Donor History Questionnaire
User Brochure

**Purpose:** The User Brochure was designed to aid the donor historian in determining if a prospective donor is eligible to donate. Each blood center must have a standard operating procedure (SOP) related to donor suitability to be used in conjunction with the User Brochure. The User Brochure does not replace an SOP for determining donor suitability. Both the User Brochure and the SOP must be available to staff performing health histories. Alternately, the User Brochure contents may be transcribed into the SOP.

**Introduction:** The Donor History Questionnaire (DHQ) must be administered on the date of donation. All prospective donors, including those that meet criteria for screening using the abbreviated DHQ, must read the Donor Educational Materials prior to completing the DHQ. They also must be given the Medication Deferral List, and a list of BSE countries to be used with the DHQ. As an alternative, one or all of the lists can be prominently displayed at the donation site for the donors’ use while they are completing the DHQ. The DHQ was designed for self-administration by the donor, with follow-up review by a trained donor historian. All donors, including those that meet criteria for screening using the abbreviated DHQ, should be instructed to complete all questions on the questionnaire. A knowledgeable donor historian should be available to the prospective donor to answer any questions concerning eligibility or the donation process. Alternatively, the DHQ may be administered by a donor historian. The method of administration of the DHQ should be in accordance with the blood center’s SOP.

Collection facilities using these screening materials should be aware that these materials were tested in English-speaking donor and non-donor groups and due to practical limitations could not be tested in all possible settings, including with non-English speaking donors.

**DHQ Format:** The DHQ questions were composed for ease of understanding by the prospective donor. The DHQ was evaluated in its current form for comprehension; therefore, the wording and the order of the questions should not be changed. Blood centers may choose to add local questions to the beginning or the end of the DHQ. The Educational Material and Medication Deferral List also must be used unabridged except for local additions. The questions are grouped by time period beginning with a question about “today” and ending with questions relating to “have you ever.” The *entire DHQ must be completed before eligibility is determined.*

The DHQ uses capture questions that may require donor historian intervention or follow-up. Capture questions are questions that cover a broad topic, and when an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. Some follow-up questions are included in the User Brochure, but since specific donor eligibility criteria may vary from one blood center to another, an affirmative response to some questions may require consultation
with the blood center’s SOP. Blood centers may implement more restrictive deferral policies than described in the User Brochure per their local SOP. If a donor is determined to be eligible despite an affirmative response to a question(s), a detailed explanation for each question must be documented in sufficient detail in a designated area on the DHQ.

Additionally, DHQ has several “attention” questions. An example of one of the attention questions is listed below.

In the past 6 weeks, have you been pregnant or are you pregnant now? (Males check “I am male”)

An inappropriate answer to the question would be a male answering “yes” or “no.” Each blood center must define the action of the donor historian when a donor inappropriately answers the attention questions.

**Abbreviated Donor History Questionnaire:** An abbreviated version of the DHQ (aDHQ) that is intended to be used by repeat blood donors.

**When is a donor considered to be a repeat blood donor?**
A blood donor is eligible to use the aDHQ if certain defined donor criteria are met and if the blood collection facility has a system in place that can determine when it is appropriate to use the aDHQ.

Repeat Donor Criteria: A donor who has previously donated two times, one donation of which occurred within the previous six months. Both donations must have been screened using the full-length DHQ.

**Is it necessary to administer the full-length questionnaire once a donor is classified as a repeat donor?**
Once the donor qualifies for the aDHQ, there is no need to administer the full-length questionnaire as long as the donor continues to qualify for the abbreviated version. However, if the donor does not qualify, — for example, if the last donation was greater than 6 months — the full-length DHQ MUST be administered.

From time to time, new donor history questions will be added. The new questions must be added to the full-length and the abbreviated DHQ. The new questions will remain on the aDHQ for one year from the date the question was added. If the question must be asked at each donation, the question will remain indefinitely on both DHQs.

**How will the blood collection facility track whether the full-length questionnaire or the abbreviated questionnaire should be administered, especially at mobile collection units?**
The blood collection facility must have a system to determine when it is appropriate to administer the abbreviated questionnaire and when the full-length questionnaire must be administered. Some of the items that the system must be able to determine are: how many
times the donor has donated, the time interval since their last donation, which questionnaire was utilized at each donation, the full-length questionnaire or the abbreviated questionnaire. If the donor was deferred at the last donation, the full-length questionnaire will be administered.

