



FORM TITLE: Risk Behavior Assessment	RELEASE DATE: 12/07/2012	
	EFFECTIVE DATE: 12/13/2012	
	PROCEDURE NUMBER: DE-03.F1	REVISION: A

Donor Name: _____ Donor Number: _____

1. Are you a male who has had sex with another male in the preceding five years?
 Yes
 No

2. Have you injected drugs for non-medical reason in the preceding five years, including intravenous, intramuscular, or subcutaneous injections?
 Yes
 No

3. Do you have hemophilia or other related clotting disorders and have received human-derived clotting factor concentrates in the preceding five years, not including receiving clotting factors once to treat an acute bleeding event more than 12 months ago?
 Yes
 No

4. Have you engaged in sex in exchange for money or drugs in the preceding five years?
 Yes
 No

5. Have you had sex in the preceding 12 months with any person who would have answered yes to any of the 4 previous items or with any person known or suspected to have HIV infection, including any person who has had a positive or reactive test for HIV virus hepatitis B (HBV) infection or clinically active (symptomatic) hepatitis C (HCV) infection?
 Yes
 No

6. Have you 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?
 Yes
 No



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7. Have you been in juvenile detention, lock up, jail or prison for more than 72 consecutive hours in the preceding 12 months?

- Yes
- No

8. Have you, anyone in your household or any of your intimate contacts ever been diagnosed with any form of hepatitis?

- Yes
- No

9. Have you lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months?

- Yes
- No

10. Within the preceding 12 months, have you undergone tattooing, ear piercing, or body piercing 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 procedures were used?

- Yes
- No

11. Have you had a past diagnosis of clinical, symptomatic viral hepatitis after your eleventh birthday, unless evidence from the time of illness documents that the hepatitis was identified as being caused by hepatitis A virus (e.g., a reactive IgM anti-HAV test), Epstein-Barr virus (EBV), or cytomegalovirus (CMV)?

- Yes
- No

12. Do you have or suspect that you have sepsis (systemic infection) at this time?

- Yes
- No



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13. Have you or any of your close contacts had a smallpox vaccine within the past eight weeks?

- Yes
- No

14. If you have had a smallpox vaccination (vaccinia virus) in the preceding eight weeks, has your scab separated spontaneously?

- N/A- I have not had a smallpox vaccination in the preceding eight weeks.
- Yes - My scab has not separated spontaneously.
- N/A- I did not acquire a scab as a result of my smallpox vaccination.
- No - My scab has not separated spontaneously.

15. If you have had a smallpox vaccination (vaccinia virus) in the preceding eight weeks, has it been 21 days post- vaccination?

- N/A- I have not had a smallpox vaccination in the preceding eight weeks.
- Yes
- No

16. If you have had a smallpox vaccination (vaccinia virus) in the preceding eight weeks and have had complications as a result of that vaccine, have your complications been completely resolved for at least fourteen days?

- N/A- I have not had a smallpox vaccination in the preceding eight weeks.
- N/A- I did not have any complications from my smallpox vaccination.
- Yes
- No



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17. Have you been diagnosed with clinically recognizable vaccinia virus infection and developed scabs or skin lesions acquired by close 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) and the resulting scab has since spontaneously separated?

- N/A- I have not been diagnosed with clinically recognizable vaccinia virus infection.
- N/A- I did not have any complications, scabs or lesions as a result of my diagnosis.
- Yes - My scab has since separated spontaneously.
- No - My scab did not separate spontaneously, but it has been three or more months since the date of the vaccination of the vaccine recipient with whom I had close contact.
- No - My scab has not yet separated.
- No - My scab did not separate spontaneously, and it has been less than three months since the date of the vaccination of the vaccine recipient with whom I had close contact.

18. Have you been diagnosed with clinically recognizable vaccinia virus infection and developed other complications of vaccinia infection acquired by close 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)?

- N/A- I have not been diagnosed with clinically recognizable vaccinia virus infection.
- Yes – but my complications have been resolved for at least fourteen days.
- No – I had no complications as a result of my diagnosis.
- Yes – but my complications have not been resolved for at least fourteen days.

19. Have you ever tested positive for or been treated for West Nile Virus?

- Yes
- No



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20. Have you had a medical diagnosis, onset of illness, or suspicion of WNV (West Nile Virus) infection (including diagnosis based on symptoms and/or laboratory results or confirmed WNV viremia) in the preceding 120 days?

- Yes
- No

21. Have you tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days?

- Yes
- No

22. Have you ever tested positive or been treated for a sexually-transmitted disease?

- Yes
- No

23. Have you been treated for or had syphilis within the preceding 12 months?

- Yes
- No

24. Have you been treated for or had Chlamydia trachomatis or Neisseria gonorrhoea infection in the preceding 12 months?

- Yes
- No

25. Have you or any of your blood relatives ever been diagnosed with Creutzfeldt-Jakob disease (CJD)?

- Yes
- No



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26. Have you ever been diagnosed with vCJD or any other form of Creutzfeldt-Jakob disease (CJD)?

- Yes
- No

27. Have you been diagnosed with dementia or another neurological disease of unknown cause?

- Yes
- No

28. Have you ever been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology?

- Yes
- No

29. Have you received a non-synthetic dura matter transplant, received human pituitary derived growth hormone, and/or have one or more blood relatives diagnosed with CJD that was not subsequently found to be an incorrect diagnosis, found to be iatrogenic, or that laboratory testing (gene sequencing) shows that you do not have a mutation associated with CJD?

