CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

When to use the "Not Approached" Option

for the Research Database Consent

CIBMTR expects all transplant centers to approach all patients for the Research Database consent. The "not approached" option should only be used in the rare event when the physician feels it would be in the best interest of the patient not to be consented.

Background Information
CIBMTR provides a protocol and consent forms for the observational research database which centers must submit to their IRB for approval. While there's one protocol, there are two consents- one for allogeneic and one for autologous transplant recipients. CIBMTR and NMDP allow the consent forms to be formatted according to each center's requirements, but requires the protocol to be submitted as written. Some centers have chosen to combine the autologous and allogeneic research database consent into one, which is acceptable.

Tandem Autologous Transplants
Most transplant centers would consider tandem autologous transplants as part of the same treatment plan and would consent the patient prior to the 1st HCT only. If that's the case, the center should report "yes" to the consent question for the 2nd HCT and provide the date when the consent was first obtained.

Tandem Autologous-Allogeneic Transplants
Most transplant centers would consider tandem autologous-allogeneic transplants as part of the same treatment plan and would consent the patient prior to the 1st HCT only. If the center has one IRB approved consent covering both the autologous and allogeneic transplants, then the center should report "yes" to the consent question for the 2nd HCT and provide the date when the consent was first obtained.

In the case where a center has separate research database consents for autologous and allogeneic HCTs, the center should obtain both consents from the patient prior to the 1st HCT. The center should then report "yes" to the consent question for the 2nd HCT & provide the date when the consent was first obtained.

Autologous HCT followed by subsequent autologous HCTs (not a tandem autologous HCT)
In this scenario, CIBMTR does not require an additional consent form to be signed. The only consent required would be the one obtained at the time of the first autologous HCT. The center should report "yes" to the consent question for the subsequent HCT and provide the date when the consent was first obtained. However, a center's IRB may require a second database consent form to be signed in this situation, and centers should refer to the higher standard set by their IRB.

Allogeneic HCT followed by subsequent allogeneic HCTs (not a tandem allogeneic HCT)
In this scenario, CIBMTR does not require an additional consent form to be signed. The only consent needed would be the one obtained at the time of the first allogeneic HCT. The center should report "yes" to the consent question for the subsequent HCT and

provide the date when the consent was first obtained. However, centers must follow their own institutional policy as well, which may require the patient be re-consented to the Research Database for a subsequent HCT.

Autologous HCT followed by subsequent allogeneic HCTs (not a tandem autologous HCT)
If the center has one IRB approved consent form covering both autologous and allogeneic transplants, then the center should report "yes" to the consent question for the 2nd HCT and provide the date when the consent was first obtained.

In the case where a center has separate research database consent forms for autologous and allogeneic HCTs, the patient would need to be re-approached prior to the subsequent allogeneic transplant and asked to sign the appropriate consent form. If the patient was not asked to sign a 2nd consent form, then "not approached" must to be reported on the Pre-TED.

Reminder-
Recipients who transfer to another facility for a subsequent HCT
Any time a recipient transfers to another transplant center, an IRB approved research database consent would need to be obtained at the new center before data could be reported to the CIBMTR.

Sincerely,
CIBMTR Data Operations

Note: This document will be located in the Pre-TED Form 2400 Instruction Manual for future reference.