CIBMTR Protocols and Consents

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Outline

- CIMBTR Protocols and Consents
  - Research Database
  - Research Sample Repository
- IRB Approval Process
- Frequently Asked Questions

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CIBMTR Protocols

- **Research Database Protocol**
  - **All allogeneic related and unrelated recipients and autologous recipients are eligible to participate**
  - **Local IRB approval required at all centers**

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CIBMTR Protocols

- **Research Sample Repository Protocol**
  - **All unrelated recipients are eligible to participate**
  - **Related recipients from 7 selected centers are eligible to participate**
  - **Local IRB approval required at all centers performing unrelated transplants**
  - **Related only, auto only centers will not participate in this protocol**

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IRB Approval Process

- Download the protocols, consent forms and NMDP/MCW IRB approval letters at www.cibmtr.org
- Non-substantive changes to consent forms may be made to meet local requirements
- No changes may be made to the protocols
- Submit protocols and consent forms to your local IRB

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IRB Approval Process

- Send a copy of local IRB approval letter and approved consent forms to NMDP Research Administration
- Two months prior to local IRB expiration date, continuing review reminder will be sent from NMDP Research Administration

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Frequently Asked Questions

If my center doesn't have local IRB approval for the Research Database Protocol when the new program is launched can we still submit data?

Yes, data can be submitted under the old NMDP research database protocol and the CIBMTR DUA until local IRB approval is obtained for the new protocol.

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Frequently Asked Questions

My center is a registration only center, we don't submit research level data, do we need to get IRB approval for the Research Database Protocol?

Yes, all centers, registration and research, must obtain IRB approval and approach all recipients for participation in the protocol. This allows the CIBMTR to use TED-level data for research.

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Frequently Asked Questions

The research database protocol includes a consent form for participants with a marrow toxic injury. Does our center need to have this consent form approved by the IRB?

All centers participating in the RITN must have local IRB approval for this consent form. Non-participating centers are encouraged to, but it is not required.

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Frequently Asked Questions

Is our center required to have a separate consent form for legal guardians or can that consent form be combined with the adult recipient consent form?

You may combine the consent form for legal guardians and adult recipients into a single consent form if your local IRB allows you to do so.

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Frequently Asked Questions

Can the consent forms for the Research Database and Research Sample Repository be combined into a single consent form?

Yes, if your local IRB allows you to combine these two research activities into one consent form. The consent form must include checkboxes for the database and research repository so it's clear what the recipient is agreeing to participate in.

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Frequently Asked Questions

Is my center participating in the Related Research Sample Repository?

Related Repository participating centers*:*

- **MD Anderson Cancer Center**
- **City of Hope National Medical Center**
- **H. Lee Moffit Cancer Center and Research**
- **Hackensack University Medical Center**
- **Children's Hospital of Wisconsin**
- **St. Jude Children's Research Hospital**
- **University of Minnesota**

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Frequently Asked Questions

What if a recipient declines to participate in the research database; what data should be submitted?

No consent, allogeneic related or unrelated

- **TED-level data must still be submitted – government requirement; used only for government required reports such as the center-specific analysis**

No consent, autologous

- **Recipient must be registered but no other data are submitted**

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Frequently Asked Questions

When can our center start using the new consent forms?

Centers can start using the new consent forms immediately after they've received local IRB approval. The new consent forms may be used prior to the launch of the SCTOD.

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Additional Questions?

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