Appendix II:
CRITERIA FOR PREVENTING TRANSMISSION of RCDADs (Relevant Communicable Disease Agents and Diseases) THROUGH TRANSPLANTATION OF HUMAN CELLS and/or TISSUE

Behavior/History Exclusionary Criteria

1) Men who have had sex with another man within the preceding five years;

2) Persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections;

3) Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates in the preceding five years;

4) Persons who have had sex in exchange for money or drugs in the preceding five years;

5) Persons who have had sex in the preceding 12 months with any person described in the 4 items above or with any person who has HIV infection, including a positive test for HIV, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection;

6) Persons who have been exposed within the preceding 12 months to known or suspected HIV, HBV, and/or HCV infected blood through percutaneous inoculation (e.g., needlestick) or through contact with an open wound, non-intact skin, or mucous membrane;

7) Children born to mothers known to be HIV-infected or at risk for HIV infection, who are 18 months of age or less and/or have been breastfed in the preceding 12 months, regardless of the child’s (donor’s) HIV status;

NOTE: Children over 18 months of age born to mothers infected with HIV or at risk for infection, who have not been breast fed within the preceding 12 months, and whose HIV antibody test, Physical Examination, and review of medical records do not indicate evidence of HIV infection, may be accepted as donors.

8) Current inmates of correctional systems (including Persons who have been in juvenile detention, lockup, jails and or prisons) and individuals who have been incarcerated for more than 72 consecutive hours during the previous 12 months;

9) Persons with a generic history of hepatitis of an unspecified etiology or a current or past diagnosis of clinical, symptomatic viral hepatitis unless evidence from the time of illness
documents that the hepatitis was diagnosed as either hepatitis A or due to cytomegalovirus or Epstein-Barr virus hepatitis. (Note: A verbal history of viral hepatitis occurring before the age of 11 years is acceptable);

10) Persons who have lived with (resided in the same dwelling) another person having viral hepatitis, except for asymptomatic hepatitis C, within who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months preceding donation;”

11) Persons who had or have been treated for syphilis or gonorrhea during the preceding 12 months. Donors may be acceptable if evidence is presented that the treatment occurred more than 12 months ago and was successful;

12) Persons who within 12 months prior to donation have undergone tattooing, acupuncture, ear or body piercing in which shared instruments are known to have been used;

13) Persons with a diagnosis of any form of Creutzfeldt-Jakob disease (CJD) or known family history (blood relative) of a person with non-iatrogenic CJD;

14) Persons with a diagnosis of dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology. Note: Cells and/or tissues from donors with dementia, confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident, brain tumor, head trauma, or toxic/metabolic dementia and who are confirmed not to have evidence of TSE on microscopic examination of the brain, may be acceptable based on an evaluation of this information by the Medical Director.);

15) Persons who have received injections of human pituitary-derived growth hormone (p-hGH);

16) Persons who are known to have received transplants of human Dura Mater;

17) Persons with encephalitis or meningitis of viral or unknown etiology that is active;

18) Persons who have received transfusions of blood or blood products outside of the United States during specific time periods in the following countries:
   a. From 1980 to present: France or the United Kingdom (includes England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, and the Falkland Islands); and/or
   b. After 1977 to present: Central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria);

19) Persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria:
   a. Spent three months or more cumulatively in the United Kingdom (U.K) from the beginning of 1980 through the end of 1996;
   b. Lived cumulatively for 5 years or more in Europe from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996); and/or
c. Is a current or former U.S. military member, civilian military employee, or dependent of a military member or civilian employee who resided at U.S. military bases in Northern Europe (Germany, U.K., Belgium, and the Netherlands) for 6 months or more from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 through 1996;

20) Persons who, within the previous 120 days, have been told by a healthcare professional that they were suspected or known to have had a West Nile Virus (WNV) infection based on symptoms, and/or those who are known to have tested positive for WNV by a NAT assay within this time frame, whichever applies;

21) Persons who are known to have risks associated with xenotransplantation\(^4\)\(^5\)\(^6\)\(^7\) (i.e. receipt of a xenotransplantation product\(^\text{5}\)\(^6\)\(^7\) or who has had intimate contact\(^\text{6}\)\(^7\) with a Recipient of a xenotransplantation product);

22) Persons who have been permanently deferred as a blood donor for unknown reasons or who have a history of positive infectious disease test results for HIV, HBV, or HCV;

23) Persons who, within the past six months, were bitten by an animal suspected to be infected with rabies. Individuals with suspected rabies shall not be accepted as donors under any circumstances (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

