

# Qualifying HPC Donors for Unrelated Bone Marrow Transplantation

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# Objectives

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The learner will be able to:

- Define donor eligibility and suitability.
- Identify agencies/regulatory documents governing stem cell donation criteria in the United States.
- Describe three criteria that are specific to peripheral blood stem cell donors.

# Outline

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## Allogeneic, unrelated donors

- Definitions
- Governing Regulations
- Stem Cell Donor Criteria
- Exceptions to Eligibility
- Summary
- Q & A



# Definitions

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- Eligibility – a determination whether a potential allogeneic cellular therapy donor meets all donor screening and testing requirements related to transmission of infectious disease as defined by applicable laws and regulations.\*
- Suitability – the medical fitness of a potential allogeneic cellular therapy donor to proceed to donation, based on established criteria relative to medical risk associated with donation, as determined by medical evaluation and physician judgment.

\*National Marrow Donor Program 23<sup>rd</sup> Edition Standards and Glossary



# Governing Regulations

## BLOOD DONOR

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- CFR – 600 and 800 Series
- Multiple FDA guidance documents
- AABB Standards for Blood Banks and Transfusion Services
- State and local regulations

## STEM CELL DONOR

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- CFR – 1270 Series
- FDA guidance document – *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*
- AABB Standards for Cellular Therapy
- FACT-JACIE International Standards for Cell Therapy
- NMDP Standards



# Governing Regulations, cont.

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- Feb. 2016 FDA guidance document on management of Zika risk
- March 2016 - *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products*

# Stem Cell Donor Criteria

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- Physical exam
  - **Weight of 110**
  - Acceptable BP and pulse
  - **Temp  $\leq 99.5$**
  - **Hgb  $\geq 12.5$**
  - **Plt  $\geq 150,000$**



## Stem Cell Donor Criteria, cont.

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- Travel history – risk of malaria, CJD
- HIV/AIDS risk
- Hepatitis risk
- History of diseases including cancer, heart, lung, babesiosis, Chagas, syphilis, gonorrhea and bleeding disorders
- History of previous transfusion, transplant or graft
- Medication history
- History of tattoos or piercings
- Pregnancy status, if applicable



# Stem Cell Donor Criteria, cont.

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- Similar questions plus:
  - Hospitalizations
  - Anesthesia problems
  - Pregnancy in 6 month window period
  - Back and neck problems
  - Head injuries
  - West Nile Virus history
- Time frame for evaluating conditions tends to be longer



# Stem Cell Donor Criteria, cont.

- Testing – within 30 days of donation and repeated on the day of donation
  - HBsAG
  - Anti-HBc
  - HBV NAT
  - HCV NAT
  - Anti-HCV
  - Antibody to HIV types 1, 2, and group O (HIV)
  - HIV NAT
  - Anti-HTLV-1/2
  - CMV
  - Syphilis
- Antibody to T. cruzi (Chagas) – only done once
- HLA typing
- WNV



# Additional Criteria for Stem Cell Donors

- Evaluation by a physician to include complete medical history and physical exam:
  - Height and weight
  - Vital signs
  - Medication history
  - Health history including pregnancy assessment, previous deferrals, contraindications to marrow or apheresis donation, or any potential for increased risk of anesthesia
  - Physical evidence or risk of communicable diseases (e.g. dementia – indicative of CJD, generalized fever or rash – indicative of sepsis or systemic infection, etc.)
  - GU focus looking for physical evidence of infection if donor reports any high-risk behavior



# Additional Criteria for Stem Cell Donors, cont.

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- Extensive donor testing
  - Chest x-ray
  - Urinalysis
  - Electrocardiogram



# Additional Criteria for Stem Cell Donors, cont.

- Lab testing

Hematology	Chemistries
Hgb/Hct	Electrolytes
Plt	BUN and Cr
CBC with diff	ALT, AST
ABO and Rh	Alkaline Phosphatase
Screening for Hgb S	LDH
Antibody screen	Glucose
	Total serum protein plus albumin or electrophoresis



