Consent & You – What It All Means
Tuesday February 2nd, 2021

Presented By:
- Michael Tierney, Clinical Research Specialist
- Justin R. Tucker, Clinical Research Associate
- Allyson Draxler, Data Acquisition Super User
- Deborah Mattila, Manager – Survey Research Group
- Kathleen Kane, Manager – Clinical Site Operations

There are no conflicts of interest to disclose.
Justin R. Tucker

- Clinical Research Associate on the Clinical Data Validation team (previously known as Audit)
- Ensure the accuracy and integrity of submitted research data
- Interim support has included
  - Protocol Coordinator for the Observational Database
  - Human Research Protection Program Specialist under the NMDP IRB
Human Research Subjects in Clinical Research

Presented by:
Justin R. Tucker, Clinical Research Associate II
Michael Tierney, Senior Clinical Research Specialist
Objectives

- Describe informed consent
- Discuss consent requirements
- Describe the purpose of an IRB
- Identify strategies to ensure regulatory compliance
- Locate additional resources
Informed Consent

• “Gatekeeper” to CIBMTR clinical research
• Informed consent is more than a form – it is a process
• Required for most types of human subject research
• Legal rights and ethical treatment must be safeguarded
• Participants must be willing, without undue coercion or influence
Federal Regulations

HHS – 45 CFR Part 46 Subpart A

FDA – 21 CFR 50 & 56

ICH – GCP E6 4.8

Institutional Policy

Sponsor Criteria / Policy

INFORMED CONSENT
Informed Consent Process

Location
Physical health
Emotional state
Psychological competency

Nature of treatment
Alternatives
Benefits
Risks
Opportunity for questions

Informed Consent Process
Informed Consent Document

Voluntary Statement

Lay language

Procedures

Contact Info

Purpose of research

Financial considerations

Confidentiality

Alternatives

Risks

Benefits

Withdrawal

Purpose of research

Informed Consent Document

CRP/DM CONFERENCE 2021 | 8
# Informed Consent Document Continued

<table>
<thead>
<tr>
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<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
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<td>Copy of consent provided?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Additional requirements?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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</table>
Institutional Review Board (IRB)
IRB Composition

• At least five members
  – Qualified
  – Diverse
  – One scientist
  – One non-scientist
  – One non-affiliated member (community representative)

• Governed by:
  – FDA
  – OHRP
  – DON
IRB Responsibilities

“Determine ethical compliance with Federal and State regulations of proposed research involving human research subjects through an objective lens.”

Achieved by:
- Ensuring human research subjects are appropriately protected
- Ensuring only ethical and scientifically valid research is being conducted
- Conducting annual, continuing review of ongoing research to ensure compliance with Federal and State regulations

**Common Rule**
- General requirements of informed consent procedures
- Basic elements must be included
- Additional elements, if required

**Revised Common Rule**
- Updates to general requirements
- Removed annual review for expedited review studies
- Additional elements required for consent process
IRB Review of Research

IRB Decision

Is this investigator qualified?

Is there notable scientific merit to the proposed research?

Do the potential benefits outweigh the potential risks?

Are the rights and welfare of participants protected?

Is subject selection equitable?

Approved with no stipulations

Approved with the following stipulations: X, Y, Z

Not approved due to A, B, and C

Additional information is required to proceed
Michael Tierney

• Senior Clinical Research Specialist on the RCI – BMT clinical operations team
• Coordinates study-related activities and ensures regulatory compliance
• Additionally, serves as the Protocol Coordinator of the Observational Database
Observational Research Database & Research Sample Repository

IRB OVERSIGHTS

NMDP IRB

Local IRB
Types of IRB Submissions (Local IRB)

- Initial submission
- Continuing review
- Amendment/Modification
- Change in study personnel
Types of IRB Submissions (NMDP IRB)

- Initial submission
- Consent/assent changes
- Reportable events
- Updates to the Study-Specific Local Context Worksheet
- Translated study documents
Types of IRB Responses

- Approved
- Approved with Stipulations
- Acknowledged
- Disapproved
- Deferred
Local IRB Sites

