

SOP TITLE: Remote Monitoring for Study Monitors	Version 1
January 2021	Page 1 of 3

PURPOSE: To outline the process of study monitors' request to gain offsite access to research subjects' medical records and research documents

SCOPE: Applies to all Montefiore Medical Center ("Montefiore") and Albert Einstein College of Medicine site personnel involved in the implementation and coordination of clinical research.

PERSONNEL RESPONSIBLE: Principal Investigator (PI), Clinical Research Coordinator (CRC), Regulatory Coordinator (RC) and other pertinent staff

DEFINITIONS:

- **EPIC**--The software used by Montefiore as the electronic medical record (EMR).
- **Epic CareLink** -- A web-based version of Epic which allows limited remote access to review medical records
- **Health Information Management (HIM) (Medical Records)**—Department responsible for the organizing, tracking and maintaining of health records at Montefiore .
- **Remote Monitoring** -The ability to access Montefiore IT Systems from an off-campus/remote location. This includes access from Einstein, a home office, physician practice, and other non-Montefiore locations.
- **Reviewer:** any monitor, auditor or reviewer performing medical record reviews on behalf of a research sponsor or contract research organization ("CRO").
- **Medical Records Reviews for Research Audits** -Instructions to request third-party reviewers' access to Epic CareLink and request records for remote source review.
- **MHS-Care Link Access Agreement***: Agreement between Research Sponsors or CROs and Montefiore for sponsors and/or CROs to be able to access Epic CareLink. In general, it will be completed once per sponsor/CRO.
- **User Confidentiality Agreement*** – Agreement, which must be signed by each User, in which the User agrees to abide by Montefiore's requirements for safeguarding patient information.
- **Reviewer General Information Spreadsheet** – Spreadsheet requires each reviewer's information needed for account creation, including name, user name, address, and date of birth. Information for each reviewer for whom a request is being made for access to CareLink or other access to patient information must be added to the spreadsheet
- **Box**- A cloud computing HIPAA compliant platform which provides file sharing, collaborating, and other tools for working with files that are uploaded to its servers. Box cannot be used for access to information in Epic.

* If signed via E-Sign signatures must be from one of the following approved methods: AdobeSign, VeriSign, DocuSign, Pandadoc. Signature must be physically signed and imported to the document or by use of a stylus or touch screen device

SOP TITLE: Remote Monitoring for Study Monitors

Version 1

January 2021

Page 2 of 3

GENERAL PROCEDURES:

- Sponsor/CRO will notify all involved trial personnel (i.e. PI and/or CRC) of the intention to conduct a remote monitoring visit. This notification should be at least two weeks prior to the planned remote visit and include the following details:
 - the planned dates of this activity
 - the planned times this activity will be conducted each day (e.g. 9am -4pm)
 - the documents required for review (e.g. data to verify eligibility, trial end points for specified trial participants)
- The conduct of remote monitoring visits should be no more frequent than on-site visits and follow existing departmental monitoring policies.
- The remote monitoring source review will occur via “read only” access to the electronic medical records (EMR) of study subjects via Epic CareLink.
- Prior to the visit, the sponsor/CRO must provide the research team with the following information:
 - The first and last name of the monitor(s) (one co-monitor for a maximum of two monitors per remote monitoring period);
 - The study title.
 - List of cases (subject numbers) and dates of service that will be reviewed;
 - The requested monitoring dates (maximum access of three (3) days. *Exception may be granted on a case-by-case basis for special circumstances*)
- Detailed guidelines in Medical Record Reviews for Clinical Research Studies Protocol (Appendix II) must be followed in requesting access to the EMR.
- The following forms must be completed prior to being granted access:
 - MHS-Care Link Access Agreement - to be executed by the sponsor or CRO
 - User Confidentiality Agreement - to be completed one per User
 - General Information Spreadsheet Template – monitor’s personal information required to create system account
 - Request Access for Medical Records Review Form –to be completed by the study team
- A login/password for access to the EMR will be provided for use on the first day of the remote monitoring. Each user will be forced to create a unique password at initial login.
- Records released to CareLink will be available for a maximum allowable of seven (7) days.
- At the end of the last day of the remote monitoring visit, the records will be removed from CareLink and no longer accessible.
- Reviewers’ access to Epic CareLink is granted for one year. After one year, access must be renewed. If reviewers are inactive for 90 days, their accounts will be deactivated and access to CareLink will need to re-request.
- Source documents not available in EPIC for review (ex: Screening logs, questionnaires) can be upload into to the institutional approved cloud-based repository, Box.

