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

D4.000 DONOR SUITABILITY

D4.200 Assessment

D4.210 Physical Assessment

Prior to the Retrieval Recovery of cells and/or tissue from a potential deceased donor, a Physical Assessment shall be performed by a Responsible Person. This shall be a recent ante-mortem or post-mortem Physical Assessment to identify evidence of: high risk behavior and signs of HIV infection or hepatitis infection; other viral or bacterial infections; or, trauma to the potential Retrieval Recovery site. 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 cells and/or tissue shall be rejected:

Note: Each risk type is followed by observational wording in parentheses suggestive of terminology that correlates with each listing (see AATB’s Guidance Document No. 1, Tissue Donor Physical Assessment Form).

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

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

32) For a male donor, physical evidence consistent with anal intercourse including perianal condyloma (insertion trauma, perianal lesions);

43) 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];

54) Disseminated lymphadenopathy (enlarged lymph nodes);

65) Unexplained Oral thrush (white spots in the mouth);

76) Blue or purple spots consistent with Kaposi’s sarcoma (blue/purple [gray/black] spots/lesions);
87) Physical evidence of recent tattooing, ear piercing, or body piercing (tattoos/piercings should be described);

88) Unexplained jaundice, hepatomegaly, or icterus. Note: Hepatomegaly may not be apparent in a Physical Assessment unless an autopsy is performed (enlarged liver, jaundice, icterus);

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

1140) Large scab consistent with recent smallpox immunization (scab);

1244) Eczema vaccinatum (lesion, scab);

1342) Generalized vesicular rash, generalized vaccinia (rash);

1443) Severely necrotic lesion consistent with vaccinia necrosum (lesion); and/or

1544) Corneal scarring consistent with vaccinial keratitis (abnormal ocular finding, scarring).

Specific documentation methods (a form) and a standard operating procedure for performing a tissue donor Physical Assessment can be found by referencing AATB Guidance Document No. 1. This method, or an equivalent method, shall be implemented.

(S) The Physical Assessment shall include documentation of findings and conditions that may affect the Quality or quantity of skin retrieved.

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