Notice of Action

Date: July 09, 2020 **Study Number:** IRB-2002-0063

Meeting Date: Expedited Review 45 CFR 46.110 Minor Changes in Previously Approved Research

Principal Investigator: Doug Rizzo

Study Title: *Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries*

Protocol Version:

Number of participants approved: Unlimited

TYPE OF REVIEW:
AMENDMENT. Documents reviewed are listed below:

- 2019 07 16 Database CMS STUDIES Adult Parent Consent v5.0.doc (Consent Form)
- 2019 07 16 Database DONOR Adult Unrelated Consent v17.0.doc (Consent Form)
- 2019 07 16 Database MARROW TOXIC INJURY Adult Parent Consent v14.0.doc (Consent Form)
- 2019 07 16 Database RECIPIENT Allo Adult Parent Consent v17.0.doc (Consent Form)
- 2019 07 16 Database RECIPIENT Allo Auto Assent 12-17 v13.0.doc (Consent Form)
- 2020 07 02 Database Record of Revisions_REDLINED.doc (Misc/Other)
- F00188 - Database RECIPIENT Allo Adult Parent Consent (Rev 18) [CLEAN].docx (Consent Form)
- F00188 - Database RECIPIENT Allo Adult Parent Consent (Rev 18) [REDLINED].docx (Consent Form)
- F00444 - Database DONOR Adult Unrelated Consent (Rev 18) [CLEAN].docx (Consent Form)
- F00444 - Database DONOR Adult Unrelated Consent (Rev 18) [REDLINED].docx (Consent Form)
- F00445 - Database MARROW TOXIC INJURY Adult Parent Consent (Rev 15) [CLEAN].docx (Consent Form)
- F00445 - Database MARROW TOXIC INJURY Adult Parent Consent (Rev 15) [REDLINED].docx (Consent Form)
- F00578 - Database RECIPIENT Auto Adult Parent Consent (Rev 15) [CLEAN].docx (Consent Form)
- F00578 - Database RECIPIENT Auto Adult Parent Consent (Rev 15) [REDLINED].docx (Consent Form)
- F01049 - Database CMS STUDIES Adult Parent Consent (Rev 6) [CLEAN].docx (Consent Form)
- F01049 - Database CMS STUDIES Adult Parent Consent (Rev 6) [REDLINED].docx (Consent Form)

Notice of Action

STATUS:
APPROVED

Amendment Approved as of: July 09, 2020

- All projects must be reviewed for continuation of work. No modification may be made in the protocol or in the wording of the IRB approved consent(s) without the prior approval of the IRB.
- For donors not covered by the NMDP IRB, additional IRB approval from participating donor centers will be required.
- Donor/recipient consent forms are attached, if applicable.
- The Principal Investigator is responsible for reviewing the information in the email that accompanies this Notice of Action.

Reconsent (if applicable)**:** The NMDP IRB determined that re-consent of study subjects is NOT required.

Authorized signature:

Electronically signed by Brian Lindberg, J.D. on 7/10/2020 7:20:21 AM