



Date

PI's name

PI's address

PI's address

Re: **PRINCIPAL INVESTIGATOR COMMITMENT FOR THE USE OF CIBMTR DATASETS**
CIBMTR request # and title [protocol or proposal must be attached]

Dear Dr. PI's last name:

The Principal Investigator (PI) requirements for use of CIBMTR datasets are outlined below. This signed agreement must be received before data for the referenced protocol/proposal will be released by the CIBMTR Coordinating Center. The data will be provided to you as a de-identified dataset; under no circumstances will the CIBMTR release the key to patient or center identity to you or any other member of the research team. CIBMTR is committed to public use of its data for the advancement of patient care and scientific debate. CIBMTR is also obligated to protect the privacy and confidentiality of human subjects as well as the rights of those who have submitted and assembled the data. We appreciate your support of those commitments.

Before receiving data from the CIBMTR, we require that you:

- **Clearly describe any anticipated proprietary use of the data or the work product that derives from use of the data.** Any proprietary uses of the data will require approval from CIBMTR prior to the release of data. CIBMTR strives to make knowledge derived from its data available for use in the public domain. This relates in part to collection of data through U.S. Governmental financial support and its underlying philosophy of making both data and study results available for the betterment of patients and science.
- **Agree to not sell information derived from the data,** unless express written permission has been received from CIBMTR.
- **Ensure protection of the data.** If accessing the data from a remote location on a time-sharing Network, computer system or LAN with any statistical package, you will not share with any other any other individual(s) any logon name or password provided by CIBMTR.
- **Agree that the data are private and confidential** and that you will have in place and shall maintain administrative, technical, procedural, and physical safeguards sufficient to protect the confidentiality

of the data, including preventing unauthorized access and use.

- **Agree to neither use nor permit others to use or to link the data** other than for the CIBMTR approved project for which it was intended. Prior to implementation of any change in the intended use of the data, a request for change must be submitted to CIBMTR and approved in writing as an amendment to this agreement
- **Agree to not use or permit others to use or to link the data** to identify individuals, or to combine the data with other patient-level information.
- **Agree to not make copies of the data. Agree to neither release nor permit others to release the files or data** therein to any person (including media and subcontractors) except with the written approval of CIBMTR in order to accomplish the study goals.
- **Certify that you are responsible** for ensuring that only staff with a “need to know” shall access the data and that any support staff assigned to this project and having access to these data will likewise follow these provisions.
- **Agree to provide a status report to CIBMTR** one year after delivery of the dataset and annually thereafter, or upon request from the CIBMTR, until the approved use of the data has been completed; this report will describe the status of the project approved for the use of these data.
- **Agree that all data will be destroyed or returned to CIBMTR** as of (provide date): _____ or upon completion of the approved use, whichever comes first; user will certify in writing to the CIBMTR such destruction of all copies, including archival copies of the data.
- **Agree to comply with all applicable laws and regulation with regard to use of the data**, including but not limited to obtaining and maintaining appropriate local IRB oversight consistent with the uses of the data where applicable. Documentation of IRB review (or documentation by the relevant IRB as to why review was deemed unnecessary under applicable regulation) must be provided to CIBMTR prior to release of the dataset to the investigator. Any publication deriving from these data must contain a statement confirming the study was conducted in accordance with all applicable human subjects’ protections laws and regulations.
- **Agree to notify CIBMTR of any change in employment and request from CIBMTR an amended agreement with the new institution before changing the location and responsibility for the data.**

If the intent is for publication and results will include clinical interpretation or conclusions, CIBMTR will require the following:

- All data, a description of the methodology applied, and conclusions resulting from these data must be reviewed and approved by the CIBMTR statistical staff at least 45 days before any presentation, press release, other display or publication to ensure appropriate interpretation of the analysis and compliance with the terms of this agreement.
- All publications or presentations of these data shall acknowledge CIBMTR as a data source.
- All acknowledgements will be reviewed and approved by CIBMTR prior to submission of the publication.
- All publications will include an acknowledgement of CIBMTR grant support.

- A copy of any abstract, publication or presentation of work derived from these data, along with a complete citation, shall be provided to the CIBMTR within 30 days of its presentation or publication.
- In situations in which the investigator has sufficient data and permission from CIBMTR to combine CIBMTR data with data from another group, the investigator agrees to share the final data file and analysis with the CIBMTR Coordinating Center.
- CIBMTR Guidelines for acquiring PubMed Central Numbers (PMCID) must be followed.

If the intent is for publication, CIBMTR is not involved in the statistical analysis and results will not include clinical interpretation, e.g. a purely methodologic study, CIBMTR will require the following:

- All publications or presentations of these data shall acknowledge CIBMTR as a data source and will acknowledge that the findings presented by the author are not the opinion of the CIBMTR or its funding sources.
- All publications will include an acknowledgement of CIBMTR grant support.
- Notification to CIBMTR if the dataset will be posted with the publication and the duration of the dataset posting.
- In situations in which the investigator has sufficient data and permission from CIBMTR to combine CIBMTR data with data from another group, the investigator agrees to share the final data file and analysis with the CIBMTR Coordinating Center.
- CIBMTR Guidelines for acquiring PubMed Central Numbers (PMCID) must be followed

By signing this Letter of Commitment, you agree to the terms as outlined above.

This agreement must be signed by you and an “authorized individual” in your institution. In the United States, an authorized individual is a person who can commit for the institution (often an Associate Dean for Research).

Please return this signed Letter of Commitment by the deadline noted in the accompanying email message (includes co-PIs).

Agreed by:

Signature of Individual Authorized to Execute Date

Signature of Principal Investigator Date

Request Number

PLEASE FAX SIGNED FORM TO CIBMTR MILWAUKEE CAMPUS: 414-805-0714