SOP TITLE: Remote Monitoring for Study Monitors

Version 1

January 2021

Page 3 of 3

- Study personnel will limit the monitor's period of remote access to source documents both in BOX and CareLink to the length of the on-site monitoring visit.
- For guidance on Box see Appendix VI
- Any use of sponsor-controlled electronic systems, other than Electronic Data Capture (EDCs), that contains appropriate security controls will need additional approval from Montefiore IT security.
- Source document copies placed in Box for remote review and that are no longer needed after the remote monitoring has concluded will be removed by Montefiore, provided the clinical investigator retains the original source documents and once the original documents can be verified at the next onsite visit.
- Remote monitoring activity must only occur on the days and times agreed. Documentation of the Monitoring Visit must be logged to capture the start date and end date of the visit.
- Video conferencing via institutional Zoom or MS Teams, WebEx Skype accounts are permitted as long as no confidential information is being shared. For example, to conduct Site Initiation Visits, Site Feasibility Visits, etc.
Montefiore retains the authority, in its sole discretion, to discontinue remote access of a monitor at any time

RESOURCES:

- Title 21 CFR 312.62—Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- Title 21 CFR 812.140—Investigator Record Keeping and Record Retention for Device Trials
- ICH GCP Consolidated Guideline—Part 4.9 Records and Reports

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>

TOOLS:

Appendix I: EPIC Care Link Navigation tip sheet
Appendix II: Medical Record Reviews for Clinical Research Studies Protocol (*Internal use only*)
Appendix III: Request Access for Medical Records Review Form (*Internal use only*)
Appendix IV: User Confidentiality Agreement (*Internal use only*)
Appendix V: General Information Spreadsheet Template (*Internal use only*)
Appendix VI: Box for Remote Monitoring (*Internal use only*)

Appendix I:

EPICCARE Link Navigation Tip Sheet

CareLink is a web-based version of Epic which allows third-party vendors to review medical records remotely.

Help and contact information

For help using an activity, click on the webpage.

- If you forget your password or can't log in, call 718-920-4554 or your contacts at HIM.
 - Jason Rivera - Site Manager – 929-285-4022 - jasriver@montefiore.org
 - Regina Laezzo - Site Manager – 718-920-9610 - rlaezzo@montefiore.org
 - Doreen Gonzalez – Senior Project Manager – 914-349-8019 – dogonzal@montefiore.org

Browser, system, and connection requirements

You must use one of the following Internet browsers to access Care Link:

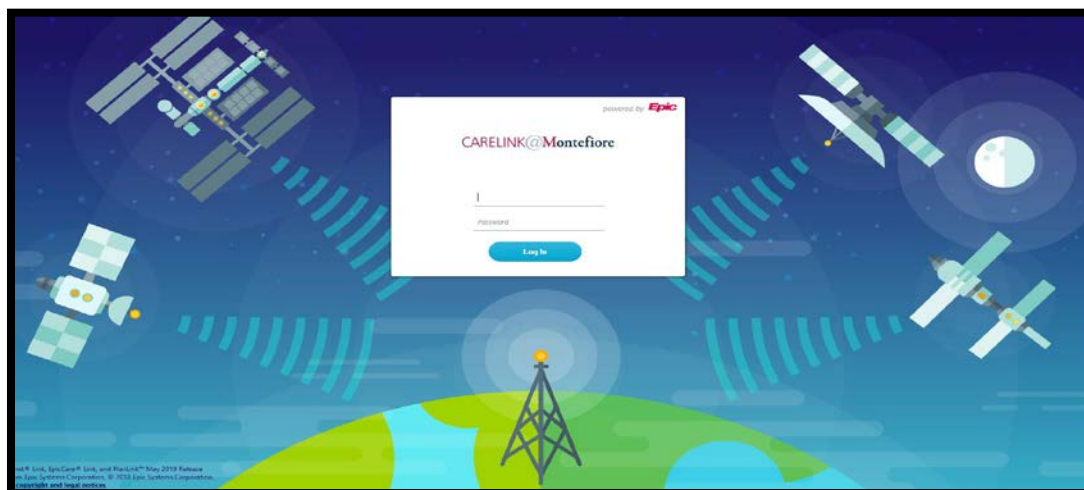
- Apple Safari
- Google Chrome
- Microsoft Internet Explorer 8 through 10
- Mozilla Firefox 10 and any later versions

