<table>
<thead>
<tr>
<th>Pages</th>
<th>Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-7</td>
<td>Policy &amp; Procedures with Data Agreement</td>
</tr>
<tr>
<td>8</td>
<td>Appendix A: Transfer of CLG Data Sets from Juniper to other Secure MHS Computers</td>
</tr>
<tr>
<td>9</td>
<td>Appendix B: CLG Quality Improvement Submission Form</td>
</tr>
<tr>
<td>10</td>
<td>Appendix C: CLG Clinical Worklist Project Submission Form</td>
</tr>
<tr>
<td>11</td>
<td>Appendix D: CLG Operational Worklist Project Submission Form</td>
</tr>
<tr>
<td>12</td>
<td>Appendix E: CLG Expedited Research Proposal Form</td>
</tr>
</tbody>
</table>
U.S. Department of Defense Military Health System

Clinical Looking Glass (CLG)

POLICIES AND PROCEDURES

SUBJECT: Use of CLG by the Military Health System (Department of Defense)

EFFECTIVE: 1/1/13 REVIEW/ REVISED: SUPERSEDES:

Program Director: Harry B. Burke, MD, PhD, harry.burke@usuhs.edu

Purpose

To assist in the use of Military Health System (MHS) data to improve patient safety and quality while maintaining patient privacy.

Scope

All users and uses of Clinical Looking Glass (CLG)

Mission

CLG is a software program created by Montefiore Medical Center. CLG has been installed on U.S. Department of Defense systems to allow authorized users to access MHS data.

CLG Review Committee

The CLG Review Committee is the supervisory group for the use of CLG in the MHS. It is chaired by the CLG Program Director. The CLG Review Committee is composed of:

CLG Program Director, Chair
Internal Medicine Residency Director (or designee)
Family Practice Residency Director (or designee)
Internal Medicine Fellowship Director (or designee)
Director of the Institutional Review Board (or designee)
Assistant Chief of Staff for Quality (or designee)
Director of Healthcare Operations (or designee)
Business of Healthcare Pillar Medical Director (or designee)
Chairman, Medicine Department (or designee)
Chairman, Family Practice Department (or designee)
Chairman, Biomedical Informatics Department (or designee)
The CLG Review Committee will set CLG policy. Review Committee decisions will be based on a majority vote of its members. The Review Committee will meet annually and on an ad hoc basis. Meetings will be called by the CLG Program Director. Both the CLG Program Director and the CLG Review Committee are empowered to request audits of users.

Data Access Modes and Data Use Agreement

CLG operates in two data access modes, namely, “restricted” and “privileged.” Restricted mode does not include names or medical record numbers, and other patient identifiers are hidden from the user (see below). In restricted mode access is provided to all analytics but output is produced in a report format without names or medical record numbers. In restricted mode a limited dataset is available but the user must request access to the limited dataset prior to using CLG.

A limited dataset under HIPAA may not include any of the following identifiers:

- 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
- Full face photographic images and any comparable images

Using CLG in the restricted mode requires compliance with the following:

- The user agrees that the cohorts of patients will not be identified and will remain in their de-identified state
- The user agrees that no attempt will be made to reverse engineer identifiers from other datasets, or to identify or contact any individuals.
- The user agrees that limited datasets may not be downloaded or stored on personal computers without written permission of the CLG Program Director.
- The user agrees to use appropriate safeguards to prevent use or disclosure of limited datasets.
- The user agrees to report any unauthorized use or disclosure of the limited datasets.
In privileged mode, names and medical record numbers are visible to support data verification and to directly address safety and quality issues. In privileged mode access is provided to all analytics and the output can include patient identifiers including names, addresses, and telephone numbers. Only authorized users may obtain identified data.

Types Of Use

I. Quality Improvement Projects

All quality improvement (QI) projects users must submit a properly completed CLG Quality Improvement Submission Form (Appendix B) to the Quality Improvement Department CLG representative with a copy going to the CLG Program Director. In addition, for a project to qualify as a quality improvement project and for it not be considered research the project must meet the following six criteria:

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 safety or quality question related to care rendered in the MHS.
3. The project is undertaken with the written consent of the user’s department chair, service chief, or administrative supervisor.
4. The department or service undertaking this work should consider in advance of the study the planned quality interventions based on the range of reasonable findings that might be made.
5. Once the study is completed, if a safety or quality issue is identified, the department, service, or administrative unit must take appropriate action to correct the issue.
6. If it is possible, follow-up surveillance should be conducted.

Quality improvement projects may not be presented or prepared for publication without the written permission of the person’s supervisor and the appropriate Public Affairs Officer.

II. Clinical Worklist Projects

Clinical worklist projects are designed for immediate patient care. These projects can be created by clinicians to assess their patient panels or by administrative personnel charged with assessing care. One example might be a clinician examining his or her patients’ A1C values. Another example might be the creation of a diabetes follow-up list in a medical home clinic in order to properly schedule patient visits. Persons wishing to perform a worklist project must inform their service chief using the CLG Clinical Worklist form (Appendix C) with a copy going to the CLG Program Director. Worklist projects may not be presented or prepared for publication without the written permission of the person’s supervisor and the appropriate Public Affairs Officer.

