**Question:** 1. Are you feeling healthy and well today?

**Donor Eligibility:** A person should be free of infectious diseases, including colds, on the day of donation. A person who is not in good health should not donate until it is determined that the underlying condition is not cause for deferral.

---

**Question #1**

Are you feeling healthy and well today?

- **Yes**
  - Is reason cause for deferral?
    - **No**
      - Accept donor
    - **Yes**
      - Defer donor per SOP

- **No**
  - Determine the reason the donor is not feeling well and healthy today. Consult SOP for deferral criteria.
**Question:** 2. Are you currently taking an antibiotic?

**Donor Eligibility:** The reason the antibiotic was prescribed must be evaluated to determine if the person has a bacterial infection that could be transmissible by blood. A person with an infection should not donate.
**Question:** 3. Are you currently taking any other medication for an infection?

**Donor Eligibility:** The reason for use of any medication for an infection must be evaluated to determine if the person has a viral, fungal, parasitic or other infection transmissible by blood. A person with an infection should not donate.

---

**Flowchart Description:**

1. **Question #3**
   - Are you currently taking any other medication for an infection?
     - **Yes**
       - Consult SOP for deferral criteria. Determine why the medication(s) was prescribed.
     - **No**
2. **Is diagnosis cause for deferral?**
   - **Yes**
     - Defer donor per SOP
   - **No**
     - Accept donor

**Next question**
**Question:** 4. Have you taken any medications on the Medication Deferral List in the time frames indicated? (Review the Medication Deferral List.)

**Donor Eligibility:** A person taking medications listed on the Medication Deferral List anytime in the timeframes indicated is deferred for the appropriate period of time.

---

**Question #4**

Medication Deferral List provided to donor.

- **Have you taken any medications on the Medication Deferral List in the time frames indicated?**
  - **Yes**
    - Refer to Medication Deferral List to determine which of the medication(s) were taken during the time frames indicated. Determine the date of last dose.
    - **Qualify or defer donor per SOP.**
    - **Next question**
  - **No**
    - **Accept donor**
**Question:** 5. Have you read the educational materials today?

**Donor Eligibility:** Donors must read the educational materials prior to donating.

- **Question #5**
- 
  - **Have you read the educational materials today?**
  - **Yes** → Next question
  - **No** → The donor must read the educational materials to proceed if he/she has not done so.
Question: 6. In the past 48 hours, have you taken aspirin or anything that has aspirin in it?

Donor Eligibility: Aspirin irreversibly inactivates platelet function. A person taking aspirin or any medication containing aspirin should not be the sole source of platelets.
**Question:** 7. In the past 8 weeks, have you donated blood, platelets or plasma?

**Donor Eligibility:** A whole blood donor may donate no more frequently than every 8 weeks. Donors of plasma, platelets or leukocytes by apheresis may donate no more frequently than every 2 days.

---

[Flowchart diagram showing the process of determining donor eligibility based on the question and subsequent actions.

1. **In the past 8 weeks, have you donated blood, platelets or plasma?**
   - **No**: Defer donor per SOP ≤ Next question
   - **Yes**: Determine date and type of donation(s). Consult SOP for donor eligibility.

2. **Is donor eligible based on donation date and type?**
   - **Yes**: Accept donor
   - **No**: Defer donor per SOP ≤ Next question]
**Question:** 8. In the past 8 weeks, have you had any vaccinations or other shots?

**Donor Eligibility:** Certain vaccinations may contain live infectious agents. A person who has been exposed to a live infectious agent in a vaccination should not donate for a specified period of time.

**Note on 8alt flowchart:** Some blood centers may choose to use a simpler but stricter deferral scheme in which all donors who received the smallpox vaccination are deferred for a minimum of 56 days, regardless of when the scab fell off. Blood centers using these criteria should use alternative Flowchart 8alt.
Is the scab still on?

Yes

Defer donor for 21 days after vaccination date or until scab spontaneously falls off, whichever is later.

No

Did the scab(s) fall off by itself?

No

Defer donor 56 days after vaccination date.

Yes

Did you have any illness or complications due to the vaccination?

Yes

Defer until 14 days after symptoms resolve.

No

Accept donor

Next question
**Question:** 8alt. In the past 8 weeks, have you had any vaccinations or other shots?

**Donor Eligibility:** Certain vaccinations may contain live infectious agents. A person who has been exposed to a live infectious agent in a vaccination should not donate for a specified period of time.
When were you vaccinated?

Fewer than 56 days ago

Defer donor for 56 days after vaccination date.

56 days ago or more

Did you have any illness or complications due to the vaccination?

