *tissue* for *transplantation*. Protocols *shall* be *established* for reviewing information at the time of the infant's delivery. Policies and *procedures should* be developed to handle information regarding the health status of the infant reported voluntarily after delivery. Written *procedures must* describe how information is evaluated.

(C) Heart *donors shall* also be evaluated for the risk of Chagas' disease.

(LD) Criteria for accepting *living donors shall* be *established* by the Medical Director or licensed physician designee.

(R) Criteria for accepting *client depositors* and potential *reproductive tissue donors shall* be *established* by the Medical Director or licensed physician designee.

(S) Potential *donors shall* be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and *skin* condition.

With amendments

D4.100 Donor Screening

Donor screening and *donor* testing procedures *shall* be *established* under the supervision of a contracted licensed physician possessing the qualifications outlined in B2.210. *Donor* eligibility criteria *shall* be established by the Medical Director of the *tissue establishment* responsible for the determination of *donor* eligibility (ref. Section 1271.50) and *shall* not conflict with these *Standards*. Each *donor shall* be evaluated according to *established* criteria. If *donor* screening and testing is under the supervision of a Medical Director other than the Medical Director responsible for final *donor* eligibility determination, the former *shall* be available upon request from the latter to provide clarification about results of *donor* screening and testing if needed.

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(A) *Donor* eligibility *shall* be documented by a physician caring for the *autologous donor*. It is not necessary to document a *physical examination*, a *donor risk assessment interview*, or medical history and medical *record* review for *autologous tissue* in the *tissue bank records*.

(BT) Except for *autologous* donations, the health status of the infant(s) *shall* be assessed in regard to information that could affect the *quality* or *safety* of the *tissue* for *transplantation*. Protocols *shall* be *established* for reviewing information at the time of the infant's delivery. Policies and *procedures should* be developed to handle information regarding the health status of the infant reported voluntarily after delivery. Written *procedures must* describe how information is evaluated.

(C) Heart *donors shall* also be evaluated for the risk of Chagas' disease.

(LD) Criteria for accepting *living donors shall* be *established* by the Medical Director or licensed physician designee.

(R) Criteria for accepting *client depositors* and potential *reproductive tissue donors shall* be *established* by the Medical Director or licensed physician designee.

(S) Potential *donors shall* be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and *skin* condition.

As amended

D4.100 Donor Screening

Donor screening and *donor* testing procedures *shall* be *established* under the supervision of a contracted licensed physician possessing the qualifications outlined in B2.210. *Donor* eligibility criteria *shall* be established by the Medical Director of the *tissue establishment* responsible for the determination of *donor* eligibility (ref. Section 1271.50) and *shall* not conflict with these *Standards*. Each *donor shall* be evaluated according to *established* criteria. If *donor* screening and testing is under the supervision of a Medical Director other than the Medical Director responsible for final *donor* eligibility determination, the former *shall* be available upon request from the latter to provide clarification about results of *donor* screening and testing if needed.

(A) *Donor* eligibility *shall* be documented by a physician caring for the *autologous donor*. It is not necessary to document a *physical examination*, a *donor risk assessment interview*, or medical history and medical *record* review for *autologous tissue* in the *tissue bank records*.

(BT) Except for *autologous* donations, the health status of the infant(s) *shall* be assessed in regard to information that could affect the *quality* or *safety* of the *tissue* for *transplantation*. Protocols *shall* be *established* for reviewing information at the time of the infant's delivery. Policies and *procedures should* be developed to handle information regarding the health status of the infant reported voluntarily after delivery. Written *procedures must* describe how information is evaluated.

(C) Heart *donors shall* also be evaluated for the risk of Chagas' disease.

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(LD) Criteria for accepting *living donors shall* be *established* by the Medical Director or licensed physician designee.

(R) Criteria for accepting *client depositors* and potential *reproductive tissue donors shall* be *established* by the Medical Director or licensed physician designee.

(S) Potential *donors shall* be evaluated on an individual basis by chart review and visual assessment for size, current medical status, and *skin* condition.

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D4.110 Age Criteria

The Medical Director and/or *tissue bank* Medical Advisory Committee *shall* determine *donor* age criteria.

(A) There are no age limits for *autologous tissue* donation.

(BT) There is no age limit for the birth mother, however, policies and *procedures shall* be written regarding gestational age limits.

(R) *Semen donors shall* be younger than 40 years of age to minimize the risk of genetic anomalies except with the written agreement of the user physician. *Oocyte donors shall* be younger than 35 years, unless an exception has been made by the Medical Director with documented agreement of the user physician.

D4.120 Physical Assessment

Prior to the *recovery* of *tissue* from a deceased *donor*, a *physical assessment shall* be performed by a *responsible person*. This *shall* be a recent ante-mortem or postmortem *physical assessment* to identify evidence of: high risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, signs of trauma or infection to the body where *recovery* of *tissue* is planned. If any of the following signs are observed or noted in any other available *record*, and are deemed to be an indication of these risks, then the *tissue shall* be rejected:

Note: Each risk type is followed by observational wording in parentheses suggestive of terminology that correlates with each listing. See Appendix III.

1) physical evidence for risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, chancroid (genital lesions);

2) physical evidence for risk of, or evidence of, syphilis (genital lesions, rash, skin lesion [non-genital]);

3) for a male donor, physical evidence consistent with anal intercourse including

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perianal condyloma (insertion trauma, perianal lesions);

4) physical evidence of non-medical percutaneous drug use such as needle tracks (and/or non-medical injection sites), including examination of tattoos (which may be covering needle tracks);

5) disseminated lymphadenopathy (enlarged lymph nodes);

6) unexplained oral thrush (white spots in the mouth);

7) blue or purple spots consistent with Kaposi's sarcoma (blue/purple [gray/black] spots/lesions);

8) physical evidence of recent tattooing, ear piercing, or body piercing (tattoos/piercings should be described);

9) unexplained jaundice, hepatomegaly, or icterus. Note: Hepatomegaly may not be apparent in a *physical assessment* unless an autopsy is performed (enlarged liver, jaundice, icterus);

10) physical evidence of sepsis, such as unexplained generalized rash/generalized petechiae, or fever (rash);

11) large scab consistent with recent smallpox immunization (scab);

12) eczema vaccinatum (lesion, scab);

13) generalized vesicular rash, generalized vaccinia (rash);

14) severely necrotic lesion consistent with vaccinia necrosum (lesion); and/or

15) corneal scarring consistent with vaccinial keratitis (abnormal ocular finding, scarring).

The form and instructions in Appendix III *must* be used to document the *tissue donor physical assessment*.

(S) The *physical assessment shall* include documentation of findings and conditions that may affect the *quality* or quantity of *skin recovered*.

D4.130 Physical Examination

(LD) Except for *autologous* and *embryo* donations, prior to the donation of *tissue* from a potential *living donor*, a *physical examination shall* be performed by the Medical Director or licensed physician designee, or by a physician involved with the individual's medical care, or designee as permitted by law. If an examination of a *living donor* was performed for other reasons, review of the findings of such an examination *shall* be performed and documented in the *donor's record*, as well as all other examination findings. After a *donor*

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risk assessment interview is completed, if any history is suspect, a directed *physical examination shall* be performed. The directed examination *shall* include any of the above applicable items (see D4.120) that would assist with information to determine whether there is evidence of high risk behavior.