On tablets, you must use iPad Safari or Android Chrome browsers.

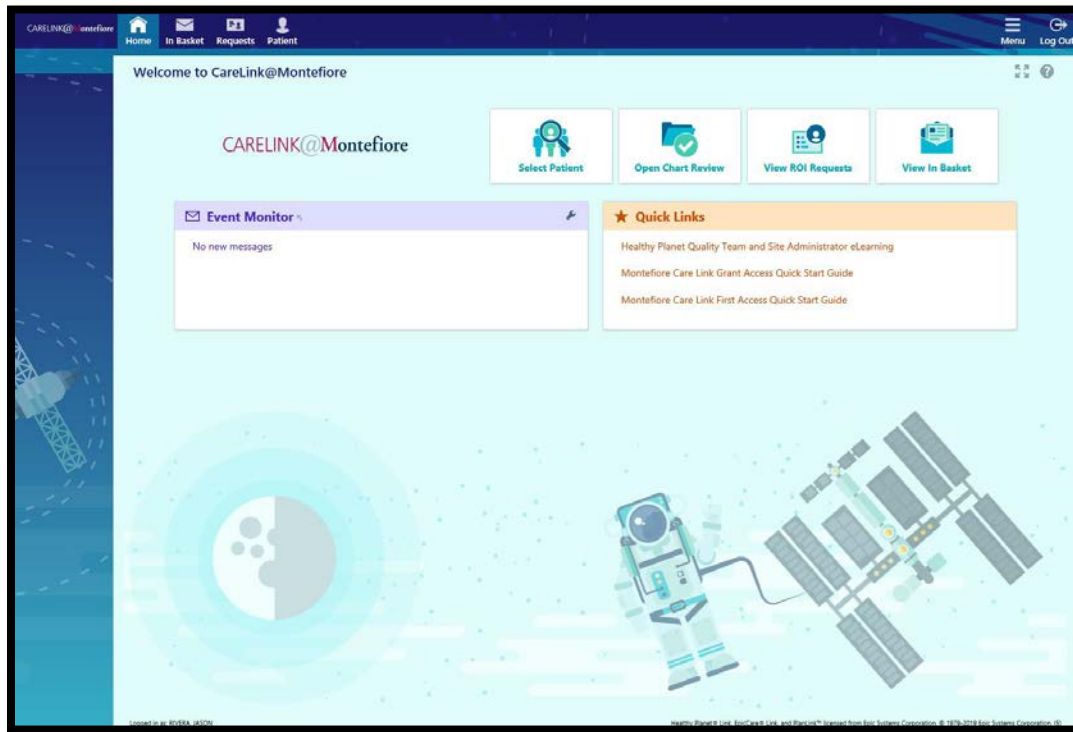
Care Link requires a minimum screen resolution of 1024x768 pixels. We recommend that you use a high- speed Internet connection to achieve the best system speed and performance.

