



## FDA Questionnaire Update, EDI

### An Update is Requested:

The Federal Drug Administration (FDA) requests that we obtain an update from all of those that donate genetic material such as egg and sperm donors, intended parents of conventional and gestational surrogacy as well as the surrogates themselves. Some of the questions are a bit odd but the FDA requires that they be asked.

Have you injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular or subcutaneous injections?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Do you have hemophilia? If yes, do you use human-derived clotting factor?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you engaged in sex in exchanged for money or drugs in the preceding five years?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you had sex in the preceding 12 months with any person described in the previous 3 items of this section or with any person known or suspected to have HIV infection, clinically active hepatitis B infection or hepatitis C infection?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you been incarcerated for more than 72 consecutive hours during the previous 12 months?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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 sharing of kitchen and bathroom facilities occurs regularly)?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you had a tattoo, ear or body piercing in the last 12 months in which instruments were shared?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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)?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Do you have a clinically recognizable vaccine virus contracted by close contact with someone who received the smallpox vaccine? 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.	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you had a medical diagnosis of WNV infection? If the answer is yes, defer donation for 120 days from the onset of symptoms or diagnosis, whichever is the later date.	<input type="checkbox"/> N	<input type="checkbox"/> Y
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?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you had a transfusion, received blood, blood products, or human organ transplant?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you been diagnosed with or treated for syphilis in the previous 12 months?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you been diagnosed with or treated for Chlamydia within the previous 12 months?	<input type="checkbox"/> N	<input type="checkbox"/> Y

FDA Questionnaire Update, EDI (*cont.*)

Have you been diagnosed or treated for Gonorrhea within the previous 12 months?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you ever been diagnosed with CJD or any other form of CJD?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you ever had a blood relative diagnosed with CJD?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you ever taken human pituitary-derived growth hormone?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you ever received a dura mater transplant?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you spent three months or more cumulatively in the United Kingdom (UK) from the beginning of 1980 through the end of 1996?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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)?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have you received any transfusion of blood or blood components in the United Kingdom (UK) between 1980 and present?	<input type="checkbox"/> N	<input type="checkbox"/> Y
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)?	<input type="checkbox"/> N	<input type="checkbox"/> Y
(Men only) Have you had sex with another man in the preceding five years?	<input type="checkbox"/> N	<input type="checkbox"/> Y
If this is a repeat donation within 6 months of your last full medical history interview, have the answers to the above questions changed?	<input type="checkbox"/> N	<input type="checkbox"/> Y

The above information, to the best of my knowledge, is true and accurate.

\_\_\_\_\_  
Intended Parent/Surrogate Printed Name

\_\_\_\_\_  
Intended Parent/Surrogate Signature

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

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