

Appendix C: Data Use Agreement – for Use of Clinical Looking Glass

MONTEFIORE MEDICAL CENTER DATA USE AGREEMENT - CLINICAL LOOKING GLASS

I have received and reviewed Montefiore Medical Center Protocol JC07.1 Appropriate Use of Clinical Looking Glass (the “Policy”) and agree to abide by its provisions. This Data Use Agreement is subject to the requirements of the Federal Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (“HIPAA”), and I agree to comply with the requirements of HIPAA applicable to the activities contemplated by this Agreement.

1. **Quality Improvement Activities.** Any Quality Improvement work with identifiers using CLG in the privileged mode will be registered with the Director of Performance Improvement prior to my undertaking the data extraction and will be undertaken under the authority of my department chair, service chief, or appropriate Operational Vice President
2. **Research In Privileged Mode.** Research with identifiers (privileged mode in Clinical Looking Glass) will only be undertaken with the express written permission of the Montefiore Medical Center’s Institutional Review Board. My use of such data and identifiers shall be subject to the requirements of the IRB. All analyses undertaken under IRB authority will be identified by me in Clinical Looking Glass with the appropriate IRB number. When not in active use, all datasets with identifiers on non-hospital located computers will be encrypted as described in the protocol.
3. **Operational Activities –** Use of Clinical Looking Glass with identifiers for hospital operational purposes (known in the application as Worklist authorization) are permitted so long as a contemporaneous record of the justification is entered in text form in Clinical Looking Glass for auditing purposes.
No sharing, transmission, or publication of HIPAA privileged data will be made from any extraction performed. This explicitly means that neither date of birth nor any geographic information to the level of aggregation smaller than zip code will be disclosed. No publication of identifiers of practitioners by name or recognizable site of work will be made without written permission of Montefiore’s Medical Director.
4. **Educational Activities -** Use of Clinical Looking Glass in privileged mode is permitted for training as indicated in section 164.501 of title 45, Code of Federal Regulations.

"Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities."

5. **Research in Restricted Mode.**

Preparation for Research – The Einstein-Montefiore IRB has ruled that Clinical Looking Glass may be used in the restricted mode by researchers without requiring IRB permission when the researcher is analyzing data for the sole purpose of determining whether there are enough patients to support a project. This blanket permission is conditioned on the following:

1. *The researcher has taken the University of Miami CITI course in protection of human subjects and has evidence of course completion and has sent the certificate and documentation to the CLG administrator."*
2. *The cohorts of patients have not been identified but remain in their deidentified state. Should the researcher wish to obtain the identifiers, then IRB permission must be sought. **The researchers make no attempt to access any alternative source of information that could allow them to establish the identity of the individual cohort members such as the pathology information system.***
3. *no sharing, transmission, or publication of hipaa privileged data has been made or will be made from any extraction performed. This explicitly means that neither date of birth nor any geographic information to the level of aggregation smaller than zip code has been shared. No text with any pathology account identifier may be shared.*
4. *Beyond establishing a sufficient Number of patients to support an IRB application for research, no actual research will be performed without IRB permission.*

Research in the restricted mode requires IRB approval with Waiver of patient consent. The CLG user must appear as Principle Investigator or Key Personnel in the IRB proposal.

I understand that I may use CLG in the restricted mode for educational purposes (training of clinicians and administrators), Quality Improvement, and for Operational studies.

I understand that a limited dataset under HIPAA does not include any of the following elements:

- Names;
- Postal address information, other than town or city, State and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; or
- Full face photographic images and any comparable images.

I also understand that using CLG in the restricted mode when my privileges do not include the privileged mode I commit myself to the following.

- A. The cohorts of patients will not be identified and will remain in their de-identified state. Should I wish to obtain the identifiers, then IRB permission will be sought.
- B. No attempt will be made to reverse engineer identifiers from other datasets available to me without IRB approval. I will not identify or contact the individuals outputted in the restricted mode.
- C. The Limited Data Sets will be encrypted when stored on non-hospital located computer disks when not in use as described in the Policy (Appendix B).
- D. For all data stored on non-hospital located computers, I commit to destroy all copies of data extracts either by media destruction or by secure deletion (overwriting the file 6 times) when I no longer have use for the Limited Data Set or in one year's time, whichever comes first.
- E. Prior to using CLG in restricted mode for research, I commit myself to completing the University of Miami CITI Internet course in protection of human subjects and will have (and provide to Montefiore upon request) evidence of course completion.
- F. I agree not to obtain, use, or disclose any PHI prohibited in the Limited Data. I further agree not to use or disclose the Limited Data Set other than as permitted or required by this Agreement or as Required by Law. Without limiting the foregoing sentence, I will not use or disclose the Limited Data Set in any manner that would violate the requirements of the HIPAA regulations if done by Montefiore.
- G. Use or disclosure of a limited data set is limited to Montefiore employees with a legitimate need to use or disclose the limited data set under the provisions of the IRB or Montefiore's policies and procedures. Examples include: Education, Operations, and IRB permitted use.

- H. I agree to ensure that any agent, to whom I provide the Limited Data Set, agrees to the same restrictions and conditions that apply through this Data Use Agreement to me with respect to such information.
- I. I agree to use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided for in this Agreement.
- J. I agree to report to Montefiore HIPAA security Officer any use or disclosure of the Limited Data Set not provided for by this Agreement of which I become aware.

Print User Name: _____ Signature: _____

User's Montefiore title: _____

If not Montefiore employee state status -student/medical student _____

User's Montefiore Department: _____

If not Montefiore Employee state institution and address: _____

Name/Title of user's supervisor (*Faculty Research Mentor*) _____

User's Email Address: _____

Supervisor's email address: _____ Date: _____

If, Fellow/ Resident/ Medical Student Date of Graduation: _____

If not Montefiore employee state date when use is no longer necessary: _____

For Researchers whose only access to CLG is in the Restricted Mode for work preparatory for research or for Medical Students

Have you completed the Citi Course? _____ YES

Have you sent the Citi Course Certificate to the CLG Admin? _____ YES

SCAN AND EMAIL THIS PAGE ONLY

Email to ITServiceDesk@Montefiore.org

Revised: 2/25/15