Uniform DRAI - Donor >12 yrs old Requirements Crosswalk

Q# or Pg #	Question or section as it appears on the "Uniform DRAI - Donor >12 yrs old 9-10-14"	FDA Final Guidance, HCT/P Donor Eligibility (8-8-07) *(relevant parts only)* *DE Final Rule not used here since Final Guidance covers expectations in more detail.*	Specific AATB Standards, 13th edition, 2012 or EBAA Medical Standards, June 2014 *(relevant parts only)*	UNOS/OPTN Policy *(includes the 2013 PHS Guideline)*	Other
Pg 1	Donor Name, Person Interviewed (name, relationship), Contact Information (phone, address, city, state, zip), The interview was conducted by (telephone or in person), Person conducting interview and completing the form (print name, signature, date/time)	**IV. DONOR SCREENING (§ 1271.75)** **C. What sources of information do I review?** 1. The donor medical history interview (§ 1271.3(n)) is a documented dialogue concerning the donor's medical history and relevant social behavior: a. With a living donor; or b. If the donor is not living or is unable to participate in the interview, then with one or more individuals who can provide the information sought. These individuals might be: • The donor's next of kin; • The nearest available relative; • A member of the donor's household; • An individual with an affinity relationship with the donor (e.g., caretaker, friend, partner); or • The donor's primary treating physician. The medical history interview may take place in person or by telephone.	**D4.220 Donor Risk Assessment** An inquiry shall be conducted with the donor (if living) or the deceased donor's next of kin, the nearest available relative, a member of the donor's household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or the primary treating physician), using a standardized questionnaire. Questions shall be formulated using these *Standards*, current federal regulations and guidance. The inquiry record shall document the donor's name, and the relationship between the donor and the interviewee(s) and shall indicate the name(s) of the interviewer(s) and interviewee(s). The questionnaire shall be maintained as part of the donor's record. **A2.000 DEFINITIONS OF TERMS**	**2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)** **2.2.2.1 Obtaining the donor's medical/ behavioral history.** The Host OPO will attempt to obtain a history on each potential donor to screen for medical conditions that may affect the donated organ function and for the presence of transmissible diseases and/or malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. This history should also be used to identify whether the potential donor has factors associated with increased risk for disease transmission, including blood borne pathogens HIV, Hepatitis B, and Hepatitis C. If the donor meets the criteria set forth in the current US Public Health Service (PHS) guidance, the Host OPO must communicate this information regarding donor history to all transplant programs	

		Since a donor medical history interview is a documented dialog (§ 1271.3(n)), if a donor medical history questionnaire is self-administered, the interviewer should review and verify the answers with the individual who has filled out the questionnaire form.	**DONOR RISK ASSESSMENT INTERVIEW** A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior……. D1.000 **Donor Eligibility** Before tissue is made available for distribution, the Donor Eligibility Determination must be made by a responsible person. Reference Appendix II for requirements related to the donor eligibility process. Prior to making an eligibility determination, the donor must be screened according to D1.200. Medical and social histories are important aspects of donor evaluation. Adequate donor evaluation includes: 4. Donor history evaluation: this must include the donor's name, social history and donor information obtained from at least one of the following: d) Donor risk assessment interview f) Treating physician interview D1.300 Documentation of Donor Information Donor screening forms and/or copies of relevant medical records reviewed must be	receiving organs from the donor.	

			completed and retained on all donated eye tissue as part of the donor record. See Section L1.000. A unique donor identifying number, i.e, medical examiner or coroner case number, hospital medical record number, social security or driver's license number, shall be obtained and recorded in the donor record. **Glossary** **Definition of Terms** **Donor Risk Assessment Interview**. A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior. For example this may be: the donor, if living; the next of kin; the nearest available relative; a member of the donor's household; other individual with an affinity relationship (e.g., caretaker, friend, significant life partner); and/or the primary treating physician. Alternatively, a living donor may complete a written questionnaire. Relevant social history is elicited by questions regarding certain activities or behaviors that are considered to place such a potential donor		

			at increased risk for a relevant communicable disease agent or disease.		
Pg 1	I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."				It is common practice by OPO, Tissue Bank, and Eye Bank professionals to include this type of preamble to prepare the interviewee.
1.	Where was she/he* born?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 27. Persons or their sexual partners who were born or lived in certain countries in Africa (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria) after 1977 (Refs. 66 and 76) (risk factor for HIV group O). *(vCJD risk could apply if the*	**Appendix II, Behavior/History Exclusionary Criteria** 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]; [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.		

		donor was born during the target time periods)	**F1.100 Donor Suitability Review** In the case of pediatric donors who have been breastfed within the past 12 months and/or are 18 months of age or less, the birth mother's risk for transmissible disease shall be evaluated for HIV, HBV, HCV and other infectious agents when indicated. See Appendix II. *(vCJD risk could apply if the donor was born in a risk country during the target time periods)* D1.000 **Donor Eligibility** Reference Appendix II for requirements related to the donor eligibility process. D1.120 Screening for FDA Defined Relevant Communicable Disease Agents and Diseases The FDA defines communicable disease agents and diseases considered relevant (Ref. Appendix I). Tissue from persons exhibiting risk factors for, clinical evidence of, or physical evidence of relevant communicable disease and high risk behavior associated with relevant communicable disease		

			must not be used for transplant purposes (Ref. Appendix II).		
2.	What was her/his* occupation?				Standard question to open interview and it relates to risk assessment at Q3.
3.	Did she/he* have any health problems due to exposure to toxic substances such as pesticides, lead, mercury, gold, asbestos, agent orange, etc.? *If yes,* 3a. Describe toxic substance and treatment.		**D4.320 Miscellaneous Adverse Conditions** Tissue from donors with any of the following conditions shall be evaluated by the Medical Director for suitability for transplantation in accordance with the tissue bank's *SOPM*: 2) Ingestion of, or exposure to, toxic substances.		Title 10 of New York Codes, Rules and Regulations, Section 52-3.4, **Selection and testing requirements for tissue donors.** (a) …tissue for clinical use shall not be released from donors with any of the following conditions: (9) except for donors of eye tissue, significant exposure to a substance that may be transferred in toxic doses, such as lead, mercury and gold;
4.	**4a.** Did she/he* have a family physician or a specialist? *If yes,*	**IV. DONOR SCREENING (§ 1271.75)** **C. What sources of information do I review?** 2. The donor medical history	D1.000 **Donor Eligibility** Before tissue is made available for distribution, the Donor Eligibility Determination must be made by a responsible		

