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

Determine the reason the person is not feeling well and healthy today. Consult SOP for deferral criteria.

Is reason cause for deferral?

No

Accept donor

Yes

Defer donor per SOP

Next question
**Question:** 2. Have you read the educational materials today?

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

- Yes: Next question
- No: The donor must read the educational materials to proceed if he/she has not done so.
**Question:** 3. 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.

- **Yes**
  - Determine donation type. Consult SOP.
  - **Yes**
    - Qualify or defer donor per SOP
    - Next question
  - **No**
    - Accept donor

- **No**
  - Accept donor
**Question:** 4. 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.

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**Flowchart:**

1. **Question #4**
   - In the past **8 weeks**, have you donated blood, platelets or plasma?
     - If **No**, go to **Defer donor per SOP**
     - If **Yes**, go to **Determine date and type of donation(s). Consult SOP for donor eligibility.**
       - If **Yes**, go to **Accept donor**
       - If **No**, go to **Defer donor per SOP**

---

Next question
**Question:** 5. 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 5alt 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 5alt.
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:** 5alt. 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.

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**Flowchart Description:**

1. **Question #5alt.**
2. **In the past 8 weeks, have you had any vaccinations or other shots?**
   - **No** → **Accept donor**
   - **Yes** → **Was the vaccination for smallpox?**
     - **No** → **Determine details of shots and vaccinations. Qualify or defer donor per SOP.**
     - **Yes** → **Continue this question on next page**

3. **Next question**
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:** 6. 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 6alt 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 6alt.

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*a* 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.

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*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: 6alt. 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.

*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:** 7. 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: 8. Female donors: Since your last donation, have you 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: 9. Since your last donation, have you had any new medical problems or diagnoses?
Donor Eligibility: Certain medical conditions may be the cause for the donor to be ineligible to donate.

![Flowchart Diagram]

- Question #9
- Since your last donation, have you had any new medical problems or diagnoses?
  - Yes: Ask donor for details regarding new issues. Qualify or defer donor per SOP.
  - No: Accept donor

Next question
**Question:** 10. Since your *last donation*, have you had any new medical treatments?

**Donor Eligibility:** Certain medical treatments might indicate an underlying medical condition that would be cause for the donor to be deferred for an appropriate period of time.

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**Flowchart Description:**

1. **Question #10**
2. **Since your last donation, have you had any new medical treatments?**
   - **Yes**: Ask donor for details regarding new medical treatments. Qualify or defer donor per SOP. 
   - **No**: Accept donor.
3. **Next question**
**Question:** 11. Since your last donation, have you taken any medications on the Medication Deferral List in the time frames indicated?

**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: 12. Since your last donation, have you been outside the United States or Canada?

Donor Eligibility: The donor must be evaluated against each of the criteria listed in this flowchart, even if a “yes” answer is provided to one of the earlier conditions.

Malaria may be transmitted through blood transfusion.
A person who has traveled to an area where malaria is considered endemic will be deferred for 12 months after departure from that area regardless of whether the person took anti-malaria prophylaxis.

*Use of the definitions are necessary in order to use the flowchart properly.*

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.

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.

There may be a risk of transmitting vCJD through blood transfusion.
A person may be at risk of developing vCJD from eating beef in Europe. A person who has spent time that adds up to 5 years or more in Europe from 1980 to the present is indefinitely deferred. (Time spent in the United Kingdom from 1980 through 1996 is also counted as cumulative time spent in Europe).

**The flowchart instructs the donor to “Review list of countries in Europe.”**
This list is based on 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

The flowchart for Question 12 begins on the next page.
Question #12

Since your last donation, have you been outside the United States or Canada?

Yes

List name of country(ies), including area within the country, and dates of travel.

Determine if donor traveled to any malaria endemic area(s) based on current guidance.*

No

Yes, travel to malaria-endemic area(s)

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

No, travel only to non-endemic area(s)

Determine if donor traveled to a European country. Review list of countries in Europe based on current guidance.**

Determine cumulative time since 1980 spent in European country(ies). Include time spent in the United Kingdom from 1980 through 1996.

Does cumulative time since 1980 add up to 5 years or more?

Yes

Defer donor indefinitely

No

Accept donor if not deferred based on any of the criteria listed above

Accept donor

Next question
**Question:** 13. Since your last donation, 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 of 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:** 14. Since your last donation, 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:** 15. Since your last donation, 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:** 16. Since your last donation, 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:** 17. Since your **last donation**, 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:** 18. Female donors: Since your last donation, 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: Since your last donation, 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 Donor Educational Material provided.
**Question:** 20. Since your last donation, 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: 21. Since your last donation, have you 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:** 22. Male Donors: Since your last donation, 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.

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**Flowchart:**

1. **Question #22**
2. Male Donors: Since your last donation, have you had sexual contact with another male?
3. If **No**, accept donor.
4. If **Yes**, defer donor.
5. Next question.
**Question**: 23. Since your last donation, 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. Since your last donation, 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. Since your last donation, 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.
Question: 26. Since your last donation, have you 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:** 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.

![Flowchart]

*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