Updates to *Standards* – D5.400 + (as amended)

A2.000 Definitions of Terms

SKIN PREP - The application of antiseptic solution to decontaminate the skin. This is a continuous process that is performed without delay between steps; it does not include shaving hair, although this can be done if preferred. The manufacturer's written recommendations must be followed, including that the antiseptic agent should remain in place for the full time.

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D5.400 Time Limits for Postmortem Tissue Recovery

When Recovery of tissue has begun, subsequent recovery steps must proceed without delay.

(C, V) Cardiac and vascular tissue *Recovery* and *Processing* time limits (i.e., *Warm* and *Cold Ischemic Times*, *Disinfection Times*, 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 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 body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the 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 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 body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 cumulative hours.

(MS, OA, S)

The *Skin Prep* shall begin within 24 hours of *Asystole* provided the 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 has not been cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 cumulative hours.

For expectations when evaluating body cooling, refer to Guidance Document No. 7.

D5.510 Recovery Cleansing and Preparation
(relevant part only)

Donor:
Cleansing, preparing (i.e., *Skin Prep*), and draping the skin shall be accomplished with the same diligence as used routinely for operative procedures. 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 Recommended Practices for Preoperative Patient Skin Antisepsis (current edition).

D5.520 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 AATB Guidance Document No. 2) shall be implemented. Areas of skin that have abrasions or puncture wounds should be avoided. All tissue shall be recovered using aseptic technique.

D5.600 Recovery Records

For *Allogeneic* tissue, details of the *Recovery* 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 General— Records Management);

3) Location and assessment of the suitability of the *Recovery Site* (see D5.500 Recovery Environment);

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) Type, *Lot* number, manufacturer, and expiration date of supplies and reagents used to recover, rinse, and transport tissue;

8) Specific tissue recovered; and

9) Other available *Relevant Medical Records*.

When applicable, the *Recovery* agency shall provide pertinent recovery record information to the *Recovery Site* facility and/or the relevant Pathologist, Medical Examiner, or Coroner.

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F1.100 Donor Suitability Review

Although the *Donor Risk Assessment Interview* may be preliminarily reviewed by technical staff to evaluate acceptability for *Collection, Recovery* or *Processing*, tissue shall not be released for transplantation without determination of donor suitability by the Medical Director or licensed physician designee. The donor suitability review shall include, but is not limited to:

1) Acceptability of the *Authorization* or *Informed Consent*;

2) Suitability of the *Recovery Site* or where *Collection* took place;

3) Pertinent information from the medical records generated at the time of death, including any pathology and laboratory reports, physician summaries, and transfusion/infusion information;

4) *Donor Risk Assessment Interview*;

5) All results of laboratory testing relevant to donor suitability;

6) Any *Plasma Dilution* calculations used to determine the acceptability of the blood sample used for testing;

7) All relevant culture results up to and through the completion of *Recovery* (e.g., blood cultures, if performed; *Pre-Sterilization/Pre-Disinfection Cultures*, if available);

8) Applicable time limits for tissue recovery;

9) Pertinent circumstantial and donor screening information relayed to *Tissue Bank* staff;

10) Results of the *Physical Assessment* or *Physical Examination*; and

11) Autopsy report, if an autopsy was performed; and

12) Any other information gathered for the purposes of disease screening as required by *Standards* and applicable laws or regulations.

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J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

J1.200 Contents

The *SOPM* shall specifically include, but shall not be limited to:

1) Donor policies and procedures, including *Informed Consent* or *Authorization*, donor suitability criteria, donor screening methods, time limits for tissue recovery, notification of confirmed positive test results, information sharing and, if applicable, reconstruction and final disposition of a deceased donor's body (D2.000, D3.000, D4.000 and D5.000);

2) Tissue *Collection*, *Recovery* and handling policies and procedures, including supplies and methods used in all aspects of the operation involving the assessment of the *Recovery Site*, *Recovery*, *Processing*, packaging, quarantine, labeling, storage, donor suitability review, and/or release of tissue (D5.000, D6.000 and Sections E, F and G);

(there are more listings; the two above are relevant to this update)