	4a(i). When was her/his* last visit? 4a(ii). Why? 4a(iii). Provide any contact information (e.g., name, group, facility, phone number, etc.): **4b**. Did she/he* use a medical facility such as a clinic or urgent care center? *If yes,* 4b(i). When was her/his* last visit? 4b(ii). Why? 4b(iii). Provide any contact information (e.g., name, group, facility, phone number, etc.):	interview (§ 1271.3(n)) is a documented dialogue concerning the donor's medical history and relevant social behavior: a. With a living donor; or b. If the donor is not living or is unable to participate in the interview, then with one or more individuals who can provide the information sought. These individuals might be: ……. • The donor's primary treating physician.	person. Reference Appendix II for requirements related to the donor eligibility process. Prior to making an eligibility determination, the donor must be screened according to D1.200. Medical and social histories are important aspects of donor evaluation. Adequate donor evaluation includes: 4. Donor history evaluation: this must include the donor's name, social history and donor information obtained from at least one of the following: f) Treating physician interview		
5.	**5a.** Did she/he* take any prescription medication recently or on a regular basis? *If yes,* 5a(i). What was it and/or what was it used for? *If a steroid, such as prednisone, ask:*	**III. THE DONOR-ELIGIBILITY DETERMINATION (§ 1271.50)** **D. What communicable disease agents or diseases, not listed in § 1271.3(r)(1), have been determined to be relevant?** <u>Sepsis</u> Availability of Appropriate	**D4.310 Infections** The Medical Director or licensed physician designee shall not release allogeneic tissue for transplantation from donors who exhibit any of the following findings: 1) Evidence, detected by review of *Relevant Medical Records* of significant active infection at the time of donation for	**3.5.9.1 Essential Information for Kidney Offers.** (xiv) Current medication and transfusion history;	

	5a(ii). How long? 5a(iii). What was the dose? **5b.** Did she/he* take any non-prescribed medication or dietary supplements? *If yes,* 5b(i). What was it and/or what was it used for?	Screening and/or Testing Measures: Appropriate screening measures have been developed for detection of sepsis, such as the medical history interview, and clinical and physical evidence. (Screening measures for sepsis are discussed in sections IV.E., IV.F. and IV.G. of this document.)	Relevant Communicable Disease Agents or Diseases (RCDADs). These include, but are not limited to: …septicemia, viral disease…. **A2.000 DEFINITIONS OF TERMS** **RELEVANT MEDICAL RECORDS**—a collection of documents including a current donor risk assessment interview, a physical assessment/physical examination of the donor, laboratory test results (in addition to results of testing for required relevant communicable disease agents), relevant donor records, existing coroner and autopsy reports, as well as information obtained from any source or records which may pertain to donor suitability regarding high risk behaviors, and clinical signs and symptoms for any relevant communicable disease agent or disease (RCDAD), and/or treatments related to medical conditions suggestive of such risk. **Appendix II, Behavior/History Exclusionary Criteria** 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.* D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria) D1.120 Screening for FDA Defined Relevant Communicable Disease Agents and Diseases D1.110 EBAA Contraindications to Transplant Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors 5. active bacterial or viral meningitis; 6. active bacterial or fungal endocarditis;		
6.	Did she/he* recently have any symptoms such as: **6a.** a fever? **6b.** cough? **6c.** diarrhea? **6d.** swollen lymph nodes or glands in the neck, armpits or groin?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 12. Persons who are deceased and have a documented medical diagnosis of sepsis or have documented clinical	*(same as immediately above)*		OPTN/UNOS DTAC requested addition of neurological symptoms to this list to collect any information known that could be related to a recent encephalopathy.

	6e. weight loss? **6f.** a rash? **6g.** sores in the mouth or on the skin? **6h.** night sweats? **6i.** severe headache? **6j.** rapid decline in mental ability? **6k.** seizures? **6l.** tremors? **6m.** difficulty walking? *If any answer in question 6. is "yes,"* ask "when" *this occurred <u>and</u>* "describe (symptom) and reasons," *if known.*	evidence consistent with a diagnosis of sepsis that is not explained by other clinical conditions at the time of death. For example, if a statement such as "rule-out sepsis" is noted in the medical records, and subsequent notations indicate a diagnosis other than sepsis, a potential donor might still be eligible. *(although section F of the guidance usually doesn't apply to the medical history interview, it's listed here as a reference due to list of symptoms provided)* **F. What clinical evidence do I look for when screening a donor?** You must review relevant medical records for clinical evidence of relevant communicable disease agents and diseases (§ 1271.75). You should look for the following examples of clinical evidence of relevant communicable disease. Except as noted in this section and in accordance with § 1271.75(d), you should determine to be ineligible any potential donor who exhibits one or more of the following examples of clinical			

		evidence of relevant communicable disease. 1. HIV infection: …. • Unexplained weight loss; • Unexplained night sweats; • Blue or purple spots on or under the skin or mucous membranes typical of Kaposi's sarcoma; • Disseminated lymphadenopathy (swollen lymph nodes) for longer than one month; • Unexplained temperature of > 100.5F (38.06C) for more than 10 days; • Unexplained persistent cough or shortness of breath; • Opportunistic infections; • Unexplained persistent diarrhea; and/or • Unexplained persistent white spots or unusual blemishes in the mouth (Ref. 79). 2. Hepatitis infection: … • Unexplained jaundice; • Unexplained hepatomegaly; and/or …… 5. WNV infection (Refs. 5, 6, and 7). Because signs and symptoms of WNV can be nonspecific, you should consider the following clinical evidence in light of other			

		information obtained about the donor in making a donor eligibility determination. • Mild symptoms might include fever, headache, body aches, or eye pain; - mild symptoms might also occasionally be accompanied by a skin rash on the trunk of the body; or - swollen lymph glands.			
7.	Did she/he* have any food or drug allergies? *If yes,* 7a. What was she/he* allergic to? 7b. Describe reaction:				**Health Canada;** see **Perfusable Organs for Transplantation, Canadian Standards Association, CAN/CSA Z900.2.3-12; 12.2 Suitability of donors**: **12.2.2.3** The history for all donors, living or deceased shall include: **(j):** any history of allergy. *Notes: (2)The information in item (j) (history of allergy) should be communicated to the recipient if it is considered to

					be clinically significant. For example, information on the presence of a life threatening allergy in the donor, with potential to be transferred to the recipient, would alert the recipient to avoid the allergen(s) in question and/or seek appropriate testing.
8.	Did she/he* know anyone who had a smallpox vaccination? *If yes,* 8a. Was **that person** vaccinated within the past two months? *If yes,* 8a(i). Did she/he* have contact with this person which includes touching the vaccination site, handling bandages that cover it, or handling bedding, clothing, or any other material that came in contact with the vaccination site?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 14. Persons who acquired a clinically recognizable vaccinia virus infection by contact with someone who received the smallpox vaccine (i.e., touching the vaccination area or the scab, including the covering bandages, or touching clothing, towels, or bedding that might have come into contact with an unbandaged vaccination area or scab) (Ref. 12).	**Appendix II, Behavior/History Exclusionary Criteria** 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; and, [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. D1.000 **Donor Eligibility**		

