**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 HCT/Ps.  **Question:** 2. Are you currently taking any other medication for an infection?

Next question

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

Is diagnosis cause for

ineligible status?

Are you currently taking an antibiotic?

No

No

Yes

Yes

Accept donor

Question #1

Consult SOP

Assess reason for antibiotics

**Donor Eligibility:** A donor with an infection that could cause bacteremia/sepsis or other relevant communicable disease should not donate. The reason for medication use must be evaluated to determine if the donor has an infection that could be transmissible by HCT/Ps.  **Question:** 3. Are you now taking or have you ever taken any medications on the Medication List?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

Are you currently

taking any other

medication for an

infection?

No

No

Yes

Yes

Consult SOP

Assess reason for medication

Accept donor

Question #2

Is diagnosis cause for

ineligible status?

**Donor Eligibility:** Donors taking certain designated medications, currently or in the past are

ineligible to donate HCT/Ps.

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

Yes

Determine the

medication(s)

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

Yes, if donor has

EVER taken this medication

Growth hormone from human pituitary glands

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

Next question

Insulin

from cows (bovine, or beef insulin)

Hepatitis B

immune globulin

Yes, within the last 12 months for exposure

to hepatitis B

Yes, if donor has taken this medication

since 1980

Yes

Unlicensed vaccine

Yes, but over a year ago, or

never taken

Accept donor

No

No

No

**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 8 weeks, have you had any vaccinations or other shots?

Next question

Have donor read educational materials

Have you read the educational materials?

Accept donor

Yes

No

Question #4

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

Next question

Was the vaccination

for smallpox?

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

Determine details of shots and vaccinations

Determine eligibility per SOP

No

More than 21 days

See next page for further questioning

Fewer than 21 days

Yes

Yes

Accept donor

No

When were you vaccinated?

In the past 8

weeks, have you had any vaccinations or

other shots?

Question #5

Next question

Accept donor

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

Donor is ineligible for 14 days after symptoms resolve. Refer to facility SOP for determination and documentation of urgent medical need.

Donor is ineligible for 2 months after vaccination date. Refer to facility SOP for determination and documentation of urgent medical need.

Did the scab fall

off by itself?

No

Yes

Yes

No

No

Yes

Did you have any

illness or complications due

to the vaccination?

Is the scab still on?

**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.

**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 is ineligible for 14 days after symptoms resolve.

Refer to facility SOP for determination and documentation of urgent medical need, as appropriate.

14 days or more

Next question

Have you had any

new skin rash, skin sore, or severe complication\* since the time of contact?

Donor is ineligible for 3 mos. from date of the contact’s vaccination or, if date is not known, 2 mos. from current date. Refer to facility SOP

for determination and documentation of urgent medical need, as appropriate.

Accept donor

Has it been 14

days since the symptoms

went away?

Less than 14 days

\*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.

Accept donor

In the past 12 weeks, have

you had contact with someone who had a smallpox vaccination?

Complication

Was it a rash or complication?

Did your

scab(s) separate

spontaneously?

Question #6

Yes

Rash

No

Yes

Yes

No

No

**Donor Eligibility:** FDA recommends waiting to collect HCT/Ps 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.**Question:** 8. In the past 12 months have you had a blood transfusion?

Next question

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

Accept donor

Yes

Has the condition been resolved and 120 days passed since positive test, diagnosis or onset of symptoms, whichever is later?

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?

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

Yes

No

No

Question #7

**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 HCT/Ps following the transfusion, due to possible transmissibility of infectious disease.

**Question:** 9. In the past 12 months have you come into contact with someone else's blood?

Next question

Donor is ineligible, but may

be collected in certain situations. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

In the past 12 months

have you had a blood transfusion?

Yes

No

Accept donor

Question #8

**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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of

urgent medical need.

Is this person known or suspected

to have HIV/AIDS, hepatitis B or C?

In the past 12 months

have you come into contact

with someone else's

blood?

No

No

Yes

Accept donor

Question #9

**Donor Eligibility:** A donor who has been exposed to someone else's blood through a needle-stick is ineligible to donate HPC, Apheresis and HPC, Marrow 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?

Next question

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

Yes

Were you exposed to

someone else's blood through the needle-stick?

No

Is this person known or

suspected to have HIV/AIDS,

hepatitis B or C?

Yes, or don’t know

No

Accept donor

No

In the past 12 months

have you had an accidental

needle-stick?

Question #10

**Donor Eligibility:** A donor who has received an allogeneic transplant or graft should be carefully evaluated for eligibility to donate HPC, Apheresis, HPC, Marrow following the transfusion, due to possible transmissibility of infectious disease.