Site not following the Revised Common Rule must submit to continuing review yearly.
Lapse in Continuing Review Approval

Site on hold until CR Approval Received
Strategies to Mitigate IRB Expiration of Consenting Documents

Lapse = becomes invalid because it is not used, claimed, or renewed; expired

- Implement strategies to safeguard against IRB expiration
  - Submit CR approval application *early*
  - Track expiration dates. Set reminders 60 days prior to expiration
  - Establish routine review of consenting documents

Questions regarding IRB expiration or consenting policies may be directed to the Database IRB team.
Process for updating consent forms NMDP IRB

• Review & insert consent form updates distributed by NMDP
  – Always use Tracked Changes

• Submit consent forms for review to NMDP study staff
  – DatabaseIRB@nmdp.org
  – RepositoryIRB@nmdp.org

• (once approval is given) Submit consent forms to NMDP IRB with NMDP Study Staff approval letter using the IRB Manager tool.
Process for updating consent forms Local IRB

• Review & insert consent form updates distributed by NMDP
  – Always use Tracked Changes
• Submit consent forms for review to NMDP study staff
  – DatabaseIRB@nmdp.org
  – RepositoryIRB@nmdp.org
• (once approval is given) Submit consent forms to Local IRB
• Send approval letter and submitted consent forms to NMDP study staff
FormsNet3SM – Consent Tool

Reporting Consent to the CIBMTR

Presented by:
Ally Draxler, Data Acquisition Super User
Ally Draxler

- Data Acquisition Super User
- Helps to implement forms and functionality within FormsNet3SM recipient module
Objectives

• Following completion of this presentation, participants will:

1. Understand why consent was removed from the form and captured within a new tool

2. Have knowledge to complete consent within the consent tool in Formsnet3
CIBMTR Consent in FormsNet3SM

• Prior to January 2021
  – Consent was captured on the Pre-TED (F2400) and CTED (F4000)
  – Consent was captured for each infusion, even if there was not a change in consent status

• After January 2021
  – Consent captured within a consent tool
  – Each consent record is captured independent of the number of infusions
  – Recipient contact info form (F2820) is made due from the tool
FN3 Data Reporting

2804: CRID Assignment → Consent Tool → 2814: Indication Form → Indication

Observational Research Database Consent: Yes
Consent for Future Contact: Yes

2400/2402: Pre-TED
4000: CTED

2820: Recipient Contact Information
Expected Outcomes

• Supports capturing consent and contact information before infusion
  – Allows CIBMTR Survey Research Group (SRG) to approach patients for pre-infusion patient-reported (PRO) surveys for clinical research
• Greater flexibility for research projects
• Increases visibility to recipients’ consent status
• Allows for better reporting, tracking and maintenance within CIBMTR
Consent Tool in Formsnet3<sup>SM</sup>

- New page located under the recipient tab
Consent Tool in Formsnet3℠

• After completing the CRID Assignment (F2804), users can proceed to the consent tool from the form processing page.
Consent Tool in Formsnet3SM

- When a recipient is pulled up within the recipient forms page, there is also a link to move between the consent tool and recipient forms.
Content of Consent Tool

Consent Information

CIBMTR Center Number: [Field]
CIBMTR Research ID: [Field]

Consent for Research Database for Hematopoietic Cell Transplantation and Cellular Therapies (NCT01166009)

1. Consent status for submitting research data to CIBMTR
   - Yes (provided permission and signed)
   - No (declined, withdrew, or no response)
   - Not approached

2. Consented to be contacted for future research
   - Yes (provided permission and signed)
   - No (declined, withdrew, or no response)
   - Not applicable (institution not currently participating or local IRB does not allow collection of data)

3. Date consent signed:

4. Date approached:
2820-Recipient Contact Information Form

• This form will come due off the consent tool instead of 2400/4000
• One per recipient
## Consent Grids

- Recipient Information
- Consent Information
- Consent History

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<tr>
<th>CBID</th>
<th>Center</th>
<th>Consent Type</th>
<th>Consent Status</th>
<th>Date of Consent</th>
<th>Data Approac...</th>
<th>Reason not ap...</th>
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<td>2020-12-05</td>
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<td>qatest18</td>
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Adding New Consent