(BT) In addition to the (LD) standard above, a *physical examination* of the birth mother *must* be performed during admission for delivery or within 14 days prior to delivery.

(R) A *physical examination must* be performed on all *anonymous* and *directed semen* and *oocyte donor*s. A repeat *physical examination shall* be performed on *anonymous semen donor*s at least every 6 months (180 days) while the *donor* is actively collecting samples in the program.

Semen donors shall not exhibit an infectious skin disease that creates a risk of contamination of the *semen*.

D4.140 Donor Risk Assessment Interview (DRAI)

A documented dialogue *shall* be conducted with the *donor* (if living) or the deceased *donor's* next of kin, the nearest available relative, a member of the *donor's* household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or the primary treating physician, using a standardized questionnaire. Questions *shall* be formulated using these *Standards*, current federal regulations and guidance.

Questions *shall* be included that evaluate past medical history for conditions that could constitute a contraindication to the release of *tissue* for *transplantation* (e.g., certain infectious diseases, malignancies, and degenerative neurologic disorders), as defined in these *Standards* (see Appendix II).

For all donors one month (28 days) of age or less, the infant and the birth mother *shall* be screened for risk of *relevant communicable disease agents and diseases* (RCDADs) and the birth mother's blood *must* be tested. Refer to D4.100 (BT) for expectations to obtain the health status of the infant *donor* of *birth tissue.*

The *donor risk assessment interview shall* document the *donor's* name, and the relationship between the *donor* and the interviewee(s) and *shall* indicate the name(s) of the interviewer(s) and interviewee(s). The questionnaire *shall* be maintained as part of the *donor's record*.

(A) The *tissue bank shall* have a policy for obtaining information from the patient's physician as to whether the *autologous donor* is at high risk for viral hepatitis or HIV infection.

(BT) The *donor risk assessment interview* of the birth mother *shall* be obtained, or previous *donor risk assessment interview* information *verified*, no more than 14 days prior to delivery. If this interview is performed after delivery it *must* be completed within 14 days of delivery.

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(LD) Interviews *must* be administered by trained staff, or if self-administered, a trained staff member *must* review and *verify* answers with the *donor* in order to facilitate comprehension and provision of accurate answers.

(R) The donor's risk assessment *shall* include a review of personal alcohol and drug use and sexually transmissible diseases in the *donor* and partner(s). The screening process also *shall* include any history of chemical and/or radiation exposure as well as family medical history and genetic background. An abbreviated *donor* screening *must* be obtained at each repeat donation and reviewed by a *responsible person*. The abbreviated screening *must* determine and document any changes in the *donor's* medical, social, travel, and sexual behavior history (including risk factors) since the previous donation that would make the *donor* ineligible.

D4.141 Family History and Genetic Background

(BT) If genetic testing has been performed or a genetic history has been obtained and the information is available, it *should* be considered for the determination of *donor* eligibility.

(R) A minimum of a three-generation family history *shall* be elicited from each prospective *donor.* If a biological family member in the prospective *donor's* family is adopted, Medical Director discretion *must* be made to determine if sufficient family history is provided to determine *donor* eligibility. The genetic history *should* be evaluated by an individual with appropriate clinical genetics education and/or training. Any significant condition in a prospective *donor* or *donor's* family history that would pose a risk of producing an offspring with a serious genetic disease or defect greater than the risk in the general population *shall* disqualify him/her as a *donor*, with the following exceptions:

1) *Anonymous donors* whose family history indicates that he/she is at risk for carrying a genetic defect *may* be accepted only if a test to detect carrier status is performed and is negative for the mutation that is known to occur in the family; or

2) *Directed gamete donors* and *anonymous* or *directed embryo donors* with any family history indicating he/she is at risk for carrying a genetic defect/condition *may* be accepted, provided the genetic risk to offspring is evaluated in writing and the *recipient(s) (R)* has reviewed the evaluation, been offered additional genetic testing, and completed an informed consent.

   If indicated by medical history, family history, or ethnic background, *anonymous donors should* be screened for Tay-Sachs disease, thalassemia, sickle cell trait, spinal muscular atrophy, and/or cystic fibrosis.

D4.150 Relevant Medical Records Review

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Prior to *tissue* donation, a preliminary review of readily available *relevant medical records shall* be conducted by a trained individual.

This review *shall* include but *may* not be limited to:

1) evidence of significant active infection at the time of donation for *relevant communicable disease agents or diseases* (RCDADs) including signs and/or symptoms of viral and fungal infection, bacteremia or sepsis;

2) risk factors for *relevant communicable disease agents or diseases* (RCDADs) as specified in Appendix II; and

3) additional *tissue donor* specific criteria as documented in the *SOPM* and compliant with written agreements/contracts.

(A) Except for *skin*, *autologous* donation *should* not be undertaken when the *autologous donor* has, or is being treated for, bacteremia or other significant bacterial infection that can be associated with bacteremia, unless such *tissue* will be secondarily *sterilized* prior to *transplantation* or treated in such a manner to minimize microbial contamination.

D4.200 Donor Testing

D4.210 Blood Specimens

Except as otherwise specified for certain *reproductive tissue donors*, infectious disease testing of *donor* blood specimens *shall* be performed for each *tissue donor* on a specimen collected at the time of donation or within 7 days prior to or after donation. If the *donor* is one month (28 days) of age or less, a blood specimen from the birth mother *must* be collected within 7 days prior to or after *tissue* donation and tested instead of a specimen from the infant *donor*. There *shall* be written *procedures* for all significant steps in the infectious disease testing process, including blood specimen collection (i.e., documentation of date/time of collection, a *donor* identifier), documentation of the *verification* of specimen *labeling*, and use of appropriate blood specimen types, *labels*, and instructions for specimen handling. *Procedures shall* conform to the test kit manufacturer's instructions for use contained in the package inserts. Specimen collection, storage, and handling *procedures shall* be described in the *SOPM*.

(R) For *anonymous* and *directed oocyte donors*, the blood specimen *must* be collected within 30 days prior to *oocyte collection*, or within 7 days post donation. Samples for infectious disease testing of *anonymous* and *directed semen donors must* be obtained within 7 days of initial *semen collection*. See D4.360 for testing requirements for *embryo donors*.

D4.211 Plasma Dilution

Tissue from a *donor* who is older than 12 years of age *shall* be determined to

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be not suitable for *transplantation* if blood loss is known or suspected to have occurred and there has been transfusion/infusion of more than 2,000 milliliters (mL) of blood (e.g., whole blood, or red blood cells) or *colloids* within 48 hours; or more than 2,000 mL of *crystalloids* within one hour; or any combination thereof, prior to *asystole* or the collection of a blood specimen, whichever occurred earlier, unless:

1) a pre-transfusion or pre-infusion blood specimen from the *tissue donor* is available for infectious disease testing; or

2) an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the *tissue donor* to ensure that there has not been *plasma dilution* sufficient to affect test results.

Tissue from a *donor* who is 12 years of age or less who has been transfused or infused at all, *shall* be determined to be not suitable for *transplantation* unless a pre-transfusion or pre-infusion blood specimen from the *tissue donor* is available for infectious disease testing, or an algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the *tissue donor* to ensure that there has not been *plasma dilution* sufficient to affect test results.

