

# **The National Marrow Donor Program Research Sample Repository: A Resource in Jeopardy**

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# **NMDP: The world's largest network facilitating unrelated donor hematopoietic cell (HC) transplantation**

- 1 Coordinating Center, Minneapolis**
- 143 Transplant centers (109 U.S.)**
  - 91 Donor centers (85 U.S.)**
- 109 Marrow collection centers (92 U.S.)**
- 87 Apheresis collection centers**
- 12 Cord Blood Banks**
- 21 HLA typing laboratories**
  - 3 DNA repositories for HLA typing**
  - 1 Research Sample Repository**

# Research Sample Repository

- **Each donor and recipient is invited to participate**
- **NMDP has assumed responsibility for donor consents, but charged transplant centers with responsibility for recipient consents**

**7,296 Paired donor-recipient participants**

**2,268/1,356 unpaired donors/recipients**

**203,961 White blood cell samples**

**109,911 EBV-transformed cell line samples**

**37,497 Serum samples**

# Consent Problems with Recipient Samples were Identified

- **Feb 2002:** Transplant Center consent issues surface
- **March:** Creation of a corrective action plan (CAP) was initiated
- **May:** NMDP instructed TCs to stop all submissions if consent processes were non-compliant
- **May:** All submissions of NMDP research papers and abstracts were halted

# Corrective Action Plan: Development

- **July:** Process changes were implemented to prevent a recurrence
- **August:** Transplant centers were provided with new protocols and consent forms approved by NMDP IRB
- **July – October:** Refined the corrective action plan with input from “everyone”

# **Corrective Action Plan: Implementation**

- **October – Present:** Preparing packages and address lists
- **November:** CAP approved by the NMDP IRB
- **November:** CAP approved by OHRP
- **First mailings began in December**

# **Corrective Action Plan: Elements**

- **All living recipients transplanted prior to May 1, 2002 will be contacted by NMDP**
- **Packets sent by Federal Express – three waves of mailings**
- **Packets contain -**
  - **Cover letter from transplant center**
  - **Explanatory letter from NMDP**
  - **Question and Answer Sheet**
  - **Consent Forms (Assent forms, if applicable)**
  - **Postage paid return envelope**
- **Packets reviewed by transplant recipients**

# **Corrective Action Plan: Elements, cont.**

- **Recipients asked to return consent indicating their decision to participate/ not participate in NMDP research**
- **NMDP IRB will be asked to consider a waiver of consent for those recipients who can't be contacted after three attempts**
- **TC will receive copies of the returned consent forms for their files**



# **Corrective Action Plan: Current Status**

- **Total packages mailed: 1,627**
- **Response rate from December: 78%**
  - Third wave went out February 12
- **“Yes” Consent rate: 92%**
- **“No” Consent rate: 1.2%**
- **Incomplete forms: 6.8%**

# **Corrective Action Plan: Issues in Implementation**

- Bad addresses create major problems**
- Return mail has been unpredictable**
- Translations are difficult and costly**
- International issues have yet to be resolved**
- Many problems can only be resolved through direct one-on-one discussions**