Montefiore

MONTEFIORE MEDICAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: APPROPRIATE USE OF CLINICAL LOOKING GLASS		NUMBER: JC07.1
OWNER: MANAGEMENT INFORMATION SERVICES		
EFFECTIVE: 10/03	REVIEW/ REVISED: 03/14	SUPERSEDES: 01/13
CROSS-REFERENCE: Administrative Policy and Procedure JC07.1a - Practical Guidance in the Use of Clinical Looking Glass		

Purpose:

To protect patient privacy while assisting clinical managers to evaluate quality of care. See also JC07.1a Practical Guidance in the Use of Clinical Looking Glass

Scope:

All end users of the clinical decision support application Clinical Looking Glass (CLG)

Preamble:

Clinical Looking Glass is a powerful software program created by the Department of Outcomes Analysis and Decision Support at the Montefiore Medical Center supporting both quality improvement efforts and Institutional Review Board (IRB) approved research. Data from operational systems (e.g., CareCast, Eagle, MOC, and MOT) are extracted and sent to the CLG database to be used for interactive analysis by CLG end users.

Supervisory Group - CLG Decision Support Group

The CLG Decision Support Group is the supervisory group for the use of CLG in the Montefiore Medical Center. Chaired by the CLG Program Director, membership includes: A senior member of the Montefiore/Einstein Institutional Review Board, Chairman of Performance Improvement, Senior Member of Hospital Bioethics, Director of Employee Health, Montefiore HIPAA security officer, Senior Representative of IT security, and Director of Decision Support.

The CLG Decision Support group will meet twice annually and ad hoc as needed and called in to session by its Chair – the CLG Program Director. The CLG Review Committee will set policy and is empowered to request audits of users.

Modes of CLG Operation

CLG operates in two modes - Restricted and Privileged. In the **Restricted mode**, names and medical record numbers of patients are hidden from the user. In the **Privileged mode**, names and medical record numbers are visible to support chart review of the medical record.

Data Content for CLG Access Modes

1. ***Restricted Access:*** Access is provided to all analytics but output is produced without names or medical record numbers. Output Data might include:

    1. dates of service
    2. Dates of birth
    3. location mapped to census block group (average 500-1500 people) or to longitude and latitude
    4. pathology identifiers numbers that can only be mapped to identifiers for those with access permission to the hospital computerized pathology system which does contains patient identifiers.
    5. Text of lab tests and pathology tests scrubbed of patient's name and medical record number

2. ***Privileged Access:*** Output can include patient identifiers: names, addresses, and telephone numbers. Social Security Number is not visible to user.

Types of CLG Use

Quality Improvement (QA) –

Projects registered with the Chairman of Quality Improvement for the purpose of evaluating the quality of care provided in the institution.

The following principles define a project as **quality improvement** not requiring IRB review.

All seven principles must be operative.

1. The study is observational in character and there is no assignment of therapy or intervention under protocol control.
2. The study must be explicitly directed to answer a question for the immediate improvement of care rendered in our system.
3. The project is undertaken with the explicit consent of the department chair, service line chief, or administrative supervisor.
4. The department or service line undertaking this work should consider in advance of the study the planned interventions based on the range of reasonable findings that might be made.
5. Once the study is completed and findings made, the department or service line should be guided by the findings in its remediation plans.
6. Follow-up surveillance is planned and undertaken, if appropriate.
7. At initiation, the study is registered with the Chair of Quality improvement

http://intranet/websitefiles/mmcintranet25168/aspapps/qmapp/login_new.asp

or the path in the Montefiore website to get there is:

Intranet > Administrative Departments > Network Performance Group > Register PI Projects

Worklist

Creation of follow up lists for immediate patient care for clinicians or administrators charged with the responsibility to render such care. An example might be the creation of a diabetes follow up list in a clinic supporting a medical home model.

Preparation for Research

Analyses performed in the Restricted mode of CLG to determine whether there are enough patients to justify a formal request of the IRB for the performance of an IRB approved research project.

Permission to use CLG in preparation for research is conditioned upon:

1. *The researcher has taken the University of Miami CITI course in protection of human subjects and has evidence of course completion.* http://www.citiprogram.org.

