

# CHANGES TO AATB STANDARDS FOR TISSUE BANKING

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## SECTION F - RELEASE AND TRANSFER OF TISSUE

### F1.000 TISSUE RELEASE—GENERAL REVIEW REQUIREMENTS

*Current (13<sup>th</sup> edition)*

#### 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 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) Autopsy report, if an autopsy was performed;
- 5) *Donor Risk Assessment Interview*;
- 6) All results of laboratory testing relevant to donor suitability;
- 7) Any *Plasma Dilution* calculations used to determine the acceptability of the blood sample used for testing;
- 8) 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);
- 9) Pertinent circumstantial and donor screening information relayed to *Tissue Bank* staff;
- 10) Results of the *Physical Assessment* or *Physical Examination*; and
- 11) Any other information gathered for the purposes of disease screening as required by *Standards* and applicable laws or regulations.

(with amendments)

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- 1) Acceptability of the ~~consent~~ *Authorization or Informed Consent*;
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- 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) Autopsy report, if an autopsy was performed;~~
- ~~5~~ 4) *Donor Risk Assessment Interview*;
- ~~6~~ 5) All results of laboratory testing relevant to donor suitability;
- ~~7~~ 6) Any *Plasma Dilution* calculations used to determine the acceptability of the blood sample used for testing;
- ~~8~~ 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*
- ~~11~~ 12) Any other information gathered for the purposes of disease screening as required by *Standards* and applicable laws or regulations.

(as amended)

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