Yes

Defer donor for 14 days after symptoms resolve.

No

Accept donor

Next question
**Question:** 9. In the past 8 weeks, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?

**Donor Eligibility:** Certain vaccinations may contain live infectious agents. A person who has had close contact with the vaccination site, bandages covering the vaccination site, or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live infectious agents and should not donate for a specified period of time following the contact. See User Brochure Glossary for specifics.

**Note on 9alt Flowchart:** Some blood centers may choose to use a simpler but stricter deferral scheme in which all donors who have been in contact with a person who received the smallpox vaccination are deferred for 56 days if they developed any subsequent complication, skin rash or sore, regardless of when the rash or sore resolved. Blood centers using these criteria should use alternative Flowchart 9alt.

*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.
**Question:** 9alt. In the past 8 weeks, have you had contact with someone who was vaccinated for smallpox in the past 8 weeks?

**Donor Eligibility:** Certain vaccinations may contain live infectious agents. A person who has had close contact with the vaccination site, bandages covering the vaccination site or materials that might have come into contact with an unbandaged vaccination site, including clothing, may be exposed to the live infectious agent and should not donate for a specified period of time following the contact. See User Brochure Glossary for specifics.

![Flowchart Diagram](image_url)

*Severe complications include the following: rash (resembling blisters) covering a small or large area of the body; necrosis (tissue death) in the area of exposure; encephalitis (inflammation of the brain); infection of the cornea (eye); and localized or systemic skin reaction in someone with eczema or other chronic skin condition.*
**Question:** 10. In the past 16 weeks, have you donated a double unit of red cells using an apheresis machine?

**Donor Eligibility:** A donor should not donate double red cells by apheresis more frequently than every 16 weeks.
**Question:** 11. In the past 12 months, have you had a blood transfusion?

**Donor Eligibility:** A person who has received an allogeneic transfusion of blood, platelets, plasma or other blood component is at increased risk for transmitting infectious diseases, and is deferred for 12 months following the transfusion.
**Question:** 12. In the past 12 months, have you had a transplant such as organ, tissue, or bone marrow?

**Donor Eligibility:** A person who has been exposed to allogeneic tissues through transplant should not donate blood for 12 months following exposure due to increased risk for transmitting infectious diseases.

[Flowchart Diagram]

- **Question #12**
  - **In the past 12 months, have you had a transplant such as organ, tissue, or bone marrow?**
    - **Yes**
      - Determine if the transplant was an allogeneic donation.
        - **Yes**
          - Defer donor per SOP
        - **No**
          - Next question
    - **No**
      - Accept donor
**Question:** 13. In the past 12 months, have you had a graft such as bone or skin?

**Donor Eligibility:** A person who has been exposed to allogeneic tissues through grafting should not donate blood for 12 months following exposure due to increased risk for transmitting infectious diseases.
**Question:** 14. In the past 12 months, have you come into contact with someone else's blood?

**Donor Eligibility:** A person who has had one of the following in the past 12 months: 1) contact with an open wound, non-intact skin or mucous membrane with the blood of a person, or 2) a needle-stick or other sharps injury from an instrument that has been used on a person, is at increased risk for transmitting infectious diseases, and is deferred for 12 months from the date of exposure.
**Question:** 15. In the past 12 months, have you had an accidental needle-stick?

**Donor Eligibility:** A person who has been exposed to someone else's blood through a needle-stick is at increased risk for transmitting infectious diseases, and is deferred for 12 months following the date of exposure.
**Question:** 16. In the past 12 months, have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?

**Donor Eligibility:** A person who has had sexual contact with a person with clinical or laboratory evidence of HIV infection is at increased risk for transmitting HIV and other infectious diseases, and is deferred for 12 months from the date of last sexual contact. HIV may be transmitted through sexual contact with an infected person.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**Question:** 17. In the past 12 months, have you had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?

**Donor Eligibility:** A person who has taken money, drugs, or other payment in exchange for sex is at increased risk for transmitting HIV and other infectious diseases. The sexual contacts of this person are also at increased risk for transmitting HIV and other infectious diseases, and are deferred for 12 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**Question:** 18. In the past 12 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything **not** prescribed by their doctor?

**Donor Eligibility:** A person who has used needles, in the past or present, to take drugs, steroids, or anything **not** prescribed by their doctor is at increased risk for transmitting HIV and other infectious diseases. The sexual contacts of this person are also at increased risk for transmitting HIV and other infectious diseases and are deferred for 12 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.