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 for the purpose of establishing 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 will be shared. No text with any pathology 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

Analyses undertaken in either the Restricted or Privileged mode to create generalizable knowledge for use other than Quality Improvements efforts in the institution. Research performed either in the restricted or privileged mode requires IRB approval.
Research performed in the privileged mode requires IRB approval with waiver of patient consent. The CLG user should appear as Principle Investigator or Key Personnel in the IRB submission.

Class of Users

- **Permanent Class** – Non-trainee Employees whose termination is under the surveillance of the Information Technology (IT) department
- **Non-Permanent Class**
    - Those under IT termination surveillance but have a defined limited tenure at the institution
        - Residents or Fellows
    - Those not under IT termination surveillance (examples include)

- Faculty from the Albert Einstein College of Medicine who are not Montefiore employees.
- Medical Students

Permanent Class users are maintained as users for the duration of their employment at Montefiore without need for annual renewal.

Non-Permanent Class Users – must have their privileges renewed annually.

Types of Users

1. Clinicians who are non-trainee employees such as attending physicians, Nurses, Physicians Assistants who manage patient care.

2. Clinicians-in-training:
    a. Fellows
    b. Residents
    c. Medical Students

3. Administrative users:
    a. Analysts who support:
        i. Quality Improvement – e.g. medical health advocates
        ii. Healthcare Operations
        iii. Business Operations

4. Researchers

Procedure for Enrollment as a user:

An individual eligible for Permanent Class CLG user status must:

1. Review
    a. this policy: JC07.1 Appropriate Use of CLG
    b. JC07.1a Practical Guidance in the Use of CLG

2. Submit the following documents to the CLG Administrator by sending an email (with attachments) to ITServicedesk@montefiore.org Subject heading: *"CLG Registration Forms."*

    a. Signed Data Use Agreement (Appendix C)
    b. Supervisory Permission Form for Use of CLG (Appendix D)

Additional Instructions for Specific Non-Permanent Class CLG users

3. Faculty Not employed at Montefiore
    a. Primary Supervisor is their department Chair
    b. Require an email authorization from Assistant Dean of Clinical Research at Montefiore Medical Center:
    Dr. Brian Currie, 2013 incumbent
    Tel: (718) 920-6078
    Email: Bcurrie@montefiore.org

4. Resident / Fellow (as part of departmental qi training activity)
    a. Training Supevisor's Permission form – for Use of Clinical Looking Glass in the privileged Mode for QI project (Appendix E) can be used for the group of residents or fellows in lieu of individual supervisory permission forms. However, each resident/fellow must submit an individual signed data use agreement (Appendix C)

5. Medical Student
    a. Primary Supervisor is their Attending Physician
    b. Duration of Access explicitly noted on data use agreement
    c. Medical Students are expected to complete University of Miami's internet course in Responsible Research (Appendix B) and provide documentation of same.

6. Medical Home Advocate
   Definition: Medical Home advocates are administrative personnel given access to Smart Reports in CLG for the purpose of producing work lists for clinicians in the direct delivery of medical care.

    a. Enrollment may be done with Appendix F : Director's Permission Form – for Use of Clinical Looking Glass by Medical Home Advocates (Appendix F).
    b. Data Use Agreement for Medical Home Advocates for Use of CLG (Appendix G).

Internet Use of Clinical Looking Glass

Clinical Looking Glass can be accessed through a secure https connection through the internet.

However, such use requires special permission as well as common sense precautions

While accessing privileged patient information a high standard of care must be exercised:

1. Unauthorized individuals should not be present as the analyses are being performed.

2. When the computer is left unsupervised access to Clinical Looking Glass should be terminated.

3. All intermediate databases, excel spreadsheets, pdf and other privileged output of CLG must be maintained in an encrypted folder whose password is known only to the authorized user. The user must prove his capability to encrypt and decrypt files by sending a file encrypted with file warden 3 (or similar program) to the Clinical Looking Glass administrator with the password to decrypt.

4. The user is required to have on his home computer (1) a licensed and active **antivirus** and (2) **firewall** software. The licensed antivirus program must be kept active and the user must update the software on a weekly basis. It is also recommended that antispyware software be placed on the home machine and run at least once a week. Spyware might attempt to capture user's passwords and retransmit to their source. The firewall will detect attempts of the spybots to communicate to their home base, but you should run anti-spyware to find those residents on your machine.

