**Question:** 1. Are you currently taking an antibiotic?

**Donor Eligibility:** A donor with an infection that could cause bacteremia/sepsis or other relevant communicable disease should not donate. The reason for antibiotic use must be evaluated to determine if the donor has a bacterial infection that could be transmissible by HPC, Cord Blood.

- **Are you currently taking an antibiotic?**
  - **Yes:** Consult SOP, Assess reason for antibiotics
  - **No:** Accept donor

- **Is diagnosis cause for ineligible status?**
  - **No:** Accept donor
  - **Yes:** Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
**Question**: 2. Are you currently taking any other medication for an infection?

**Donor Eligibility**: A donor with an infection that could cause bacteremia/sepsis or other relevant communicable disease should not donate. The reason for antibiotic use must be evaluated to determine if the donor has a bacterial infection that could be transmissible by HPC, Cord Blood.

```
Question #2

Are you currently taking any other medication for an infection?

No

Accept donor

Yes

Consult SOP
Assess reason for antibiotics

Is diagnosis cause for ineligible status?

No

Yes

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

Next question
```
Question: 3. Are you now taking or have you ever taken any medications on the Medication List?

Donor Eligibility: Donors taking certain designated medications, currently or in the past are ineligible to donate HPC, Cord Blood.

Question #3

Medication List was provided to donor

Are you now taking or have you ever taken any medications on the Medication List? No

Accept donor

Accept donor

Yes

Determine the medication(s)

Growth hormone from human pituitary glands

Yes, if donor has EVER taken this medication

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

Insulin from cows (bovine, or beef insulin)

Yes, if donor has taken this medication since 1980

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

Hepatitis B immune globulin

Yes, within the last 12 months for exposure to hepatitis B

Donor is ineligible but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

Unlicensed vaccine

Yes, but over a year ago, or never taken

Unlicensed vaccine

Yes

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

No

Next question
**Question:** 4. Have you read the educational materials?

**Donor Eligibility:** Donors must read the educational materials prior to donating and have an opportunity to have their questions answered.
**Question:** 5. In the past 12 weeks, have you had any vaccinations or other shots?

**Donor Eligibility:** Certain vaccinations may contain live infectious agents. A donor who has been exposed to a live infectious agent via vaccination is ineligible for a specified period of time.
Is the scab still on?

Yes

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

No

Did the scab fall off by itself?

No

Yes

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

Yes

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

Yes

Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

No

Accept donor

Next question
**Question:** 6. In the past 12 weeks, have you had contact with someone who had a smallpox vaccination?

**Donor Eligibility:** Certain vaccinations may contain live infectious agents. A donor 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 is ineligible for a specified period of time. See 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 12 months have you been told by a healthcare professional that you have West Nile Virus infection or any positive test for West Nile Virus?

**Donor Eligibility**: FDA recommends waiting to collect HPC, Cord Blood from the donor until the condition is considered to be resolved and at least 120 days from the positive test, or onset of symptoms or diagnosis, whichever is the later date.

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**Question #7**

In the past 12 months have you been told by a healthcare professional that you have West Nile Virus infection or any positive test for West Nile Virus?

- **Yes**
  - Determine the dates of positive or reactive test result, diagnosis and recovery in relation to the collection date

- **No**
  - Accept donor

---

If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
**Question:** 8. In the past 12 months have you had a blood transfusion?

**Donor Eligibility:** A donor who has received an allogeneic transfusion of blood, platelets, plasma or other blood component should be carefully evaluated for eligibility to donate HPC, Cord Blood following the transfusion due to possible transmissibility of infectious disease.

---

**Question #8**

- **In the past 12 months have you had a blood transfusion?**
  - **No** → **Accept donor**
  - **Yes** → **Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.**
**Question**: 9. In the past 12 months have you come into contact with someone else's blood?

**Donor Eligibility**: Persons who have had one of the following during the preceding 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, are ineligible for 12 months from the date of exposure. Infectious disease may be spread through contact with blood.
**Question:** 10. In the past 12 months have you had an accidental needle-stick?

**Donor Eligibility:** A donor who has been exposed to someone else's blood through a needle-stick is ineligible to donate HPC, Cord Blood for 12 months following exposure, due to possible transmissibility of infectious disease.
**Question:** 11. In the past 12 months have you had a transplant or graft from someone other than yourself, such as organ, bone marrow, stem cell, cornea, sclera, bone, skin, or other tissue?

**Donor Eligibility:** A donor who has received an allogeneic tissue transplant or graft (see above) should be carefully evaluated for eligibility to donate HPC, Cord Blood following the transplant, due to possible transmissibility of infectious disease.

