Additional Clarification Points around the 10-CMSMDS-1 study

1. Is this a new clinical study?

No. This study is not requesting any additional information, or dictating any sort of treatment for this patient population. CMS has approved the submitted CIBMTR study plan to use the CIBMTR Research Database as a qualifying mechanism to gather data on this patient population while providing a way to provide coverage for the allogeneic transplant.

A copy of the letter from CMS approving the CIBMTR study plan can be found on the study web page [www.cibmtr.org/HCTforMDS](http://www.cibmtr.org/HCTforMDS) under Study Reference Materials.

2. How does my center “get started?”

If your center already participates in the CIBMTR Research Database, you have very little to do to “get started.” All centers will submit a Verification of Participation form. This form can be found on the study web page [www.cibmtr.org/HCTforMDS](http://www.cibmtr.org/HCTforMDS) under Study Reference Materials.

For those centers who agree to participate, your center will become active for this study. This will ensure that all eligible 10-CMSMDS-1 patients will be assigned to the Comprehensive Reporting track. This level of reporting is necessary to capture the data criteria set forth by CMS as qualifying for the CED. This study is using the existing mechanisms of the CIBMTR to collect the required data for these recipients.

After we have received your completed form, and you have agreed to participate, your center will then be ready to enroll patients.

3. Is IRB approval required from my institution for this study?

If your center already participates in the CIBMTR Observational Research database, IRB approval for this study is not required from your Institution. CMS approved the use of the CIBMTR Research Database protocol and consent as a means to collect data for this patient population. There is no separate study protocol or study consent that is associated with the 10-CMSMDS-1 study—therefore there is no need for an amendment or a new protocol to be submitted to the local IRB.

4. Are there any additional steps to enroll a patient?

Around the time that the Form 2400 (Pre-TED) is completed, a patient registration form must also be submitted for each patient and sent to the CIBMTR via fax or email. This form is not included with the Comprehensive Report Forms in Forms Net. It is a separate paper registration form that is being used as a tool to track patient enrollment. It can be found on the study page [www.cibmtr.org/HCTforMDS](http://www.cibmtr.org/HCTforMDS).

Please contact Anne Dircks, at [adircks@nmdp.org](mailto:adircks@nmdp.org) or 612-884-8209 with any study related questions.