Technical note: When you use a firewall and popup blocker on your home computer you will have to instruct your software to allow clinical looking glass to open new windows

Procedure for Obtaining Internet Access:

1. Submit Internet Use Affidavit (Appendix A) to CLG administrator
2. Have Supervisor resubmit (Appendix D) Supervisor's Permission Form – for Use of Clinical Looking Glass with internet permission enabled.
3. Take the E-test (see below).

E-Test Privacy and Security

The user is required to take an e-test to demonstrate proficiency in issues regarding patient privacy and security when he seeks to obtain access to Clinical Looking Glass across the internet and when his training on Clinical Looking Glass is online without direct contact with a trainer. The address of this e-test is:

https://montefiore.plateau.com/learning/user/portal.do?siteID=CLG&landingPage=login

Individuals who are not Montefiore employees need to have a temporary profile created for them in the e-testing application by the Clinical Looking Glass administrator (914.457.6022).

Procedure for Renewal of Privilege:

Permanent Class users do not require annual renewal of access. They are approved for the duration of their employment and are deactivated upon notification by Montefiore's IT department of their termination.

Non-Permanent Class Users are to be renewed annually in June. Their supervisors are to be asked for confirmation that their privilege is to be renewed.

On an annual basis accounts that have been enrolled at least a year but have not been accessed in a year's time will be deactivated.

Audit of CLG Use

CLG tracks each query run by each participant, permitting review of the audit trail as necessary and provides the CLG director with administrative reports to track ongoing use.

On an annual basis the CLG Program Director will perform an audit of use of the preceding year for all use of CLG with identifiers.

QA
A list of all those users who contemporaneously claimed QA privilege for a data run is to be generated and shared with the Chairman of Quality Improvement to confirm that those individuals contemporaneously had the claimed privilege.

Worklist

A list of all the worklist justifications by individual is to be reviewed for reasonableness of claim - face validity. Inadequate documentation will result in follow up communication.

IRB approved Use
A list of all identifier use will document the user, the time he accessed identifiers, and the claimed IRB permission. This list will be shared with the IRB to assure that the claim of IRB access was legitimate during the year of interest.

Both the Institutional Review Board and the Performance Improvement Department will have access to a smart report in Clinical Looking Glass that can identify all those who have accessed patient identifiers claiming either IRB or QA preapproval.

Professional Courtesy

Clinical Looking Glass provides an option for analyses with deidentified patient data – Restricted Mode. This is critical to ensure patient privacy and to meet HIPAA requirements. Provider identity is not deidentified even when patient identity is shielded. Provider identity is essential to permit users to find their patients for analysis and its availability is in keeping with common practice in the NewYork State Sparcs data set (hospital discharges State of NY) where deidentified patient information is available with identified clinicians. While Montefiore recognizes the compelling need for provider identifiers for legitimate QI, IRB, and health services research projects, it is incumbent upon the user community to treat the information on providers as privileged, belonging to the institution, and its use subject to “norms of professional courtesy.” Professional courtesy means that analyses attached to providers should be shared with those providers if the analyses reveal results felt to be important to that provider or his patients and felt to be correct. Analyses in CLG are often preliminary and without validation with record review often may not be taken at face value. The CLG user is not expected to share every hypothesis generating analysis with every provider because without validation the implications are not straightforward. However, an analysis that the CLG user believes to be true with significant clinical implications should be shared. This somewhat fuzzy notion is subsumed in the phrase “professional courtesy” and is a sensibility to be developed in the user community. Serious Issues of Quality should be referred to the Director of Performance Improvement.

Special Concerns

Practitioner Names in CLG

Practitioners do not have privacy protection under HIPAA. In fact, Sparcs reports practitioner’s names and the state publishes practitioner’s names in report cards for cardiothoracic surgery. This issue was discussed in the Decision Support Group. Despite this general leniency with regard to access to practitioner’s names, we do not feel comfortable giving a blanket permission to rebroadcast practitioner’s names without specific institutional and IRB permission. Note, practitioner names are important for quality improvement projects or health services research when you are trying to cluster outcomes by practitioner, or by practitioner skill level (intern, resident, or attending), or by year of practice (three years, 15 years of practice).