Logging In/ Reviewing Records / Logging Out

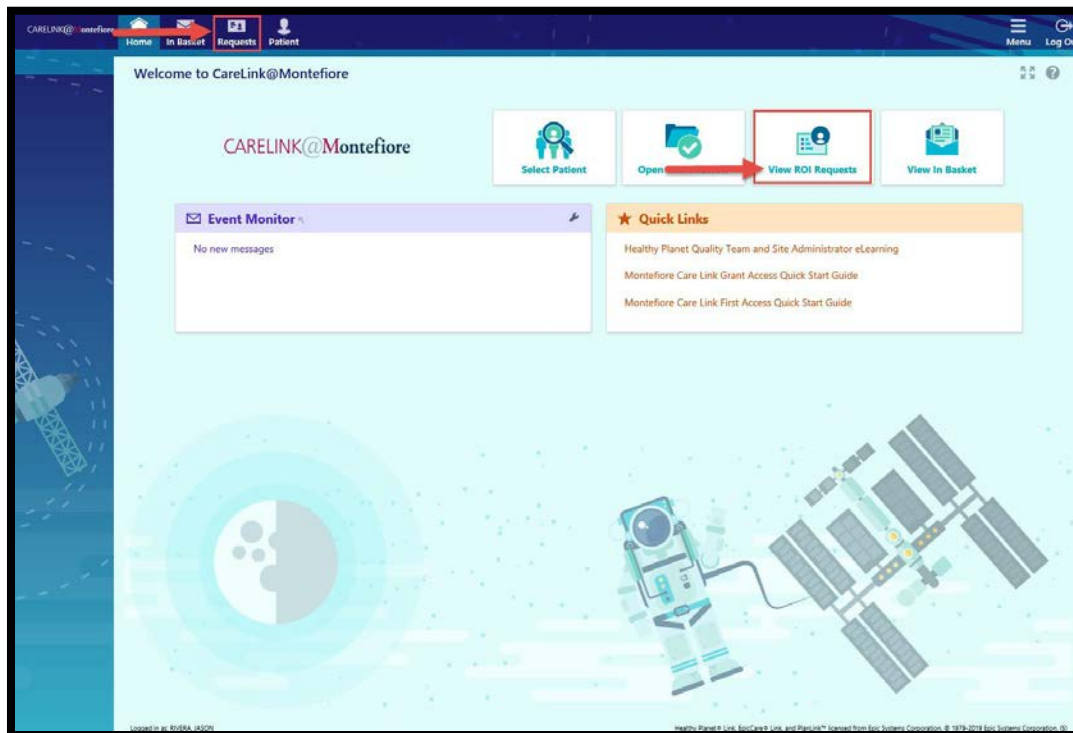
- 1) Select the link below to begin the login process
<https://carelink.montefiore.org/EpicCareLink>
- 2) Use your username and password to login



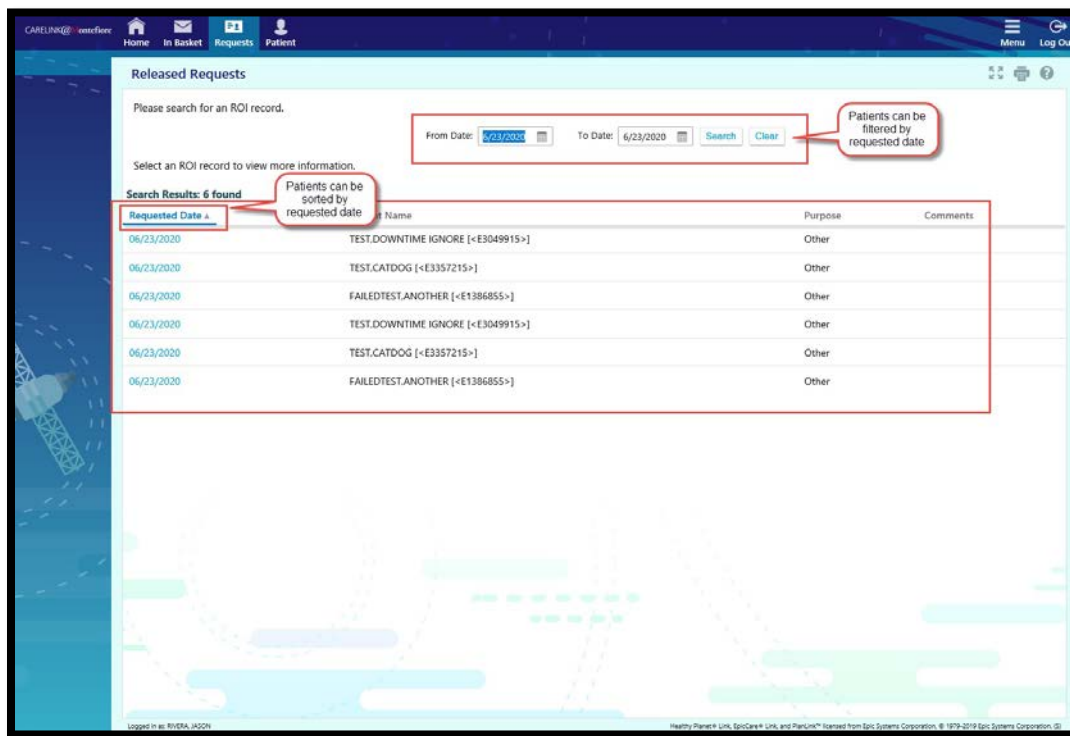
3) Upon Login you will be directed to the EPIC CARE Link Home Screen