When the fluids transfused are in the ‘‘blood’’ category (alone, or in combination with *colloids* and/or *crystalloids*), a comparison of the total volume of these fluids with the *donor's* estimated blood volume *shall* be performed, in addition to a comparison of the total volume of *colloids* and/or *crystalloids* with the *donor's* estimated plasma volume. Since every possible clinical situation cannot be described where *plasma dilution may* affect test results, the *SOPM should* describe how to address additional circumstances when *plasma dilution may* have occurred (e.g., large volumes of transfusions/ infusions administered in the absence of blood loss). It may be necessary to use a pre-transfusion/infusion blood specimen or apply an algorithm in those instances.

Alternative algorithms to evaluate *plasma dilution* can be used if justified.

D4.220 Infectious Disease Testing

Results of initial infectious disease and/or confirmatory testing *shall* be used as one component of determining *donor* eligibility. Testing used for *donor* eligibility *shall* be performed by laboratories that are registered with FDA as a tissue establishment for testing and are either certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, and test kit licensing/approval.

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FDA-licensed, approved, or cleared ***donor* screening** tests *must* be used, except when testing for *Chlamydia* or *gonorrhea* in which case, an FDA-licensed, cleared or approved diagnostic test *must* be used.

A new test *shall* be implemented when AATB and/or FDA issues notification to that effect. Prior to that time, use of the new test, even if FDA-licensed, approved, or cleared for *donor* screening, is voluntary. Tests specifically labeled for use with specimens collected after the *donor's* heart has stopped beating instead of a more generally labeled test *shall* be used when applicable and when available. *

A list of *donor* screening tests that have been licensed for use with specimens collected after the *donor's* heart has stopped beating can be accessed at the FDA/CBER website.

*See AATB Bulletin No. 06-45 ''Intent of Update to Standard D4.353.'' (Note: this standard is currently D4.220)

Rapid antigen and/or antibody testing for infectious disease *may* be performed in addition to the required tests. Results of these tests *must* be evaluated (see F1.140) and shared (see D4.300) in accordance with policies and *procedures*.

If a laboratory that performs organ *donor* testing performs the initial testing in duplicate or triplicate, the *tissue bank must* obtain and review the results of all individual tests performed. Individual test results *shall* be shared in accordance with B1.510, D4.300, and K1.100.

All *tissue* from *donors* who test repeatedly reactive on a required screening test *shall* be *quarantined* and *shall* not be used for *transplantation*. There *shall* be written *procedures* for all significant steps in the infectious disease testing process that *shall* conform to the manufacturer's instructions for use contained in the package inserts for required tests. These *procedures shall* be readily available to the personnel in the areas where the *procedures* are performed unless impractical. The manufacturer's instructions *shall* be followed in regard to acceptable *donor* specimens and their handling. *Donor* sample testing *shall* be performed, and test results interpreted according to the manufacturer's instructions in the package insert for the particular infectious disease marker.

Additional testing to confirm or supplement infectious disease test results *may* be performed at the discretion of the Medical Director using FDA-licensed, confirmatory test kits when commercially available. Results of infectious disease testing *shall* be evaluated prior to disclosure of availability of positive test results (see D4.232).

Current (14th Edition)
D4.230 Required Infectious Disease Tests

Excluding *autologous, embryo donor,* and *client depositor tissue*, all human *tissue* intended for *transplantation shall* be from *donors* who are tested and found to be negative for:

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1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti- HIV-1 and anti-HIV-2);

2) nucleic acid test (NAT) for HIV-1;

3) hepatitis B surface antigen (HBsAg);

4) nucleic acid test (NAT) for the hepatitis B virus (HBV);

5) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);

6) antibodies to the hepatitis C virus (anti-HCV);

7) nucleic acid test (NAT) for HCV; and

8) syphilis (a non-treponemal or treponemal-specific assay *may* be performed).

Donors of viable leukocyte-rich *tissue* (e.g., *semen*, certain (CT)) *shall* also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of d*onors* of other *tissue* types *may* be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

All test results *shall* be documented in the *donor's record*.

(R) In addition to the infectious disease tests listed above, all *anonymous* and *directed semen* and *oocyte donors shall* undergo testing for *Neisseria gonorrhea* and *Chlamydia trachomatis*. The manufacturer's requirements for specimens *must* be met. If the reproductive *tissue* is *collected* by a method that ensures freedom from contamination of the *tissue* by infectious disease organisms that may be present in the genitourinary tract, then these tests are not required.

All *anonymous* and *directed semen donors shall* also be tested for total antibody to cytomegalovirus (anti-CMV—total, meaning IgG and IgM).

Required tests for *anonymous* and *directed embryo donors* are listed in D4.231.

Client depositors who deposit *semen*, testicular fluid or *tissues*, *oocytes* or ovarian *tissue*, or *embryos*, *shall* be tested prior to use for:

1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);

2) hepatitis B surface antigen (HBsAg); and

3) antibodies to hepatitis C virus (anti-HCV).

With amendments

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1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti- HIV-1 and anti-HIV-2);

2) nucleic acid test (NAT) for HIV-1;

3) hepatitis B surface antigen (HBsAg);

4) nucleic acid test (NAT) for the hepatitis B virus (HBV);

5) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);

6) antibodies to the hepatitis C virus (anti-HCV);

7) nucleic acid test (NAT) for HCV; and

8) syphilis (a non-treponemal or treponemal-specific assay *may* be performed).

Donors of viable leukocyte-rich *tissue* (e.g., *semen*, certain (CT)) *shall* also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of d*onors* of other *tissue* types *may* be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

(LD) For *tissue* establishments located within the United States (U.S.), all living *donors*, excluding *autologous donors*, shall be tested and found to be negative for WNV NAT when *recovery, collection*, or *acquisition* occurs from June 1st through October 31st every year. Ref. D4.231 (R)

For *tissue* establishments located outside the U.S. importing *tissues* to the U.S., all *living donors*, excluding *autologous donors*, shall be tested year-round and found to be negative for WNV NAT.

All test results *shall* be documented in the *donor's record*.

(R) In addition to the infectious disease tests listed above, all *anonymous* and *directed semen* and *oocyte donors shall* undergo testing for *Neisseria gonorrhea* and *Chlamydia trachomatis*. The manufacturer's requirements for specimens *must* be met. If the reproductive *tissue* is *collected* by a method that ensures freedom from contamination of the *tissue* by infectious disease organisms that may be present in the genitourinary tract, then these tests are not required.

All *anonymous* and *directed semen donors shall* also be tested for total

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antibody to cytomegalovirus (anti-CMV—total, meaning IgG and IgM).

Required tests for *anonymous* and *directed embryo donors* are listed in D4.231.

Client depositors who deposit *semen*, testicular fluid or *tissues*, *oocytes* or ovarian *tissue*, or *embryos*, *shall* be tested prior to use for:

1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
2) hepatitis B surface antigen (HBsAg); and
3) antibodies to hepatitis C virus (anti-HCV).

As amended

D4.230 Required Infectious Disease Tests

Excluding *autologous, embryo donor,* and *client depositor tissue*, all human *tissue* intended for *transplantation shall* be from *donors* who are tested and found to be negative for:

1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti- HIV-1 and anti-HIV-2);

2) nucleic acid test (NAT) for HIV-1;

3) hepatitis B surface antigen (HBsAg);

4) nucleic acid test (NAT) for the hepatitis B virus (HBV);

5) total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);

6) antibodies to the hepatitis C virus (anti-HCV);

7) nucleic acid test (NAT) for HCV; and

8) syphilis (a non-treponemal or treponemal-specific assay *may* be performed).