What action should be taken when it is determined that an incorrect questionnaire has been administered?
The blood collection facility must have a standard operating procedure describing actions in this circumstance. If a full-length questionnaire has been administered when a donor qualified for an abbreviated questionnaire, no additional action is required with regard to donor or product suitability. If an abbreviated questionnaire was administered when a full-length questionnaire should have been administered, the SOP must ensure that the donor unit is not made available for distribution (quarantined) until donor suitability issues have been resolved. If the unit has already been distributed, then it should be treated as post-donation information, including submission of a biological product deviation report to the FDA if appropriate.

User Brochure Format: The User Brochure is modular and uses flow-charting to guide the donor historian through the donor questionnaire process. Each question is a complete section that begins on a new page, so that changes to the DHQ and the aDHQ can be easily modified in the User Brochure. Each section contains the following information:

- **Question:** Question number and the question.
- **Donor Eligibility:** This section provides additional information to the donor historian on donor eligibility requirements for each question.
- **Note:** Optional field; additional relevant information relating to the donor question.
- **Flow Chart:** Each question is flow-charted using standard flow-charting symbols.
  - **Square** -- Statement
  - **Diamond** -- Question/decision point
  - **Oval** -- Action
  - **Arrow** -- Move to the next question

Each question ends with an ARROW that indicates to “move to the next question;” however, blood centers must follow their established policies concerning whether or not the donor suitability process is terminated when it is known that the donor will be deferred.

**Donor Deferrals:** For some questions, a “yes” answer calls for a required deferral, either indefinitely or for a specified period of time. A required deferral is designated in the flow chart by the Action “Defer donor.” The donor historian may need to refer to the blood center’s SOP to determine if and when the donor may be eligible to return.

For other questions, a “yes” answer may not require a deferral; rather, it may trigger a line of questioning to determine if the donor is eligible. The donor historian will need to refer to the blood center’s SOP for follow-up questions to determine suitability. This type of deferral is designated in the flow chart by the Action “Defer donor per SOP.” For
example, if a donor answers “yes” to the question “In the past 12 months, have you had a blood transfusion?,” certain blood centers may ask further questions regarding the kind of blood. Some blood centers may allow donors with confirmed receipt of autologous blood only to donate. Other centers may simply defer all donors who received blood in the last 12 months, regardless of whether the blood was allogeneic or autologous.

Each blood center’s SOP must define how the donor responses to the follow-up questions will be documented on the DHQ. Responses should be documented with sufficient detail to determine the reason for donor acceptance or deferral.

**References:** A list of references concerning donor eligibility is included at the end of the questions.
GLOSSARY

The following terms are defined in the context of their use in the Donor History Questionnaire.

QUESTIONNAIRE TERMS

Attention Question – Questions in the Donor History Questionnaire that are designed to test if the donor is paying attention. EXAMPLE: In the past six weeks, have you been pregnant or are you pregnant now? (Males check: “I am Male”)

Capture Question – A question that covers a broad topic. When an affirmative answer is given, additional follow-up questions to elicit additional information are asked by the donor historian. EXAMPLE: Have you ever been to Africa? If the donor answers yes, additional questions must be asked.

Self-administered Questionnaire – A questionnaire that the donor completes on his/her own, followed by donor health historian review.

Abbreviated Questionnaire – An abbreviated version of the Donor History Questionnaire that is intended to be used by repeat blood donors.

Repeat blood donor – A donor who has previously donated two times, one donation of which occurred within the previous six months. Both donations must have been screened using the full-length Donor History Questionnaire.

TYPES OF CONTACT

Contact with Blood – (1) a needlestick or other sharps injury from an instrument that has been used on any individual or patient; (2) exposure to non-intact skin (e.g., skin that is chapped, abraded, or afflicted with dermatitis); (3) a human bite that breaks the skin; (4) exposure to eye, nose, or mouth i.e., the mucous membranes.

Sexual Contact – The meaning of the words “sexual contact with” and “sex” are identical, and apply to any of the following activities, whether or not a condom or other protection was used: (1) Vaginal sex (contact between penis and vagina); (2) Oral sex (mouth or tongue on someone’s vagina, penis, or anus); (3) Anal sex (contact between penis and anus).
Close Contact with Smallpox Vaccination Site – Touching the vaccination site, including the bandages covering the vaccination site; touching/handling materials that might have come into contact with an unbandaged vaccination site including clothing, towels, and bedding.

Lived With – Residing in the same dwelling. EXAMPLES: house, dormitory, apartment.

TYPES OF DEFERRAL

Indefinite Deferral – Prospective donor is unable to donate blood for someone else for an unspecified period of time due to current regulatory requirements. EXAMPLE: A prospective donor who states that they lived in England for 1 year in 1989 would be deferred indefinitely. This donor would not be able to donate blood until the current requirement changes. These donors may be eligible to donate autologous blood.