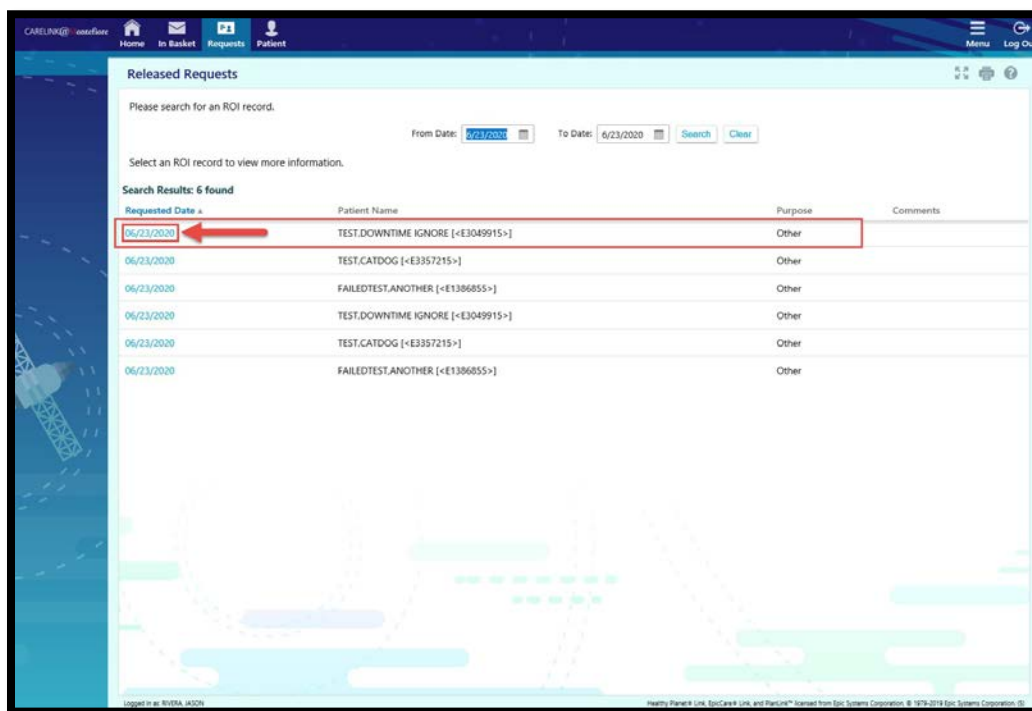
4) Select **View ROI Request** or in the top toolbar select **Requests**