Donors of viable leukocyte-rich *tissue* (e.g., *semen*, certain (CT)) *shall* also be tested and found to be negative for antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II). Note: HTLV testing of d*onors* of other *tissue* types *may* be required by law and/or regulation, including, where applicable, foreign laws and/or regulations.

(LD) For *tissue* establishments located within the United States (U.S.), all living *donors*, excluding *autologous donors*, shall be tested and found to be negative for WNV NAT when *recovery, collection*, or *acquisition* occurs from June 1st through October 31st every year. Ref. D4.231 (R)

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For *tissue* establishments located outside the U.S. importing *tissues* to the U.S., all *living donors*, excluding *autologous donors*, shall be tested year-round and found to be negative for WNV NAT.

All test results *shall* be documented in the *donor's record*.

(R) In addition to the infectious disease tests listed above, all *anonymous* and *directed semen* and *oocyte donors shall* undergo testing for *Neisseria gonorrhea* and *Chlamydia trachomatis*. The manufacturer's requirements for specimens *must* be met. If the reproductive *tissue* is *collected* by a method that ensures freedom from contamination of the *tissue* by infectious disease organisms that may be present in the genitourinary tract, then these tests are not required.

All *anonymous* and *directed semen donors shall* also be tested for total antibody to cytomegalovirus (anti-CMV—total, meaning IgG and IgM).

Required tests for *anonymous* and *directed embryo donors* are listed in D4.231.

Client depositors who deposit *semen*, testicular fluid or *tissues*, *oocytes* or ovarian *tissue*, or *embryos*, *shall* be tested prior to use for:

1) antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
2) hepatitis B surface antigen (HBsAg); and
3) antibodies to hepatitis C virus (anti-HCV).

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Current (14th Edition)

D4.231 Repeat Testing of Living Donors

(R) All donated *semen* from *anonymous donors shall* be frozen and *quarantined* for at least 6 months. After such time and prior to release of *semen*, the *donor shall* be retested for anti-HIV-1, HIV-1 NAT, anti-HIV-2, HBsAg, anti-HBc, HBV NAT, anti-HCV, HCV NAT, anti-HTLV-I, anti-HTLV-II, syphilis, and for anti-CMV. *Anonymous donor semen shall* not be made available for use unless results of all tests, excluding CMV and syphilis, are negative or nonreactive. Results of all testing performed *must* be interpreted as in F1.140. All tests for infectious diseases *shall* be repeated at least every 6 months while the *semen donor* remains an active participant in the *donor* program and after any lapse exceeding 6 months.

Oocyte donor tissue is not subject to *quarantine* and the *donor* is not subject to repeat testing.

For *directed* or *anonymous donation* of *embryos* created by sexually

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intimate *client depositors*, the *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After the 6-month *quarantine* and prior to release of the *embryo(s)* for *transfer*, appropriate measures *should* be taken to test the sexually intimate *client depositor* male and female for anti-HIV-1 anti-HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. In addition, the male *should* be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II.

For *directed* or *anonymous donation* of *embryos* created using one *anonymous* or *directed* egg or *sperm donor*, *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After such time and prior to release of the *embryo(s)* for *transfer*, appropriate measures *should* be taken to test the *client depositor* for anti-HIV-1, anti- HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. If the *client depositor* is male, he *should* also be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II. A *Summary of Records* for the *gamete donor must* be provided prior to release.

For *directed* or *anonymous donation* of *embryos* created using both an *anonymous* or *directed* egg and sperm *donor*, a *donor summary of records must* be obtained for both donors.

"Appropriate measures" means using available resources to accomplish the testing. If the *client depositor* cannot be tested due to death or inability to locate the person, *directed* or *anonymous donation* of the *embryos* can still be completed.

With amendments

D4.231 Repeat Testing of Living Donors

(R) All donated *semen* from *anonymous donors shall* be frozen and *quarantined* for at least 6 months. After such time and prior to release of *semen*, the *donor shall* be retested for anti-HIV-1, HIV-1 NAT, anti-HIV-2, HBsAg, anti-HBc, HBV NAT, anti-HCV, HCV NAT, anti-HTLV-I, anti-HTLV-II, syphilis, and for anti-CMV. *Anonymous donor semen shall* not be made available for use unless results of all tests, excluding CMV and syphilis, are negative or nonreactive. Results of all testing performed *must* be interpreted as in F1.140. All tests for infectious diseases *shall* be repeated at least every 6 months while the *semen donor* remains an active participant in the *donor* program and after any lapse exceeding 6 months. For repeat semen *donors* who have already had testing performed and for whom retesting at ≥ 6 months is required, *testing* at each *donation* is not required. For such repeat semen *donor*s, WNV NAT testing shall be performed at the time of, or within 7 days before or after the first donation that is recovered within the June 1st through October 31st testing period, even if an earlier specimen was already collected and tested.

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Oocyte donor tissue is not subject to *quarantine* and the *donor* is not subject to repeat testing.

For *directed* or *anonymous donation* of *embryos* created by sexually intimate *client depositors*, the *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After the 6-month *quarantine* and prior to release of the *embryo(s)* for *transfer*, appropriate measures *should* be taken to test the sexually intimate *client depositor* male and female for anti-HIV-1 anti-HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. In addition, the male *should* be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II.

For *directed* or *anonymous donation* of *embryos* created using one *anonymous* or *directed* egg or *sperm donor*, *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After such time and prior to release of the *embryo(s)* for *transfer*, appropriate measures *should* be taken to test the *client depositor* for anti-HIV-1, anti- HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. If the *client depositor* is male, he *should* also be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II. A *Summary of Records* for the *gamete donor must* be provided prior to release.

For *directed* or *anonymous donation* of *embryos* created using both an *anonymous* or *directed* egg and sperm *donor*, a *donor summary of records must* be obtained for both donors.

"Appropriate measures" means using available resources to accomplish the testing. If the *client depositor* cannot be tested due to death or inability to locate the person, *directed* or *anonymous donation* of the *embryos* can still be completed.

As amended

D4.231 Repeat Testing of Living Donors

(R) All donated *semen* from *anonymous donors shall* be frozen and *quarantined* for at least 6 months. After such time and prior to release of *semen*, the *donor shall* be retested for anti-HIV-1, HIV-1 NAT, anti-HIV-2, HBsAg, anti-HBc, HBV NAT, anti-HCV, HCV NAT, anti-HTLV-I, anti-HTLV-II, syphilis, and for anti-CMV. *Anonymous donor semen shall* not be made available for use unless results of all tests, excluding CMV and syphilis, are negative or nonreactive. Results of all testing performed *must* be interpreted as in F1.140. All tests for infectious diseases *shall* be repeated at least every 6 months while the *semen donor* remains an active participant in the *donor* program and after any lapse exceeding 6 months. For repeat semen *donors* who have already had testing performed and for whom retesting at ≥ 6 months is

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required, *testing* at each *donation* is not required. For such repeat semen *donor*s, WNV NAT testing shall be performed at the time of, or within 7 days before or after the first donation that is recovered within the June 1st through October 31st testing period, even if an earlier specimen was already collected and tested.

