

Medical Record Review Protocol for Clinical Research Studies

This protocol provides instructions to facilitate requests for clinical research reviewers to obtain access to Epic Care Link and request records for online or onsite reviews.

Definitions

- Reviewer is defined as any monitor, auditor or reviewer performing medical record reviews required by and on behalf of the sponsor of the clinical research study.
- Research Sponsor is the company sponsoring the clinical research study.
- Contract Research Organization (CRO) is a contracted company hired to provide clinical research services on behalf of the Research Sponsor.
- Principal Investigator (PI) is a Montefiore representative who is the liaison between Montefiore and the research sponsor/CRO, and is responsible for the conduct of the study

Health Information Management (HIM) Contacts

Requests for Review of Medical Records

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Requests for Access to Epic Care Link

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Medical record reviews for clinical research studies may be performed online remotely or in-person onsite. Online reviews are performed via Epic Care Link and onsite reviews via Release to Inspector.

In preparation for a review, Principal Investigators (PI) or Designees are required to identify the type of review that will be conducted, online vs. onsite, and follow the necessary steps to request medical records.

Online Medical Records Reviews

Online Medical Records Reviews are conducted via Care Link. Care Link is a web-based version of Epic which allows limited remote access to review medical records. PI or designees are required to:

1. Request access to Care Link
2. Submit list of medical records for review after access to Care Link is granted

Note: If online access is already established, submit request for medical records only, see below #2 Requesting Medical Records for Online Review

1. Request Access to Care Link

PI or Designees must submit a request for access and required documentation via email for each Reviewer. The activation process will take approximately 7-10 business days *after* all required documentation is received.

Each Reviewer may have access to Care Link for up to one year. After one year, access must be renewed. If Reviewers are inactive for 90 days, their accounts will be deactivated, and access will need to be reactivated by contacting MIT Help Desk at 718-920-4554.

Requests for access are reviewed and granted on a case-by-case basis. Montefiore reserves the right to deny access in its sole discretion. Upon completion of the activation process, each Reviewer will receive a username, temporary password, and a guide on how to login and navigate through Care Link.

Each Reviewer's access to specific medical records in Epic Care Link is activated for a **three-day period**.

PI or Designees are responsible for notifying HIM when a reviewer no longer needs access to Care Link, so Montefiore can deactivate the account.

Required Documentation

- 1) **Care Link Access and Use Agreement for Research Sponsors** – To be completed and signed* by an **authorized** signatory of Research Sponsor/CRO (one agreement per Research Sponsor/CRO). *Do not submit this agreement again if the Research Sponsor/CRO already has one on file with HIM. Contact HIM for verification, or to view full list of Research Sponsors/CROs with Care Link access, click here: <http://intranet/clinical-research#ExistingRS>*
- 2) **User Confidentiality Agreement for Research Monitors** – To be completed and signed* by each Reviewer (one agreement per Reviewer)
- 3) **Reviewer General Information Spreadsheet** – Spreadsheet requires Reviewer's information needed for account creation. Information for **each** Reviewer who completes a Confidentiality Agreement **must** be added to the spreadsheet. *Please ensure to complete columns A – O*
- 4) **Copy of IRB approval**

***Acceptable signatures:**

1. Handwritten and imported in PDF document.
2. Adobe Sign (draw option **only** via mouse or touch screen)
*Please note, a computer-generated signature will **NOT** be accepted.*
3. DocuSign with accompanying certificate for validation
4. Pandadoc

Process for Requesting Access to Care Link

- 1) PI or Designee sends email to HIMCarelink@montefiore.org. The email must include:
 - a. Subject should state: **Request for Remote Care Link Access**
 - b. In body of email specify:
 1. Date when access is needed.
 2. Research Sponsor/CRO Name
 3. Title, IRB Number and Velos ID number
 4. Reviewer's Name(s)

- c. Completed and signed required documents as attachments:
 - For **new Research Sponsor/CRO and Reviewers** attach:
 1. Care Link Access and Use Agreement for Research Sponsors (*one per organization*)
 2. User Confidentiality Agreement for Research Monitors (*one per reviewer*)
 3. Reviewer General Information Spreadsheet
 4. Copy of IRB approval
 - For **new Reviewers and existing Research Sponsor/CRO** attach:
 5. User Confidentiality Agreement for Research Monitors (*one per reviewer*)
 6. Reviewer General Information Spreadsheet
 7. Copy of IRB approval