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**Flowchart:**

- **Question #11**
  - In the past 12 months have you had a transplant or graft from someone other than yourself, such as organ, bone marrow, stem cell, cornea, sclera, bone, skin, or other tissue?
    - **Yes**
      - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
    - **No**
      - Accept donor

- **Next question**
**Question:** 12. 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:** Persons who have had sexual contact with persons with clinical or laboratory evidence of HIV infection are ineligible for 12 months from the date of last 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 educational materials provided.
**Question:** 13. 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:** Persons who have had sexual contact with anyone who has taken money or drugs or other payment for sex in the preceding 5 years are ineligible 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 educational materials provided.
**Question:** 14. 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:** Persons who have had sexual contact with persons who have used needles to take drugs, steroids, or anything **not** prescribed by their doctor in the preceding 5 years are ineligible 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 educational materials provided.

**Note:** The phrase "use of a needle" 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.
**Question:** 15. In the past 12 months have you had sexual contact with a male who has ever had sexual contact with another male?

**Donor Eligibility:** Women who have had sexual contact with men who have had sexual contact with another man even one time in the preceding 5 years are ineligible for 12 months from the date of 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 educational materials provided.
Question: 16. In the past 12 months have you had sexual contact with a person who has hepatitis?

Donor Eligibility: Persons who report having had sexual contact with a person who has viral hepatitis are ineligible for 12 months from the time of last exposure. Hepatitis, particularly hepatitis B, may be spread through sexual contact. Hepatitis C, although potentially a concern, is not frequently spread by sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.
**Question:** 17. In the past 12 months have you lived with a person who has hepatitis?

**Donor Eligibility:** In certain cases, living with a person with viral hepatitis puts the donor at risk for acquiring viral hepatitis as well (definition of living with is residing in the same dwelling, EXAMPLES: house, dormitory, apartment).

- **Yes**
  - Determine type of hepatitis
    - **Non-viral**
    - **Viral**
      - Determine type of viral hepatitis
        - Asymptomatic hepatitis C
        - Hepatitis A or B, symptomatic hepatitis C, or unknown
          - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

- **No**
  - Accept donor
  - Next question
**Question:** 18. In the past 12 months have you had a tattoo?

**Donor Eligibility:** Persons who have had a tattoo in the previous 12 months are ineligible for 12 months from the date of the tattoo application, unless applied by a state regulated entity with sterile needles and non re-used ink. Unless tattoos have been applied using sterile needles and non re-used ink, there may be a risk of transmission of infectious disease.

**Note:** Tattoos include tattoo "touch ups", tattoos applied by oneself, and those applied by others.
**Question:** 19. In the past 12 months have you had ear or body piercing?

**Donor Eligibility:** Persons who have had ear or body piercing during the previous 12 months are usually ineligible for 12 months from the date of the procedure. Unless ear or body piercing has been done using single-use equipment, there may be a risk of transmission of infectious disease.

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**Diagram:**

1. Question #19
2. In the past 12 months have you had ear or body piercing?
   - Yes:
     - Determine if piercing was performed using sterilized equipment
       - Yes: Accept donor
       - No: Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
   - No: Accept donor

3. Next question
**Question:** 20. In the past 12 months have you had or been treated for syphilis or other sexually transmitted infections?

**Donor Eligibility:** Sexually transmitted disease histories require careful evaluation by the cord blood bank medical director because of the possibility of transmission of disease to the baby through the cord blood.

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**Question #20**

In the past 12 months have you had or been treated for syphilis or other sexually transmitted infections?

- **No**
  - Accept donor

- **Yes**
  - HPV or genital herpes?
    - **Yes**
      - Is this infection active?
        - **Yes**
          - Donor is ineligible unless baby was delivered by C-section and membranes remained intact. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
        - **No**
          - Accept donor if no evidence of infection.
    - **No**
      - Syphilis?
        - **Yes**
          - Is this infection active?
            - **Yes**
              - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
            - **No**
              - Accept donor if no evidence of infection.
        - **No**
          - Other sexually transmitted infections?
            - **Yes**
              - Is this infection active?
                - **Yes**
                  - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
                - **No**
                  - Accept donor if no evidence of infection.
            - **No**
              - Next question
**Question:** 21. In the past 12 months have you been in juvenile detention, lockup, jail, or prison for more than 72 hours?

**Donor Eligibility:** Persons who have been detained or incarcerated in a facility (juvenile detention, juvenile correctional facility, lockup, jail, or prison) for more than 72 consecutive hours (3 days) are ineligible for 12 months from the last date of incarceration. These persons are at higher risk for exposure to infectious disease.

