Notice of Action

Date: August 18, 2023 **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 v3.0, August 2023

Number of participants approved: Unlimited

TYPE OF REVIEW:

AMENDMENT. Documents received are listed below:

- 0416 PRO Data Collection Adult Patient ICF v4.0_CLEAN.docx (Consent Form)
- 0416 PRO Data Collection Adult Patient ICF v4.0_TRACKED.docx (Consent Form)
- Core PRO survey - Adult_English_v3.0_CLEAN.docx (Surveys)
- Core PRO survey - Adult_English_v3.0_TRACKED.docx (Surveys)
- Form-0022 Record of Change Log R03_PRO ICF v3-v4.pdf (Misc/Other)
- Form-0022 Record of Change Log R03_PRO Protocol v2-v3.pdf (Misc/Other)
- Form-0022 Record of Change Log R03_PRO Survey v2-v3.pdf (Misc/Other)
- PRO Protocol Consent Form Electronic screenshots_v4.0.pptx (Consent Form)
- PRO Protocol Survey Electronic screenshots_v3.0.pptx (Surveys)
- Protocol for Collection of PRO Data_v3.0_CLEAN.docx (Protocol)
- Protocol for Collection of PRO Data_v3.0_TRACKED.docx (Protocol)
- Study 0416 pre-consent script (adult recipient)_v4.0 CLEAN.docx (Surveys)
- Study 0416 pre-consent script (adult recipient)_v4.0 TRACKED.docx (Surveys)
- Study 0416 PRO Data Collection_Adult Patient ICF_Verbal-Phone Script v4.0 CLEAN.docx (Surveys)
- Study 0416 PRO Data Collection_Adult Patient ICF_Verbal-Phone Script v4.0 TRACKED.docx (Surveys)
- Study 0416 PRO ICF and first survey cover letter (adult recipient ENGLISH)_v4.0 CLEAN.docx (Surveys)
- Study 0416 PRO ICF and first survey cover letter (adult recipient ENGLISH)_v4.0 TRACKED.docx (Surveys)
- Study 0416 PRO Protocol email templates (adult recipient ENGLISH)_v4.0 CLEAN.docx (Surveys)
- Study 0416 PRO Protocol email templates (adult recipient ENGLISH)_v4.0 TRACKED.docx (Surveys)

Notice of Action

STATUS:
APPROVED

Amendment Approved as of: August 18, 2023

- 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 Margaret L MacMillan MD on 08/18/2023 5:34 PM ET