**Note:** The phrase "used needles" includes intravenous use, "skin popping" (injection under the skin), “mainlining” (arterial injection) and any other use of a needle to administer drugs, steroids or anything else **not** prescribed by their doctor for intravenous use.
Question: 19. Male Donors: In the past 12 months, have you had sexual contact with another male?

Donor Eligibility: A male who has had sexual contact with another male is at increased risk for transmitting HIV and other infectious diseases, and is deferred for 12 months from the date of the last sexual contact with a male. HIV and other diseases may be transmitted through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**Question:** 20. Female donors: In the past 12 months, have you had sexual contact with a male who had sexual contact with another male in the past 12 months?

**Donor Eligibility:** A male who had sexual contact with another male is at increased risk for transmitting HIV and other infectious diseases. The sexual contacts of the male are also at increased risk for transmitting HIV and other infectious diseases, and are deferred for 12 months from the date of the last sexual contact. HIV and other diseases may be transmitted through sexual contact.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**Question:** 21. In the past 12 months, have you had sexual contact with a person who has hepatitis?

**Donor Eligibility:** A person who has had sexual contact with a person who has viral hepatitis may be at increased risk for transmitting infection, and is deferred for 12 months from the date of last contact. Hepatitis, particularly hepatitis B, may be spread through sexual contact.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**Question:** 22. In the past 12 months, have you lived with a person who has hepatitis?

**Donor Eligibility:** In certain cases, a person living with someone who has viral hepatitis is at increased risk for acquiring viral hepatitis as well. A person who is living with a person with viral hepatitis is deferred for 12 months following the date of the last contact. See User Brochure Glossary.
Question: 23. In the past 12 months, have you had a tattoo?

Donor Eligibility: A person who has had a tattoo in the past 12 months is deferred for 12 months from the date of the tattoo application, unless applied by a state regulated entity with sterile needles and non-reused ink. There may be a risk of transmission of infectious diseases when tattoos have been applied using non-sterile needles and/or reused ink.

Note: Tattoos include tattoo "touch ups", tattoos applied by oneself, and those applied by others.
**Question:** 24. In the past 12 months, have you had ear or body piercing?

**Donor Eligibility:** A person who has had ear or body piercing during the past 12 months is at increased risk for transmitting HIV and other infectious diseases, and is deferred for 12 months from the date of procedure, unless ear or body piercing has been done using single-use equipment. There is an increased risk for transmitting HIV and other diseases if the equipment is re-used.
**Question:** 25. In the past 12 months, have you had or been treated for syphilis or gonorrhea?

**Donor Eligibility:** A person who has had syphilis or gonorrhea, treatment for either, or a confirmed reactive screening test for syphilis is at increased risk for transmitting disease, and is deferred for 12 months after the date treatment is completed.
Question: 26. In the past 12 months, have you been in juvenile detention, lockup, jail, or prison for more than 72 consecutive hours?

Donor Eligibility: A person who has been detained or incarcerated in a facility (juvenile detention, lockup, jail, or prison) for more than 72 consecutive hours (3 days) is at increased risk for transmitting HIV and other transmissible diseases, and is deferred for 12 months from the last date of incarceration.

Note: The reason for incarceration (e.g. white-collar crimes, child support) does not change the deferral.

In the past 12 months, have you been in juvenile detention, lockup, jail, or prison for more than 72 consecutive hours?

Yes

Determine if the period of incarceration was 72 consecutive hours

No

Accept donor

No

Yes

Defer donor

Next question
**Question:** 27. In the past 3 years, have you been outside the United States or Canada?

**Donor Eligibility:** Malaria is a transfusion-transmitted disease; eligibility to donate is not mitigated by use of malaria chemoprophylaxis when traveling.

* In general, residents of a malaria-endemic country will be deferred for 3 years after departure from the country of residence if they remain free from unexplained symptoms suggestive of malaria. Prior residents of malaria-endemic countries who live in non-endemic countries for 3 consecutive years without travelling to a malaria-endemic area, will then be deferred for 12 months after subsequent travel to a malaria-endemic area. Prior residents of malaria-endemic countries who have not lived in non-endemic countries for 3 consecutive years, and then travel to a malaria-endemic area will be deferred for 3 years after the recent travel to a malaria-endemic area.

A person who is not a prior resident of malaria-endemic countries and travels to a malaria-endemic area is deferred for 12 months after departure from that area.

* **Note:** Use of the definitions (excerpts are provided below) provided in the August 2014 FDA “Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria” are necessary in order to use the flowchart properly. The guidance can be found by date and title on the FDA website at the following link: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm

**Definitions**

**Malaria-endemic area** - Any areas with malaria where CDC recommends anti-malarial chemoprophylaxis in travelers in the most current version of the *CDC Health Information for International Travel* (commonly known as *The Yellow Book*) at the time the donor is screened.

