

# Donor Eligibility and Selection

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# Donor Selection Criteria

# Goals

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- Safety for the donor
- Safety for the recipient
- System based on honesty
- Is blood safe for the recipient?
- How safe is safe enough?

# The Consequences of a “Zero Risk Blood Supply”

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- Caution guides action (Precautionary Principle)
- Extreme aversion to risk taking by standard setting agencies
- All screening tests require high sensitivity and results in some false reactives
- Regulatory agencies reluctant to consider elimination of tests/questions

# Two Needs in the Blood Business

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- A safe (enough) blood supply
- A plentiful (enough) blood supply

# FDA's Five Layers of Blood Safety

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1. Donor screening and deferral based on geographic, behavioral and medical risk factors (donor education, self deferral, donor interview).
2. Laboratory testing for infectious diseases and deferral (HIV-1/2, HBV, HCV, HTLV I/II, WNV, syphilis, *T. cruzi*, *Zika* and in certain areas *Babesia*).
3. Deferral registries to prevent use of blood from deferred donors.
4. Quarantine controls to prevent unit release pending verification of donor suitability.
5. Investigation and correction of deviations.

FDA's approach is to optimize each safety layer

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# The Rules

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- 21 Code of Federal Regulations (CFR) 610.41, 640.3, 640.63, etc.
- FDA Guidances
- NY State Register Subpart 58-2
- Professional Standards
  - AABB Standards
- Internal SOPs

# Blood Donor Qualification

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- **21 CFR 640.3** The suitability of a donor as a source of Whole Blood shall be determined by a qualified physician or by persons under his supervision and trained in determining suitability. Such determination shall be made on the day of collection from the donor by means of medical history, a test for hemoglobin or hematocrit level, and such physical examination as appears necessary...
- If a donor's responses to the screening questions are incomplete or unclear, the collector may clarify them within 24 hours of donation and still be compliant with the "day of collection" requirement



# Donor Incentives

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- **21 CFR 606.121(c)(5)**
  - **A paid donor is a person who receives monetary payment for a blood donation**
  - **Benefits, such as time off from work, membership in blood assurance programs, and other benefits that are not readily convertible to cash, do not constitute monetary payment. Small gifts of limited monetary value may be used.**

# Types of Donations

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- **Homologous (Allogeneic or Directed)**
  - **Rigid criteria to protect both the donor and the recipient**
- **Autologous**
  - **Blood is only for the donor, so history is not necessarily relevant**
  - **More lenient physical criteria**
  - **Rules allow for medical judgment**

# Homologous Blood Donation

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- Read Educational Materials
- Donor demographics
  - Required information- need to uniquely identify the donor for **TRACKABILITY**
    - Full name
    - Donor identification
    - Permanent address
    - Date of birth and age
    - Date of last donation

# The Donor Health History Form

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- **Donor safety issues – eg. cardiac history.**
- **Recipient safety issues**
  - **People at risk for infection (viral and bacterial)**
  - **Screen for diseases with no corresponding test**

# Privacy for the Donor

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- **Any DHQ can be totally self administered including high risk questions.**
- **The donor must be provided privacy to fill out his/her donor health questionnaire (DHQ)**
- **Many DHQ are administered via electronic processes**

# Criteria for Donation

## Mini Physical

# Temperature

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- To be acceptable
  - Maximum of 37.5°C or 99.5°F
- Issue is possible systemic bacterial infection.
- If not acceptable, defer for 1 day.

# Blood Pressure and Pulse

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- To be acceptable
  - Systolic BP between 90-180 mmHg
  - Diastolic BP between 50-100 mmHg
  - Pulse 50-100
- For BP, responsible MD has to be on site to examine the donor and determined that their health would not be adversely affected by donating. For Pulse the same has to be determined, but MD may do so over the phone.
- If not acceptable, defer for 1 day.



# Arm Inspection

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- To be acceptable
  - Phlebotomy site must be clear of any signs of infection or intravenous drug use
- If signs of IV drug use (e.g. track marks), permanently defer the donor.
- If signs of skin infection, defer until the condition is clear.
- If no suitable veins for venipuncture can be palpated, defer the donor for 1 day.

# Hemoglobin or Hematocrit

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- Minimum hgb/hct levels
  - Females 12.5 g/dl hgb or 38% hct for WB and non-DRBC apheresis
  - Males 13.0 g/dl hgb or 39% hct
- DRBC apheresis requires a minimum HGB of 13.3 g/dl hgb or 40% hct for either gender
- Maximum 20 g/dl hgb or 60% hct if donating WB
- Maximum 18 g/dl hgb or 54% hct if donating plateletapheresis, plasmaapheresis, and leukoapheresis due to viscosity issues
- If the Hgb/Hct is too low or too high, defer for 1 day.