- Yes
- No

30. Since 1977, have you or any of your intimate contacts ever traveled to or lived in Europe or Africa?

- Yes
- No

31. Have you spent 3 months or more, cumulatively, in the UK (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands) from the beginning of 1980 through the end of 1996?

- Yes
- No



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32. Are you a current or former US military member, civilian military employee, or dependent of a military member or civilian employee, who has resided at US military bases in northern Europe (Germany, Belgium, and Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, or Italy) for 6 months or more cumulatively from 1980 through 1996?

- Yes
- No

33. Have you lived cumulatively for 5 years or more in Europe (Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, England, Northern Ireland, Scotland, Wales, Isle of Man, Channel Islands, Gibraltar, Falkland Islands, and Yugoslavia) from 1980 until present?

- Yes
- No

34. Have you received any transfusion of blood or blood components in the UK (England, Northern Ireland, Scotland, Wales, Isle of Man, Channel Islands, Gibraltar, Falkland Islands) or France between 1980 and the present?

- Yes
- No

35. Were you or any of your sexual partners born in or have you or any of your sexual partners lived in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria after 1977?

- Yes
- No

36. Have you received a blood transfusion or any medical treatment that involved blood in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria after 1977?

- Yes
- No



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37. Have you or any of your intimate contacts ever undergone a medical procedure involving non-human (animal) cells, tissues or organs?

- Yes
- No

38. Have you been the recipient of a xenotransplantation product (transplantation, implantation, or infusion) of either cells, tissues or organs from a nonhuman animal source (this includes human bodily fluids, cells, or organs that have had ex-vivo contact with live nonhuman animal cells, tissues, or organs)?

- Yes
- No

39. Has anyone you have had close contact with (e.g., intimate or living in the same household, where sharing of kitchen and bathroom facilities occurs regularly) been the recipient of a xenotransplantation product (transplantation, implantation, or infusion) of either cells, tissues or organs from a nonhuman animal source (this includes human bodily fluids, cells, or organs that have had ex-vivo contact with live nonhuman animal cells, tissues, or organs) not including the product Epicel?

- Yes
- No

40. Does your medical history or medical records show any evidence of a diagnosis or a prior positive or reactive screening test result for HIV?

- Yes
- No

41. Have you ever had unexplained weight loss?

- Yes
- No

42. Have you ever had unexplained night sweats?

- Yes
- No



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43. Have you ever had blue or purple spots on or under the skin or mucous membranes typical of Kaposi's sarcoma?

- Yes
- No

44. Have you ever had disseminated lymphadenopathy (swollen lymph nodes) for longer than one month?

- Yes
- No

45. Have you ever had an unexplained temperature of greater than 100.5F (38.6 C) for more than 10 days?

- Yes
- No

46. Have you ever had unexplained persistent cough or shortness of breath?

- Yes
- No

47. Have you ever had opportunistic infections (infection that takes advantage of a weakened immune system)?

- Yes
- No

48. Have you ever had unexplained persistent diarrhea?

- Yes
- No

49. Have you ever had unexplained persistent white spots or unusual blemishes in the mouth?

- Yes
- No



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50. Does your medical history or medical records show any evidence of a diagnosis or a prior positive or reactive screening test result for Hepatitis B Virus or Hepatitis C Virus?

- Yes
- No

51. Have you ever had unexplained jaundice?

- Yes
- No

52. Have you ever had unexplained hepatomegaly (enlarged liver)?

- Yes
- No

53. Have you had a past diagnosis of clinical, symptomatic viral hepatitis after your eleventh birthday that was not later identified as being caused by hepatitis A virus, Epstein Barr Virus, or cytomegalovirus?

- Yes
- No

54. Within the past 120 days, have you experienced unexplained fever, headache, body aches, Or eye pain that may have been accompanied by skin rash on the trunk of the body or by swollen lymph glands?

- Yes
- No

55. Within the past 120 days, have you been diagnosed with a severe illness such as encephalitis, meningitis, meningoenkephalitis, or acute flaccid paralysis?

- Yes
- No



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56. Within the past 120 days, have you had signs and symptoms of severe illness, including headache, high fever, neck stiffness, stupor, disorientation, coma, tremors, convulsions and muscle weakness or paralysis?

- Yes
- No

57. Have you, in the last 12 months, been diagnosed with sepsis (including bacteremia, septicemia, sepsis syndrome, systemic infection, systemic inflammatory response syndrome (SIRS) or septic shock)?

- Yes
- No

58. Have you ever had clinical evidence of infection with two or more of the following systemic responses to infection if unexplained: temperature of greater than 100.4F (38C), elevated heart rate, elevated respiratory rate or elevated white blood cell count?

- Yes
- No

59. Have you, in the last 12 months, experienced more severe signs of sepsis including unexplained hypoxemia, elevated lactate, oliguria (less than normal urination), altered mentation and hypotension (low blood pressure)?

- Yes
- No

60. Have you, in the last 12 months, had a blood test that resulted in a positive blood cultures associated with the conditions in the previous question?

- Yes
- No

61. Does your medical history or medical records show any evidence of a diagnosis or a prior positive or reactive screening test result for HTLV?

- Yes
- No