III. Operational Worklist Authorizations
Operational worklist projects are designed for business operations and healthcare operations to use CLG for administrative purposes. Persons wishing to perform a worklist project must inform their service chief using the CLG Operational Worklist form (Appendix D) with a copy going to the CLG Program Director. Worklist projects may not be presented or prepared for publication without the written permission of the person’s supervisor and the appropriate Public Affairs Officer.

IV. Analysis In Preparation For Research

Analyses in preparation for research (APR) are used to determine whether there are enough patients to justify a study. APRs are conducted: (1) only in the restricted mode and (2) only by qualified investigators. A qualified investigator must have a current University of Miami CITI certificate. No research may be conducted in the APR capacity.

V. Research

Research is an investigation undertaken in either the restricted or privileged mode to create generalizable knowledge. There are two approval routes. (1) Research that the investigator believes to be exempt or minimal risk may be submitted to the CLG Research Review Committee. (2) All other research must be submitted directly to the Intuitional Review Board (IRB).

The CLG Research Review Committee (RRC) is chaired by the CLG Program Director. It is composed of at least 7 members who are currently active MHS researchers. The researcher who wishes to submit to the CLG RRC will complete and submit the CLG Expedited Research Proposal form (Appendix E). The CLG RRC will evaluate the proposal. If the proposal is properly completed and if the research is deemed exempt or minimal risk, the CLG RRC may, at its discretion, approve the study proposal. If the CLG RRC does not approve the study it will request that the investigator submit the proposal to the IRB. All approved Expedited Research Proposals will be filed with the IRB. The IRB has the right to rescind any CLG RRC approval at any time.

Classes Of Users

There are two classes of users, namely, permanent and non-permanent. Permanent users are maintained as users for the duration of their employment without the need for annual renewal. Non-permanent users must have their privileges renewed annually. Examples of non-permanent users include medical and nursing students, residents, and fellows. Non-Permanent users are to be renewed annually in July. Their supervisors will be asked to confirm that their CLG privilege be renewed. On an annual basis accounts that have been enrolled for at least one year but have not been accessed in a year’s time will be deactivated.
Audit Of Use

CLG tracks each query of every user. This creates an audit trail that allows the CLG Review Committee to review all CLG activity by all users and compare their use to their permissions. On at least an annual basis the CLG program staff will perform an audit of the users during the preceding year. In addition to annual audits, anyone who uses CLG for any purpose may be audited at any time for any reason without notice to the user. Further, the CLG Review Committee has access to a smart report in CLG that identifies the users who have accessed patient identifiers based on either QI or IRB.

Clinician Identity

Clinician identity is not de-identified even when patient identity is shielded because clinicians do not have privacy protection under HIPAA. However, unless a project is specifically designed to assess clinicians, clinician identity should be kept confidential. There are important reasons for this policy. One reason is that CLG results are usually preliminary; they have not been validated by the clinical record, and therefore are potentially incorrect. The second reason is that CLG results can be misinterpreted, leading to issues related to professional courtesy. The only caveat to this policy is when serious quality or safety issues are detected. In this situation the clinician should be notified and the researcher, clinician, and a representative of the CLG Program Director should resolve the issue and, if appropriate, take action to correct the situation.

Data Use Agreement

I have received and reviewed this “Policies and Procedures” document and I agree to abide by its provisions, including those related to use of MHS data. 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 Policies and Procedures document.

Attestation

By signing below, the user is confirming that he/she has read, understands, and will comply with the U.S. Department of Defense Military Health System (MHS) Clinical Looking Glass Policies and Procedures (including appendices). User must completely fill out section below:

User Name (print): _____________________________ Date___________________
User Title: ________________________________________
User Institutional Affiliation including Department: ____________________________________
User Phone: __________________             User Email________________________________

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User Type (circle): Clinician / Fellow / Resident / Medical Student (includes Nursing or Allied Health) / Administrator / Other (specify) ____________________________

If, Fellow / Resident / Student  Date of Graduation: ________________

If non-permanent user state date when use is no longer necessary: ________________

User Signature: ________________________________

Supervisor Name (print) ________________________________

Supervisor Signature: ________________________________

Supervisor Title: ________________________________

Supervisor Phone: ________________  Email: ________________________________

Date: ________________
Appendix A: Transfer of CLG Data Sets from Juniper to other Secure MHS Computers

As per the direction of the SPAWAR Information Assurance Officer (sean.perryman@navy.mil), CLG users may only use DoD email or SAFE AMRDEC (https://safe.amrdec.army.mil/Safe2/Default.aspx) to transfer necessary files/content to other secure military computers.