# Iron and blood donors

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## The problem -

- **1 unit of whole blood removes 200 - 250mg iron**
- **The body only absorbs about 4 mg of iron on a daily basis. Diet is not usually sufficient to replace the iron lost, especially if the donor gives frequently (up to every 56 days).**
- **Also Hgb/HCT POC measurements are poor indicators of iron stores. They will return to pre-donation levels before iron stores are replenished Therefore donor eligible to give again and iron stores continue to diminish.**
- **Current intervention is to educate donors about iron loss and recommend iron replacement via vitamins or supplements.**

# AABB Association Bulletin

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- **Concern about iron deficiency or iron absence**
  - Provide iron pills to donor or voucher to get iron pills at pharmacy
  - Do ferritin testing and provide results with recommendations
  - Modify intervals to allow for fewer donations per year.
  - Risk Based Decision Making group organized to review prior to making a standard.
  - Association bulletins are recommendations, standards are requirements.

# Age Qualification

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- **To be acceptable the donor must to be between 16 and 75**
  - **Must have parental permission (NY) or consent (NJ) to participate in blood drive**
  - **Donor still consents to donation**
- **If over 75, donors may be accepted at the discretion of the medical director. Yearly review of health status needed.**

# Criteria for Donation

## Donor History Questions

## Are you currently 110 pounds or more?

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- Required by NYS if collecting WB into 500ml bags
  - If the donor answers “NO,” to this question
    - The donor must be deferred
- OR
- A donor weighing between 40 kg (88 lbs) and 50 kg (110 lbs) may donate a volume proportionate to the donor’s weight provided the anticoagulant is reduced and the container is appropriately labeled

# Preventing donor reactions and injuries

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- While pre-syncopal and syncopal reaction rates among whole blood donors are often cited as 3-7%,
- Rates are higher among first time and female donors. Donors under the age of 20 have an increased rate of reactions, while increasing age is associated with decreasing rates.
- NYBC reaction rates are between 5-6% in 16-18 year old donors. Some other centers have reported higher rates.



# Reactions and Young Donors

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- Blood centers have become increasingly reliant on young donors to maintain adequate supply.
- It is estimated that up to 20% of all donations are made by donors under the age of 20. (AABB Association Bulletin 08-04)
- Recent reports confirm that the younger the donor, the higher the reaction rate, with 16 and 17 year olds having the highest rates.
- First time teen whole blood donors have reaction rates about twice that of first time young adults donors and first time teen-age female donors have higher rates than males.

# Reactions, con't

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- Though morbidity associated with reactions is limited, their number should be minimized for three reasons.
  - 10-15% of donors who suffer syncopal reactions are at an increased risk for injury from associated falls.
  - Donors who suffer such reactions are less likely to return for repeat donation.
  - Requests for repeat blood drives in those schools with high reactions rates may meet with resistance from school administrators.

# What to do?

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- In the US up to 10.5 mL/kg of blood may be collected. This estimates that  $\leq 15\%$  of blood volume is collected from a donor weighing at least 110 lbs.
  - Small female donors may actually be giving up to 17.5% of their blood volume.
  - In Europe only 13% of a donor's blood volume is collected.
- A wide variety of interventions have been suggested to reduce reactions among teens, including:
  - consumption of pre-donation water to cause gastric distention
  - distraction techniques and improved interaction between donor and phlebotomist,
  - performance of muscle tension exercises during donation
  - increased post donation recovery before leaving the site
  - providing salty snacks
- The success of these interventions has been mixed

# What else?

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- Redirect eligible teen donors to automated red cell donation with fluid replacement or plateletapheresis donations that entail reduced volume loss
- Recently many centers have implemented strategies to restrict donation by teens to those with blood volumes over 3500 mL or limit collections to 15% of donor blood volume

# **New York** *Blood Center*

## DONOR NOMOGRAM (Ages 16 to 18 Years of Age)

Guide for **male donors** – ages 16 to 18 Years

Height	4' 10"	4' 11"	5' or taller
Donor must weigh at least	120 lb	115 lb	110 lb

Guide for **female donors** – ages 16 to 18 Years

Height	4' 10"	4' 11"	5'	5' 1"	5' 2"	5' 3"	5' 4"	5' 5"	5' 6" or taller
Donor must weigh at least	146 lb	141 lb	138 lb	133 lb	129 lb	124 lb	118 lb	115 lb	110 lb

## Are you now taking or have you ever taken any medications on the Medication Deferral List?

- **The donor must answer “NO” to this question. If the donor answers “YES,” defer for the correct period of time.**

Have you read the educational materials and had your questions answered?