	If yes, 8a(i)a. Did she/he* experience any symptoms or complications such as a rash, fever, muscle aches, headaches, nausea, or eye involvement? *If yes,* 8a(i)a(i). Explain:	• For living donors who developed skin lesions as a result of contact with someone who received the smallpox vaccine, you should question the donor regarding the loss of the scab, and you should examine the skin. For cadaveric donors, you should examine the skin. • If no scab is present, we do not recommend deferral of: o a cadaveric donor; o a living donor if the scab spontaneously separated; or o after three months from the date of vaccination of the vaccine recipient, a living donor whose scab was otherwise removed. • If a scab is present, you should consider: o a cadaveric donor to be ineligible; or o a living donor to be deferred until the scab spontaneously separates. You should defer persons who developed other complications of vaccinia infection acquired through contact with a vaccine recipient until 14 days after all vaccinia complications have completely resolved. Note: We do not recommend deferral of a cadaveric donor who previously had complications of vaccinia	(reference Appendix II for FDA donor criteria)		

		acquired through contact with a vaccine recipient, but has no visible signs of vaccine complications, if the date of resolution of the vaccinia complications is unknown. We do not recommend deferral of contacts who never developed skin lesions or other complications of vaccinia infection.			
9.	In the past **12 months** was she/he* in lockup, jail, prison, or any juvenile correctional facility? *If yes,* 9a. How long? 9b. Where? 9c. Why?	IV. DONOR SCREENING (§ 1271.75) E. What risk factors or conditions do I look for when screening a donor? …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 8. Persons who have been in juvenile detention, lock up, jail or prison for more than 72 consecutive hours in the preceding 12 months (Refs. 29, 67, and 68) (risk factor for HIV, Hepatitis B and Hepatitis C).	**Appendix II, Behavior/History Exclusionary Criteria** 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)	***PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation; Public Health Reports / July–August 2013 / Volume 128*** *(relevant part only)* Donors who meet one or more of the …. criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infection. Each factor listed reflects increased risk of all three pathogens as an aggregate, as there is overlap of associated risk, even though each factor does not convey risk from all pathogens equally. • People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the	

				preceding 12 months.	
10.	In the past **12 months** was she/he* bitten or scratched by any pet, stray, farm, or wild animal? *If yes,* 10a. What kind of animal? 10b. When? 10c. Did she/he* receive any medical treatment? *If yes,* 10c(i). By whom? 10d. Was the animal suspected of having rabies? 10e. Was the animal quarantined or tested? *If yes,* 10e(i). Which one? *If yes to tested,* 10e(ii). What was the result?		**Appendix II, Behavior/History Exclusionary Criteria** 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); **D1.110 EBAA Contraindications to Transplant** Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors 7. suspected rabies and persons who, within the past six months, were bitten by an animal suspected to be infected with rabies;		Title 10 of New York Codes, Rules and Regulations, Section 52-3.4, **Selection and testing requirements for tissue donors.** (a)… allogeneic tissue for clinical use shall not be released from donors with any of the following conditions: (11) within the preceding six months, receipt of a bite from an animal suspect of rabies; (b) Individuals with suspected rabies or evidence of HIV infection shall not be accepted as donors under any circumstances.
11.	In the past **12 months** was she/he* told by a healthcare professional that they had a West Nile virus infection?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors do I look for when screening a**	**D4.310 Infections** The Medical Director or licensed physician designee shall not release allogeneic tissue for		

	If yes, 11a. When was she/he* diagnosed? *If this occurred within the past 4 months ask:* 11a(i). What was the name of the doctor/clinic?	**donor?** 15. Persons who have had a medical diagnosis or suspicion of WNV infection (based on symptoms and/or laboratory results, or confirmed WNV viremia) you should defer for 120 days following diagnosis or onset of illness, whichever is later (Refs. 5, 6, and 7) 16. Persons who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days (Refs. 5 and 7). **II. THE DONOR-ELIGIBILITY DETERMINATION, C. What is a "relevant communicable disease agent or disease"?** FDA believes that the following communicable disease agents and diseases meet these standards for identification of relevant communicable disease agent or disease not specifically identified in the regulations: West Nile Virus (WNV).	transplantation from donors who exhibit any of the following findings: 1) Evidence, detected by review of *Relevant Medical Records* of significant active infection at the time of donation for Relevant Communicable Disease Agents or Diseases (RCDADs). These include, but are not limited to: … WNV… **Appendix II, Behavior/History Exclusionary Criteria** 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. D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
12.	In the past **12 months** did she/he* have any shots or immunizations, such as for the flu, MMR, yellow fever, hepatitis B, etc.?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?**	**Appendix II, Behavior/History Exclusionary Criteria** 26) Persons who have had a recent smallpox vaccination		

	If yes, 12a. When? 12b. What kind was it? *<u>If smallpox/vaccinia is named</u>, ask these questions:* 12b(i). Did she/he* experience any symptoms or complications such as a rash, fever, muscle aches, headaches, nausea, or eye involvement? *If yes,* 12b(i)a. When did these symptoms resolve? 12b(ii). Did the scab <u>fall off</u> or was it <u>picked off</u>? 12b(ii)a. When?	…..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 13. Persons who have had smallpox vaccination (vaccinia virus) in the preceding **8 weeks** (Ref. 12) should be evaluated as follows: a. For persons who had no vaccinia complications (see Appendix 4 for definition of vaccinia complication): • You should defer the donor until after the vaccination scab has separated spontaneously, or for 21 days post-vaccination, whichever is the later date, and until the physical examination or physical assessment includes a confirmation that there is no scab at the vaccination site. • In cases where a scab was removed before separating spontaneously, you should defer the donor for two months after vaccination. Note: We do not recommend deferral of a cadaveric donor who was vaccinated at least 21 days ago and who has no visible scab, if you are unable to obtain a history of how the scab separated. b. For persons who have experienced vaccinia complications (see Appendix 4),	(vaccinia virus) and persons who acquired a clinically recognizable vaccinia virus infection by close contact[8] with someone who received the smallpox vaccine		

		you should defer the donor until 14 days after all vaccinia complications have completely resolved. Note: We do not recommend deferral of a cadaveric donor who previously had vaccinia complications but who currently has no visible signs of vaccinia complications, if you are unable to obtain a history of the exact date of resolution of the vaccinia complications.			
Pg 7	This is a reminder these are standard questions we ask in every interview. Answer to the best of your knowledge with a "Yes" or "No."				From NCHS studies, a reminder was advised at this point of the interview.
13.	In the past **12 months** did she/he* get a tattoo, touch up of an old tattoo, or permanent makeup? *If yes,* 13a. Were shared or non-sterile instruments, needles or ink used? 13b. Was the procedure performed outside of the United States or Canada? *If yes,* 13b(i). Where?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 10. Persons who have undergone tattooing, ear piercing or body piercing in the preceding 12 months, in which sterile procedures were not used, e.g., contaminated instruments and/or ink were	**Appendix II, Behavior/History Exclusionary Criteria** 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		

		used, or shared instruments that had not been sterilized between uses were used (Ref. 69).			
14.	In the past **12 months** did she/he* have acupuncture, ear or body piercing? *If yes,* 14a. Were shared or non-sterile instruments or needles used? 14b. Was the procedure performed outside of the United States or Canada? *If yes,* 14b(i). Where?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 10. Persons who have undergone tattooing, ear piercing or body piercing in the preceding 12 months, in which sterile procedures were not used, e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used (Ref. 69).	**Appendix II, Behavior/History Exclusionary Criteria** 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
15.	**15a.** In the past **12 months** did she/he* live with a person who has hepatitis? *If yes,* 15a(i). What type of hepatitis did **<u>that person</u>** have? 15a(ii). Was that person sick from the virus during that time, such as having	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 9. Persons who have lived with	**Appendix II, Behavior/History Exclusionary Criteria** 9) Persons who have lived with (resided in the same dwelling) another person having viral hepatitis, except for asymptomatic hepatitis C, within 12 months preceding donation;		

