Notice of Action

Date: June 06, 2022 **Study Number:** IRB-2002-0063

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

Principal Investigator: Patricia Steinert, PhD

Relying Institution: MASTER

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

Protocol Version: Research Database June 2022 version 9.1

Number of participants approved: Unlimited

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

- 2022 06 27 Database Record of Revisions.doc (Misc/Other)
- 2022 06 27 Research Database Protocol v9.1_Clean.doc (Protocol)
- 2022 06 27 Research Database Protocol v9.1_Redlines.doc (Protocol)
- CITI Completion Certificate.5.4.2022.steinert.pdf (Human Subjects Protection Training)
- CURRICULUM VITAE.STEINERT PATRICIA.March.2022..pdf (Curriculum Vitae)
- Database Adult Unrelated Donor Research Consent Form v20_CLEAN.docx (Consent Form)
- Database Adult Unrelated Donor Research Consent Form v20_Redlines.docx (Consent Form)
- Database CMS STUDIES Adult Parent Consent v8_CLEAN.docx (Consent Form)
- Database CMS STUDIES Adult Parent Consent v8_Redlines.docx (Consent Form)
- Database MARROW TOXIC INJURY Adult Parent Consent v17_CLEAN.docx (Consent Form)
- Database MARROW TOXIC INJURY Adult Parent Consent v17_Redlines.docx (Consent Form)
- Database RECIPIENT Allo Adult Parent Consent v20_CLEAN.docx (Consent Form)
- Database RECIPIENT Allo Adult Parent Consent v20_Redlines.docx (Consent Form)
- Database RECIPIENT Auto Adult Parent Consent v17_CLEAN.docx (Consent Form)
- Database RECIPIENT Auto Adult Parent Consent v17_Redlines.docx (Consent Form)

STATUS:
APPROVED

Notice of Action

Amendment Approved as of: June 03, 2022

- 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.
- If NMDP donors are research subjects on the study, additional IRB/Ethics Review approval from international donor centers may be required.
- NMDP IRB-approved 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 Meggan McCann on 06/07/2022 1:01 PM ET