Oocyte donor tissue is not subject to *quarantine* and the *donor* is not subject to repeat testing.

For *directed* or *anonymous donation* of *embryos* created by sexually intimate *client depositors*, the *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After the 6-month *quarantine* and prior to release of the *embryo(s)* for *transfer*, appropriate measures *should* be taken to test the sexually intimate *client depositor* male and female for anti-HIV-1 anti-HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. In addition, the male *should* be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II.

For *directed* or *anonymous donation* of *embryos* created using one *anonymous* or *directed* egg or *sperm donor*, *embryos shall* be *quarantined* (stored) for at least 6 months from the date of creation. After such time and prior to release of the *embryo(s)* for *transfer*, appropriate measures *should* be taken to test the *client depositor* for anti-HIV-1, anti- HIV-2, HBsAg, anti-HBc, anti-HCV, and for HIV-1 NAT, HBV NAT, HCV NAT, and syphilis. If the *client depositor* is male, he *should* also be tested for anti-CMV, anti-HTLV-I, and anti-HTLV-II. A *Summary of Records* for the *gamete donor must* be provided prior to release.

For *directed* or *anonymous donation* of *embryos* created using both an *anonymous* or *directed* egg and sperm *donor*, a *donor summary of records must* be obtained for both donors.

"Appropriate measures" means using available resources to accomplish the testing. If the *client depositor* cannot be tested due to death or inability to locate the person, *directed* or *anonymous donation* of the *embryos* can still be completed.

Announcement date: January 31, 2019 (Bulletin 19-1)
Effective date: July 31, 2019 (6-month implementation period)

D4.232 Disclosure and Availability of Positive Infectious Disease Test Results

The *donor*, if living, *shall* be provided test results as required by applicable law or regulation. For deceased *donors*, the *authorizing person should* be contacted regarding the availability of infectious disease test results that may be of medical significance as determined by the Medical Director or licensed

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physician designee. Contact *should* include the means by which available test results *should* be requested. If a *document of gift* was used (i.e., there is no *authorizing person*), contact regarding the availability of infectious disease test results *should* be made to the person who would have been the *authorizing person* had no gift been made during the life of the *donor*, or to the person authorized to make arrangements for final disposition of the body. These *records should* be provided upon written request as permitted by law or regulation. Positive test results *shall* be reported to state and/or local health department(s) as required by law or regulation.

Contact regarding availability and/or disclosure of test results *shall* be documented.

D4.240 Archived Samples *(last amended January 9, 2019)*

A policy *shall* be *established* to collect and preserve serum, plasma, or hematopoietic *tissue* samples from *donors* for an appropriate duration after the *recovery*, *collection*, or *acquisition* date as/if prescribed by a *quality*, safety, and legal risk assessment conducted by the *tissue* bank to mitigate the establishment's specific risk exposure. For samples from *donors* determined to be ineligible/unsuitable, or samples from eligible donors approaching expiration of their preservation term as defined by organizational policy, *tissue* establishments may have written agreements with third parties for long-term archiving of serum, plasma, or hematopoietic *tissue* samples 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.

D4.250 Semen Analysis

(R) **Semen *Donors***: Prior to enrollment of a *donor* in the sperm *donor* program, his *semen shall* be tested for sperm quality and found acceptable for such parameters as sperm motility, concentration, and post-thaw motility. *Donors shall* be excluded unless the specimen meets criteria set by the Medical Director and, when appropriate, the Medical Advisory Committee. Criteria for *directed donors may* differ from those for *anonymous donors*. Sperm quality tests *shall* be repeated at a frequency determined by the *tissue bank*.

Client Depositors: A *semen* analysis, that includes sperm concentration and motility, at a minimum, *shall* be performed. The *reproductive tissue bank shall*

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make pertinent test results available to the *client depositor*'s physician.

D4.300 Information Sharing

The *tissue bank* that recovers *tissues must* have a *procedure(s)* for receiving, investigating, evaluating, and documenting *donor* information as well as how they will share *records* with all establishments who are known to have also *recovered tissues*, or to have received *recovered tissues*, from the same *donor*:

1) *record* sharing *should* occur as new information is received and this *must* be documented and included in the *records;*

2) relevant *records* that could affect eligibility determinations *must* be sent without delay to *tissue banks* that will determine *donor* eligibility of *recovered tissues* and/or the *donor;*

3) the *tissue bank* that *recovers tissue must* share *tissue recovery* culture (*pre-sterilization/ pre-disinfection culture)* information with all *tissue banks* to which *tissue* from shared *donors* was sent. If defined in a written agreement, an eye bank can choose not to receive *pre-sterilization/pre-disinfection culture* results; and

4) if any *tissue bank* determines a *donor* to be ineligible, this determination *must* be communicated in writing to the *tissue bank* that *recovered tissues*, and the *tissue bank* that *recovered tissues must* share this information with all establishments that are known to have *recovered tissues*, or to have received *recovered tissues*, from the same *donor.*

Written *procedures must* describe how this information is received, evaluated, and disseminated in a timely fashion.

Any *tissue* testing performed after it has been *disinfected* or subjected to *processing* (e.g., in-*process* testing, post-*processing* microbiological testing, final cultures) is not considered relevant *donor records* for the *tissue bank* that *recovered tissues* and, if such results are reported, would not be expected to be shared with *tissue banks* who received *recovered tissues* from a shared *donor.*

D5.000 RECOVERY, COLLECTION, AND ACQUISITION

Policies and *procedures shall* be established for the *recovery, collection,* or *acquisition* of *tissue* in accordance with *Standards*. Reagents, supplies, materials, and equipment *shall* be of appropriate grade for intended use, and approval for use *shall* be documented. All *tissue must* be uniquely identified and traceable to the *donor* from *recovery, collection,* or *acquisition* through transport and receipt at the *processing* or storage facility. The environment in which *tissue* can be obtained, and techniques that *should* be used, *shall* be specified. *Recovery, collection, acquisition* and *preservation shall* occur within a time interval appropriate for retention of *tissue quality* and *shall* be compatible with intended use of the *tissue*. Detailed *records* of the *tissue* donation *shall* be maintained that include information regarding relevant packaging, transportation, and, when applicable, *donor* reconstruction steps.

D5.100 Reagents, Supplies, Materials, and Equipment *(last amended May 31, 2018)*

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All critical supplies, reagents, materials, and equipment approved for use for recovery, collection, or acquisition shall be identified and specifications (e.g., sterile where applicable) documented. A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, lot number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of the staff performing the inspection. The tissue bank shall maintain records of all supplies, reagents, materials, and equipment from receipt through period of time used. All reagents, supplies, materials and equipment shall be used and stored in accordance with manufacturers' instructions, unless qualified/validated for intended use or storage.

All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with tissue shall be properly cleaned, decontaminated, and sterilized prior to use for recovery, collection, or acquisition according to written procedures prepared to prevent contamination or cross-contamination. Records shall be maintained that document sterilization steps. All reagents, supplies, and materials shall be used and stored in accordance with manufacturers' instructions unless qualified/validated for intended use or storage. Adequate controls must exist to prevent mix-ups between acceptable and unacceptable items.

D5.110 Stock Rotation

Reagents, supplies, and materials with expiration dates or production dates *shall* be stored in a manner to facilitate inventory rotation. Items not bearing an expiration or production date *shall* be labeled with the date of acquisition and stored in a manner to facilitate inventory rotation. Older items *should* be used first and not used if expired or quality has been compromised.