24) Persons who have known or suspected sepsis at the time of death, or at the time of donation in the case of a Living Donor;

25) Persons who, when there is a known person-to-person transmission of Severe Acute Respiratory Syndrome (SARS) CoV occurring in the world:
   a. have been diagnosed with SARS or are suspected to have SARS within the preceding 28 days;
   b. have been determined to have had close contact\(^\text{7}\), with someone who has been diagnosed with SARS or who is suspected of having SARS, within 14 days after last exposure, even if asymptomatic during this time; and/or,
   c. have traveled to or resided in areas affected by SARS within 14 days of death (or donation if a Living Donor);

25) Persons who, since 1977, were born in or have lived in any area of central or west Africa (includes Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, and Nigeria) and persons known to have had sexual contact with any such person\(^3\);

26) Persons who have had a recent smallpox vaccination (vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close contact\(^8\) with someone who received the smallpox vaccine;

27) Persons whose cause of death (COD) cannot be determined and there is likelihood of other exclusionary criteria; and

28) Persons who are known to have malaria or be at risk for malaria; and
29) Reproductive donors who have had or have been treated for *Chlamydia trachomatis* or *Neisseria gonorrhoea* infection in the preceding 12 months. If infection and treatment occurred more than 12 months ago, evidence of successful treatment such as a negative test result, must be documented.

1 **RELEVANT COMMUNICABLE DISEASE AGENT OR DISEASE (RCDAD)** – a potentially infectious *Microorganism*, virus, or other disease agent that may pose a risk of transmission to Recipients of, or those who come in contact with, cells and/or tissues. These disease agents/diseases: have sufficient incidence and/or prevalence to affect the potential donor population; could be fatal, life-threatening, result in permanent impairment, or necessitate medical or surgical intervention to preclude permanent impairment; and, for which appropriate screening measures have been developed or an appropriate screening test for donor specimens has been cleared, approved, or **FDA**-licensed, and is available. They can also be those disease agents or diseases that could place potential donors and/or Recipients at risk due to accidental or intentional release. RCDADs applicable to all cell and/or tissue donors are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, SARS (when applicable), WNV, vaccinia, and sepsis. Donors of viable, leukocyte-rich cells and/or tissues must additionally consider HTLV I/II, and donors of reproductive cells and/or tissues must generally consider *Chlamydia trachomatis* and *Neisseria gonorrhoea*.

2 **CLINICALLY ACTIVE HEPATITIS C** - infection with hepatitis C virus when it is symptomatic. This means that: the person demonstrates related symptoms such as jaundice, icterus, fatigue, abdominal pain, loss of appetite, nausea, vomiting, diarrhea, low grade fever, headache, joint pain, and/or "flu-like symptoms" AND HCV infection is suspected or has been diagnosed or anti-HCV (EIA) testing is positive. Also, knowledge of a recent/current positive test for HCV NAT would qualify as a clinically active HCV infection.

3 **Tissue Banks using an HIV test that has been approved by FDA to include a donor screening claim for detection of HIV Group O antibodies are not required to screen for this risk history.**

4 **European countries to be used for deferral of donors based on geographic risk of Bovine Spongiform Encephalopathy (BSE):** Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom, and Yugoslavia.

5 **XENOTRANSPLANTATION** – any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (1) live cells, tissues, or organs from a nonhuman animal source; or (2) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs.

6 **XENOTRANSPLANTATION PRODUCT** – live cells, tissues, or organs used in xenotransplantation. Biological products, drugs, or medical devices sourced from nonliving cells, tissues, or organs from nonhuman animals, including but not limited to porcine insulin and porcine heart valves, are not considered xenotransplantation products.
XENOTRANSPLANTATION INTIMATE CONTACT: An “intimate contact of a xenotransplantation product recipient” is a person who has engaged in activities that could result in the intimate exchange of body fluids with a xenotransplantation product recipient. Examples of intimate contacts include, but are not limited to, sexual partners, household members who share razors or toothbrushes, and health care workers or laboratory personnel with repeated percutaneous, mucosal, or other direct exposures. Mere sharing of domicile or casual contact, such as hugging or kissing without the exchange of saliva, would not be interpreted as intimate contact.

CLOSE CONTACT: SEVERE ACUTE RESPIRATORY SYNDROME (SARS): Having cared for, lived with, or having had direct contact with respiratory secretions and/or body fluids of a patient known to be a suspect SARS case.

CLOSE CONTACT: SMALLPOX - Physical contact with the vaccination site, touching the bandages or covering of the vaccination site, or handling bedding or clothing that had been in contact with an un-bandaged vaccination site.

Sources:


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