



**North Carolina Center for Reproductive Medicine
FDA Questionnaire**

Please print and fill out.

Return to NCCRM 400 Ashville Ave #200 Cary NC 27518

Phone (919) 233-1680 Fax (919)233-1685

- yes no 1. (Men only) Have you had sex with another man in the preceding five years?
- yes no 2. Have you injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular or subcutaneous injections?
- yes no 3. Do you have hemophilia? If yes, do you use human-derived clotting factor?
- 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 described in the 4 items of this section or with any person known or suspected to have HIV infection, clinically active hepatitis B infection or hepatitis C 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 7. Have you been incarcerated for more than 72 consecutive hours during the previous 12 months?
- yes no 8. Have you had close contact within 12 months preceding donation with another person having clinically active viral hepatitis (e.g., living in the same household where shaving of kitchen and bathroom facilities occurs regularly)?
- yes no 9. Have you had a tattoo, ear piercing or body piercing in the last 12 months in which instruments were shared?
- yes no 10. Have you been diagnosed with viral hepatitis after age 11? Unless evidence from the time of illness documents that the hepatitis was identified as hepatitis A (e.g., a reactive IgM anti-HAV test)?
- yes no 11. Have you had a recent smallpox vaccination (vaccinia virus) in the last 60 days? If less than 60 days, did the scab separate by some other means than spontaneously?

- yes no 12. Do you have a clinically recognizable vaccinia virus contracted by close contact with someone who received the smallpox vaccine? The physical assessment should also check for this. If the answer is yes to this question, defer donation for 90 days or 14 days after all complications have resolved, whichever is the later date.
- yes no 13. Have you had a medical diagnosis of WNV infection? If the answer is yes, defer donation for 28 days from the onset of symptoms or 14 days after the condition has resolved, whichever is the later date.
- yes no 14. Have you had both a fever and a headache (simultaneously) during the 7 days prior to donation? If yes, defer donation for 28 days.
- yes no 15. Are you or any close contacts a xenotransplantation product recipient? Have you, your sexual partner or any member of his/her household ever had a transplant or other medical procedure that involved being exposed to live cells, tissues or organs from an animal?
- yes no 16. Have you had a transfusion or received blood or blood products in the last 48 hours?
- yes no 17. Have you been diagnosed with or treated for Chlamydia?
- yes no 18. Have you been diagnosed or treated for Gonorrhea?
- yes no 19. Have you ever been diagnosed with vCJD or any other form of CJD?
- yes no 20. Have you ever had a diagnosis of dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology?
- yes no 21. Have you ever had a blood relative diagnosed with CJD?
- yes no 22. Have you ever taken human pituitary-derived growth hormone?
- yes no 23. Have you ever received a dura mater transplant?
- yes no 24. Have you spent three months or more cumulatively in the United Kingdom (UK) from the beginning of 1980 through the end of 1996?
- yes no 25. Are you a current or former member of the U.S. Military, civilian military employee or dependant of a military member or civilian employee who resided at U.S. bases in Northern Europe (Germany, UK, Belgium and the Netherlands) for 6 months or more from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal and Italy) for 6 months or more from 1980 through 1996?
- yes no 26. Have you lived cumulatively for 5 years or more in Europe from 1980 until the present (this criterion includes time spent in the UK from 1980 through 1996)?

- yes no 27. Have you received any transfusion of blood or blood components in the United Kingdom (UK) between 1980 and present?
- yes no 28. Have you injected bovine insulin since 1980, unless you can confirm that the product was not manufactured after 1980 from cattle in the United Kingdom (UK)?
- yes no 29. If this is a repeat donation within 6 months of your last full medical history interview, have the answers to the above questions changed?

The following questions only need to be asked if there is a SARS outbreak in the world. Contact the CDC website (www.cdc.gov/ncidod/sars/index.htm) or call the CDC (888-246-2675) to obtain the up-to-date information concerning areas affected by SARS. If there are cases of SARS, ask the following questions, otherwise not N/A.

- yes no 30. Have you traveled to or resided (the areas affected) in the last 14 days?
- yes no 31. Have you had close contact with someone who has traveled to or resided (the areas affected) in the last 14 days?
- yes no 32. Have you been treated for SARS or suspected you had SARS in the last 28 days?
- yes no 33. Have you had close contact within the previous 14 days with persons with SARS or suspected SARS?

Authorized person completing form:

Print Name

Signature

Date