	abdominal pain, joint pain, exhaustion, fever, nausea, vomiting, diarrhea, or yellowing of the eyes or skin? **15b.** In the past **12 months** did she/he* live with a person who has tuberculosis? *If yes,* 15b(i). Describe what happened and when.	(resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months (Ref. 69).	D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
16.	In the past **12 months** did she/he* come into contact with someone else's blood? *If yes,* 16a. Describe what happened and when: 16b. Was the other person involved known to have had, or suspected of having, HIV or hepatitis?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 6. Persons who have been exposed in the preceding 12 months to known or suspected HIV, HBV, and/or HCV-infected blood through percutaneous inoculation (e.g., needle stick) or through contact with an open wound, non-intact skin, or mucous membrane (Refs. 18 and 64).	**Appendix II, Behavior/History Exclusionary Criteria** 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
17.	In the past **12 months** did she/he* have an accidental	**IV. DONOR SCREENING (§ 1271.75)**	**Appendix II, Behavior/History**		

	needle-stick? *If yes,* 17a. Describe what happened and when: 17b. Was the needle contaminated with blood from someone known to have had, or suspected of having, HIV or hepatitis?	**E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 6. Persons who have been exposed in the preceding 12 months to known or suspected HIV, HBV, and/or HCV-infected blood through percutaneous inoculation (e.g., needle stick) or through contact with an open wound, non-intact skin, or mucous membrane (Refs. 18 and 64).	**Exclusionary Criteria** 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
Pg 9	As I described before, I want to remind you of the sensitive and personal nature of some of these questions. For medical and health reasons, we are required to ask these questions about all potential donors. Next, I will ask you about her/his* sexual history.				Preamble to prepare interviewee for risk questions related to sexual behavior.
18.	In the past **12 months** did she/he* have a sexually transmitted infection such as syphilis, gonorrhea, chlamydia, or genital ulcers, herpes, or genital warts? *If yes,* 18a. What was it?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors….	**Appendix II, Behavior/History Exclusionary Criteria** 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	***PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation; Public Health Reports / July–August 2013 / Volume 128*** *(relevant part only)*	

		17. Persons who have been treated for or had syphilis within the preceding 12 months. We do not recommend deferral of donors if evidence is presented that the treatment occurred more than 12 months ago and was successful.	ago and was successful; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)	Donors who meet one or more of the …. criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infection. Each factor listed reflects increased risk of all three pathogens as an aggregate, as there is overlap of associated risk, even though each factor does not convey risk from all pathogens equally. • People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months	
Pg 9	For the next part, sexual activity and sex refer to any method of sexual contact including vaginal, anal, and oral. I will read each question and you should answer to the best of your knowledge with a "Yes" or "No."			***PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation; Public Health Reports / July–August 2013 / Volume 128*** *(relevant part only)* Donors who meet one or more of the …. criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infection……The first six risk factors address sexual contact; the definition of "had sex" refers to any method of sexual contact, including vaginal, anal, and oral contact:	Educating the historian in regard to meaning of 'sexual activity' and 'sex' is required when using this form and the filter question format. A reminder regarding 'to the best of your knowledge' is advised at this point of the interview.

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19.	In the past **5 years** was she/he* sexually active, even once? *If yes, complete the following questions (19a. to 19g.)* For the following set of questions, think about the past 5 years: 19a. Did she/he* have sex in exchange for money or drugs? *If yes,* 19a(i) When? 19b. **MALE DONOR only:** Did he have sex with another male? (N/A) Donor is Female *If yes,* 19b(i). When? 19c. Did she/he* have sex with a person who has had sex in exchange for money or drugs? *If yes,* 19c(i). When? 19d. **FEMALE DONOR only:** Did she have sex with a male who had sex with another male? (N/A) Donor is Male *If yes,* 19d(i). When?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 1. Men who have had sex with another man in the preceding 5 years (Refs. 17 through 46) (risk factor for HIV and Hepatitis B). 2. Persons who have injected drugs for a non-medical reason in the preceding 5 years, including intravenous, intramuscular, or subcutaneous injections (Refs. 18, 21, 22, 25, 27, 29, 33, 34, 36, 38, 42, and 45 through 59) (risk factor HIV, Hepatitis B and Hepatitis C). 3. Persons with hemophilia or other related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years (Refs. 18 and 60) (risk factor for HIV, Hepatitis B and Hepatitis C). A donor who received clotting factors once to treat an acute bleeding event more than 12 months ago may be eligible to donate.	**Appendix II, 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[2] infection; [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,	***PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation; Public Health Reports / July–August 2013 / Volume 128*** *(relevant part only)* Donors who meet one or more of the …. criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infection. Each factor listed reflects increased risk of all three pathogens as an aggregate, as there is overlap of associated risk, even though each factor does not convey risk from all pathogens equally. The first six risk factors address sexual contact; the definition of "had sex" refers to any method of sexual contact, including vaginal, anal, and oral contact: • People who have had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months • Men who have had sex with men (MSM) in the preceding 12 months • Women who have had sex with a man with a history of MSM behavior in the preceding 12	

	19e. Did she/he* have sex with a person who used a needle to inject drugs that were not prescribed by their own doctor? *If yes,* 19e(i). When? 19f. Did she/he* have sex with a person who has received medication for a bleeding disorder such as hemophilia? *If yes,* 19f(i). Do you know the name of the medication? *If yes,* 19f(i)a. What was it? 19f(ii). Was the medication human derived? 19f(iii) When was it used? 19g. Did she/he* have sex with a person who had a positive test for, or was suspected of having, Hepatitis B, Hepatitis C, or HIV? *If yes,* 19g(i). Which virus and when? 19g(ii). Was that person sick from the virus during that time, such as having	4. Persons who have engaged in sex in exchange for money or drugs in the preceding 5 years (Refs. 18, 21, 22, 24, 25, 27, 29, 33, 34, 38, 40, 44, 45, 46, 61, 62, and 63) (risk factor for HIV, Hepatitis B and Hepatitis C). 5. Persons who have had sex in the preceding 12 months with any person described in criteria 1 through 4 of this section or with any person who has HIV infection, including a positive or reactive test for HIV virus (Refs. 17 and 18), hepatitis B infection (Ref. 64), or clinically active (symptomatic) hepatitis C infection (Refs. 65 and 66).	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. D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)	months • People who have had sex in exchange for money or drugs in the preceding 12 months • People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months • People who have had sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months	

	abdominal pain, joint pain, exhaustion, fever, nausea, vomiting, diarrhea, or yellowing of the eyes or skin?				
20.	In the past 5 years, did she/he* receive medication for a bleeding disorder such as hemophilia? *If yes,* 20a. When? 20b. What was the reason? 20c. Do you know the name of the medication? *If yes,* 20c(i). What was it?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 3. Persons with hemophilia or other related clotting disorders who have received human-derived clotting factor concentrates in the preceding 5 years (Refs. 18 and 60) (risk factor for HIV, Hepatitis B and Hepatitis C). A donor who received clotting factors once to treat an acute bleeding event more than 12 months ago may be eligible to donate.	**Appendix II, Behavior/History Exclusionary Criteria** 3) Persons with hemophilia or related clotting disorders who have received human-derived clotting factor concentrates in the preceding five years; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
21.	Did she/he* **EVER** use or take drugs, such as steroids, cocaine, heroin, amphetamines, or anything **NOT** prescribed by her/his* doctor? *If yes,* 21a. What was it? 21b. How often and how long	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 2. Persons who have injected	**Appendix II, Behavior/History Exclusionary Criteria** 2) Persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections; D1.000 **Donor Eligibility**	**3.6 ALLOCATION OF LIVERS** **3.6.9 Minimum Information for Liver Offers.** **3.6.9.1** Essential Information Category. (vii) Social and drug activity histories; **3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information**	