**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?

Next question

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

Yes

No

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?

Accept donor

Question #11

**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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of

urgent medical need.

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?

Accept donor

No

Yes

Question #12

**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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances for

use and documentation of urgent medical need.

Was the other person’s high

risk activity within the preceding

5 years?

No

No

Yes

Accept donor

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?

Yes

Question #13

**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. Female donors: In the past 12 months have you had sexual contact with a male who has ever had sexual contact with another male? (Males: check “I am male.”)

Next question

No

Accept donor

No

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances for

use and documentation of urgent medical need.

Yes

Yes

Was the other person’s high

risk activity within the preceding

5 years?

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?

Question #14

**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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances for

use and documentation of urgent medical need.

No

No

Female donors: In the

past 12 months have you had sexual

contact with a male who has ever had sexual contact with another male?

(Males: check “I am male.”)

Yes

Accept donor

Was the other person’s

high risk activity within the preceding 5 years?

Yes

Question #15

**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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Asymptomatic hepatitis C

Hepatitis B,

symptomatic hepatitis C,

or unknown

Determine type

of viral hepatitis

Viral

Determine type

of hepatitis

No

Accept donor

Yes

In the past 12 months

have you had sexual contact

with a person who has hepatitis?

Question #16

Non-viral

**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). **Question:** 18. In the past 12 months have you had a tattoo?

Next question

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

Determine type

of hepatitis

Asymptomatic hepatitis C

In the past 12 months

have you lived with a person

who has hepatitis?

Non-viral

Hepatitis B,

symptomatic hepatitis C,

or unknown

Determine type

of viral hepatitis

Viral

No

Accept donor

Yes

Question #17

**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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Yes

No

Determine if tattoo was applied with sterile needles and non re-used ink

No

Accept donor

Yes

In the past 12 months

have you had a tattoo?

Question #18

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

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Determine if piercing was performed using sterilized equipment

Yes

No

No

Accept donor

Yes

In the past 12 months

have you had ear or

body piercing?

Question #19

**Donor Eligibility:** Persons who have had syphilis treatment or a confirmed reactive screening test for syphilis in the preceding 12 months are ineligible. FDA does not recommend deferral if a donor’s treatment occurred more than 12 months ago and was successful. If the treatment was **not** successful, the donor should be deferred.

Question #20

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

No

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.

Yes

Syphilis?

Yes

No

Is this infection active?

Other sexually transmitted infections?

Yes

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 deferral.**Question:** 22. In the past 3 years have you been outside the United States or Canada?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Yes

In the past 12 months

have you been in juvenile detention,

lockup, jail, or prison

for more than 72 hours?

No

No

Determine if donor was incarcerated for more than 72

consecutive hours

Accept donor

Yes

Question #21

**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.

**\* 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.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM080784.pdf>

**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 #22

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

No

Yes

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

Only non-endemic country(ies)

Malaria-endemic country(ies)

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

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

≤24 hours

Malaria-endemic area(s)

>24 hours

Only non-endemic area(s)

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

**Accept Donor**

≤5yrs

>5 years, continuously

Next question

Go to next page

Go to next page

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

No

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

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

Next question

Yes

No

Yes

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

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.

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

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 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.**Question:** 24. Male Donors: In the past 5 years, have you had sexual contact with another male, even once? (Females: Check “I am female.”)

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

In the past 5 years have you

received money, drugs, or other payment

for sex?

Accept donor

No

Yes

Question #23

**Donor Eligibility:** Male donors who have had sexual contact with another male, even once, may be at risk of transmitting infectious disease. 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:** 25. In the past 5 years, have you used needles to take drugs, steroids, or anything not prescribed by your doctor?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Accept donor

No

Yes

Male Donors: In the past 5 years,

have you had sexual contact with another male, even once?

(Females: Check “I am female.”)

Question #24

**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:** 26. 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. \*)

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Accept donor

No

Yes

In the past 5 years, have you

used needles to take drugs, steroids, or anything not prescribed by your

doctor?

Question #25

**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 HCT/Ps. **Question:** 27. 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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

\* See UK Countries Appendix in the User Brochure.

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.\*)

Accept donor

No

Yes

Question #26

**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 HCT/Ps. **Question:** 28. 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. \*)

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

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?

Did you

spend a total time 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?

No

Yes

No

Accept donor

Yes

Question #27

**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 HCT/Ps.

\* See Appendix – vCJD countries of risk – Europe in the User Instructions.