- **If the donor answers “NO” to this question, inquire why (s)he answered “NO”**
- **The donor must indicate that (s)he has read and understood the Blood Donor Educational Materials to be eligible**

# In the past three years have you been outside the United States or Canada?

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- If the donor answers “YES,” determine if the donor has traveled to an area at risk for malaria.
- If malarial risk exists, defer the donor for a total of 12 months from the date of the donor’s return from the malarial area or Iraq.
- If the donor had malaria, defer the donor for 3 years from the last symptoms.
- If the donor is an immigrant, refugee, citizen, or resident who lived in a malarial area for more than 5 years, defer the donor for 3 years upon return from the malarial area. If they visit a malarial area within the 3 year period from return.
- Does NOT address vCJD.



# Have any of your relatives had Creutzfeldt-Jakob Disease?

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- If the donor answers “YES,” permanently defer the donor.
- Some types of CJD are inherited.
- A donor who has a non-blood related blood relative with CJD is acceptable.

From 1980 through 1996 did you spend time that adds up to 3 months or more in the United Kingdom?

- **If the donor answers “YES,” indefinitely defer the donor due to risk of vCJD.**
- **There is no acceptable criteria for a donor who has spent more than 3 months in the UK from 1980 to 1996.**

**From 1980 through 1996 were you a member of the US Military, a civilian military employee, or a dependent of a member of the US Military?**

- **If the donor answers “YES,” check to see when and where the donor was.**
- **Defer indefinitely, due to risk of vCJD, if 6 months or more spent in:**
  - **Belgium, Netherlands, and/or Germany from 1980 -1990**
  - **Spain, Portugal, Turkey, Italy, and/or Greece from 1980 -1996**

**From 1980 to the present did you spend time that adds up to 5 years or more in Europe?**

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- If the donor answers “YES,” verify that the donor was in countries at risk for vCJD, and if so defer the donor indefinitely.**
- There is no acceptable criteria for a donor who has spent 5 or more years in Europe from 1980 to the present.**

From 1980 to the present did you receive a blood transfusion in the United Kingdom or France?

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- If the donor answers “YES,” defer the donor indefinitely due to risk of vCJD.
- There is no acceptable criteria for someone who has received a blood (RBCs, platelets, plasma, cryoprecipitate, or granulocytes) transfusion in the UK or France from 1980 to the present.

## Male Donors: In the past 12 months, have you had sexual contact with another male?

- **Change from lifetime deferral to one year deferral made in 2016.**
- **If the donor answers “YES,” defer the donor until year is expired due to risk of HIV (and other known and unknown viruses).**
- **Next steps - continue to assess more individual risk assessment.**

# Have you ever had Babesiosis?

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- **If the donor answers “YES,” permanently defer the donor.**
  - **There is no acceptable criteria for a donor who has had Babesiosis.**
  - **Babesiosis can and has been transmitted by transfusion.**
  - **We test all of our red blood cell collections for babesia microti antibody (avg reactive rate is 0.6%)**
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# Donation Criteria for Homologous Apheresis Platelet Collections

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- Need to meet usual allogeneic blood donation requirements
- A platelet count recommended before the first donation. If not possible pre-donation sample must be evaluated after the donation. The donor's platelet count must be above 150/ $\mu$ l before subsequent plateletapheresis occurs
  - Can use a count from the previous collection to qualify donors
- No Asa 2 days, Plavix or Ticlid 14 days



# Donation Criteria for Homologous Apheresis Platelet Collections (cont'd)

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- no more than 24 Platelet, apheresis collections in a rolling 12-month period.
- the interval between each collection of Platelets, apheresis should be at least two days with no more than two procedures in a 7-day period.
- the interval between collection of a double or triple Platelets, apheresis and any subsequent collection of Platelets, apheresis should be at least 7 days.

# Donation Criteria for Apheresis Plasma Donations

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- **Need to meet usual allogeneic blood donation requirements**
- **Occasional plasma donors**
  - The donor must not have donated more than 12 liters in a rolling 12 months (14.4 liters if the donor weighs >175 lbs)
- **Frequent plasma donors**
  - Donation is more frequent than every 4 weeks
  - RBC loss must not exceed 25ml per week
  - At least 48 hours between successive procedures, and no more than 2 procedures within 7 days
  - Serum or plasma must be tested for total protein and serum protein electrophoresis or quantitative immunoglobulins. Results must be normal.

**Thank you!**

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