



June 27, 2022

To: Transplant Center Medical Directors, Data Managers, and PIs

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Subject: Amendment to CIBMTR Research Database Protocol

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### **Protocol Amendment: Version 9.1**

Due to a change in the Overall Principal Investigator, the Protocol and Consent documents associated with the *Protocol for a Research Database for Hematopoietic Cell Transplantation, and Other Cellular therapies and Marrow Toxic Injuries*, have been amended and were approved by the NMDP IRB on June 3, 2022. The effective date in MasterControl for this protocol amendment and corresponding consent documents is today, June 27, 2022. The Protocol document and complete Record of Revisions are available on the CIBMTR website ([CIBMTR Research Database Protocol and Consent Forms](#)).

### **Informed Consent Document Revisions**

The protocol amendment was approved along with revisions to the below Informed Consent Forms. The following documents are available on the CIBMTR [website](#):

- F00444 Donor Adult Unrelated Consent Form, Version 20 (English)
- F00578 Recipient Auto Adult Parent Consent Form, Version 17
- F00188 Recipient Allo Adult Parent Consent Form, Version 20
- F01049 CMS Studies Adult Parent Consent Form, Version 8
- F00445 Marrow Toxic Injury Adult Parent Consent Form, Version 17

### **Summary of Changes**

Below is a summary of changes made to the Protocol Document and Consent Forms. A complete list of changes is available in the Record of Revisions posted on the CIBMTR Website.

- Protocol – Updated title page to remove Dr. Douglas Rizzo as the Overall Study PI and replaced with Dr. Patricia Steinert, PhD.
- All Adult/Parent Consent Forms (Allogeneic Recipient, Auto Recipient, Unrelated Donor, CMS, and Marrow Toxic Injury) – removed Dr. Rizzo as a contact in Section 7.
- All Adult Parent Consent Forms (Allogeneic Recipient, Auto Recipient, Unrelated Donor, CMS, and Marrow Toxic Injury) – Updated version/revision number and copyright year in footer.

## Information for Donor Centers

### *Instructions for Donor Centers That Currently use the NMDP IRB*

- The updated consents are included in the Auto-fillable Information Packet. NMDP/Be The Match Donor Center 001 and donor centers that have an IRB Authorization Agreement with the NMDP IRB should begin using the new consent forms effective immediately. No additional local review or approval is necessary. The NMDP IRB has determined that no re-consent of study participants is needed due to the changes.

### *Instructions for Donor Centers That Currently Use Their Own Local IRB*

- CIBMTR will allow submission of the Protocol and revised consent form at the time of local IRB continuing review, but no later than December 31, 2022. The NMDP IRB has determined that no re-consent of study participants is needed due to the changes.

## Information for Treatment Centers

### *Instructions for Transplant Centers That Currently Use the NMDP IRB*

1. Insert the new revisions into your previously NMDP IRB-approved consent forms using the track changes function. Email your updated redlined consents for review as soon as possible to [DatabaseIRB@nmdp.org](mailto:DatabaseIRB@nmdp.org).
2. Following approval by the Database protocol team, submit the redlined consents with the protocol team's approval email into **IRBManager** for NMDP IRB approval using the *IRB Request for Study Amendment* xForm. The NMDP IRB has determined that no re-consent of study participants is needed due to the changes.

### *Instructions for Transplant Centers That Currently Use Their Own Local IRB*

- CIBMTR will allow submission of the revised Protocol and consent forms at the time of local IRB continuing review or no later than December 31, 2022. The NMDP IRB has determined that no re-consent of study participants is needed due to the changes.

## Questions or Concerns

For questions or concerns regarding the Research Database Protocol or Consent Forms, please contact the Database team at [DatabaseIRB@nmdp.org](mailto:DatabaseIRB@nmdp.org)