Accept donor

No

Yes

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.\*)

Question #28

**Note:** When calculating time spent in Europe include time spent in the United Kingdom from 1980 – 1996 only.**Question:** 29. 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. \*)

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

**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 HCT/Ps. **Question:** 30. Have you ever had a positive test for the HIV/AIDS virus?

Next question

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 is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

\* See Appendix – vCJD countries of risk – United Kingdom in the User Instructions.

Accept donor

No

Yes

Question #29

**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:** 31. Have you ever had hepatitis or a positive test for hepatitis?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Have you ever had a positive

test for the HIV/AIDS virus?

Accept donor

No

Yes

Question #30

**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).**Question:** 32. Have you ever had malaria?

Next question

Was it before your

11th birthday?

No

Yes

Donors with clinical, symptomatic viral hepatitis after age 11, are ineligible.\*. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

viral hepatitis

Non-viral hepatitis

No

Determine if it was viral hepatitis

Yes

Question #31

Have you ever had hepatitis or a positive

test for hepatitis?

\* 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).

Accept donor

Determine how old

donor was

**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:** 33. Have you ever had Chagas disease and/or a positive test for *T. cruzi*?

Next question

Donor has risk of

malaria, but may be collected in certain situations. Refer to facility SOP for circumstances for use and documentation

of urgent medical need.

Asymptomatic ≤ 3 yrs

Have you been asymptomatic for more than 3 years while residing in a non-endemic country?

Asymptomatic >3 yrs

Accept donor

Yes

No

Have you ever had malaria?

Question #32

**Donor Eligibility:** Donors who have tested positive or reactive for *T. 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 HCT/Ps.\*

**Question:** 34. Have you ever had babesiosis?

\* NOTE: *T. cruzi* is not considered a relevant communicable disease agent or disease (RCDAD) with the FDA and therefore is not a required disease to screen or test for according to the FDA. <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm151757.htm>. It is the responsibility of the user/reader of this document to check FDA’s current requirements for screening and/or testing donors of HCT/Ps to ensure that risk factors for all RCDADs are evaluated, and to note any new RCDADs.  
  
A donor will be considered ineligible if they are screened or tested for *T. cruzi*, and the screening and/or testing results are positive or shows risk.

Next question

Have you ever had Chagas disease and/or a positive test for *T. cruzi*?

Donor has risk of Chagas disease, but may be collected in certain situations. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

No

Yes

Question #33

Accept donor

**Donor Eligibility:** Donors who have had babesiosis are ineligible. Donors who have had babesiosis are ineligible due to the potential risk of transmitting Babesiosis through HCT/Ps.\*

No

\* NOTE: Babesiosis is not considered a relevant communicable disease agent or disease (RCDAD) with the FDA and therefore is not a required disease to screen or test for according to the FDA. <https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm151757.htm>. It is the responsibility of the user/reader of this document to check FDA’s current requirements for screening and/or testing donors of HCT/Ps to ensure that risk factors for all RCDADs are evaluated, and to note any new RCDADs.   
  
A donor will be considered ineligible if they are screened or tested for babesiosis, and the screening and/or testing results are positive or shows risk.

Next question

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

Yes

Accept donor

Have you ever had babesiosis?

Question #34

**Question:** 35.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. HTLV refers to Human T-cell Lymphotropic Virus.

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

No

Yes

Accept donor

Question #35

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

Next question

**Question:** 36. 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.

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Was it from a human source?

No\*

Yes

Have you

ever received

a dura mater (or brain covering) graft?

Accept donor

No

Yes

Question #36

**Question:** 37. 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 after 1977, the donor may 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. \*See Appendix for African countries.

**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.

**Question:** 38. Have you ever been in Africa?

Next question

No

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Yes

Was this sex partner born

in or did he or she live in any of the African countries listed on the appendix?

Left after 1977

Left before 1977

Yes

No

Accept donor

Have you ever had

sexual contact with anyone who was born in or lived in Africa?

Did this sex partner leave Africa before or after 1977?

Question #37

**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.

Yes

**Question:** 39. Have you ever been diagnosed with any neurological disease?

Consult SOP to determine if donor

is ineligible due to being born in,

living in or travel to these

African countries.

Were

you born in,

lived in or did you travel to

Africa before or after

1977?

After 1977

Has donor spent time in African countries listed on the appendix?

Yes

\* 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.

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

No

Question #38

Have you

ever been in Africa?

Yes

No

No

When you traveled

there, did you receive

a blood transfusion or any

other medical

treatment that involved blood?

No

Before 1977

Accept donor

Yes

Yes

Next question

**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 HCT/Ps. In the event of urgent medical need, additional criteria may be used to evaluate donors with neurological disease other than vCJD/CJD.**Question:** 40. Have you ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?