Marketing

Only the Office of Planning Analysis should provide data from the CLG to the Marketing Department when given written approval by the HIPAA Privacy Officer. When lists of patients are sent to the Marketing department, both the transmitter of the data and the recipient of the data have an obligation to respect and protect patient confidentiality and the privacy of patient information.

- Only mailings that contain no clinical information about particular patients should be sent out from the Marketing Department.
- Mailings for marketing purposes that contain clinical information about a particular patient may only come from the patient's physician or the Montefiore CMO, which has overall responsibility for longitudinal patient care.

Some clinical information, such as that related to HIV status, psychiatric diagnosis and treatment, and child abuse, is particularly sensitive. Special safeguards must be in place to protect patient privacy and confidentiality in such cases.

Development Office

Only the Office of Planning Analysis should provide data from the CLG to the Development Office when given written approval by the HIPAA privacy Officer. However, when names of former patients are extracted from the CLG and sent to the Development Office by any analyst, both the transmitter of the data and the recipient of the data have an obligation to respect and protect patient confidentiality and the privacy of patient information.

- Only patient information that is essential to effective institutional development efforts should be provided to the Development Office.
- Specific clinical information such as patient diagnosis should not be included in the data that are generated for the Development Office.
- Patient information that is generated for marketing and development purposes should be in a form that creates the least risk to patient privacy.
- Solicitations for fund raising that contain clinical information should only come from the patient's physician.

Appendix A: Technical Addendum / Internet Use Affidavit

While the rapid change in Information Technology makes any specific recommendation of software short lived, this protocol will make an explicit recommendation for the purpose of demonstrating the care that should be exercised in treating the data extracted from Clinical Looking Glass in the Privileged Mode. This addendum is not to restrict researchers to this one solution but to give general guidance that if accepted and incorporated in the Institutional Review Board Application will reassure the IRB of the researcher's appropriate concern.

Once data is extracted using Clinical Looking Glass it must be stored on some medium be it hard drive, optical, CD, zip drive, memory key.

In the days of paper records, it was sufficient to say that the data was under "lock and key" in a secure environment with access only to those with appropriate permission.

Given the easy transportability of vast privileged data in the media described above, the natural tendency of researchers to bring their research to machines convenient to them no matter what they might affirm and honestly mean at the time of affirmation, a more rigorous standard must be insisted upon.

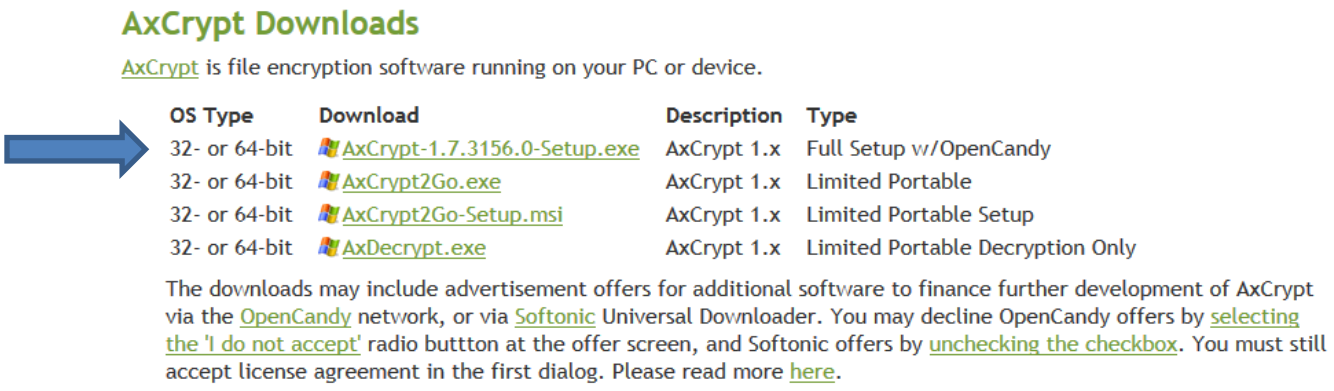
The data must be encrypted when not in use and not stored on a hospital-located password protected computer. This means that whenever the investigator is not directly manipulating the data he has the affirmative responsibility of encrypting the data so that no one who accesses the physical media can compromise the privacy of the subjects of the study. This includes, but is not limited to, an obligation to encrypt the data when leaving the data unattended for any reason.