Permanent Deferral – Prospective donor will never be eligible to donate blood for someone else. EXAMPLE: A prospective donor states that he/she has Hepatitis C. Additionally, some permanent deferrals may result from the testing performed on a previous donation. These donors may be eligible to donate autologous blood.

Temporary Deferral – Prospective donor is unable to donate blood for a limited period of time. EXAMPLE: A prospective donor who discloses that he/she received a tattoo is temporarily deferred for 12 months after he/she received the tattoo.
**Question:** 1. Are you feeling healthy and well today?

**Donor Eligibility:** A donor should be free of infectious diseases and colds on the day of donation. Donors who are 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**
    - Accept donor
  - **No**
    - Consult SOP and assess donor to determine if deferral is indicated.

- **Next question**
Question: 2. Have you read the educational materials and had your questions answered?

Donor Eligibility: Donors must read the educational materials prior to donating and have an opportunity to have their questions answered.
**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. Donors who are taking aspirin or any aspirin containing medication should not be the sole source of platelets.

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**Question #3**

- In the past 48 hours have you taken aspirin or anything that has aspirin in it?
  - No: Accept donor
  - Yes: Consult SOP for action

Next question
**Question:** 4. (Female Donors) In the past 6 weeks, have you been pregnant or are you pregnant now? (Males: check “I am male.”)

**Donor Eligibility:** A female with a known pregnancy or who has been pregnant in the last 6 weeks should not donate blood.
**Question:** 5. In the past 8 weeks have you donated blood, platelets or plasma?

**Donor Eligibility:** Frequency of whole blood donation is a minimum of every 8 weeks; plasma, platelets or leukapheresis is a minimum of every 48 hours.

![Flowchart diagram showing the process for determining donor eligibility based on donation history.](flowchart_diagram.png)
**Question:** 6. In the past 8 weeks, have you had any vaccinations or other shots?

**Donor Eligibility:** Certain vaccinations may contain live viruses. A donor who has been exposed to a live virus via vaccination should not serve as a donor. For other shots, refer to SOP.
When were you vaccinated?

Less than 21 days — See next page for further questioning.

21 days or more

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

Yes — When did the illness or complication resolve?

Less than 14 days — Defer donor for 14 days after symptoms resolve.

14 days or more

No

Accept donor.

Accept donor.

Next question
Is the scab still on?  
Yes → Defer donor for 21 days after vaccination date.  
No → Did the scab fall off by itself?  
Yes → Did you have any illness or complications due to the vaccination?  
Yes → When die the symptoms resolve?  
Less than 14 days → Defer donor until 14 days after vaccination date.  
14 days or more → Accept donor.  
No → Defer donor for 21 days after vaccination date.  
No → Accept donor.  
Accept donor. → Next question
**Question:** 7. In the past 8 weeks, have you had close contact with the smallpox vaccination site of someone else?

**Donor Eligibility:** Certain vaccinations may contain live viruses. 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 virus and should not serve as a donor.

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**Question #7**

- **In the past 8 weeks, have you had close contact with the smallpox vaccination site of someone else?**
  - **Yes**
    - **Have you had any new skin rash or skin sore since the time of contact?**
      - **No**
        - **Accept donor.**
      - **Yes**
        - **Was it a rash?**
          - **No**
            - **Question further. Did the scab separate spontaneously?**
              - **No**
                - **Defer 3 mos. from date of the vaccination; If date is not known, defer 2 mos. from current date.**
              - **Yes**
                - **Accept donor.**
          - **Yes**
            - **Has it been 14 days since the rash went away?**
              - **Less than 14 days**
                - **Defer for 14 days after symptoms resolve.**
              - **14 days or more**
                - **Accept donor.**

- **No**
  - **Accept donor.**
**Question:** 8. 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:** 9. Since your last donation, have you had any new medical problems or diagnoses?

**Donor Eligibility:** Certain medical conditions may be cause for the donor to be ineligible to donate.
**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 ineligible to donate.
**Question:** 11. Since your last donation, have you taken any of the medications on the Medication Deferral List?

**Donor Eligibility:** Donors taking certain designated medications, currently or in the past, must not donate blood.

- **Yes:** if donor has EVER taken one of these medications.
- **No:** Accept donor

**Medication Deferral List** was provided to donor, with educational materials

- Since your last donation, have you taken any of the medications on the Medication Deferral List?
  - Yes
  - No

Determine the
- medication(s) and
- when last dose was taken.

- Tegison
- human GH
- Beef insulin from U.K.?

- Yes, if donor has EVER taken one of these medications.
- Indefinite deferral
No, the donor took another medication on the list.