**Malaria-endemic country** - Any country having an area or areas with malaria where CDC recommends anti-malarial chemoprophylaxis in travelers in *The Yellow Book* at the time the donor is screened. A country that has any malaria-endemic areas should be considered to be malaria-endemic in its entirety.

**Residence in a malaria-endemic country** - Residence is defined as a continuous stay of longer than 5 years in a country or countries having any malaria-endemic area. In determining residence, consideration is by malaria-endemic country and not by malaria-endemic area since the geographic distribution of malaria-endemic areas may change during the period of residence, or the resident may have traveled from a non-endemic area to an endemic area in the country during his or her stay.

**Travel to a malaria-endemic area** - Any travel to or through a malaria-endemic area or areas, as identified by CDC. The duration of travel to a malaria-endemic area is defined as more than 24 hours to less than 5 years. Note that a passage greater than 24 hours through a malaria-endemic area while on route to a malaria-free area is considered a sufficient possible exposure to trigger donor deferral.
Question #27

In the past 3 years, have you been outside the United States or Canada?

Yes

Determine if donor was in any malaria-endemic country(ies)

Malaria-endemic country(ies)

Determine length of stay in malaria-endemic country(ies)

≤5yrs

Determine if donor was in any malaria-endemic area(s)

Only non-endemic area(s)

Malaria-endemic area(s)

Determine donor's length of stay in malaria-endemic area(s)

≤24 hours

Accept donor

>24 hours

Continue this question on next page

No

Only non-endemic country(ies)

Determining donor's length of stay in malaria-endemic area(s)

>24 hours

Continue this question on next page

Next question
Was donor EVER a resident (lived for >5 years, continuously) in malaria-endemic country(ies) prior to this recent travel?

Yes

Subsequent to this residency did donor ever have a 3 year period in which they remained in non-endemic country(ies) without travel to malaria-endemic area(s)?

Yes

Defer for 3 years from most recent date of departure from malaria-endemic area

No

Defer for 12 months from most recent date of departure from malaria-endemic area

No

Has donor traveled (>24 hours) in malaria-endemic area(s) after leaving malaria-endemic country(ies) of residence?

Yes

Defer for 3 years from date of departure from malaria-endemic country of residence

No

Next question
**Question:** 28. From 1980 through 1996, did you spend time that adds up to 3 months or more in the United Kingdom? (Review list of countries in the UK.*)

**Donor Eligibility:** A person who has spent time that adds up to 3 months or more in the United Kingdom from 1980 through 1996 is indefinitely deferred. Donors may be at risk of developing vCJD from eating beef from the United Kingdom are indefinitely deferred. There may be a risk of transmitting vCJD through blood transfusion.

*See the January 2016 FDA guidance “Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry.”

The guidance can also be found by date and title on the FDA website at the following link: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm
Question: 29. From 1980 through 1996, were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?

Donor Eligibility: Members of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military are indefinitely deferred if they spent a total of 6 months or more associated with a military base in any of the following countries: From 1980 through 1990 in Belgium, the Netherlands, or Germany; From 1980 through 1996 in Spain, Portugal, Turkey, Italy or Greece. These donors may be at risk of developing vCJD from eating beef from the UK and are indefinitely deferred. There may be a risk of transmitting vCJD through blood transfusion.
**Question:** 30. From 1980 to the present, did you spend time that adds up to 5 years or more in Europe? (Review list of countries in Europe.*)

**Donor Eligibility:** A person who spent time that adds up to 5 years or more in Europe from 1980 to the present may be at risk of developing vCJD from eating beef in Europe and is indefinitely deferred. There may be a risk of transmitting vCJD through blood transfusion.

*See the January 2016 FDA guidance “Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry.” The guidance can also be found by date and title on the FDA website at the following link: [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm)
**Question:** 31. From 1980 to the present, did you receive a blood transfusion in the United Kingdom or France? (Review country lists.*)

**Donor Eligibility:** A person who received a transfusion of blood, platelets, plasma, cryoprecipitate, or granulocytes in the UK or France from 1980 to the present may be at risk of developing vCJD through transfusion, and is indefinitely deferred. There may be a risk of transmitting vCJD through blood transfusion.

*See the January 2016 FDA guidance “Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry.” The guidance can also be found by date and title on the FDA website at the following link: [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm)*
**Question:** 32. Female donors: Have you ever been pregnant or are you pregnant now?