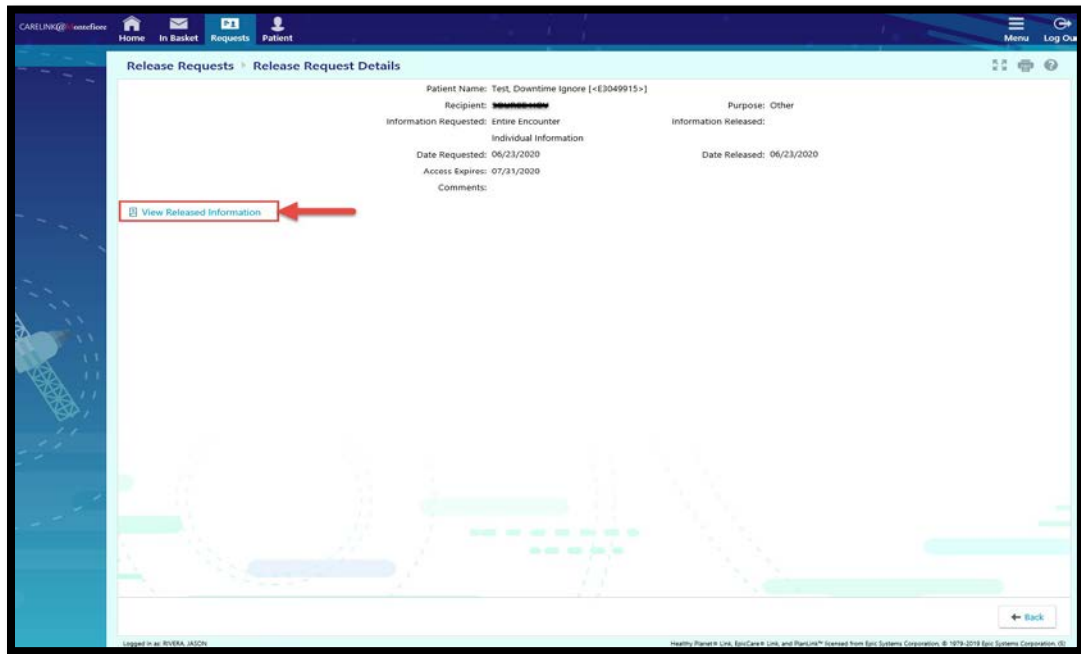
- 5) The **Released Requests** screen will open displaying the cases requested. Cases can be sorted by Requested Date by clicking on arrow. Cases can be filtered by using the filter function.



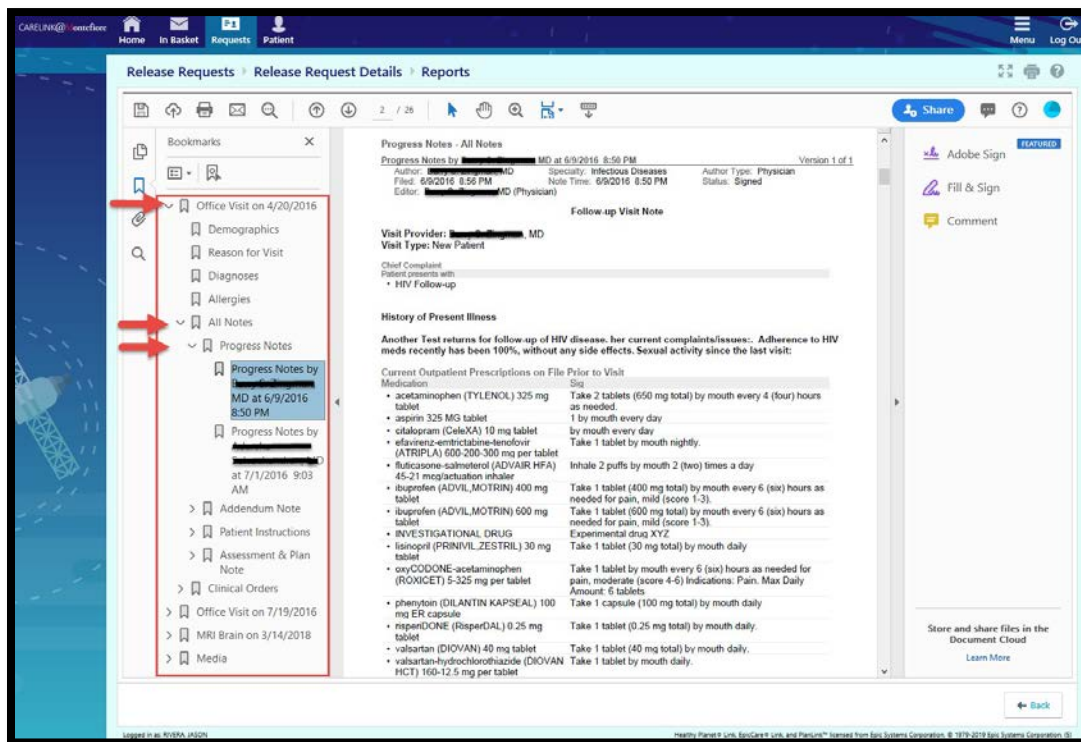
- 6) Click on the blue **requested date** to open the selected patient's record.