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*.

D5.210 Verification Procedures

D5.211 Confirmation *(last amended April 19, 2017)*

Prior to *recovery* or *collection,* staff *shall* confirm that in the case of a deceased *donor*, *authorization* for donation has been obtained and documented in a *document of gift/authorization*. Except for autologous tissue, *informed consent must* be obtained and documented prior to the initial *collection* from living donors. If *informed consent* was not obtained prior to *recovery* (e.g., *surgical bone*) or *acquisition*, it *must* be obtained as soon as practical after *recovery* or *acquisition.*

D5.212 Donor Identity

Prior to initiation of *tissue recovery, collection,* or *acquisition* the potential *donor's* identification *shall* be *verified* with the *donor's* name as stated on the *record* of *informed consent* or *document of gift/authorization. Donor* identity *verification shall* be documented in the donor record prior to *tissue recovery,*

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collection, or *acquisition*. *Records shall* indicate the staff member(s) involved and include the source of the *verification* information (e.g., hospital wristband, medical examiner number, driver's license, or government issued identification with photograph).

(A, SB) Identification of the *donor shall* be the responsibility of the hospital staff involved with the *recovery.*

(BT) Identification of the birth mother *shall* be the responsibility of the hospital staff, or the *tissue bank* staff member involved with *acquisition.*

D5.300 Tissue Recovery, Collection, and Acquisition

Recovery, *collection*, or *acquisition shall* be performed using aseptic or clean techniques appropriate to the specific *tissue* type and intended use. *Tissue must* be *labeled* using a *donor* identifier and a description according to the *SOPM* (see G1.100).

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 *donor's* 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*.

D5.320 Collection

(R) *Collection* of *anonymous donor semen shall* be made at the *reproductive tissue bank* using a *sterile collection* container. 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*. The *collection* container *shall* be *labeled* with the date of *collection* and the *donor's* identification or, in the case of *client depositors or directed donors*, the name. The time of *collection shall* also be recorded.

D5.330 Acquisition

(BT) Methods for *acquisition* of *birth tissue shall* be safe, aseptic, and ensure accurate identification of *tissue* post delivery.

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Birth tissue shall be *packaged* post-delivery using a *sterile* receptacle/transport package in a controlled environment. Prior to *acquisition*, the *birth tissue* receptacle/transport package *shall* be *labeled*.

D5.340 Pooling

Pooling tissue from multiple *donors shall* not occur during *recovery, collection, acquisition* or *storage*.

D5.400 Time Limits for Postmortem Tissue Recovery

When *recovery* of *tissue* has begun, subsequent *recovery* steps *mus*t proceed without delay.

(C, V) *Cardiac tissue* and *vascular tissue recovery* and *processing* time limits (i.e., *warm* and *cold ischemic time*, *disinfection time*, and the *perfusion time* [specific to *vascular tissues*]) *shall* be established by each individual *tissue bank*; however, the following upper time limits for initiation of *recovery* of specific *tissue* types *shall* not be exceeded.

(C) *Warm ischemic time* (C) *shall* not exceed 24 hours from *asystole* if the *donor's* body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *asystole*. The time limit *shall* not exceed 15 hours if the *donor's* body was not cooled or refrigerated. If the *donor's* body is cooled for a period of time then not cooled for a period of time, the time period the *donor's* body is not cooled cannot exceed 15 cumulative hours.

(V) 1) *Perfusion time shall* not exceed 12 hours from *asystole*; and

2) *warm ischemic time* (V) *shall* not exceed 24 hours from *asystole* if the *donor's* body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *asystole*. The time limit *shall* not exceed 15 hours if the *donor's* body was not cooled or refrigerated. If the *donor's* body is cooled for a period of time then not cooled for a period of time, the time period the *donor's* body is not cooled cannot exceed 15 cumulative hours.

(MS, OA, S)

The *skin prep shall* begin within 24 hours of *asystole* provided the *donor's* body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *asystole*. The *skin prep* shall begin within 15 hours of death if the deceased *donor's* body has not been cooled or refrigerated. If the *donor's* body is cooled for a period of time then not cooled for a period of time, the time period the *donor's* body is not cooled cannot exceed 15 cumulative hours.

For expectations when evaluating cooling of a *donor's* body, refer to Guidance Document No. 7.

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D5.500 Recovery Environment

All *tissue shall* be *recovered* in an aseptic or clean fashion using standard surgical preparation with *sterile* packs, instrumentation, and technique. Prior to *recovery*, the *recovery site must* be evaluated for suitability using pre-established criteria designed to control contamination and *cross-contamination* (see Appendix IV). The *recovery site* evaluation *must* be documented, however, if the *recovery site* is an operating room in a heath care facility, no documented site evaluation is required.

D5.510 Recovery Site Suitability Parameters

These *must* address the control of:

1) size/space;

2) lighting;

3) plumbing and drainage for the intended use;

4) the physical state of the facility (i.e., state of repair);

5) ventilation;

6) cleanliness of room and furniture surfaces;

7) pests;

8) traffic;

9) location;

10) other activities occurring simultaneously;

11) sources of contamination; and

12) the ability to appropriately dispose of biohazardous waste and handle contaminated equipment.

D5.520 Recovery Cleansing and Preparation *(last amended May 31, 2018)*

Environment:
An evaluation of the *recovery* site *must* be performed to identify potential sources of contamination (see Appendix IV). All working surfaces (e.g., back table, Mayo stand, *recovery* table) used during *recovery must* be *decontaminated* using a bactericidal/antimicrobial agent. All cleansing and *disinfecting* events performed by tissue bank personnel shall be documented. For guidance, refer to Guideline for environmental cleaning in Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. (current edition).

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Technician:
Technician gowning, gloving, and movement *shall* be accomplished with the same diligence as used routinely for operative procedures. *Aseptic* technique shall be followed. For guidance, refer to AORN's Guideline for sterile technique (current edition). Persons performing the surgical *recovery shall* perform a surgical scrub or wash of their hands and forearms prior to *recovery.* For guidance, refer to AORN's for hand hygiene (current edition). A head cover, eye shields and mask *shall* be worn at the time of scrub, and a Sterile gown and gloves shall be donned after the scrub/wash. For guidance, refer to AORN's Guideline for surgical attire (current edition).

Donor:
Cleansing, preparing (i.e., skin prep), and draping the skin *shall* be accomplished with the same diligence as used routinely for operative procedures. Unless otherwise *qualified*/*validated*, agents used *shall* be antimicrobial skin preparation products, as specified in the SOPM, and *shall* be used in accordance with manufacturers' guidelines/instructions. For guidance, refer to AORN's Guideline for preoperative patient skin antisepsis (current edition).

D5.530 Recovery Technique

Specific *tissue recovery* operations that control contamination and *cross- contamination* (e.g., sequencing of the tissue *recovery*, use of well-defined zone *recovery* techniques, and isolation draping in the presence of trauma; see Appendix IV *shall* be implemented. Areas of *skin* that have abrasions or puncture wounds *should* be avoided. All *tissue shall* be *recovered* using aseptic technique.

D5.531 Cultures Obtained at Recovery

(MS, OA, S, SB)
If performed, the technique used to obtain cultures of *recovered tissues shall* be appropriate for the *tissue* type, and performed according to written instructions.

