This is a reminder to all US HCT centers of the distinct differences between:

1. Participation in the “Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries” (Research Database)
2. Participation in specific sub-studies to support Center for Medicare Services (CMS) Coverage with Evidence Development (CED) requirements.

Patients with indications eligible for CED under CMS eligibility requirements

- Must agree to participate in and sign consent for the individual CED sub-study (Prospective Assessment of Allogeneic Hematopoietic Cell Transplantation in Patients with Medicare Coverage) to receive payment coverage for HCT under Medicare.
- By consenting to participate, these patients’ data are then available for specific studies designed to inform Medicare payer policy as outlined in the study protocol agreed by Medicare.
- Their data is collected using standard Center for International Blood and Marrow Transplant Research® (CIBMTR) data collection forms.
- In order for these patients’ data to also be available for other studies under the Research Database protocol, they must consent separately to the Research Database. CIBMTR is preparing minor revisions to the CMS studies consent form and anticipates making these available to US centers in the next few months.

Consent to participate in an individual CMS CED study

- Should be clearly distinguished from voluntary participation in the Research Database protocol.
- Although CIBMTR requests centers approach all patients to consider participation in the Research Database, patients who participate in a CMS CED study are NOT required to participate in the Research Database protocol.
- Centers are reminded to carefully distinguish consent to participate for a specific CMS CED study from consent to participate in the Research Database when completing the consent fields in FormsNet Consent Tool.

In summary, centers should do the following with regards to the CMS CED sub-studies and Research Database:

Approach all eligible patients to consider participation in both the CMS CED sub-study and Research Database with two separate consent forms.

During the consent discussion, make the following points clear to the patient:
- Participation in the CMS CED sub-study is required for the patient to receive payment coverage for HCT under Medicare.
- By joining the CMS CED sub-study, the patient’s data will be used for studies to inform Medicare payer policy.
- Participation in the Research Database is NOT required for the patient to receive payment coverage for HCT under Medicare.
- By joining the Research Database, the patient’s data may be used for other studies.

Report patient consent status in FormsNet as follows:
- Report consent to the CMS CED sub-study on the CMS Registration Form 2554.
- Report consent to the Research Database in the Consent Tool. This information used to be reported on the Pre-TED Form 2400.

Questions
Questions about CMS CED protocols can be directed to Center Support via CIBMTR Center Support.
Questions related to consent or IRB can be directed to DatabaseIRB@nmdp.org.