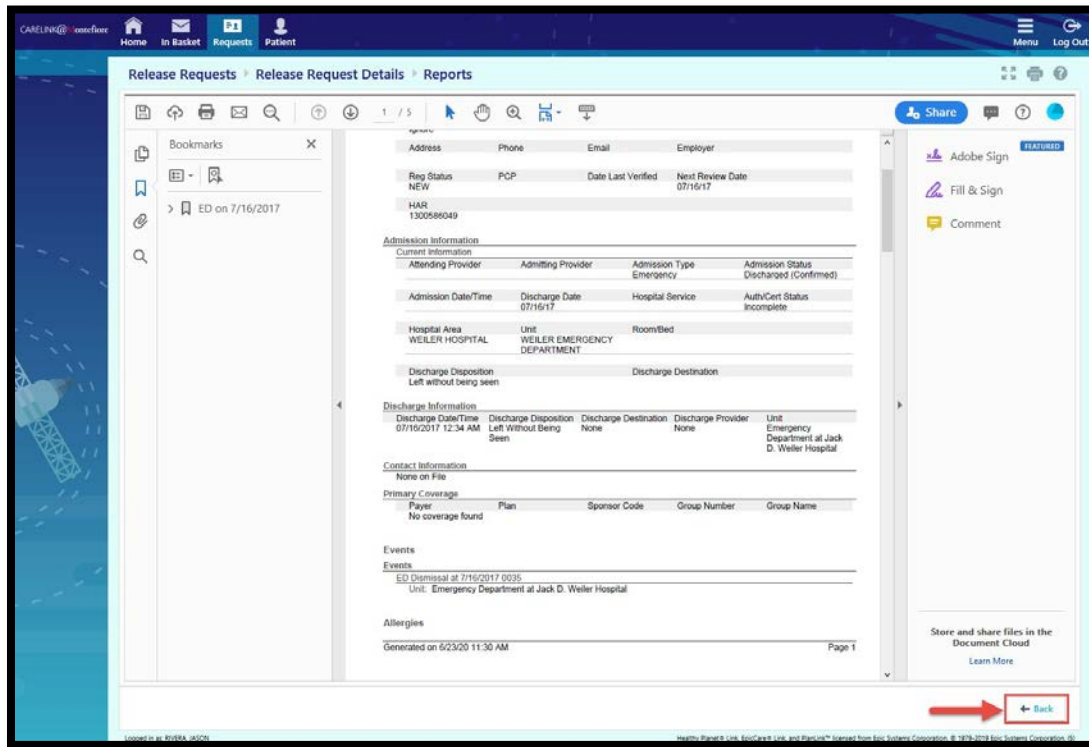
7) The following **Release Request Details** screen will open. Click on **View Released Information**.



8) The **Reports** screen will open with a PDF of the requested records. On the left-hand pane user is able to view encounters associated with release. By selecting arrow on the encounter, the sub groups will display.



9) When finished click the **Back** button to return to the list of patients.



10) Be sure to click on **Log Out** to securely log out of Carelink.