D5.600 Delivery Environment and Cultures Obtained Prior to Acquisition

D5.610 Delivery Environment

(BT) If the delivery location is an operating room in a health care facility, no documented site evaluation is required, however, any other location of delivery *must* meet the requirements at D5.500 and D5.510. Such an evaluation *must* be documented.

D5.620 Cultures Obtained Prior to Acquisition

(BT) If performed, the technique used to obtain cultures prior to *acquisition shall* be appropriate and performed according to written instructions.

D5.700 Records

D5.710 Recovery Records

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For *allogeneic tissue*, details of the *tissue* donation *shall* be documented in the *recovery record*. *Recovery records shall* include, but not be limited to:

1) name, and address of the *recovery* agency;

2) date, time and staff involved in all significant steps performed during the *recovery* (documentation *shall* be as per C1.100);

3) location and assessment of the suitability of the *recovery site*;

4) documentation of the *physical assessment* or *physical examination*;

5) documentation of any *errors*, *accidents*, or *deviations* that occurred;

6) *donor* name, age, and sex;

7) the type, *lot* number, manufacturer, and expiration date of *critical* reagents, supplies and materials, and the identification of equipment, used to *recover*, rinse, and/or transport *tissue*; and

8) specific *tissue recovered*; and

9) other available *relevant medical records*.

The *tissue bank* or agency r*ecovering* the *tissue shall* provide a *record* of the *tissue* recovered, date of *recovery*, name and address of the *recovery* agency, and name of the *donor* to the *recovery site* facility.

(A) The following information regarding *autologous tissue recovery shall* be documented:

1) name and address of the institution in which the *autologous tissue* was *recovered*;

2) date and time the *autologous tissue* was *recovered*;

3) name of the physician *recovering* the *autologous tissue;*

4) *donor* name, age, sex, and hospital medical record number and/or social security number; and

5) type of *tissue recovered*.

D5.720 Delivery and Post-Delivery Records

Details of the delivery and post-delivery time period through *acquisition shall* be documented in the *donor's record*. These *records shall* include, but not be limited to the:

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1) birth mother's name;

2) infant *donor's* gestational age;

3) name and address of the health care facility and the identification of the delivery environment/location;

4) date and time of the delivery;

5) the physician or other authorized practitioner involved with the delivery, or designee as permitted by law;

6) information to allow tracking of *critical* reagents, supplies and materials provided by the *tissue bank*;

7) specific *tissue(s) acquired*;

8) other available *relevant medical records*; and

9) documentation of any *errors*, *accidents*, or *deviations* that occurred.

D5.800 Packaging, Labeling, and Transport

D5.810 Post Recovery Packaging and Labeling

Immediately following *recovery* of each individual *tissue* at the *recovery site, recovered tissue shall* be individually and aseptically wrapped or enclosed and *shall* be immediately *labeled* with the unique *donor* identifier and the description according to the *SOPM* (see G1.100). *Tissue shall* be maintained at defined environmental temperatures until the time of transport to the *processing* center. Maintenance of such temperatures *shall* be documented. The receptacle/transport package *must* be designed to prevent contamination of the contents and allow for aseptic presentation of the *tissue* at the time of *processing*.

(A) Immediately following *recovery* of the *autologous tissue, it shall* be individually and aseptically wrapped. The package *shall* be *labeled* immediately with definitive *autologous donor* identifying information such as the patient's name, hospital registration number, security number, birth date, etc., and *shall* be prominently labeled "FOR AUTOLOGOUS USE ONLY."

(C) *Recovered cardiac tissue shall* be rinsed and *packaged* in an isotonic, *sterile* solution such as normal saline, lactated Ringer's solution, PlasmaLyte®, transplant organ perfusate (e.g., Belzer's UW solution, Collin's solution) or tissue culture media, immediately following *recovery.* The volume of the transport solution *should* be adequate to cover the entire heart, including the vessels and valves. The type, *lot* number, manufacturer, and expiration date *shall* be documented.

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(V) Immediately following *recovery, vascular tissue shall* be gently flushed and packaged in an isotonic *sterile* solution such as tissue culture media. Normal saline solution *should* not be used. The type, *lot* number, manufacturer, and expiration date of all reagents used for *recovery* and *packaging shall* be documented.

(S) *Recovered skin tissue shall* be *packaged* in a *sterile* solution immediately following *recovery* or *packaged* by another method that maintains the integrity of the *tissue* for its intended use (e.g., decellularized dermis). If in solution, the volume of transport solution *must* be adequate to cover the entire *skin*. The type, *lot* number, manufacturer, and expiration date(s) *shall* be documented.

D5.820 Post Delivery Packaging and Labeling

(BT) Following delivery, *tissue shall* be aseptically contained. *Labeling* that includes a unique *donor* identifier and the description according to the *tissue bank's SOPM* (see G1.100) *shall* be performed prior to transport. The receptacle/transport package *must* be designed to prevent contamination of the contents and allow for aseptic presentation of the *tissue* at the time of *processing*.

Tissue shall be maintained at defined environmental temperatures until the time of transport to the processing center. Maintenance of such temperatures *shall* be documented.

Current (14th Edition)

D5.830 Tissue Transport

Tissue shall be transported in a manner *established* by the *tissue bank* that permits required environmental conditions for the duration of transport necessary to maintain the integrity of the *tissue* for its intended use. Transportation temperatures do not require monitoring if the *packaging* and transport conditions have been *validated* to maintain the required environmental conditions, including temperatures. The receptacle/*transport package must* indicate that "*DONATED HUMAN TISSUE*" is enclosed and *must* include the name and address of the originating agency and *processing* center (if different). All human *tissue processed* or shipped prior to determination of *donor* eligibility *must* be under *quarantine*, accompanied by *records* assuring identification of the *donor* and indicating that the *tissue* has not been determined to be suitable for *transplantation* (e.g., "Quarantine"; "Donor Eligibility Has Not Been Completed"; and "Not Suitable for Transplant in its Current Form").

(A, LD, CT)
When *wet ice temperatures* would be injurious to the *tissue recovered*, it *may* be transported at appropriate temperatures and within time limits that maintain the *quality* of the *tissue* for its intended use.

(C, V) The transport *package shall* be transported at *wet ice temperatures*. Time of acceptance of the *tissue* into the *processing* center *shall* be documented. *Cardiac tissue* and *vascular tissue shall* be received at the *processing* location

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within sufficient time following *recovery* to allow for the start of *disinfection* within the *established cold ischemic time* limit.

(MS) The *recovered tissue shall* be wrapped in an aseptic fashion with at least one moisture barrier and *shall* be transported at *wet ice temperatures* or colder. The maximum time that *recovered tissue shall* remain at *wet ice temperatures*, prior to either *processing* or freezing, *shall* be no longer than a time limit *established* by a *validated procedure* that maintains *tissue quality*.

(OA) The *recovered tissue shall* be transported at *wet ice temperatures*. The maximum time that *recovered tissue shall* remain at *wet ice temperatures* prior to *processing shall* be no longer than a time limit *established* by a *validated procedure* that maintains *tissue quality*.

(S) If the *tissue* is to be *cryopreserved*, the *skin* transport *package shall* be transported at *wet ice temperatures* or *packaged* by another method that maintains the *quality* of the *tissue* for its intended use.