Soriatane?
- Yes within last 3 years.
  - Defer donor
- Yes, over 3 years ago.
  - or
  - Never taken it.

Avodart?
- Yes within last 6 months.
  - Defer donor
- Yes, over 6 months ago.
  - or
  - Never taken it.

• Proscar
• Propecia
• Accutane?
- Yes, within the last month.
  - Defer donor
- Yes, but over a month ago.
  - or
  - Never taken it.

Hepatitis Blg
- Yes, within the last year for exposure to Hepatitis B.
  - Defer donor
- Yes, but over a year ago,
  - or
  - Never taken it.

Accept donor

Next question
**Question:** 12. Since your last donation, have you been outside the U.S. or Canada?

**Donor Eligibility:** Donors who have been outside the U.S. or Canada should be evaluated for eligibility. Travel to certain areas may constitute reason for deferral. (See additional flow charts.)

- If donor traveled to:
  - African country--refer to flow chart #8a
  - European country--refer to European country list and flow chart #8b
  - UK--refer to UK country list and flow chart #8c
  - Malarial country--refer to flow chart #8d

- Is donor deferred for travel to any of these countries?
  - Yes: Apply appropriate deferral(s)
  - No: Accept donor

- Next question
Donor Eligibility: Donors who have lived in certain countries in Africa since 1977 (see list below) are indefinitely deferred. Donors who have received a blood transfusion or any other medical treatment in Africa are indefinitely deferred. Donors may have been exposed to rare strains of HIV that are not detected by current test methods.

12a. Flow chart for Africa travel, residence or place of birth

- Have you ever been in Africa?
  - No: Accept donor
  - Yes: Were you born in or did you travel to Africa before or after 1977?
    - Before 1977: No
    - After 1977: Have you spent time in any of the following countries in Africa: Cameroon, Central African Empire, Chad, Congo, Equatorial Guinea, Gabon, Niger or Nigeria?
      - No: Is donor deferred for travel to or being born in African countries?
        - No: While you were there, did you receive a blood transfusion or any other medical treatment?
          - No: Defer donor indefinitely
          - Yes: Defer donor indefinitely
        - Yes: Next question
      - Yes: Consult SOP to determine if deferral is indicated.
        * Apply deferral as indicated or continue.

**12b. Flow chart for time spent in Europe.**

**Donor Eligibility:** Donors who have spent time that adds up to five (5) years or more in Europe from 1980 to the present are indefinitely deferred. Donors may be at theoretical risk of developing vCJD from eating beef in Europe. There may be a theoretical risk of transmitting vCJD through blood transfusion.

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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.)

Yes

Defers donor indefinitely

No

Accept donor

Next question
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**Donor Eligibility:** Donors who have spent time that adds up to three (3) months or more in the United Kingdom from 1980 through 1996 are indefinitely deferred. Donors may be at theoretical risk of developing vCJD from eating beef from the UK. There may be a theoretical risk of transmitting vCJD through blood transfusion.

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12c. Flow chart for time spent in the United Kingdom. (Review list of countries in the UK.)

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.)

- Yes → Defer donor indefinitely
- No → Accept donor

Next question
12d. Flow chart for time spent outside U.S. or Canada in the past three years.

**Donor Eligibility:** Immigrants, refugees, or citizens coming from a country in which malaria is considered endemic will be deferred for 3 years after departure from the area if they have been free from unexplained symptoms suggestive of malaria. Donors who have traveled to a country where malaria is considered endemic will be deferred for 12 months after returning from that area regardless of whether or not they took anti-malaria prophylaxis. Malaria may be transmitted through blood transfusion. The donors shall be accepted or deferred based on the Malaria Risk Countries as designated by your institution.
**Question:** 13. Since your last donation, have you come into contact with someone else’s blood?

**Donor Eligibility:** A donor who has been exposed to someone else’s blood should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease. (See Glossary for definition of “contact with blood.”)
**Question:** 14. Since your last donation, have you had an accidental needle-stick?

**Donor Eligibility:** A donor who has been exposed to someone else's blood through a needle-stick should not donate blood for 12 months following exposure, due to possible transmissibility of infectious disease.
**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:** Persons who have had sexual contact with persons with clinical or laboratory evidence of HIV infection are deferred 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:** 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:** Persons who have given money or drugs in exchange for sex (sexual contact) 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 educational materials 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:** Persons who have had sexual contact with persons who, in the past or present, have used needles to take drugs, steroids, or anything not prescribed by their doctor 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 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: 18. Since your last donation, have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?