Standards of encryption will clearly evolve over time so it is difficult to make a specific recommendation. **AxCrypt** is the leading open source file encryption software for Windows. It integrates seamlessly with Windows to compress, encrypt, decrypt, store, send and work with individual files.

To install go to the following link:

http://www.axantum.com/AxCrypt/Downloads.html

1. Select the **Full Setup Install**:



AxCrypt Downloads

AxCrypt is file encryption software running on your PC or device.

OS Type	Download	Description	Type
32- or 64-bit	AxCrypt-1.7.3156.0-Setup.exe	AxCrypt 1.x	Full Setup w/OpenCandy
32- or 64-bit	AxCrypt2Go.exe	AxCrypt 1.x	Limited Portable
32- or 64-bit	AxCrypt2Go-Setup.msi	AxCrypt 1.x	Limited Portable Setup
32- or 64-bit	AxDecrypt.exe	AxCrypt 1.x	Limited Portable Decryption Only

The downloads may include advertisement offers for additional software to finance further development of AxCrypt via the OpenCandy network, or via Softonic Universal Downloader. You may decline OpenCandy offers by selecting the 'I do not accept' radio buttton at the offer screen, and Softonic offers by unchecking the checkbox. You must still accept license agreement in the first dialog. Please read more here.

2. After the download is complete please move forward in the installation.

Emerging Health INFORMATION TECHNOLOGY

Internet User Affidavit

In recognition of the privilege to access Clinical Looking Glass across the internet, I commit to the following when using a non-hospital located computer:

1. Commit to use CLG across the internet only with a computer that has
    a. Antivirus (updated at least weekly)
    b. Antispyware (updated at least weekly)
    c. Software Firewall

2. Commit to encrypt all CLG output stored on the non-hospital computer even if it is without identifiers.

In witness to this commitment I affix my name, signature, and date.

_____	_____	_____
Printed Name	Signature	Date

Office Use only below:

I have reviewed the encrypted file and document the user's ability to encrypt a file

_____	_____	_____
Printed Name	Signature	Date

Appendix B: CITI Course

Collaborative IRB Training Initiative (CITI)
Human Subjects Research Educational Module

Introduction:

The Albert Einstein College of Medicine has contracted with the University of Miami for the faculty and staff to take the Collaborative IRB Training Initiative (CITI) computer-based training program. This web-based course is a mandated educational requirement for AECOM faculty and staff who participate in human subject research.

The CITI program has been developed in 16 modules and will take 4-6 hours to complete. Faculty and staff who are required to complete this course must do so prior to approval of a protocol by either the AECOM CCI or the MMC IRB. You are encouraged to review the modules in separate "log-on" sessions, but do recommend that you take the respective quiz at the conclusion of each session.

You are permitted only one attempt to complete each quiz. The software will not allow you to leave the quiz to find an answer and then re-enter later on to complete that same quiz. Therefore, once you enter a quiz, you must answer all questions and then click on the 'submit' button to get credit for completing the quiz. AECOM will receive notification that you have completed the course when you have reviewed all required modules and completed all required quizzes.

To register for this course, visit: http://www.citiprogram.org. Within 24 hours after registration, you will receive an e-mail with your username and password for access to the course material.

ALBERT EINSTEIN COLLEGE OF MEDICINE

MONTEFIORE MEDICAL CENTER
INSTITUTIONAL INSTRUCTION PAGE

The University of Miami Collaborative IRB Training Initiative (CITI) course content has been significantly revised and updated. The breadth of information provides a broad base of educational material for all individuals who are involved in the conduct of human subject research. The Albert Einstein College of Medicine requirements for completion of this tutorial have been structured to offer each researcher a program that has been tailored to address issues associated with their area of study. In this regard, please note that to fulfill the education requirement, you need to follow the instructions below.
Research staff who registers for this course should **indicate on both the initial registration page and on the final comments page** their area(s) of research. The options are as follows:

1. Biomedical Research (includes Epidemiological Research)
2. Drug and/or Device Research (same as #1 above, plus Module #12: "FDA Regulated Research")
3. Social/Behavioral Research
4. Students (a subset of Social/Behavioral Research requirements)