**Note:** The reason for incarceration (e.g. white-collar crimes, child support) does not change the ineligibility.
**Question:** 22. In the past 3 years have you been outside the United States or Canada?

**Donor Eligibility:** Donors should be carefully evaluated before being selected to donate HCT/Ps as malaria may be transmitted through transfusion or transplant. 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.

Donors who are not prior residents of malaria-endemic countries and travel to a malaria-endemic area will be deferred for 12 months after departure from that area.


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

- No
- 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)?

- No
- Yes

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

- No
- Yes

Donor has risk of malaria for 3 years from date of departure from malaria-endemic country of residence. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

Donor has risk of malaria for 12 months from most recent date of departure from malaria-endemic area. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

- Next question
**Question:** 23. In the past 5 years have you received money, drugs, or other payment for sex?

**Donor Eligibility:** Donors who received money, drugs, or other payment for sex may be at risk for HIV and other diseases transmitted by sexual contact.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

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**Flow Chart:**

**Question #23**

- **In the past 5 years have you received money, drugs, or other payment for sex?**
  - **Yes**
    - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
  - **No**
    - Accept donor

**Next question**
**Question**: 24. In the past 5 years, have you used needles to take drugs, steroids, or anything not prescribed by your doctor?

**Donor Eligibility**: Donors who are past or present needle-using drug users are at risk due to potential transmission of infectious disease.

**Note**: The phrase “use of a needle” 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.
**Question:** 25. From 1980 through 1996 did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK. *)

**Donor Eligibility:** Donors who have spent time that adds up to 3 months or more in the United Kingdom from 1980 through 1996 may be at risk of developing vCJD from eating beef from the UK. There may be a risk of transmitting vCJD through HPC, Cord Blood.

* See UK Countries Appendix in the User Brochure.
**Question:** 26. 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 or civilian military employee?

**Donor Eligibility:** Members of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military or civilian military employee who spent a total of 6 months or more associated with a military base in any of the following countries may be at risk of developing vCJD from eating beef from the UK: from 1980 through 1990 in Belgium, the Netherlands, or Germany; from 1980 through 1996 in Spain, Portugal, Turkey, Italy or Greece. There may be a risk of transmitting vCJD through HPC, Cord Blood.
**Question:** 27. From 1980 to the present did you spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.*)

**Donor Eligibility:** Donors who have 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. There may be a risk of transmitting vCJD through HPC, Cord Blood.

**Note:** When calculating time spent in Europe include time spent in the United Kingdom from 1980 – 1996 only.

* See Appendix – vCJD countries of risk – Europe in the User Instructions.
**Question:** 28. From 1980 to the present did you receive a transfusion of blood or blood components in the United Kingdom or France? (Review list of countries in the UK.)*

**Donor Eligibility:** Donors who received a transfusion of blood or blood components (platelets, plasma, cryoprecipitate, granulocytes or other components) in the UK or France from 1980 to the present may be at risk of developing vCJD through transfusion. There may be a risk of transmitting vCJD through HPC, Cord Blood.

* See Appendix – vCJD countries of risk – United Kingdom in the User Instructions.
**Question**: 29. Have you ever had any positive test for the HIV/AIDS virus?

**Donor Eligibility**: Donors with clinical or laboratory evidence, including prior reactive screening tests, of HIV/AIDS are ineligible. Donors with clinical or laboratory evidence of HIV/AIDS are ineligible due to potential transmission of infectious disease.

*Question #29*

- **Have you ever had any positive test for the HIV/AIDS virus?**
  - **No** → **Accept donor**
  - **Yes** → **Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.** → **Next question**
Question: 30. Have you ever had hepatitis, or any positive test for hepatitis?

Donor Eligibility: Donors who have a prior reactive screening test for hepatitis or a history of viral hepatitis after their 11th birthday are ineligible, unless evidence from the time of illness documents that the hepatitis was identified as being caused by Hepatitis A virus, Epstein-Barr Virus (EBV) or cytomegalovirus (CMV).

* Donors are ineligible “unless evidence from the time of illness documents that the hepatitis was identified as being caused by Hepatitis A virus, Epstein-Barr Virus (EBV) or cytomegalovirus (CMV).” (“Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” Guidance for Industry, August 2007).
**Question:** 31. Have you ever had malaria?

**Donor Eligibility:** Prospective donors who have had malaria and received an appropriate treatment are ineligible for three years after becoming asymptomatic while residing in a non-endemic country. Malaria can be transmitted by HCT/Ps.
**Question:** 32. Have you ever had Chagas disease and/or any positive test for *T. cruzi*?