All transfer of files/content are covered by DIACAP 851001p:

2. APPLICABILITY AND SCOPE
2.1. This Instruction applies to anyone using the DoD version of Clinical Looking Glass
2.1.2. DoD-owned ISs and DoD-controlled ISs operated by a contractor or other entity on behalf of the Department of Defense that receive, process, store, display, or transmit DoD information, regardless of classification or sensitivity, consistent with Reference (b).
Appendix B: CLG Quality Improvement Submission Form

I have reviewed the U.S. Department of Defense Military Health System (MHS) Administrative Policies and Procedures (including appendices) for use of Clinical Looking Glass and am requesting authorization to use Clinical Looking Glass in the following manner (check one or type X in front):

1. Choose level of access (check one or type X in front):
   - [ ] Restricted Mode (no patient identifiers except for pathology account number)
   - [x] Privileged Mode (access to patient identifiers)

2. Briefly state the nature of your inquiry into CLG: ______________________________

USER: I am authorized by the institution to authorize the use of identified data for Quality Improvement (QI) projects in my area of responsibility. I understand that all projects will be registered with the Quality Improvement Department CLG representative with a copy going to the CLG Program Director. I have previously completed and will comply with the Policy and Procedures document including its data use agreement.

**User Name** (Print) _______________ Signature ________________________
Department_______________________ Phone___________________________
email____________________________ Date ________________________

SUPERVISOR: I authorize the above individual to use Clinical Looking Glass. 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. Privileged requests mean I allow access to patient identifiers. 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.

**Supervisor Name** (Print) __________ Signature ________________________
Department_______________________ Phone___________________________
email____________________________ Date ________________________

CLG QI REPRESENTATIVE: I received the QI Submission Form on (Date) ________________

☐ Copy sent to CLG Program Director (check box when complete)

**CLG QI Rep Name** (Print) _______________ Signature ________________________

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Appendix C: CLG Clinical Worklist Project Submission Form

I have reviewed the U.S. Department of Defense Military Health System (MHS) Administrative Policies and Procedures (including appendices) for use of Clinical Looking Glass and am requesting authorization to use Clinical Looking Glass in the following manner (check one or type X in front):

1. Choose level of access (check one or type X in front):
   - ___Restricted Mode (no patient identifiers except for pathology account number)
   - ___Privileged Mode (access to patient identifiers)

2. Briefly state the nature of your inquiry into CLG: ________________________________


USER: I am authorized by the institution to authorize the use of identified data for Clinical Worklist projects in my clinic. I understand that all projects will be registered with my Service Chief with a copy going to the CLG Program Director. I have previously completed and will comply with the Policy and Procedures document including its data use agreement.

User Name (Print) ___________________________ Signature __________________________
Department ___________________________ Phone ___________________________
email ___________________________ Date __________________________

SERVICE CHIEF: I authorize the above individual to use Clinical Looking Glass. 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. Privileged requests mean I allow access to patient identifiers. 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.

☐ Copy sent to CLG Program Director (check box when complete)

Svc Chief Name (Print) ___________________________ Signature __________________________
Department ___________________________ Phone ___________________________
email ___________________________ Date __________________________
Appendix D: CLG Operational Worklist Project Submission Form

I have reviewed the U.S. Department of Defense Military Health System (MHS) Administrative Policies and Procedures (including appendices) for use of Clinical Looking Glass and am requesting authorization to use Clinical Looking Glass in the following manner (check one or type X in front):

1. Choose level of access (check one or type X in front):
   
   _____Restricted Mode (no patient identifiers except for pathology account number)
   
   _____Privileged Mode (access to patient identifiers)

2. Briefly state the nature of your inquiry into CLG: ________________________________

USER: I am authorized by the institution to authorize the use of identified data for Operational Worklist projects for the organization. I understand that all projects will be registered with my Service Chief with a copy going to the CLG Program Director. I have previously completed and will comply with the Policy and Procedures document including its data use agreement.

User Name  (Print) _________________  Signature ________________________

Department_______________________ Phone___________________________

e-mail____________________________  Date ________________________

SERVICE CHIEF: I authorize the above individual to use Clinical Looking Glass. 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. Privileged requests mean I allow access to patient identifiers. 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.

☐ Copy sent to CLG Program Director (check box when complete)

Svc Chief Name (Print) _____________  Signature ________________________

Department_______________________ Phone___________________________

email____________________________  Date ________________________
Appendix E: CLG Expedited Research Proposal Form

Protocol number:

Protocol title:

Principal investigator (USER):

Co-investigators: (if any)

Date submitted:

Anticipated study time interval: (duration of the study)

Hypothesis: (one per protocol)

Background/literature review: (one to two paragraphs)

Why is this study important?

Type of data: (deidentified vs. identified, if identified provide justification)

Cohort: (type of patient. out vs. inpatient; single vs. multi-institutional)

Dataset time interval:

Independent variables:

Dependent variable:

Method of analysis: (descriptive/inferential statistics)

Relationship between expected results and hypothesis:

Study limitations: (confounders, patient population, etc.)

USER: I am authorized by the institution to authorize the use of identified data for Clinical Worklist projects in my clinic. I understand that all projects will be registered with my Service Chief with a copy going to the CLG Program Director. I have previously completed and will comply with the data use agreement.

User Name (Print) ___________________ Signature ________________________
Department________________________ Phone___________________________
email_____________________________ Date ____________________________

CLG Research Committee approval on (date) __________ (initials) ___

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