	was it used? 21c. When was it last used? 21d. Were needles used? *If no,* 21d(i). How was it taken?	drugs for a non-medical reason in the preceding 5 years, including intravenous, intramuscular, or subcutaneous injections (Refs. 18, 21, 22, 25, 27, 29, 33, 34, 36, 38, 42, and 45 through 59) (risk factor HIV, Hepatitis B and Hepatitis C).	(reference Appendix II for FDA donor criteria)	**for Thoracic Organ Offers.** **3.7.12.1 Essential Information.** (iv) … and drug activity histories; **3.7.12.2 Desirable Information for Heart Offers.** (f) Two or more of the following: vii. History of cocaine or amphetamine use. ***PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation; Public Health Reports / July–August 2013 / Volume 128*** *(relevant part only)* Donors who meet one or more of the …. criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infection. Each factor listed reflects increased risk of all three pathogens as an aggregate, as there is overlap of associated risk, even though each factor does not convey risk from all pathogens equally. • People who have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months.	

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22.	Did she/he* **EVER** have a transplant or medical procedure that involved being exposed to live cells, tissues or organs from an animal? **22b.**Did she/he* live with, or have sex with, a person who had?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 29. Persons who are xenotransplantation product recipients or intimate contacts of a xenotransplantation product recipient (Ref. 77). For the purpose of this document, we define the following terms: • *Xenotransplantation* is 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. • *Xenotransplantation products* include live cells, tissues, or organs used in xenotransplantation. Biological products, drugs, or medical devices sourced from nonliving	**Appendix II, Behavior/History Exclusionary Criteria** 21) 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); (superscript references 5,6,7 above match the FDA definitions) D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		

		cells, tissues or organs from nonhuman animals, including but not limited to porcine insulin and porcine heart valves, are not considered xenotransplantation products. • *Xenotransplantation product* recipient means a person who undergoes xenotransplantation. • *Intimate contact of a xenotransplantation product* recipient means a person who has engaged in activities that could result in intimate exchange of body fluids, including blood or saliva, with a xenotransplantation product recipient. Examples of intimate contacts include sexual partners, household members who share razors or toothbrushes, and health care workers or laboratory personnel with repeated percutaneous, mucosal, or other direct exposures. We do not consider sharing of housing or casual contact, such as hugging or kissing without the exchange of saliva, to be intimate contact.			
23.	Was she/he* **EVER** told by a physician that she/he* had a disease of the brain or a neurological disease such as Alzheimer's, Parkinson's, multiple sclerosis, or	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be	**Appendix II, Behavior/History Exclusionary Criteria** 14) Persons with a diagnosis of dementia or any degenerative or demyelinating disease of the		

	epilepsy? *If yes,* 23a. What was she/he* told by a physician?	ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 20. Persons who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology (Refs. 3 and 75). Potential donors who have a diagnosis of delirium (e.g., delirium caused by toxic/metabolic diseases or recent head trauma) would not necessarily be considered to have a diagnosis of dementia and should be evaluated by the Medical Director. (HCT/Ps from donors with dementia confirmed by gross and microscopic examination of the brain to be caused by cerebrovascular accident or brain tumor and who are confirmed not to have evidence of TSE on microscopic examination of the brain may be acceptable based on an evaluation by the Medical Director).	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 TSE on microscopic examination of the brain, may be acceptable based on an evaluation of this information by the Medical Director.); *Possibly related but this will fit better where a query regarding recent neuro symptoms will be added:* 17) Persons with encephalitis or meningitis of viral or unknown etiology that is active; **D1.110 EBAA Contraindications to Transplant** Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors 4. Active viral encephalitis of unknown origin or progressive encephalopathy (e.g., subacute		

			sclerosing panencephalitis, progressive multifocal leukoencephalopathy, etc.); 5. active bacterial or viral meningitis; 12. Parkinson, amyotrophic lateral sclerosis, multiple sclerosis, and Alzheimer disease.		
24.	Was she/he* **EVER** refused as a blood donor or told not to donate? *If yes,* 24a. What was the reason?		**Appendix II, Behavior/History Exclusionary Criteria** 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; *Also:* 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);		
25.	Did she/he* **EVER** have any kind of surgery?	**IV. DONOR SCREENING (§ 1271.75)**	**Appendix II, Behavior/History**	**3.5.9 Minimum Information/Tissue for**	

	If yes, 25a. What kind? 25b. Where? 25c. When?	**E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 21. Persons who are at increased risk for CJD (Refs. 3 and 75). Donors are considered to have an increased risk for CJD if they have received a non-synthetic dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD (see criterion 22 of this section). 29. Persons who are xenotransplantation product recipients or intimate contacts of a xenotransplantation product recipient (Ref. 77). a. For the purpose of this document, we define the following terms: *i. Xenotransplantation* is 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	**Exclusionary Criteria** 16) Persons who are known to have received transplants of human *Dura Mater* 21) 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); **D1.110 EBAA Contraindications to Transplant** Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors B. Donors for Penetrating Keratoplasty Procedures 1. Prior intraocular or anterior segment surgery a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc. b. Laser photoablation surgery (these corneas may be used for tectonic grafting and posterior lamellar procedures). c. Corneas from patients with anterior segment (e.g.,	**Kidney Offer.**☐ **3.5.9.1 Essential Information for Kidney Offers.** (vi) Current history of abdominal injuries and operations;	

		contact with live nonhuman animal cells, tissues, or organs.	cataract, intraocular lens, glaucoma filtration surgery) may be used if screened by specular microscopy and meet the eye bank's endothelial standards. 2. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button. C. Donors for Anterior Lamellar Keratoplasty Procedures or Tectonic Grafts Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable). D. Donors for Epikeratoplasty Procedures Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable). Death to preservation time may be extended. E. Donors for Endothelial Keratoplasty Procedures		

			Criteria are the same as listed for penetrating keratoplasty, except that tissue with non-infectious anterior pathology that does not affect the posterior stroma and endothelium is acceptable. Surgeons must be notified of any prior pathology prior to placing tissue for transplant. F. Scleral Tissue Donors Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the cornea is acceptable for use. Death to preservation time may be extended.		
26.	Did she/he* **EVER** travel or live outside of the United States or Canada? *If yes,* 26a. Where? 26b. When and for how long? 26c. Did she/he* EVER receive a blood transfusion or other medical treatnmnet outside of the United States or Canada? *If yes,* 26c(i). What occurred (which one)? 26c(ii). Describe where and	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 23. Persons who spent three months or more cumulatively in the United Kingdom (U.K.) (see Appendix 5) from the beginning of 1980 through the end of 1996 (Refs. 3 and 75). 25. Persons who spent 5 years or more cumulatively in Europe (see Appendix 5) from 1980 until the present (note this	**Appendix II, Behavior/History Exclusionary Criteria** 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); 19) Persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the		