**Donor Eligibility:** Donors who have tested positive or reactive for *Trypanosoma cruzi* antibodies using an FDA-licensed or investigational *T. cruzi* donor screening test, or have had a medical diagnosis of *T. cruzi*, are ineligible due to the potential risk of transmitting Chagas disease through HPC, Cord Blood.

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**Flowchart:**

- **Question #32**
  - **Have you ever had Chagas disease and/or any positive test for *T. cruzi***?
    - **No**
      - **Accept donor**
    - **Yes**
      - **Donor has risk of Chagas disease, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.**

**Next question**
**Question:** 33. Have you ever had babesiosis?

**Donor Eligibility:** Donors who have had babesiosis are ineligible due to the potential risk of transmitting Babesiosis through HPC, Cord Blood.

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**Have you ever had babesiosis?**

- **Yes**
  - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.

- **No**
  - Accept donor

**Next question**
**Question:** 34. Have you ever received a dura mater (or brain covering) graft?

**Donor Eligibility:** Donors who have received a human dura mater transplant or graft may be at risk for Creutzfeldt-Jakob disease and are ineligible. Any non-human source should be further evaluated to determine if it is a cleared or approved medical device.
**Question:** 35. Have you ever had sexual contact with anyone who was born in or lived in Africa?

**Donor Eligibility:** If the donor had a sex partner who was born in or lived in certain countries in Africa (see appendix for HIV Group O countries of risk-Africa) after 1977, the donor will be ineligible. Donors who have had sexual contact may have been exposed to rare strains of HIV that are not consistently detected by all current test methods.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

* Facilities using an HIV test that has been approved by FDA to include a donor screening claim for detection of Group O viruses may eliminate this question during screening.

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Flowchart:

1. **Question #35**
   - Have you ever had sexual contact with anyone who was born in or lived in Africa?
     - No → **Accept donor**
     - Yes
       - Did this sex partner leave Africa before or after 1977?
         - Left before 1977
           - No
             - Was this sex partner born in or did he or she live in any of the African countries listed on the appendix?
               - No
                 - Donor is ineligible, but may be collected in certain situations. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
               - Yes
                 - Next question
         - Left after 1977
           - Yes → Next question
**Question:** 36. Have you ever been in Africa?

**Donor Eligibility:** Donors who were born in, lived in or have traveled to certain countries in Africa since 1977 (see appendix for HIV Group O countries at risk-Africa) are ineligible. Donors who have received a blood transfusion or any other medical treatment involving the use of blood in certain countries in Africa are ineligible. Donors may have been exposed to rare strains of HIV that are not consistently detected by all current test methods.

* Facilities using an HIV test that has been approved by FDA to include a donor screening claim for detection of Group O viruses may eliminate this question during screening.
**Question: 37.** Have you ever been diagnosed with any neurological disease?

**Donor Eligibility:** Any donor who has been diagnosed with vCJD or any other form of CJD, dementia, any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology, may not be eligible to donate HPC, Cord Blood. If the cord blood is collected, refer to facility SOP for circumstances for use and documentation of urgent medical need.
**Question:** 38. Have you ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?

**Donor Eligibility:** Donor is considered ineligible if exposed to live xenotransplant sources.

**Note:** "Xenotransplantation refers to procedures in which live cells, tissues, or organs from an animal are transplanted, implanted, or infused into a human patient. It also includes procedures in which human body fluids, cells, tissues or organs are removed from the human body, come into contact with live animal cells, tissues, or organs, and then are placed back into a human patient." (1) Examples include transplanted organs such as hearts, livers, or kidneys; in burn patients - the use of certain skin grafts that have been grown on mouse "feeder" cells; or, supportive care of liver transplant candidates by running their blood through a column of pig liver cells. The rationale for excluding xenotransplant recipients as donors is based on concerns that viruses or microorganisms carried by animals may be spread to humans, who may, in turn, infect other people through sexual, household contact, or other activity.

**Question:** 39. Have you ever tested positive for HTLV, had adult T-cell leukemia or had unexplained paraparesis (partial paralysis affecting the lower limbs)?

**Donor Eligibility:** Donors with clinical or laboratory evidence, including reactive screening tests, of HTLV are ineligible due to potential transmission of infectious disease transmission of infectious disease. HTLV refers to Human T-cell Lymphotropic Virus.
**Question:** 40. Has your sexual partner or a member of your household ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?

**Donor Eligibility:** Donors who have had sexual contact with or have lived with a person who has ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal is considered ineligible.

