Appendix II:
CRITERIA FOR PREVENTING TRANSMISSION of RCDADs (Relevant Communicable Disease Agents and Diseases)[1] THROUGH TRANSPLANTATION OF HUMAN 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 who have had sex in exchange for money or drugs in the preceding five years;

4) persons who have had sex in the preceding 12 months with any person described in the 3 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[2] infection;

5) 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;

6) children born to mothers known to be infected with, or at risk for, HIV, HBV or HCV infection, who are 18 months of age or less and/or have been breastfed within the preceding 12 months, regardless of the child's (*donor*) HIV, HBV or HCV status;

   Note: Children over 18 months of age born to mothers infected with, or at risk for, HIV, HBV or HCV infection, who have not been breastfed within the preceding 12 months and whose infectious disease testing, *physical examination/physical assessment*, and review of medical records do not indicate evidence of HIV, HBV or HCV infection, *may* be accepted as *donor*.

7) persons who have been in a juvenile *correction*al facility, lockup, jail or prison for more than 72 consecutive hours in the preceding 12 months;

8) 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);

9) persons who have lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C[2] infection in the preceding 12 months;

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

11) 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;

12) 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;

13) 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: *Tissues* from *donor* 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 transmissible spongiform encephalopathy (TSE) on microscopic examination of the brain, *may* be acceptable based on an evaluation of this information by the Medical Director;

14) persons who have received injections of human pituitary-derived growth hormone (pit-hGH);

15) persons who are known to have received transplants of human *dura mater;*

16) persons with encephalitis or meningitis of viral or unknown etiology that is active;

17) persons who have received transfusions of blood or blood products outside of the United States (U.S.) 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)[3].

18) persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria:

    a) spent 3 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[4] 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 (i.e., Germany, Belgium, and the Netherlands) for 6 months or more from 1980 through 1990, or elsewhere in Europe (i.e. Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more from 1980 through 1996;

19) 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;

20) persons who are known to have risks associated with xenotransplantation[5] (i.e., receipt of a xenotransplantation product[6] or who has had intimate contact[7] with a *recipient* of a xenotransplantation product);

21) 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;

22) persons who, within the past 6 months, were bitten by an animal suspected to be infected with rabies. Individuals with suspected rabies *shall* not be accepted as *donor* under any circumstances (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

23) persons who had known or suspected sepsis at the time of death, or at the time of donation in the case of a *living donor* (as determined by medical record review);

24) 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];

25) 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;

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

27) persons who are known to have malaria or be at risk for malaria;

28) *reproductive donor* who have had or have been treated for *Chlamydia trachomatis* or *Neisseria gonorrhea* 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.

29) *living donor* who received a blood transfusion within the preceding 12 months unless approved by the Medical Director in conformance with generally accepted standards of practice (see Title 10 of New York Codes, Rules and Regulations, Section 52-3.4);

30) birth tissue donated at vaginal delivery when there is significant local viral, parasitic, mycotic, or bacterial infection of the birth canal and, for any delivery, a current intrauterine infection (as determined by medical record review)*;*

~~31) persons with a history of being diagnosed with Ebola virus disease or who are at risk based on current CDC risk information; and~~

~~32) based on current recommendation published in FDA guidance, persons who have been determined to be at risk for infection with Zika virus.~~

31) Persons with a history (ever) of tuberculosis disease (sometimes referred to as “active” or “clinically active” tuberculosis).

32) Persons with a history of latent (“inactive”) tuberculosis infection initially diagnosed within the past two (2) years (i.e., the individual has had a positive test for tuberculosis).[9]

33) For tissues intended to ultimately retain viable cells (i.e., all products comprising or containing tissues that are processed in a manner to retain living cells – including reproductive cells), tissues from persons meeting any of the following criteria are not suitable for transplant due to risk of tuberculosis:

a. aged ≥ 65 (except for cryopreserved skin, where age ≥ 65 is acceptable)
b. who, within the past 2 years, traveled for ≥3 months or immigrated from a country with most current available tuberculosis incidence of ≥ 20 (rate per 100,000 population) available on WHO TB country profile website: https://worldhealthorg.shinyapps.io/tb_profiles/
c. with exposure to an individual with tuberculosis disease within the past 2 years
d. with (latent) tuberculosis infection > 2 years ago (i.e., positive TB test > 2 years ago)
e. experiencing homelessness housed in shelters or other congregate setting, ≤2 years ago
f. have been incarcerated ≤2 years ago
g. with End Stage Renal Disease ([Chronic Kidney Disease (CKD) 5]) with or without dialysis
h. who have received solid organ transplant

34) Except for cryopreserved skin, which is subject to medical director discretion, tissues intended to ultimately retain viable cells from persons with at least one risk factor from each column below for exposure to, and/or reactivation of, tuberculosis are not suitable for transplant:

Exposure Risk Factors	Reactivation Risk Factors
who had birth, travel, or residence ≥ 3 months cumulative in a country with most current available tuberculosis incidence of ≥ 20 (rate per 100,000 population) that occurred > 2 years ago	with advanced kidney disease, pre-dialysis—otherwise known as CKD Stage 4, GFR < 30
ever experiencing homelessness and were housed in shelters or other congregate settings > 2 years ago	with diabetes mellitus
have been incarcerated ≥ 2 years ago	with cirrhosis or alcoholic liver disease
who have had exposure to an individual with tuberculosis disease > 2 years ago	with alcohol use disorder/ excessive or heavy alcohol use
	who use immunosuppressive medications

[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, *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. There can also be those disease agents or diseases that could place potential *donor* and/or *recipients* at risk for infection due to accidental or intentional release. RCDADs applicable to all *tissue donor* are (but are not limited to): HIV 1/2, HBV, HCV, human TSE, syphilis, communicable disease risks associated with xenotransplantation, WNV, vaccinia, and sepsis. *Donor* of viable, leukocyte-rich *tissues must* additionally consider HTLV I/II, and *donor* of *reproductive tissues must* generally consider *Chlamydia trachomatis* and *Neisseria gonorrhea*.

[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 *donor* based on geographic risk of Bovine Spongiform Encephalopathy (BSE): Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic/Czechoslovakia, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic/Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, ~~or~~ former Yugoslavia, and Republic of Macedonia/North Macedonia~~, and Czechoslovakia~~.

[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.

[7]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.

[8]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.