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Transplant centers should ask all recipients if they are willing to provide consent to participate in the Observational Database. Those centers participating in the Related Research Sample Repository should also ask all recipients and/or donors if they are willing to provide consent.

## 6.1 United States Transplant Centers – Institutional Review Board (IRB) Approval:

To be compliant with United States Federal Regulations for human research subject protection, transplant centers must obtain IRB-approved informed consent from recipients to allow data submitted to the Observational Database to be used for research studies. All transplant centers must have local IRB approval for the Observational Database Research protocol. This includes all transplant centers participating as *TED only* and *Comprehensive Report Form* centers (see section 3). All transplant centers that are NMDP member centers must also have local IRB approval for the Research Sample Repository protocol. The transplant centers participating in the Related Research Sample Repository will submit research samples on related recipients and their donors in addition to the samples on unrelated donor recipients.

Transplant centers that perform only related donor HSCT and/or autologous HSCT will not submit research samples, and therefore do not need to obtain local IRB approval for the repository protocol.

The NMDP and CIBMTR have written protocols and informed consent documents for the Observational Database and Research Sample Repository. The protocols and consent documents should be downloaded from the CIBMTR website and submitted to the transplant center's local IRB for review and approval. The protocols and consent forms must be submitted to the local IRB as written by the NMDP and CIBMTR; however, the documents may be formatted according to each site's requirements. The Observational Database and Research Sample Repository protocols and consent forms can be obtained from the CIBMTR website at: http://www.cibmtr.org/DataManagement/ProtocolConsent/index.html

Upon obtaining local IRB approval, the NMDP IRB Office must receive a copy of the local IRB's approval letter, approved protocol and informed consent documents. The NMDP IRB Office tracks the IRB approval for the Observational Database and Research Repository protocols at each participating center. Sites will receive a renewal reminder approximately two months in advance of the local continuing review date. Local IRB approval for these protocols must be current at all times. Failure to have current local

IRB approval may impact a center's ability to meet CPI requirements for data and sample submission.

**NOTE:**
Submit IRB approval documents to the CIBMTR Research Administration designee. For contact information, see appendix J.

If the recipient does not consent to participate in the Observational Database, then CIBMTR will not use the recipient's data for research studies. However, the data provided on the TED forms will be used for evaluation of the C.W. Bill Young Cell Transplantation Program, and federally required analysis such as center-specific analysis. This applies to recipients of allogeneic (related and unrelated) HSCT. For autologous recipients who do not consent to participate in research, the CIBMTR requests that the following minimal data be submitted: year of birth, diagnosis, transplant type, and date of transplant. This information will help ensure that the epidemiological integrity of the database is maintained, and does not require provision of any significant health information that could identify the recipient, nor will this information be used in any analysis.

**6.2 International Centers - Institutional Review Board (IRB) Approval:** International transplant centers must follow their country's laws and regulations governing human subjects and privacy protection. The transplant center is responsible for obtaining the necessary institutional review and approval for Observational Database.

If the recipient does not consent to participate in the Observational Database according to the laws and regulations of their country, the CIBMTR requests that the following minimal data be submitted: year of birth, diagnosis, transplant type and date of transplant. This information will help ensure that the epidemiological integrity of the database is maintained, and does not require provision of any significant health information that could identify the recipient, nor will this information be used in any analysis. This applies to recipients of allogeneic (related and unrelated) and autologous HSCT.

**6.3 Observational Database:** When a recipient consents to participate in the Observational Database, their data are contained in the CIBMTR's Observational Database and used for research. The database includes recipient baseline and outcome data for related and unrelated allogeneic transplants from any cell source, and for autologous transplants. Data are also collected on unrelated donors and their donation experiences. The data contained in the database are observational data.

The primary purpose of the Observational Database is to have a comprehensive source of data that can be used to study hematopoietic stem cell transplantation.

Studies in which these data may be used include:

- How well recipients recover from their transplants
- How recovery after transplantation can be improved
- Long-term outcomes after transplantation
- How access to transplantation for different groups of recipients can be improved
- How well donors recover from collection procedures
- The application and success of transplantation in the management of marrow-toxic injuries

**6.4 Research Sample Repository:** The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donor, or cord blood unit. Related allogeneic recipients and/or donors will participate at selected transplant centers.

The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic stem cell transplantation.

Studies in which these data may be used include:

- Improve the understanding of tissue matching for hematopoietic stem cell donors and recipients
- Determine and evaluate the factors that affect transplant outcome
- Study the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types)