# Additional Criteria for Stem Cell Donors, cont.

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- ◉ Non-medical factors

- Current living situation
- Recent stressors in his/her life
- Situational factors such as recent legal problems, family crisis, language barriers, financial problems, etc.
- Indicators of possible psychological issues
  - Slow speech or movements
  - Forgetfulness or difficulty with comprehension
  - Anxiety/panic attacks
  - Previous suicide attempts



# Additional Criteria for Stem Cell Donors, cont.

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- Specific psychological disorders

- Schizophrenia
- Mental retardation
- Dementia
- Depression
- Substance abuse
- Eating disorders
- Personality disorders



# Additional Criteria for Stem Cell Donors, cont.

- Criteria specific to peripheral blood stem cell donors
  - Current treatment with lithium
  - Presence of sickle cell disease (HgbS)
  - History of head injury or concussions\*
  - Current pregnancy/breastfeeding (contraindication for filgrastim)
  - Sensitivity to filgrastim or E. coli-derived products
  - History of autoimmune disorders
  - History of DVT or pulmonary embolism
  - History of iritis or episcleritis
  - Plt count < 150 at time of baseline assessment
    - Mild thrombocytopenia defined as Plt 130-149
    - Defer if < 130



# Differences in Criteria for Stem Cell Donors

- ◉ Question 7 and 8 re. pregnancy
  - Likely in the next 6 months?
  - # of pregnancies - used by transplant center for donor selection
- ◉ Questions 4, 12 and 13 re. hospitalizations and experience with anesthesia
- ◉ Question 15 re. back, neck, hip or spine problems
- ◉ Question 25 addresses “other conditions” and includes an assessment for head injuries



# Differences in Criteria for Stem Cell Donors, cont.

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- Questions 26 and 27 re. West Nile Virus
- Question 32 re. CNS diseases or dementia with unknown causes
- Questions 52 and 53 re. MSM risks
- Questions 56 and 57 re. travel or residence in African countries



# Exceptions to Eligibility

- Exceptions to specific criteria for individual donors are allowed under certain circumstances by NMDP, AABB, FACT, and FDA
- Decision of what will be allowed is dependent on what the criteria is and what the risk is to the donor and/or recipient
- Donor must be notified of clinically significant abnormal findings
- DC and AC MDs determine if findings constitute unacceptable risk for donor and if donor donates, the finding is reported to NMDP
- TC MD determines if abnormal finding poses unacceptable risk to recipient, and approves in writing (recipient is also notified and counseled)



# Exceptions to Eligibility, cont.

- Specific labeling requirements apply when
  - Donor testing/screening is not performed - **NOT EVALUATED FOR INFECTIOUS SUBSTANCES**
  - Donor testing/screening is incomplete or donor presents with risk factors/clinical evidence - **WARNING: Advise recipient of communicable disease risks and NOT EVALUATED FOR INFECTIOUS SUBSTANCES**
  - Donor testing/screening is abnormal – **WARNING: Reactive test results for (name of disease agent or disease)**



# Resources

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- CFR - 1270
- AABB Standards for Cellular Therapy, 6<sup>th</sup> Edition
- FDA – Guidance for Industry *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*. August 2007
- FACT-JACIE International Standards for Cellular Therapy – Product Collection, Processing and Administration, Fifth Edition
- WMDA Standards
- WMDA Donor Medical Suitability Recommendations



# Resources

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## ● NMDP

- National Marrow Donor Program 22<sup>nd</sup> Edition Standards and Glossary
- F00280 – Donor Health History Screening Questionnaire
- A00329 – Rationale and Action Guide for Health History Questionnaire at HR/CT/WU
- A00262 – Assessment Tool at HR/CT/WU
- A00328 – Assessing Non-Medical Factors Affecting Donor Suitability
- A00220 – Physical Assessment Requirements for Marrow and Peripheral Blood Stem Cell Donors
- F00806 – Addendum to Physical Examination
- A00560 – Rational and Action Guide: Zika Virus Infection Assessment



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Sincere thanks to

- National Marrow Donor Program/Be the Match

Questions?