	when: *If international travel or residency is extensive, be aware of query regarding vaccinations or other shots (within the past 12 months) at question #11.*	criterion includes time spent in the U.K. from 1980 through 1996) (Refs. 3 and 75). 26. Persons who received any transfusion of blood or blood components in the U.K. or France between 1980 and the present (Refs. 3 and 75). 28. Persons who have received a blood transfusion or any medical treatment that involved blood in the countries listed in criterion 27, after 1977 (Refs. 66 and 76) (risk factor for HIV group O).	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[4] from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996); D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
27.	Was she/he* **EVER** a U.S. military member, a civilian military employee, or a dependent of either? *If yes,* 27a. Did she/he* ever live or work on a U.S. military base outside the United States? *If yes,* 27a(i). In which country or countries? 27a(ii). When? *If this occurred between 1980 and 1996 in Europe:* 27a(ii)a. How long? *(estimate total time)*	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 24. Persons who are current or former U.S. military members, civilian military employees, or dependents 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 cumulatively from 1980 through 1990, or elsewhere in	**Appendix II, Behavior/History Exclusionary Criteria** 19) Persons determined to be at risk for variant CJD (vCJD) because they are known to meet any of the following criteria: 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		

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	If in the military in the past 12 months, be aware of query regarding vaccinations or other shots at question #12.	Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996 (Refs. 3 and 75).	months or more from 1980 through 1996; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
28.	Did she/he* **EVER** use or take growth hormone? *If yes,* 28a. When was it used? 28b. What kind was it?	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 21. Persons who are at increased risk for CJD (Refs. 3 and 75). Donors are considered to have an increased risk for CJD if they have received a non-synthetic dura mater transplant, human pituitary-derived growth hormone, or have one or more blood relatives diagnosed with CJD (see criterion 22 of this section).	**Appendix II, Behavior/History Exclusionary Criteria** 15) Persons who have received injections of human pituitary-derived growth hormone (pit-hGH) D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)	**2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)** 2.2.2.1 Obtaining the donor's medical/ behavioral history. Potential donors who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) carry potential risk of prion disease. The Host OPO will attempt to obtain information regarding whether a potential donor has history of risk of prion disease (prior exposure or receipt of non recombinant HPDGH). If so, the Host OPO must communicate this information to all transplant programs receiving organs from the donor.	
29.	Did she/he* **EVER** have a positive or reactive test for: **29a.** the HIV/AIDS virus? *If yes,* 29a(i). Explain: **29b.** hepatitis?	*(although section F of the guidance usually doesn't apply to the medical history interview, it's listed here as a reference because it fits)* **F. What clinical evidence do I look for when screening a donor?**	**Appendix II, Behavior/History Exclusionary Criteria** 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		**CAN/CSA Z900.2.2, Safety of Tissue for Transplantation, Donor Suitability Assessment**

	If yes, 29b(i). Explain: **29c**. HTLV-I or HTLV-II? *If yes,* 29c(i). Explain: **29d.** *T. cruzi* or told she/he* has Chagas' disease? *If yes,* 29d(i). Explain:	You must review relevant medical records for clinical evidence of relevant communicable disease agents and diseases (§ 1271.75). You should look for the following examples of clinical evidence of relevant communicable disease. Except as noted in this section and in accordance with § 1271.75(d), you should determine to be ineligible any potential donor who exhibits one or more of the following examples of clinical evidence of relevant communicable disease. HIV infection: • A prior positive or reactive screening test for HIV; Hepatitis infection: • A prior positive or reactive screening test for hepatitis B virus or hepatitis C *(to date, T. cruzi/Chagas' disease has only appeared in draft guidance as a potential new RCDAD)*	for HIV, HBV, or HCV; **D4.000 DONOR SUITABILITY** **D4.100 General** (C) Heart donor*s* shall also meet the following criteria: 3) Heart valve donors shall be evaluated for the risk of Chagas' disease. **D4.310 Infections** The Medical Director or licensed physician designee shall not release allogeneic tissue for transplantation from donors who exhibit any of the following findings: 1) Evidence, detected by review of *Relevant Medical Records* of significant active infection at the time of donation for Relevant Communicable Disease Agents or Diseases (RCDADs). These include, but are not limited to: …tuberculosis…. D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		**12.3 Contraindications/Exclusion Criteria** **12.3.1** In addition to the contraindications/exclusion criteria listed in Clause 12.3.3 of CSA Standard Z900.1, exclusion criteria for tissue also includes, but is not limited to: "hepatitis" **CSA-Z900.2.2-12, CSA Tissue Standard**, Section 13.1.2 (c) – exclude persons with HTLV-I or HTLV-II. ***Clinical Decision*** Tissue Standard 13.1.5 – Chagas' Disease. **Section 12.2.2.4, CSA Organ Standard** requires that a history for deceased donors include any history

					of tuberculosis, hepatitis, or other communicable disease.
30.	Did she/he* **EVER** have liver disease or hepatitis? *If yes,* 30a. What kind? 30b. When?	*(although section F of the guidance usually doesn't apply to the medical history interview, it's listed here as a reference because it fits)* **F. What clinical evidence do I look for when screening a donor?** You must review relevant medical records for clinical evidence of relevant communicable disease agents and diseases (§ 1271.75). You should look for the following examples of clinical evidence of relevant communicable disease. Except as noted in this section and in accordance with § 1271.75(d), you should determine to be ineligible any potential donor who exhibits one or more of the following examples of clinical evidence of relevant communicable disease. Hepatitis infection: • A prior positive or reactive screening test for hepatitis B virus or hepatitis C	**Appendix II, Behavior/History Exclusionary Criteria** 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); 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
31.	Did she/he* **EVER** have malaria? *If yes,*		**Appendix II, Behavior/History Exclusionary Criteria** 28) Persons who are known to		**CAN/CSA Z900.2.2, Safety of Tissue for**

	31a. When? 31b. Where was she/he* treated?		have malaria or be at risk for malaria;		**Transplantation, Donor Suitability Assessment 12.3 Contraindications/Exclusion Criteria 12.3.1** In addition to the contraindications/exclusion criteria listed in Clause 12.3.3 of CSA Standard Z900.1, exclusion criteria for tissue also includes, but is not limited to: (b) malaria; and Also a requirement by the European Eye Bank Association's (EEBA) Agreements on Minimum Standards (Jan 2008) **CONTRAINDICATIONS TO THE USE OF DONOR OCULAR TISSUE FOR TRANSPLANTATION**

					1 INFECTIONS: 1.14 Active malaria
32.	Did she/he* **EVER** have cancer? *If yes,* 32a. What type? *If skin cancer:* 32a(i). What kind? 32b. When was it diagnosed? 32c. Describe when and where surgery, radiation, or chemotherapy occurred: 32d. Was the cancer considered cured? *If yes,* 32d(i). When?		**D4.340 Malignancies** Donors with current or prior diagnosis of malignancy shall be evaluated by the Medical Director or licensed physician designee for suitability in accordance with the tissue bank's *SOPM*. The evaluation shall include: the type of malignancy, clinical course, and treatment prior to acceptance of a donor. The evaluation and reasons for acceptance shall be documented in the donor's record. **D1.110 EBAA Contraindications to Transplant** Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors 9. intrinsic eye disease; a. retinoblastoma; b. malignant tumors of the anterior ocular segment or known adenocarcinoma in the eye of primary or metastatic origin; 10. active leukemias; or		