With amendments

D5.830 Tissue Transport

Tissue shall be transported in a manner *established* by the *tissue bank* that permits required environmental conditions for the duration of transport necessary to maintain the integrity of the *tissue* for its intended use. Transportation temperatures do not require ~~monitoring~~ *verification* if the *packaging* and transport conditions have been *validated* to maintain the required environmental conditions, including temperatures. The receptacle*/transport package must* indicate that "*DONATED HUMAN TISSUE*" is enclosed and *must* include the name and address of the originating agency and *processing* center (if different). All human *tissue processed* or shipped prior to determination of *donor* eligibility *must* be under *quarantine*, accompanied by *records* assuring identification of the *donor* and indicating that the *tissue* has not been determined to be suitable for *transplantation* (e.g., "Quarantine"; "Donor Eligibility Has Not Been Completed"; and "Not Suitable for Transplant in its Current Form").

(A, LD, CT)
When *wet ice temperatures* would be injurious to the *tissue recovered*, it *may* be transported at appropriate temperatures and within time limits that maintain the *quality* of the *tissue* for its intended use.

(C, V) The transport *package shall* be transported at *wet ice temperatures*. Time of acceptance of the *tissue* into the *processing* center *shall* be documented. *Cardiac tissue* and *vascular tissue shall* be received at the *processing* location within sufficient time following *recovery* to allow for the start of *disinfection* within the *established cold ischemic time* limit.

(MS) The *recovered tissue shall* be wrapped in an aseptic fashion with at least one moisture barrier and *shall* be transported at *wet ice temperatures* or colder. The maximum time that *recovered tissue shall* remain at *wet ice temperatures*, prior to either *processing* or freezing, *shall* be no longer than a time limit *established*

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	Board of Governors:	10-9-18	AATB Bulletin 19-1	

by a *validated procedure* that maintains *tissue quality*.

(OA) The *recovered tissue shall* be transported at *wet ice temperatures*. The maximum time that *recovered tissue shall* remain at *wet ice temperatures* prior to *processing shall* be no longer than a time limit *established* by a *validated procedure* that maintains *tissue quality*.

(S) If the *tissue* is to be *cryopreserved*, the *skin* transport *package shall* be transported at *wet ice temperatures* or *packaged* by another method that maintains the *quality* of the *tissue* for its intended use.

As amended

D5.830 Tissue Transport

Tissue shall be transported in a manner *established* by the *tissue bank* that permits required environmental conditions for the duration of transport necessary to maintain the integrity of the *tissue* for its intended use. Transportation temperatures do not require *verification* if the *packaging* and transport conditions have been *validated* to maintain the required environmental conditions, including temperatures. The receptacle/*transport package must* indicate that "*DONATED HUMAN TISSUE*" is enclosed and *must* include the name and address of the originating agency and *processing* center (if different). All human *tissue processed* or shipped prior to determination of *donor* eligibility *must* be under *quarantine*, accompanied by *records* assuring identification of the *donor* and indicating that the *tissue* has not been determined to be suitable for *transplantation* (e.g., "Quarantine"; "Donor Eligibility Has Not Been Completed"; and "Not Suitable for Transplant in its Current Form").

(A, LD, CT)
When *wet ice temperatures* would be injurious to the *tissue recovered*, it *may* be transported at appropriate temperatures and within time limits that maintain the *quality* of the *tissue* for its intended use.

(C, V) The transport *package shall* be transported at *wet ice temperatures*. Time of acceptance of the *tissue* into the *processing* center *shall* be documented. *Cardiac tissue* and *vascular tissue shall* be received at the *processing* location within sufficient time following *recovery* to allow for the start of *disinfection* within the *established cold ischemic time* limit.

(MS) The *recovered tissue shall* be wrapped in an aseptic fashion with at least one moisture barrier and *shall* be transported at *wet ice temperatures* or colder. The maximum time that *recovered tissue shall* remain at *wet ice temperatures*, prior to either *processing* or freezing, *shall* be no longer than a time limit *established* by a *validated procedure* that maintains *tissue quality*.

(OA) The *recovered tissue shall* be transported at *wet ice temperatures*. The maximum time that *recovered tissue shall* remain at *wet ice temperatures* prior to *processing shall* be no longer than a time limit *established* by a *validated procedure* that maintains *tissue quality*.

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(S) If the *tissue* is to be *cryopreserved*, the *skin* transport *package shall* be transported at *wet ice temperatures* or *packaged* by another method that maintains the *quality* of the *tissue* for its intended use.

Announcement date: January 31, 2019 (Bulletin 19-1)
Effective date: July 31, 2019 (6-month implementation period)

D5.900 Reconstruction of a Deceased Donor's Body

Unless there is a specific request from a medical examiner, pathologist, or a funeral home, the surgical incision(s) *shall* be closed in an aesthetic fashion and the deceased *donor's* body prepared for the next portion of the *recovery* or for transportation to an appropriate facility. The *donor's* body *shall* be reconstructed in accordance with the *SOPM*. Reconstruction *should* employ techniques consistent with funeral home guidelines and/or medical examiner or pathologist requests. Documentation of *donor* reconstruction (if applicable) and disposition of the *donor's* body *shall* be maintained in the *donor's record*.

D6.000 STORAGE OF TISSUE

Storage, including temporary *storage*, of *recovered, acquired, or collected tissue shall* be in conformance with *storage* temperature and monitoring expectations provided by the t*issue bank* that will *process* the *tissue*. See C1.300, E3.330, E3.331, and E3.340.

D6.100 Quarantine Controls *(last amended May 31, 2018)*

Adequate controls *must* exist to prevent mix-ups, contamination, *cross-contamination*, and ensure *tissue* is identified as acceptable or unacceptable during all stages of *recovery*, receipt, *storage*, *processing* and *distribution*. If physical segregation is deemed unnecessary, justification *must* be *established*, and *must* include a risk assessment and use of a *validated electronic system*. Considerations for the risk assessment *shall* include:

1) potential severity of impact if controls fail to prevent mix-up, contamination or *cross-contamination*;
2) probability of failure to occur;
3) likelihood of identifying a failure before it reaches a customer;
4) existing controls to prevent failure; and
5) back-up plan for failure of *validated electronic system*.

If physical segregation is deemed necessary, segregated areas *must* be appropriately *labeled*.

D6.200 Segregation

The *SOPM must* address when the segregation of *tissue* during *storage* is indicated and how it will be appropriately segregated to avoid contamination, *cross-contamination* and mix-ups.

Considerations for assessment of risk include, where applicable:

1) *donor* infectious disease test results are unavailable or this testing will not be performed;

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2) the intended use of the *tissue* is primarily for *transplantation* or is restricted to research or education;

3) *autologous tissue* is segregated from *allogeneic tissue*;

4) the *donor* has been determined to be ineligible;

5) the ability of *packaging* and *labeling* to withstand *storage* temperatures, and/or

6) the ability to *decontaminate storage* equipment or the *storage* area should an accident occur.

Appropriate segregation *must* include considerations above and *storage must* be in clearly defined and labeled areas (shelves or compartments) of the *storage* equipment or *storage* area.

D6.300 Storage Equipment

Freezers and refrigerators used for *storing tissue shall* be regularly maintained, calibrated, and monitored according to written *QC procedures*. See the *series of standards* at J5.000.