**Note:** "Xenotransplantation refers to procedures in which live cells, tissues, or organs from an animal are transplanted, implanted, or infused into a human patient. It also includes procedures in which human body fluids, cells, tissues or organs are removed from the human body, come into contact with live animal cells, tissues, or organs, and then are placed back into a human patient." (1) Examples include transplanted organs such as hearts, livers, or kidneys; in burn patients - the use of certain skin grafts that have been grown on mouse "feeder" cells; or, supportive care of liver transplant candidates by running their blood through a column of pig liver cells. The rationale for excluding xenotransplant recipients as donors is based on concerns that viruses or microorganisms carried by animals may be spread to humans, who may, in turn, infect other people through sexual, household contact, or other activity.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the educational materials provided.

**Question:** 41. Have any of your relatives, the baby’s father or any of the baby’s other relatives had Creutzfeldt-Jakob disease?

**Donor Eligibility:** Donors with a blood relative with Creutzfeldt-Jakob disease are ineligible. Evaluations should include the baby’s father or any of the baby’s other blood relatives. A donor response such as “do not know” that indicates a lack of familiarity with the CJD disease can be considered a negative response.
**Zika Additional Question:** 1. At any time during the pregnancy have you had a medical diagnosis of a Zika virus infection?

**Donor Eligibility:** Donors with a medical diagnosis of Zika virus infection at any time during the pregnancy are ineligible due to the potential risk of transmitting Zika virus through HCT/Ps. The Zika virus, which is spread by mosquitos, has recently emerged in the Americas. While most Zika virus infections are asymptomatic, or self-limited, infections have been associated with serious birth defects (i.e. microcephaly) and a neurological condition, Guillain-Barré syndrome. Therefore, donors who have a history of infection with Zika virus, are ineligible for donation of cord blood from that pregnancy or up to 6 months after symptom resolution, whichever is the longer.

The symptoms of Zika virus infection are: fever, rash, joint pain, muscle pain, conjunctivitis (red eyes), headache.


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The additional flow chart illustrates the decision process:

1. **Zika Additional Question #1**
   - At any time during the pregnancy have you had a medical diagnosis of a Zika virus infection?
2. **If No:** Accept donor
3. **If Yes:**
   - Donor is ineligible, but may be collected in certain situations. Refer to facility SOP for circumstances for use and documentation of urgent medical need or 21 CFR 1271.65(b) or 21 CFR 1271.90

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DHQ-HPC, Cord Blood Flow Chart v1.6 eff. August 2018
**Zika Additional Question:** 2. At any time during the pregnancy have you lived in or traveled to an area with an increased risk for Zika virus transmission? (Have donor review current list of locations on CDC webpage [https://www.cdc.gov/zika/areasatrisk.html](https://www.cdc.gov/zika/areasatrisk.html).)

**Donor Eligibility:** The Zika virus, which is spread by mosquitoes, has recently emerged in the Americas. While most Zika virus infections are asymptomatic, or self-limited, infections have been associated with serious birth defects (i.e. microcephaly) and a neurological condition, Guillain-Barré syndrome. Therefore, donors are ineligible for cord blood donation who have been to areas with an increased risk for Zika virus transmission at any time during the pregnancy.

**NOTE:** An “area with an increased risk for transmission” of Zika virus is an area included on the CDC website listing of areas with local vector-borne (i.e., mosquito-acquired) transmission of Zika virus or where the potential is suspected based on epidemiological evidence. For the current listing, refer to: [https://www.cdc.gov/zika/areasatrisk.html](https://www.cdc.gov/zika/areasatrisk.html).

**Zika Additional Question:** 3. At any time during the pregnancy have you had sexual contact with a person who, in the 6 months prior to sexual contact, has had a Zika virus infection or lived in or traveled to an area with an increased risk for Zika virus transmission?

**Donor Eligibility:** The Zika virus can be transmitted from person to person by sexual contact, and the Zika virus may remain in semen for several weeks. A case of female-to-male sexual transmission of ZIKV has also been reported, and ZIKV has been detected in genital and endocervical swabs from infected females. Donors who provide a history of having had sexual contact with a person who, in the 6 months prior to the sexual contact, has had Zika virus infection OR lived in or traveled to an area with an increased risk for Zika virus transmission are ineligible for donation of cord blood resulting from that pregnancy. (Have donor review list of locations on CDC webpage [https://www.cdc.gov/zika/areasatrisk.html](https://www.cdc.gov/zika/areasatrisk.html).)

The symptoms of Zika virus infection are: fever, rash, joint pain, muscle pain, conjunctivitis (red eyes), headache.