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			11. active disseminated lymphomas		
33.	Did she/he* **EVER** smoke? *If yes,* 33a. What was it? *If cigarettes:* 33a(i). How many packs per day? 33b. How many years? 33c. Did she/he* quit? *If yes,* 33c(i). When?			**3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information for Thoracic Organ Offers.** **3.7.12.1 Essential Information.** (iv) Cardiopulmonary…. histories; **3.7.12.2 Desirable Information for Heart Offers.** (f) Two or more of the following: ii. History of significant smoking **3.7.12.3 Essential Information for Lung Offers.** (v) Smoking history.	
34.	**34a.** Did she/he* **EVER** have lung disease such as asthma, COPD, or emphysema? *If yes,* 34a(i). Explain: **34b.** Did she/he* **EVER** have tuberculosis, or a positive skin or blood test for tuberculosis? *If yes,* 34b(i). Did she/he* receive treatment? *If yes,* 34b(i)a. When? 34b(i)b. How long?		**D4.310 Infections** The Medical Director or licensed physician designee shall not release allogeneic tissue for transplantation from donors who exhibit any of the following findings: 1) Evidence, detected by review of *Relevant Medical Records* of significant active infection at the time of donation for Relevant Communicable Disease Agents or Diseases (RCDADs). These include, but are not limited to: …tuberculosis….	**3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information for Thoracic Organ Offers.** **3.7.12.1 Essential Information.** (iv) Cardiopulmonary…. histories;	**CAN/CSA Z900.2.2, Safety of Tissue for Transplantation, Donor Suitability Assessment** **12.3 Contraindications/Exclusion Criteria** **12.3.1** In addition to the contraindications/exclusion criteria listed in Clause 12.3.3 of CSA Standard Z900.1, exclusion criteria

					for tissue also includes, but is not limited to: (c) tuberculosis
35.	Did she/he* **EVER** drink alcohol? *If yes,* 35a. What type? 35b. How often? 35c. How much? 35d. How long?			**3.8 Pancreas Allocation Policy** **3.8.2.2 Essential Information for Pancreas Offers.** 14. Alcohol use (if known);	
36.	Did she/he* **EVER** have diabetes? *If yes,* 36a. For how many years? 36b. Was it treated? *If yes,* 36b(i). How?			**3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information for Thoracic Organ Offers.** **3.7.12.1 Essential Information.** vi. History of diabetes	
37.	**37a.** Did she/he* **EVER** have kidney disease, kidney stones, or frequent kidney infections? *If yes,* 37a(i). What did she/he* have?			**3.5 ALLOCATION OF DECEASED KIDNEYS** **3.5.9 Minimum Information/Tissue for Kidney Offer.☐** **3.5.9.1 Essential Information for Kidney Offers.** 3.5.9.1 (vii) Pertinent past medical or social history;	

	If yes, 37a(ii). When? **37b.** Was she/he* **EVER** treated with dialysis? *If yes,* 37b(i). Was it peritoneal dialysis or hemodialysis? *If yes,* 37b(ii). When?			***PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation; Public Health Reports / July–August 2013 / Volume 128*** *(relevant part only)* Donors who meet one or more of the …. criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infection. Each factor listed reflects increased risk of all three pathogens as an aggregate, as there is overlap of associated risk, even though each factor does not convey risk from all pathogens equally. Donors who meet the following criterion should be identified as being at increased risk for recent HCV infection only: • People who have been on hemodialysis in the preceding 12 months.	
38.	Did he/she* **EVER** have high blood pressure or high cholesterol? *If yes,* 38a. Which one (or both)?			**3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information for Thoracic Organ Offers.** **3.7.12.2 Desirable Information for Heart Offers.**	

	38b. For how many years?			(f) Two or more of the following: i. History of hypertension v. History of Hyperlipidemia	
39.	Did she/he* **EVER** have a heart attack or heart disease, such as a weak heart, a heart valve problem or an infection involving the heart? *If yes,* 39a. Explain: 39b. How was it treated?		**D4.320 Miscellaneous Adverse Conditions** Tissue from donors with any of the following conditions shall be evaluated by the Medical Director for suitability for transplantation in accordance with the tissue bank's *SOPM*: (C) Heart donors shall also meet the following criteria: 1) There shall be no history of bacterial endocarditis, rheumatic fever, or a cardiomyopathy of viral or idiopathic etiology; 2) Any history of previous cardiac surgery (i.e., CABG), semilunar valvular disease, closed chest massage (CPR), cardiac defibrillations, penetrating cardiac injury, or other potentially deleterious cardiac intervention shall be evaluated on a case-by-case basis; and 3) Mitral valve donors shall not have a history of mitral valve disease, including mitral valve prolapse. **D1.110 EBAA Contraindications to Transplant**	**3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information for Thoracic Organ Offers.** **3.7.12.2 Desirable Information for Heart Offers.** (f) Two or more of the following: i. History of hypertension iv. Strong family history of coronary artery disease	

			Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors 6. active bacterial or fungal endocarditis;		
40.	Did she/he* **EVER** have circulation problems of the legs, such as varicose veins, blood clots, leg ulcers, or skin discoloration of the feet or ankles? *If yes,* 40a. Explain:		**D4.320 Miscellaneous Adverse Conditions** Tissue from donors with any of the following conditions shall be evaluated by the Medical Director for suitability for transplantation in accordance with the tissue bank's *SOPM*: (V) Vascular donors shall also meet the following criteria: 1) Veins—There shall be no history of vein stripping, varicose veins, or evidence of venous insufficiency; 2) Arteries—There shall be no known (reported) history of peripheral vascular disease or systemic vasculitis;		
41.	Did she/he* **EVER** have an autoimmune disease such as systemic lupus erythematosis, rheumatoid arthritis, sarcoidosis, etc.? *If yes,*		**D4.320 Miscellaneous Adverse Conditions** Tissue from donors with any of the following conditions shall be evaluated by the Medical Director for suitability for transplantation in accordance with the tissue bank's *SOPM*:		

	41a. What was it? 41b. Did she/he* take steroids? *If yes, complete 5a(ii) and 5a(iii).*		1) History of autoimmune diseases; (MS) In addition to the general exclusion criteria, the following medical conditions shall also preclude musculoskeletal tissue donation: 1) Rheumatoid arthritis; 2) Systemic lupus erythematosus; 3) Polyarteritis nodosa; 4) Sarcoidosis; and 5) Clinically significant metabolic bone disease.		
42.	Did she/he* **EVER** have any eye problems, procedures, or surgery? *If yes to eye problems:* 42a. What kind of eye problems? *If yes to eye surgery or procedures:* 42b. What kind of surgery or procedure was performed and why? 42c. Which eye(s)? ❑ left ❑ right ❑ unknown 42d. What is the name and/or phone number of her/his*		**D1.110 EBAA Contraindications to Transplant** Tissue from persons with the following are potentially health threatening for the recipient(s) or pose a risk to the success of the surgery and shall not be offered for surgical purposes: A. All Ocular Donors 2. congenital rubella; 3. Reyes Syndrome within the past three months; 8. Down Syndrome-exclusive for penetrating keratoplasty or anterior lamellar keratoplasty; 9. intrinsic eye disease; a. retinoblastoma; b. malignant tumors of the anterior ocular segment or known adenocarcinoma in the		

