

Authorization for collaboration of USIDNET data with that of CIBMTR

USIDNET would like to collaborate the data of individuals with Primary Immune Deficiency Diseases (PIDD's) that are treated by bone marrow or stem cell transplantation, with that of the Center for International Blood and Marrow Transplant Research (CIBMTR). All bone marrow transplant must by law now be reported to a central database held by the Center for International Blood and Marrow Transplant Research (CIBMTR), which is, like the USIDNET Registry, a password-protected database with assigned code numbers rather than patient names. The data collected before transplantation in the USIDNET Registry are important for those doctors who perform the bone marrow /stem transplantation. During and after the stem cell transplantation, the transplant doctors will collect and submit clinical data, laboratory details and the status of the transplant to the CIBMTR Registry. Once the bone marrow transplantation procedure has been completed, patients will be followed by their immunologists to be completely informed about the details of their bone marrow transplantation, the data collected in the CIBMTR- Registry will then be transferred to the USIDNET National Registry.

CIBMTR data is used for approved research projects to determine best practices for transplants. USIDNET has worked with CIBMTR to harmonize data forms so that PID patient data does not have to be completely re-entered if a transplant is performed. If you (your child) have a transplant to treat your PID, would you direct the code numbers of the USIDNET Registry and the CIBMTR Registry to be linked?

Yes

No _____

Consent and Assent Instructions:

Consent: Subjects legal age of consent and older must sign on the subject line below

For subjects under legal age of consent, consent is provided by the Legally Authorized Representative

Assent: Is not required for subjects 12 years and younger

Is required for subjects ages 13 through age of legal consent using the Assent Section below

Subject Name: _____

Print Name

CONSENT SIGNATURE:

Subject: _____

Signature (if no legally authorized representative is used)

Date: _____ Time: _____

Legally Authorized Representative: _____

(when applicable)

Signature

Date: _____ Time: _____

Authority of Subject's Legally Authorized Representative or their Relationship to the Subject

I have explained the nature, purposes, benefits, and risks of participation in the registry to the above subject/legally authorized representative. I have also offered to answer any questions the above subject/legally authorized representative might have with respect to the registry and have fully and completely answered all such questions.

Signature of Principal Investigator/Delegate/Person Conducting Informed Consent Discussion

Print Name of Person Conducting Informed Consent Discussion

Date: _____ Time: _____

ASSENT SIGNATURES, For Subjects Ages 13 through age of legal consent:

Assent:

This research study has been explained to me and I agree to be in this study.

Subject's Signature for Assent: _____

Printed Name of Subject: _____

Date: _____ Time: _____ Age (years): _____

I confirm that I have explained the study to the extent that is compatible with the subject's ability to understand, and that the subject has agreed to be in the study.

Signature of Person Conducting Assent Discussion: _____

Date: _____ Time: _____

Copy of consent form given to research participant on (date) _____ by (initials) _____