The requirements for completion of the modules differ, depending on your category of research. There are now two sets of modules, one for Biomedical Research and the other for Social/Behavioral Research. Additionally, depending on your research interests, there is a set of three optional modules that you may complete. All of this detail is outlined in the tables below:

AECOM/MMC CITI EDUCATION REQUIREMENTS
REQUIRED MODULES FOR ALL RESEARCHERS

MOD	BIOMEDICAL RESEARCH	SOCIAL/BEHAVIORAL RESEARCH
1	History and Ethics*	
2	Defining Research and Regulatory Overview	Defining Research*
3	Informed Consent	Regulatory Overview*
4	Social Behavioral Research	Assessing Risks*
5	Records Based Research	Group Harms
6	Genetics Research	Informed Consent*
7	Vulnerable Subjects - Overview	Privacy and Confidentiality*
9	Vulnerable Subjects - Minors	Research with Children°
10	Vulnerable Subjects - Women and Fetus	Research in Public Schools°
11	Vulnerable Subjects - Group Harms	International Research°
12	FDA Regulated Research *(Required only for Researchers using Investigational Drugs and/or Devices)*	Research Using the Internet*
14	HIPAA & Human Subjects Research*	
15	Human Subjects Research in the Workplace: Workers as Vulnerable Subjects°	
16	Conflict of Interest in Human Subjects Research*	
--	Hot Topics (Content Will Change Frequently - Read Only – No Quiz)	

*** Required for Ferkauf and Wurzweiler Students (SBR: 1, 2, 3, 4, 6, 7, 12, 14, 16)**
° Required as applicable for Ferkauf and Wurzweiler Students (SBR: 9, 10, 11, 15)

AECOM CITI EDUCATION
OPTIONAL ADDITIONAL MODULES FOR ALL RESEARCHERS

MOD	BIOMEDICAL RESEARCH	SOCIAL/BEHAVIORAL RESEARCH
8	Vulnerable Subjects – Prisoners	Research with Prisoners
13	Human Subjects Research at The VA	

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 it's 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. **<u>Research in Restricted Mode.</u>**

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_____
(Department Chairman or Chief)

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 No

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

Citi Ccourse Certificate Number_____
Citi Course Date_____

Email completed form to: ITServiceDesk@montefiore.org

Appendix D: Supervisor's Permission Form – for Use of Clinical Looking Glass

I have reviewed the Montefiore Policy and Procedure JC07.1 Authorized Use of Clinical Looking Glass and request that the person listed below be trained in Clinical Looking Glass and request that he/she be authorized to use Clinical Looking Glass in the following manner:

User's Name: _____
(**Please print clearly**)

Check all that Apply

____ Restricted Mode (no patient identifiers except for pathology account number) **only Preparatory for Research and no other use**. (Needs CITI training)

____ Restricted Mode (no patient identifiers except for pathology account number) for one of the following purposes – Education, Quality improvement, Operations.

____ Privileged Mode – Quality Improvement Projects (access to identifiers)

____ Privileged Mode with IRB approved Projects (access to identifiers). IRB approval letter and project must be scanned and sent to ITServiceDesk@montefiore.org. The Subject line heading should read ***"CLG Privileged Access."***

Warning: Enable Internet Use with Extra caution!

____Internet Use in Restricted Mode for any one of the following purposes – Education, Quality improvement, Research or Operations.

____ Internet Use in Privileged Mode – Quality Improvement Projects (access to identifiers)

____ Internet Use in Privileged Mode with IRB approved Projects (access to identifiers). IRB approval letter and project must be scanned and sent to ITServiceDesk@montefiore.org. The Subject line heading should read ***"CLG Internet/Privileged Access."***

I am authorized by the institution to authorize the use of identified data for Quality Improvement (QI) projects in my area of responsibility. If I am privileging for Quality Improvement projects with identifiers, it is with the understanding that all such projects (privileged mode) will be registered with the Director of Performance Improvement using the Montefiore Performance Improvement Intranet Registration site in advance of seeking identifiers.

Should I authorize internet access, I am aware of the serious commitment required of the user to use encryption on all materials generated and to have an update firewalls, antivirus, and antispyware on the internet computer. I have reviewed the seriousness of this requirement with the user.