	eye doctor or eye clinic?		eye of primary or metastatic origin; c. active ocular or intraocular inflammation: conjunctivitis, keratitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis; or d. congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and keratoglobus; B. Donors for Penetrating Keratoplasty Procedures 1. Prior intraocular or anterior segment surgery a. Refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc. b. Laser photoablation surgery (these corneas may be used for tectonic grafting and posterior lamellar procedures). c. Corneas from patients with anterior segment (e.g., cataract, intraocular lens, glaucoma filtration surgery) may be used if screened by specular microscopy and meet the eye bank's endothelial standards. 2. Pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the		

			corneal button. C. Donors for Anterior Lamellar Keratoplasty Procedures or Tectonic Grafts Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable). D. Donors for Epikeratoplasty Procedures Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the corneal endothelium, (e.g., donors with a history of endothelial dystrophy or iritis are acceptable). Death to preservation time may be extended. E. Donors for Endothelial Keratoplasty Procedures Criteria are the same as listed for penetrating keratoplasty, except that tissue with non-infectious anterior pathology that does not affect the posterior stroma and endothelium is acceptable. Surgeons must be notified of any prior pathology prior to placing tissue for transplant.		

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			F. Scleral Tissue Donors Criteria are the same as listed for penetrating keratoplasty, except that tissue with local eye disease affecting the cornea is acceptable for use. Death to preservation time may be extended.		
43.	Did she/he* or **any** of her/his* relatives have Creutzfeldt-Jakob disease, which is also called CJD or variant CJD? *If yes,* 43a. Who did? *If a relative,* 43a(i). Is this person a blood relative? (Note: The definition of blood relative is a person who is related through a common ancestor and not by marriage or adoption) *If yes,* 43a(ii). Which blood relative? 43b. Is there a physician, relative, or other person who can provide more information? *(document discussion)*	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 22. Persons who have a history of CJD in a blood relative (Refs. 3 and 75) unless: • The diagnosis of CJD was subsequently found to be an incorrect diagnosis; • The CJD was iatrogenic; or • Laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD.	**Appendix II, Behavior/History Exclusionary Criteria** 9) 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; D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		
44.	**44a.** Did her/his* family have a history of diabetes?			**3.7 ALLOCATION OF THORACIC ORGANS** **3.7.12 Minimum Information**	

	If yes, 44a(i). Describe type of relative, such as mother, father, sister, brother, etc.: **44b.** Did her/his* family have a history of coronary artery disease, which is a buildup of plaque in the heart's arteries? *If yes,* 44b(i). Describe type of relative, such as mother, father, sister, brother, etc.:			**for Thoracic Organ Offers.** **3.7.12.2 Desirable Information for Heart Offers.** (f) Two or more of the following: iv. Strong family history of coronary artery disease **3.8 Pancreas Allocation Policy** **3.8.2.2 Essential Information for Pancreas Offers.** 15. Familial history of diabetes;	
Final Questions					
45.	Are there other medical conditions you are aware of that we have not discussed? *If yes,* 45a. Describe:				Accepted practice; promotes 'dialogue' with interviewee
46.	Do you now have any concerns that her/his* donation should not proceed? *If yes,* 46a. Can you share your concerns?				Accepted practice; promotes 'dialogue' with interviewee
47.	Regarding these questions, are there other people, including healthcare professionals, who may	**IV. DONOR SCREENING (§ 1271.75)** **C. What sources of information do I review?**	**D4.220 Donor Risk Assessment** An inquiry shall be conducted with the donor (if living) or the deceased donor's next of kin, the nearest available relative, a member of the		Accepted practice; promotes 'dialogue' with interviewee

	provide additional information? *If yes,* 47a. Name(s) and contact information:	1. The donor medical history interview (§ 1271.3(n)) is a documented dialogue concerning the donor's medical history and relevant social behavior: a. With a living donor; or b. If the donor is not living or is unable to participate in the interview, then with one or more individuals who can provide the information sought. These individuals might be: • The donor's next of kin; • The nearest available relative; • A member of the donor's household; • An individual with an affinity relationship with the donor (e.g., caretaker, friend, partner); or • The donor's primary treating physician.	donor's household, other individual with an affinity relationship (caretaker, friend, significant life partner) and/or the primary treating physician), using a standardized questionnaire. Questions shall be formulated using these *Standards*, current federal regulations and guidance. **A2.000 DEFINITIONS OF TERMS** **DONOR RISK ASSESSMENT INTERVIEW** A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior……. D1.000 **Donor Eligibility** Before tissue is made available for distribution, the Donor Eligibility Determination must be made by a responsible person. Reference Appendix II for requirements related to the donor eligibility process. Prior to making an eligibility determination, the donor must be screened according to D1.200. Medical and social histories are important aspects of donor evaluation. Adequate donor evaluation includes: 4. Donor history evaluation: this must include the donor's name, social history and donor information obtained from at least one of the following: d) Donor risk assessment interview f) Treating physician interview **Glossary** **Definition of Terms** **Donor Risk Assessment Interview**. A documented dialogue in person or by telephone		

			with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior…..		
48.	Do you have any questions about these questions? *If yes,* 48a. Document:	**IV. DONOR SCREENING (§ 1271.75)** **C. What sources of information do I review?** 1. The donor medical history interview (§ 1271.3(n)) is a documented dialogue concerning the donor's medical history and relevant social behavior: **….**	**A2.000 DEFINITIONS OF TERMS** **DONOR RISK ASSESSMENT INTERVIEW** A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior……. **Glossary** **Definition of Terms** **Donor Risk Assessment Interview**. A documented dialogue in person or by telephone with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior….		
Pg 20	*Note to Interviewer: Question 49, the HIV-1 Group O Risk Question, must be asked if the test kit being used for HIV-1 **Ab** testing is not labeled to include HIV-1 Group O. Check here if question skipped* ❑.				Note to Interviewer.
49.	Did she/he* **EVER** have sex with a person who was born in or lived in any country in Africa? *If yes,* 49a. When was the person born, or when did the person live, in Africa? *If since 1977:*	**IV. DONOR SCREENING (§ 1271.75)** **E. What risk factors or conditions do I look for when screening a donor?** …..you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors…. 27. Persons or their sexual	**Appendix II, Behavior/History Exclusionary Criteria** 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]; [3]Tissue Banks using an HIV test that has been approved by FDA to include a donor screening		

	49a(i). What country were they from?	partners who were born or lived in certain countries in Africa (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria) after 1977 (Refs. 66 and 76) (risk factor for HIV group O). Note: Establishments utilizing an HIV-1/2 antibody donor screening test that has been licensed by FDA and is specifically labeled in the Intended Use Section of the package insert as sensitive for detection of HIV group O antibodies may delete items 27 and 28 from their screening procedures. If such establishments continue to ask items 27 and 28, the donor eligibility may be based on the results of the donor screening test regardless of the answers to items 27 and 28. Establishments that do not utilize an HIV antibody donor screening test that has been licensed by FDA for detection of HIV group O antibodies should continue to ask these items.	claim for detection of HIV Group O antibodies are not required to screen for this risk history. D1.000 **Donor Eligibility** (reference Appendix II for FDA donor criteria)		