**Donor Eligibility:** A female who is pregnant now or was pregnant in the past 6 weeks is deferred for the safety of the donor. Previous pregnancies are associated with developing antibodies that can cause TRALI, a serious transfusion complication. Blood centers have SOPs for donor qualification and testing to reduce this risk of TRALI.
Question: 33. Have you ever had a positive test for the HIV/AIDS virus?

Donor Eligibility: A person with clinical or laboratory evidence of HIV/AIDS is at increased risk for transmitting HIV and other infectious diseases, and is indefinitely deferred.

Flowchart:

- **Question #33**
  - **Have you ever had a positive test for the HIV/AIDS virus?**
    - **Yes**
      - **Defer donor indefinitely**
    - **No**
      - **Accept donor**

- **Next question**
**Question:** 34. Have you ever used needles to take drugs, steroids, or anything *not* prescribed by your doctor?

**Donor Eligibility:** A person who has used needles, in the past or present, to take drugs, steroids, or anything *not* prescribed by their doctor is at increased risk for transmitting HIV and other infectious diseases, and is indefinitely deferred.

**Note:** The phrase "used needles" includes intravenous use, "skin popping" (injection under the skin), "mainlining" (arterial injection) and any other use of a needle to administer drugs, steroids or anything else *not* prescribed by their doctor for intravenous use.
**Question:** 35. Have you ever received money, drugs, or other payment for sex?

**Donor Eligibility:** A person who has received money, drugs, or other payment for sex is at increased risk for HIV and other infectious diseases, and is indefinitely deferred.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**Question:** 36. Have you ever had malaria?

**Donor Eligibility:** A person who has had malaria and received an appropriate treatment is deferred for three years after becoming asymptomatic while residing in a non-endemic country. Malaria can be transmitted through blood transfusion.
**Question:**  37. Have you ever had Chagas disease?

**Donor Eligibility:**  A person who has had Chagas disease is indefinitely deferred. Chagas disease can be transmitted by blood.
Question: 38. Have you ever had babesiosis?

Donor Eligibility:  A person who has had babesiosis is indefinitely deferred. Babesiosis can be transmitted by blood.
**Question:** 39. Have you ever received a dura mater (or brain covering) graft or xenotransplantation product?

**Donor Eligibility:** A person who has received an allogeneic dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease, and is permanently deferred. Autologous dura mater grafts are acceptable.

A person who has received a xenotransplantation product is indefinitely deferred. Xenotransplantation is defined to include any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source or (b) 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.

*Xenotransplantation definitions are provided in the January 19, 2001 document “PHS Guideline on Infectious Disease Issues in Xenotransplantation”. The guidance is available at www.fda.gov.*

**Note:** Nonliving biological products or material from nonhuman animals, such as porcine heart valves and porcine insulin, are not classified as xenotransplantation products for the purposes of this definition.
**Question:** 40. Have you ever had any type of cancer, including leukemia?

**Donor Eligibility:** A person with a history of cancer must be evaluated to determine their eligibility to donate.

- **Have you ever had any type of cancer, including leukemia?**
  - **Yes**
  - **No**

  **Consult SOP and assess donor**

  - **Is history of cancer reason for deferral?**
    - **No**
    - **Yes**

  **Defer donor per SOP**

  **Accept donor**

  **Next question**

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Question: 41. Have you ever had any problems with your heart or lungs?

Donor Eligibility: A person must be free of acute respiratory disease. A person with a history of diseases of the heart and lungs, including acute lung diseases or colds, must be evaluated.
**Question:** 42. Have you ever had a bleeding condition or a blood disease?

**Donor Eligibility:** A person with hemophilia or related clotting disorder that requires treatment should be deferred to prevent harm by the large bore needles used during the donation process.  
**Note:** See the December 2015 FDA guidance, “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.” The guidance can also be found by date and title on the FDA website at the following link: [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm)
**Question:** 43. Have any of your relatives had Creutzfeldt-Jakob disease?

**Donor Eligibility:** A person with a blood relative with Creutzfeldt-Jakob disease is indefinitely deferred due to the risk of transmission.

**Note:** If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, the donor is eligible. Gene sequencing of the donor is not necessary to demonstrate that the donor is not at risk for familial CJD. Sequencing of the family member with CJD or the appropriate parent of the donor, if the CJD-affected family member was a second-degree relative, may be sufficient to demonstrate that the donor does not have a mutation associated with familial CJD, as stated in the January 2016 guidance* found on the FDA website under Blood guidances.

*See the January 2016 FDA guidance “Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry.” The guidance can also be found by date and title on the FDA website at the following link: [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/default.htm)