Outline

• Overview of CIBMTR research protocols
• Local IRB review requirements
• CIBMTR expectations for inviting patients to participate in CIBMTR protocols
• Forms 2400 and 2804 consent questions
• Path for patients who decline consent
• FAQs about consent
CIBMTR Research Protocols

• Research Database
  – Auto and allogeneic related/unrelated patients
  – Patient medical record data used in research
  – Foundational to all CIBMTR research programs

• Research Sample Repository
  – Allogeneic related/unrelated donors and patients
  – Pre-transplant blood sample collected
  – Combine sample analysis data with clinical data
  – Foundational to immunobiology research program
Transplant Center IRB Approval

• NMDP IRB approved protocols posted to CIBMTR website
• Protocols must be submitted to local IRB
  – All centers submit research database
  – Research sample repository dependent on center participation
• Federal regulations require annual IRB review
• Transplant centers submit to their IRB according to local annual review date
• Annually, local IRB approvals / consent forms must be submitted to CIBMTR
CIBMTR Expectations

- Every allogeneic and auto patient should be approached to participate in research database protocol
- Every allogeneic patient and their donor at participating centers should be approached for research sample repository protocol
- Patients and donors who agree to participate must sign the institutional IRB-approved consent form
- In rare circumstances, patients may not be approached at the discretion of transplant center staff
Auto Consent
Form 2804 r4, q. 4

For autologous HCTs where the recipient has not given consent to allow his/her transplant data to be used for research, complete only questions 1 through 18, and 21 (year of birth only), then skip to signature line.

Specify the planned cell source(s) for HCT:

3 Specify HSC source:
   - Autologous
   - Allogeneic, unrelated
   - Allogeneic, related

4 Has the recipient signed an IRB-approved consent form for submitting research data to the NMDP/CIBMTR?
   - Yes (patient consented)
   - No (patient declined) - Complete only questions 1 through 18, and 21 (year of birth only), and 39
   - Not applicable (patient not approached) - Complete only questions 1 through 18, and 21 (year of birth only), and 39
Scenario: Auto Patient Declines

• Answer Form 2804 r4, q. 4 “no”
• Complete questions 1-18, 21 and 39
  – These data allow CIBMTR to determine if “decline” patients are adding bias into the database
• No further forms for patient become due
<table>
<thead>
<tr>
<th>Consent Questions: 63 - 70</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>63</strong> Has the recipient signed an IRB-approved consent form for submitting research data to the NMDP / CIEMTR?</td>
</tr>
<tr>
<td>- Yes (patient consented)</td>
</tr>
<tr>
<td>- No (patient declined)</td>
</tr>
<tr>
<td>- Not approached</td>
</tr>
</tbody>
</table>

| **64** Date form was signed: YYYY-MM-DD |

| **67** Has the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIEMTR? |
| - Yes (patient consented) |
| - No (patient declined)   |
| - Not approached          |
| - Not applicable (center not participating) |

| **68** Date form was signed: YYYY-MM-DD |
Scenario: Allo Patient Declines

- Only TED level forms become due
- Data only used for government reporting / program analysis purposes – never for research
  - Center Specific analysis
  - Center volumes
  - Other non-research program analysis
- Research sample declined, complete Excuse Code form
Scenario: Allo Patient on Clinical Trial Using CIBMTR Data Declines

- On 2400 indicate the trial patient is enrolled on
- Mark “no” consent for database (2400 r4, q. 63)
- CRFs will come due
- Data will be only used for:
  - Clinical trial analysis
  - Non-research reporting purposes
- Once data collection for trial ends, patient will be switched to TED track
Scenario: Auto Patient on Clinical Trial Using CIBMTR Data Declines

- Mark “no” consent for database (2804 r4, q. 63)
- Inform CRC that a 2400 needs to come due
- Mark “no” consent for database (2400 r4, q. 63)
- CRFs will come due
- Data will be only used for clinical trial analysis
- Once data collection for trial ends, all data collection ends
Frequently Asked Questions
Patient Transfers to Another Institution

Question:
When a patient transfers to another institution, does the patient need to sign a database consent form at the new institution?

Answer:
Yes, the new institution’s IRB-approved consent form must be signed.
Patient Has a Subsequent Transplant

**Question:**

If a patient has a subsequent transplant does a new consent form need to be signed?

**Answer:**

- No, if both the first and subsequent transplants are allo transplants.
- No, if the first and subsequent transplants are an auto and an allo and the original consent form included both types of transplants.
Patient Has a Subsequent Transplant

**Answer:**

- No, if the initial transplant procedure included multiple transplants, e.g., an auto followed by a planned allo, (all considered part of the initial transplant package).
- Yes, if an auto transplant is followed by an unplanned allo transplant and the original consent form did not include both transplant types.
Reporting Consent for Subsequent Transplants

**Question:**
How should Form 2400 r4, q. 63 and 64 be completed for a subsequent transplant?

**Answer:**

a. New consent not required: answer “Yes” to q. 63; enter date of original consent in q. 64.

b. New consent required: answer “Yes” to q. 63; enter new consent date in q. 64.
Research Database Consent Signed After Transplant Date

**Question:**
Can the patient sign the research database consent form after the transplant has occurred?

**Answer:**
Yes, because there is no research intervention with the patient. All data submitted are collected as part of the standard medical record.
Research Sample Repository
Consent Signed After Blood Draw

**Question:**
Can the patient sign the research repository consent form after the blood has been drawn?

**Answer:**
- No, the blood draw is a research intervention.
- No research intervention may occur prior to patient consent.
- If blood was drawn before consent was obtained, notify CRC to have sample destroyed.
Expired Consent Form

Question:
Is it acceptable for a patient to sign a consent form that is expired; i.e., not within IRB approval period.

Answer:
• No, patient must sign a consent form that is within the IRB approval period.
• If expired consent form is signed, patient must sign a new consent form within IRB approval period.
Consent Form Contains Blank Fields

Question:
Do all the fields on the consent form need to be completed?

Answer:
• All blanks on consent form must be completed.
• Some IRBs require information not mandated by federal regulations, e.g., signature of witnessing health care professional.
Minor Patient Reaches Age of Majority

Question:
When a minor patient reaches the age of majority must a new consent form be signed for the research database?

Answer:
The CIBMTR relies on a transplant center’s local IRB to make that determination.
Patient Becomes a Vulnerable Subject

**Question:**
If a life event occurs that causes a patient to enter a vulnerable subject category, can data still be submitted, e.g., patient is incarcerated?

**Answer:**
The CIBMTR relies on a transplant center’s local IRB to determine if the patient should be withdrawn from the study or if other steps need to be taken to allow the patient’s continued participation.
Patient Withdraws from Research Database or Sample Repository

**Question:**
What should I do if a patient asks to withdraw from the Research Database or Sample Repository Protocol?

**Answer:**
- Submit error correction to 2400 r4 q. 63 or 67 to change to “no consent.”
- Patient’s data not used for future research.
- Notify CRC; research sample will be destroyed.
Patients at International Centers

**Question:**
Do international centers have to follow the US regulations for consent for reporting research data and submitting research samples?

**Answer:**
No, international centers are required to follow the regulations of their country.