My authorization of an individual to use Clinical Looking Glass in the restricted mode means that I am enabling this individual to use Clinical Looking Glass with access to dates of birth dates of service, and pathology account numbers, but no names, addresses, or telephone numbers. The justification for use under the restricted access mode is for any of the following purposes:

1. Quality Improvement - to answer QI questions
2. Education - to support the educational mission of the institution
3. Research - to support evaluation of potential research questions
4. Operations

I will advise the Clinical Looking Glass Administrator of any change in status of this person that meaningfully impacts upon his/her right to use Clinical Looking Glass. Specifically, if the individual listed below leaves my employ, I will immediately advise the Clinical Looking Glass administrator to terminate privileges.

Print User's First Name:_____ Print User's Last Name_____

Department:_____ Title:_____

Phone:_____ Page_____

Cell:_____ Email:_____

Print Supervisor's Name:_____ Title:_____
(***Department Chairman or Chief***)

Department: _____

Phone:_____ Page:_____

Email:_____

Signature:_____ Date:_____

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

Email completed form to: ITServiceDesk@montefiore.org

Appendix E: Training Supervisor's Permission Form – for Use of Clinical Looking Glass in the Privileged Mode for QI project

I have reviewed the Montefiore Policy and Procedure JC07.1 Authorized Use of Clinical Looking Glass and request that the individuals listed below previously approved for Restricted Access in Clinical Looking Glass now be permitted Privileged access to undertake supervised QI projects as part of their training in the modern practice of medicine.

I am the responsible party for the supervision of the resident's/fellow's training and will ensure that the residents/fellows understand the issues of confidentiality, patient privacy, and will take care to protect patient privacy in any materials developed in the course of this project.

I will advise the CLG Administrator when the privilege status of the named parties is to be reduced to restricted in the future.

Print Supervisor's Name:_____ Title:_____
(Residency Program Director)

Department: _____

Phone:_____ Page:_____

Email:_____

Signature:_____ Date:_____

Named Residents/Fellows:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Email completed form to: ITServiceDesk@montefiore.org

Appendix F: Director's Permission Form – for Use of Clinical Looking Glass by Medical Home Advocates

I have reviewed the Montefiore Policy and Procedure JC07.1 Authorized Use of Clinical Looking Glass and request that the individuals listed below be given access to smart reports to be used in support of the medical home mission of my area of responsibility.

I am the responsible party for the training and supervision of these medical home advocates and will ensure that each has his own password and uses his access to support the mission of the medical home. Such use is considered **worklist authorization** for identifiers in Clinical Looking glass and the Medical Home advocates will record MHA as the justification for their access.

I will review with the Medical Home advocates under my supervision the issues of confidentiality, patient privacy, and will take care to protect patient privacy in any materials developed in the course of this effort.

I will advise the CLG Administrator when any of those listed below have left the institution so that their access can be terminated.

Print Supervisor's Name:_____ Title:_____
(Medical Director)

Department: _____

Phone:_____ Page:_____

Email:_____

Signature:_____ Date:_____

Named Medical Home Advocate (print):

Appendix G: Data Use Agreement for Medical Home Advocates – for Use of Clinical Looking Glass

MONTEFIORE MEDICAL CENTER
DATA USE AGREEMENT Medical Home Advocate - 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 it's implementing regulations ("HIPAA"), and I agree to comply with the requirements of HIPAA applicable to the activities contemplated by this Agreement.

As a Medical Home Advocate my access to identified patient data is for Operational purposes only to support the direct care of patients in the medical home. When using Clinical Looking Glass for a Medical Home Activity, I will document the authority for accessing identifiers using the **worklist** option and recording **MHA** (medical home advocate)

I have been advised that accessing **patient information for research is strictly prohibited** and I am prohibited from seeking or providing data for research**.**

Should I wish to participate in research activities using Clinical Looking Glass, I have been informed that I need to take the beginner and advanced CLG training provided for all research analysts.

1. Print User's Name

2. User's Signature Date

3. User's Montefiore title:

4. User's Montefiore Department:

5. Name / Title of user's supervisor (***Medical Director***)

6. User's Email address

7. Montefiore supervisor's email address

Scan and email Form to ITServiceDesk@montefiore.org