



March 20, 2020

To: Center Medical Directors, Data Managers, and IRB PIs

From: Bronwen E Shaw, MD PhD
CIBMTR Associate Chief Scientific Director

Subject: **COVID-19 Impact to CIBMTR Network Centers**

On March 16, 2020, a [memo](#) from the CIBMTR was sent to Transplant Centers regarding the potential impact of COVID-19 on CPI requirements. Since that time, the CDC recommendations have evolved for healthcare organizations and communities. Our response to COVID-19 continues to evolve due to the fluid nature of the situation. The following information, processes, and guidelines will be continuously evaluated and updated as needed.

During this historic event, thank you for willingness and capability to be flexible and focused on serving the patient and your transplant center's needs.

- CIBMTR will continue to collect data and reimburse centers during this time.
- FormsNet3 is fully operational, including CIBMTR Center Support (<http://nmdp.service-now.com/csm>) to answer any of your center's questions.

We understand that data, including enrollment (CRID generation) may be sent to CIBMTR at a reduced rate, or not at all, during this pandemic. We also understand that each center will have different capabilities, and that many (if not most) staff are working remotely and have variable access to FormsNet3 and their institutional data. We also know some staff are being directed to perform other tasks.

We ask that if your center is still submitting data, please prioritize the [Transplant Center Specific Analysis](#) (queries, data review, and follow-up), [Consecutive Transplant Audit \(CTA\)](#), and recipients on studies, especially BMT CTN.

The following is being done to lessen the burden on centers, in addition to meeting CDC recommendations.



CPI & CTA

Effective immediately, CIBMTR is **suspending CPI requirements for the trimester ending April 30, 2020** for all product types (Allogeneic Related, Allogeneic Unrelated, Autologous, and Cellular Therapy (CT) infusions).

- Please note, during this time, your center must still have current IRB documents (renewal letters and consents) on file with NMDP
- CTA will be extended by a trimester with a final due date of December 31, 2020.
- It is currently impossible to predict the impact of this situation on future CPI requirements; we will continue to communicate with you as the situation develops.

Consent to CIBMTR Research Database

CIBMTR strongly recommends sites continue to consent patients to the research database, particularly if this can be done by the clinical staff already consenting the patient to their transplant. We believe this is acceptable as there is no impact to the patient of being on the protocol (such as extra visits or lab studies). Even if CRID generation and data submission are delayed, it is important to obtain consent so data can be provided later and be used for research.

- As a reminder, the [Stem Cell Therapeutic and Research Act of 2005](#) *still* requires U.S. transplant centers to submit outcomes data on all allogeneic transplants, both related and unrelated, when either the donor or the recipient resides in the United States, or if the collection or infusion takes place in a U.S. center. However, if the patient does not sign a consent, those data can only be used by the C.W. Bill Young Cell Transplant Program and not for research studies.

Consent to CIBMTR Research Repository

CIBMTR recommends sites continue to consent patients and submit samples, if safe for the patients and clinical staff. CIBMTR is suspending CPI Phase III requirements for the trimester ending April 30, 2020 and will consider all missed samples as excused with no excuse code forms required.

Clinical Data Validation (Audit)

Due to travel restrictions, on-site CIBMTR Data Audits are currently on hold. Any center currently scheduled for an on-site audit March through September 2020 will be contacted by the CIBMTR ahead of their audit to determine if remote access to each center's EMR can be granted in order to conduct the audit remotely. If remote access is not an option, the center's on-site data audit will be rescheduled in FY21. The CIBMTR will also be monitoring the travel restrictions in order to continually reassess the plan for on-site audits resuming as soon as possible.

We will continue to communicate as the situation changes. If you have any questions or need clarification, please contact Eileen Tuschl, Data Operations-Sr. Manager of Customer Service and Education at etuschl@mcw.edu.