- 2) PI or Designee receives email confirmation from HIM.
- 3) HIM reviews request and documentation provided. If the forms are incomplete or have invalid signatures, the PI or designee is notified and is required to re-send updated forms via email to HIMCarelink@montefiore.org.
- 4) HIM processes the request to have Reviewers activated in the system.
- 5) Upon creation of account, HIM sends two (2) emails:
 - First email is sent to both Reviewer and PI or designee to notify them that the account for Reviewer has been created.
 - Second email is sent to the Reviewer with the following:
 - a. Username
 - b. Employee ID
 - c. Password
 - d. Hyperlink to access Care Link
 - e. Epic Care Link Navigation Tip Sheet

2. **Requesting Medical Records for Online Review**

Once the Reviewer has access to Care Link, PI or Designee is required to send a request for medical records to HIM via email to HIM-MRreviews@montefiore.org. ***Request must be submitted 3 business days prior to scheduled review.***

Required Documentation

Completed "Request to Review Patient Medical Record(s)" form and/or associated patient list.

- Patient list **must** include Patient Name, MRN and Dates of Service – *if review is for a large number of patients, requestor can submit a list on an Excel spreadsheet or Word document and attach it to the email.*

Upon receipt of the required documentation the requested records will be released to Care Link for online review and will be available for up to three days, unless otherwise requested.

Requesting Records for Review

- 1) PI or Designee sends email to HIM-MRreviews@montefiore.org
 - a Subject should state: **Care Link Research Review**
 - b In body of email specify:
 - i. Date of review
 - ii. Research Sponsor/CRO
 - iii. Name Reviewer Name(s)
- 2) PI or Designee must attach:
 - the “Review Patient Medical Record(s)” form with associated patient list
- 3) PI or Designee receives email confirmation from HIM.
- 4) Once the medical records are released to requester, HIM sends another email advising that requested records have been released to Care Link and the timeframe provided for the review.
- 5) If the review requires additional information or a time extension to complete the review, the PI or designee should notify HIM via email to HIM-MRreviews@montefiore.org.

PI or Designee notifies HIM via email to HIM-MRreviews@montefiore.org if the review requires additional information or a time extension to complete the review.

Onsite Medical Records Reviews

Onsite medical records reviews are conducted via Release to Inspector. Release to Inspector allows viewing requested medical records only in a secure work queue in PDF format.

PI or Designee is required to send a request for medical records to HIM via email to HIM-MRreviews@montefiore.org. **Request must be submitted 3 business days prior to scheduled review.** Release to Inspector for onsite review and will be available for the duration of the review.

*Onsite reviews using Release to Inspector require a **Public Sign-on Workstation** with Epic Production application.*

Required documentation:

Completed “Request to Review Patient Medical Record(s)” form and/or associated patient list.

1. Patient list **must** include Patient Name, MRN and Dates of Service – *if review is for a large number of patients, requestor can submit a list on an Excel spreadsheet or Word document and attach it to the email.*
2. Copy of IRB approval

Upon receipt of the required documentation the requested records will be released to Care Link for *online review and will be available for up to three days, unless otherwise requested.*

Requesting Records for Review

- 1) PI or Designee sends email to HIM-MRreviews@montefiore.org

- c Subject should state: **Onsite Research Review**
- d In body of email specify:
 - iv. Date of review
 - v. Research Sponsor/CRO
 - vi. Name Reviewer Name(s)
 - vii. IRB number

- 2) PI or Designee must attach:
 - the “Review Patient Medical Record(s)” form with associated patient list
 - a copy of the IRB approval

- 3) PI or Designee receives email confirmation from HIM.

- 4) Once the medical records are released to requester, HIM sends another email advising that requested records have been released Release to Inspector. Username, Password and Key for release to inspector is supplied in a separate email.

- 5) PI or Designee notifies HIM via email to HIM-MRreviews@montefiore.org if the review requires additional information or a time extension to complete the review.