Next question

Donor is ineligible, but may

be collected in certain situations. Refer to facility SOP for circumstances for use and documentation of urgent medical need.

Determine if diagnosis was for

dementia, or degenerative disease of the CNS, or demyelinating disease of the CNS, or other neurological diseases of unknown origin

Have you ever been diagnosed

with any neurological disease?

Accept donor

No

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.

No

Determine

Diagnosis/cause

Date(s) of occurrence

No

Was the diagnosis

for vCJD/CJD?

Yes

Yes

Question #39

**Donor Eligibility:** Donor is considered FDA 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 #40

(1) U.S. Department of Health and Human Services Secretary's Advisory Committee on Xenotransplantation. Report on the State of the Science in Xenotranaplantation. Draft, Sept 2004, page 1.

Accept donor

No

Yes

Have you ever had

a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from an animal?

**Question:** 41. 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?

Next question

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

**Donor Eligibility:** Donors exposed to blood, saliva, or other body fluids through activities such as deep kissing, shared toothbrushes, razors or needles, or through open wounds or sores are considered FDA-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.

(1) U.S. Department of Health and Human Services Secretary's Advisory Committee on Xenotransplantation. Report on the State of the Science in Xenotranaplantation. Draft, Sept 2004, page 1.

Accept donor

Not exposed

Determine if donor was exposed to blood, saliva, or other body fluids

Yes

No

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?

Question #41

**Question:** 42. Have any of your relatives had Creutzfeldt-Jakob disease?

Next question

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

Exposed

**Donor Eligibility:** Donors with a blood relative with Creutzfeldt-Jakob disease are ineligible. A donor response such as “do not know” that indicates a lack of familiarity with the CJD disease can be considered a negative response.

**Note:** If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, or if the blood relative was exposed to the disease through iatrogenic means (medical treatment), the donor is eligible.

Was the disease from the result of a surgical procedure or injection of growth hormone?

No/Unknown

Yes

Was this person related by blood or by marriage?

Question #42

No

Accept donor

Related by blood

Yes

Related by marriage

Have any of your relatives had Creutzfeldt-Jakob disease?

Donor is ineligible, but may be

collected in certain situations. Refer

to facility SOP for circumstances

for use and documentation of urgent medical need.

Next question

**Zika Additional Question:** 1. For Living donor – In the past 6 months have you had a Zika virus infection?

**Donor Eligibility:** Donors with a medical diagnosis of Zika virus infection within the past 6 months 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 for 6 months after resolution of symptoms.

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

(See May 2018 FDA Guidance: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)**Zika Additional Question:** 2. For living donor – In the past 6 months have you lived in or traveled to an area with an increased risk for Zika virus transmission? (Have donor review list of locations on CDC webpage <https://www.cdc.gov/zika/areasatrisk.html>.)

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

For

Living donor –

In the past 6 months have you had a Zika virus infection?

No

Next question

Yes

Accept donor

Zika Additional Question #1

**Donor Eligibility:** 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 been to an area with an increased risk for Zika virus transmission are ineligible for donation for 6 months after the date of departure from the area.

**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>.

(See May 2018 FDA Guidance: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)

Zika Additional Question #2

For

living donor

– In the past 6

months have you lived in

or traveled to an area with an increased risk for

Zika virus transmission? (Refer

to current list on CDC

webpage. <https://www.cdc.gov/zika/areasatrisk.html>.)

**Zika Additional Question:** 3. For living donor – In the past 6 months 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?

No

Accept donor

Next question

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

**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 6 months following date of last sexual contact. (Have donor review list of locations on CDC webpage <https://www.cdc.gov/zika/areasatrisk.html>.)

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

NOTE: Refer to CDC’s website for more information on the signs and symptoms of Zika virus infection: <http://www.cdc.gov/zika/symptoms/index.html>.

(See May 2018 FDA Guidance: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)

Next question

Zika Additional Question #3

For

living donor

– In the past 6 months 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?

No

Accept donor

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

**May omit question number 4 if this type of donation is not applicable to your program.**

**Zika Additional Question:** 4. For Non-Heart-Beating (Cadaveric) donor – In the past 6 months has the donor had a medical diagnosis of a Zika virus infection?

**Donor Eligibility:** Donors with a medical diagnosis of Zika virus infection within the past 6 months 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 for 6 months after resolution of symptoms.

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

(See May 2018 FDA Guidance: <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>)

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

No

Yes

Accept donor

Zika Additional Question #4

For

Non-Heart-Beating

(Cadaveric) donor – In the past 6 months has the donor had a medical diagnosis of a Zika virus

infection?