Notice of Action

NMDP[SM] Institutional Review Board

IRB Registration: IRB00001253 Assurance: FWA00000441

Date: May 26, 2026 **Study Number:** IRB-2019-0416

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

Principal Investigator: Rachel Cusatis, PhD

Relying Institution: NMDP/CIBMTR

Study Title: *PROTOCOL FOR COLLECTION OF PATIENT REPORTED OUTCOMES (PRO) DATA*

Protocol Version: PRO May 8, 2026/v3.1

Number of participants approved: Unlimited

TYPE OF REVIEW:

AMENDMENT. Documents received are listed below:

- PRO Data Collection_Adult Patient ICF_CMMI_ENGLISH_v2.0-v2.1 TRACKED.docx (Consent Form)
- PRO Data Collection_Adult Patient ICF_ENGLISH_v6.0-v6.1_TRACKED.docx (Consent Form)
- PRO Data Collection_Parent-Guardian ICF_CMMI_ENGLISH_v2.0-v2.1_TRACKED.docx (Consent Form)
- PRO Data Collection_Parent-Guardian ICF_ENGLISH_v1.0-v1.1_TRACKED.docx (Consent Form)
- PRO Protocol Email templates_CMMI Adult_ENGLISH_v3.0-v4.0 TRACKED.docx (Misc/Other)
- PRO Protocol Email templates_CMMI Adult_ENGLISH_v4.0.docx (Misc/Other)
- PRO Protocol Email templates_CMMI Pediatric_ENGLISH_v3.0-v4.0 TRACKED.docx (Misc/Other)
- PRO Protocol Email templates_CMMI Pediatric_ENGLISH_v4.0.docx (Misc/Other)
- PRO Protocol Email templates_Engagement and Retention_All Groups_ENGLISH_v1.0.docx (Misc/Other)
- PRO Protocol Email Templates_Standard Adult_ENGLISH_v5.0-v6.0 TRACKED.docx (Misc/Other)
- PRO Protocol Email Templates_Standard Adult_ENGLISH_v6.0.docx (Misc/Other)
- PRO Protocol Email templates_Standard Pediatric_ENGLISH_v1.0-v2.0 TRACKED.docx (Misc/Other)

- PRO Protocol Email templates_Standard Pediatric_ENGLISH_v2.0.docx (Misc/Other)
- PRO Study_Record of Change Log_Protocol v3.1 and Consent Updates_15May2026.pdf (Misc/Other)
- Protocol for Collection of PRO Data_v3.0-v3.1_Clean.docx (Protocol)
- Protocol for Collection of PRO Data_v3.0-v3.1_TRACKED.docx (Protocol)

STATUS:
APPROVED

Amendment Approved as of: May 23, 2026

- 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 Sunita Nasta MD on 05/27/2026 5:15 PM ET