Donor Eligibility: Persons who have had sexual contact with one of the following: 1) any person with hemophilia or related clotting disorders; or 2) any person who has received clotting factor concentrates is deferred for 12 months. 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:** 19. Female donors: Since your last donation, have you had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")

**Donor Eligibility:** Women who have had sexual contact with men who have had sexual contact with another man even one time since 1977 are deferred 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:** 20. Since your last donation, have you 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 list below) after 1977, the donor is indefinitely deferred. Donors who have had sexual contact may have been exposed to rare strains of HIV that are not detected by 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.
**Question:** 21. Since your last donation, have you come into contact with blood from a person who has hepatitis?

**Donor Eligibility:** Persons who have had one of the following during the preceding 12 months: 1) contact of an open wound, non-intact skin or mucous membrane with the blood of a person with hepatitis, or 2) a needle-stick or other sharps injury from an instrument that has been used on a person with hepatitis, are deferred for 12 months from the date of exposure. Hepatitis may be spread through contact with blood.
**Question:** 22. Since your last donation, 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 hepatitis are to be deferred for 12 months from the time of last exposure. Hepatitis, particularly hepatitis A and 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 educational materials provided.

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**Question #22**

Since your last donation, have you had sexual contact with a person who has hepatitis?

- **Yes**
  - Determine type of hepatitis.
  - Asymptomatic Hepatitis C
  - Hepatitis A or B, Symptomatic Hepatitis C, or unknown
  - Defer donor

- **No**
  - Accept donor

**Next question**
**Question:** 23. Since your last donation, have you lived with a person who has hepatitis?

**Donor Eligibility:** In certain cases, living with a person with hepatitis puts the donor at risk for acquiring hepatitis as well.
**Question:** 24. Since your last donation, have you received money, drugs, or other payment for sex?

**Donor Eligibility:** Donors who received money, drugs, or other payment for sex are permanently deferred. HIV and other diseases may be 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:** 25. (Male Donors) Since your last donation, have you had sexual contact with another male, even once? (Females: Check “I am female.”)

**Donor Eligibility:** Male donors who have had sexual contact with another male, even once, since 1977 are permanently deferred. Males who have had sex, even once, with males may be at risk of transmitting infectious diseases. 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:** 26. Since your last donation, have you had a tattoo?

**Donor Eligibility:** Persons who have had a tattoo in the previous 12 months are deferred for 12 months from the date of the tattoo application. Unless tattoos have been applied using single-use needles and single-use ink, there may be a risk of transmission of infectious diseases.

**Note:** Tattoos include tattoo "touch ups", tattoos applied by oneself, and those applied by others.
Question: 27. Since your last donation, have you had ear or body piercing?

Donor Eligibility: Persons who have had ear or body piercing during the previous 12 months are usually deferred for 12 months from the date of procedure. Unless ear or body piercing has been done using single-use equipment, there may be a risk of transmission of infectious diseases.
**Question:** 28. Since your last donation, 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, lockup, jail, or prison) for more than 72 consecutive hours (3 days) are deferred for 12 months from the date of occurrence. These persons are at higher risk for exposure to infectious diseases.

**Note:** The reason for incarceration (e.g. white-collar crimes, child support) does not change the deferral.
**Question:** 29. Since your last donation, 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 indefinitely deferred due to potential transmission of infectious diseases.
Question: 30. Have any of your relatives had Creutzfeldt-Jakob disease?

Donor Eligibility: Donors with a blood relative with Creutzfeldt-Jakob disease are indefinitely deferred.

Note: If laboratory testing (gene sequencing) shows that the donor does not have a mutation associated with familial CJD, the donor is eligible.
Donor qualification requirements are located in 21 CFR 640.3 and AABB Standards for Blood Banks and Transfusion Services (Standard 5.4; 5.5; and 5.4.1A in the 21st Edition).

Additional donor qualification requirements may be found in FDA memoranda and guidance:

FDA Memorandum October 7, 1988: Revised Guidelines for the Collection of Platelets, Pheresis.

FDA Memorandum, December 12, 1991: Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing.


FDA Memorandum, July 28, 1993: Deferral of Blood and Plasma Donors Based on Medications.

FDA Memorandum December 22, 1993: Donor Suitability Related to Laboratory Testing For Viral Hepatitis and a History of Viral Hepatitis.

FDA Memorandum July 26, 1994: Recommendation for Deferral of Donors for Malaria Risk.


Blood Products Advisory Committee Meeting June 16, 2000: Update on Sexual Transmission of HCV.

FDA Guidance, January 9, 2002: Revised Preventive Measures to Reduce the Possible Risk of Recent Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products.

Avodart Consumer Information, January 14, 2003: 


FDA Guidance, December 2002: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients.