

CHANGES TO AATB STANDARDS FOR TISSUE BANKING
14th Edition

Appendix II:
CRITERIA FOR PREVENTING TRANSMISSION of RCDADs
(Relevant Communicable Disease Agents and Diseases)¹
THROUGH TRANSPLANTATION OF HUMAN TISSUE

Current (14th Edition)

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 C² 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 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's*) 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 *donors*.

- 8) persons who have been in a juvenile correctional facility, lockup, **jail or prison** for more than **72 consecutive hours** in the preceding **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 who has **hepatitis B** or clinically active (symptomatic) **hepatitis C²** infection in the preceding **12 months**;
- 11) persons who had or have been **treated for syphilis** or **gonorrhea** during the **preceding 12 months**.

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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: 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 transmissible spongiform encephalopathy (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** (pit-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 (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.
- 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 Europe⁴ 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, 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;

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- 21) persons who are known to have risks associated with **xenotransplantation**⁵ (i.e., receipt of a xenotransplantation product⁶ or who has had intimate contact⁷ 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 had 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, 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 person³;
- 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;
- 28) persons who are known to have **malaria** or be at risk for malaria;
- 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.
- 30) *living donors* 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);
- 31) **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**;
- 32) persons with a history of being diagnosed with **Ebola** virus disease or who are at risk based on current CDC risk information; and
- 33) based on current recommendation published in FDA guidance, persons who have been determined to be at **risk** for infection with **Zika** virus.

With Amendments

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;
- 43) persons who have had **sex in exchange for money** or drugs in the preceding five years;
- ~~5~~4) persons who have had **sex** in the preceding **12 months** with any person described in the ~~4~~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 C² infection;
- ~~6~~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;
- ~~7~~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's*) 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 *donors*.
- ~~8~~7) persons who have been in a juvenile correctional facility, lockup, **jail or prison** for more than **72 consecutive hours** in the preceding **12 months**;
- ~~9~~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);
- ~~10~~9) persons who have lived with (**resided in the same dwelling**) another person who has **hepatitis B** or clinically active (symptomatic) **hepatitis C²** infection in the preceding **12 months**;
- ~~11~~10) 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~~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;
- ~~13~~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;
- ~~14~~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 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 transmissible spongiform encephalopathy (TSE) on microscopic examination of the brain, *may* be acceptable based on an evaluation of this information by the Medical Director;

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- ~~15~~14) persons who have received injections of **human pituitary-derived growth hormone** (pit-hGH);
- ~~16~~15) persons who are known to have received **transplants of human *dura mater***;
- ~~17~~16) persons with **encephalitis** or **meningitis** of viral or unknown etiology that is active;
- ~~18~~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.
- ~~19~~18) 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 Europe⁴ 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, 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~~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;
- ~~21~~20) persons who are known to have risks associated with **xenotransplantation**⁵ (i.e., receipt of a xenotransplantation product⁶ or who has had intimate contact⁷ with a recipient of a xenotransplantation product);
- ~~22~~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;
- ~~23~~22) 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~~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*;
- ~~25~~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 person³;

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- ~~26~~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;
- ~~27~~26) persons whose **cause of death (COD) cannot be determined** and there is likelihood of other exclusionary criteria;
- ~~28~~27) persons who are known to have **malaria** or be at risk for malaria;
- ~~29~~28) *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.
- ~~30~~29) *living donors* 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);
- ~~31~~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**;
- ~~32~~31) persons with a history of being diagnosed with **Ebola** virus disease or who are at risk based on current CDC risk information; and
- ~~33~~32) based on current recommendation published in FDA guidance, persons who have been determined to be at **risk** for infection with **Zika** virus.

As Amended

Behavior/History Exclusionary Criteria:

- 1) men who have had **sex with another man** within the preceding **five years**;
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- 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 C² 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's*) HIV, HBV or HCV status;

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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 *donors*.

- 7) persons who have been in a juvenile correctional 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);
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 - 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 **three months** or more cumulatively **in the United Kingdom** (U.K.) from the beginning of **1980** through the end of **1996**;

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- b) lived cumulatively for **5 years** or more in Europe⁴ 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, 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**;
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 - 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;
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32) based on current recommendation published in FDA guidance, persons who have been determined to be at **risk** for infection with **Zika** virus.

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