• Reporting a new recipient
• Adding additional consent for an existing recipient
Updating Consent

• Consent can be edited by selecting the edit icon on the necessary consent row
• Users will be required to provide a change reason when making any change to consent
Completing 2400/2402 without consent reported

<table>
<thead>
<tr>
<th>Status</th>
<th>Center</th>
<th>Event</th>
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<tbody>
<tr>
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<td></td>
<td>2020-12-01</td>
<td>2402</td>
<td>Pre-TED</td>
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Consent not yet reported
Transfer Scenarios

• When a recipient transfers centers, reporting consent should follow the new center’s IRB requirements

• A reminder will appear within the transfer emails to let centers know to use the consent tool, if necessary
Locking Consent for Audit

- When a recipient has been selected for audit, consent is also audited.
- Once consent is reviewed for audit, it will be locked in FN3.
- The consent rows that have been locked will appear in orange.
Resources

• Consent Tool Instructions – Data Management Guide
• Consent Tool E-learning
• Frequently Asked Questions Document
How Does CIBMTR Use Research Database Consent?

Clinical Trials and Patient Reported Outcomes (PRO) Studies

Presented By:
Deborah Mattila, Manager – Survey Research Group
In this presentation, we will answer…

• How does Research Database consent relate to clinical trial consent?
• What is the PRO Data Collection protocol?
• What is the consent process for the PRO Data Collection protocol?
How does Research Database consent relate to clinical trial consent?

• Prospective clinical trials have their own consent forms and are independent from the Research Database consent
  – Often clinical trial consents allow for use of CIBMTR data in the clinical trial
  – Clinical trials may require patients to be on the CRF track, bypassing randomization based on Research Database consent.
What is the PRO Data Collection Protocol?

- Companion to Research Database protocol that allows CIBMTR Survey Research Group (SRG) to approach and consent patients for routine collection of PRO survey.
- PRO data are added to the research database and can be used for future observational studies.
- Dr. Bronwen Shaw is the protocol Principal Investigator (PI).
- All operations are managed by SRG.
What is the PRO Data Collection Protocol?

• Core set of PRO domains asked prior to HCT/CT, then at Day 30 (CAR-T only), Day 100, Day 180, Day 365 and annually, thereafter.
  
  – PROMIS domains – Physical Function, Fatigue, Sleep Disturbance, Pain Interference, Anxiety, Depression, Cognitive Function, Ability to Participate in Social Roles and Activities, Sexual Function
  
  – Comprehensive Score for financial Toxicity (COST), Occupational Functioning, Sociodemographics.
What is the PRO Data Collection Protocol?

• Eligibility criteria:
  – Consent to Research Database – with agreement to future contact by CIBMTR
  – Age 18+ (expanding to pediatric in 2021)
  – English-speaking (expanding to Spanish-speakers in 2021)
  – To give time for PRO data collection consent, report of Research Database consent, and completion of contact information must be \( \geq 2 \) weeks pre-infusion (HCT or CT).

• Currently piloting with three centers to work through logistics
  – Reaching out to additional sites in 2021
What is the consent process for the PRO Data Collection protocol?

- Site consents patient to Research Database protocol
- SRG approaches patient for PRO Data Collection protocol

  - Complete consent tool with date of consent and if patient agreed to CIBMTR contact
  - Complete Recipient Contact Info (F2820)
  - Complete Indication Form (F2814) with estimated treatment dates

  - Call to describe protocol
  - Email/mail consent form and baseline PRO survey
  - Track completion and follow-up with non-responders
  - Use planned infusion/planned HCT date on F2814 to know when to start/end contact

- Patient receives HCT or CT

  - Report treatment dates on Pre-TED (F2400) or CTED (F4000)

- Collect post-HCT/CT PRO surveys

  - Use dates from F2400 or F4000 for scheduling
PRO Data Collection team

Group mailbox  PRO-Surveys@nmdp.org

• Deborah Mattila, Survey Research Group Manager
  – dmattila@nmdp.org

• Ada Moreno, Bilingual Survey Research Associate
  – amoreno4@nmdp.org
Any Questions