

Background:

Clinical trials at the University of Kentucky, per contractual relationship and terms, may be monitored periodically by the sponsor or specified third party (“research monitor”). The research monitor reviews study regulatory documents, source documents, and site study data to ensure the investigator is abiding by the study protocol requirements and adhering to good clinical practice (GCP) and regulatory requirements. Source documents include, but are not limited to, original or certified copies of clinical patient charts, pharmacy dispensing records, and imaging. At UK HealthCare (UKHC), patient clinical records are currently housed in electronic health records (EHR), specifically Epic.

Source documentation can be housed in electronic systems such as REDCap (if 21 CFR Part 11 Compliance is not required).

Purpose:

This process document outlines the UKHC institutional expectations for ensuring standardized procedures by which clinical research study teams request EHR and REDCap access for research monitors, expectations for communication, and review and audit processes related to this access.

Process:

Please reference the Epic [Research Study Team Handbook](#) and the Epic F1 Help dashboard for Study teams for detailed instructions on how to request a LinkBlue ID for your monitor, and how your monitor can request an EpicCare Link account.

EHR Oversight:

UKHC Office of Corporate Compliance Privacy Team may generate an audit report of the research monitor access in Epic upon request of the study team or as a matter of a routine audit. If a research monitor is found to violate appropriate access of permitted patient records, the Privacy Team will take any further action necessary per audit findings, including but not limited to revocation of research monitor access.

Access to items not in the EHR (currently Epic):

For additional reference, the list of documents converted into UKHC’s instance of Epic launched June 5, 2021. If research monitor access is needed for items not in Epic, the study team may utilize the following methods to assist with remote monitor access to review applicable patient medical records or source documentation on a case-by-case basis via one of the following approved methods:

- **Zoom meeting** - either UKHC HIPAA compliant platform or UK campus platform

- Must create unique meeting ID for each session
- Must utilize unique password for each session
- **Secure email** - #Secure or #Encrypt MUST be typed at the beginning of the subject line
- **Microsoft Teams** - a private site must be created with guest access for the research monitor
- **One Drive** - see One Drive sharing instructions at <https://www.ctcs.uky.edu/about-ctcs/cores/regulatory-knowledge-and-support-core/remote-monitoring-clinical-trials>)
- **REDCap** – For information regarding REDCap go to <https://www.ctcs.uky.edu/education-training/seminar-series-and-workshops/participant-recruitment-series/services-resources-2>
 - In order for research monitors to have view access to a study in REDCap, the following is required:
 - The IRB approved Informed Consent Form/HIPAA Authorization must allow for research monitor review of the data.
 - If monitor is internal to UK they will need the following:
 - To request A REDCap account select “Request a REDCap Account” on the website.
 - The monitor will need to be given user rights to the study. The user rights should be limited to just the amount of information needed to monitor the study. (i.e. if PHI is not needed then PHI rights should not be granted).
 - If monitor is external to UK they will need the following:
 - If they do not have a LinkBlue ID, they can sign up for one by [clicking here](#). For access reason, please select CCTS membership. Their request will be processed within 4 working days. They will receive an email to activate their account at the email address provided in the request. Please check junk mail. Once activated, a CCTS membership request can be made.
 - If externally sponsored, the Clinical Trial Agreement (CTA) must allow the monitors access to the data.
 - If externally sponsored and if no CTA is in place, the research monitor must have a Business Associate Agreement (BAA) in place for the study.
 - To request a REDCap account:
 1. The research monitor must have a UK LinkBlue ID. See [Research Study Team Handbook](#)
 2. Go to <https://www.ctcs.uky.edu/education-training/seminar-series-and-workshops/participant-recruitment-series/services-resources-2>
 3. Select “Request a REDCap Account”

Note: The monitor will need to be given user rights to the study. The user rights should be limited to just the amount of information needed to monitor the study. (i.e., if protected health information (PHI) is not needed then PHI rights should not be granted).



See below for list of what was converted into Epic

Exhibit A

UK HealthCare		EHR Conversion Scope of Years	
Conversion Data Set	Data Type Description		Exceptions
Patients	Key patient identifiers and demographics, such as MRNs, name, address, sex, and date of birth.	All	
Vitals	Basic vitals and triwavelet data (e.g. height, weight), most often used for pediatric growth charting.	3	Pediatric Height, weight, head circ : ALL Outpatient Height and Weight : 2012 - Current
Historic Encounters	Defines how "visit," history and clinical data such notes and results, are grouped in chart review.	3	
Notes	Notes may include H&P, Progress Notes, transcription or dictated reports, and other documentation.	3	OpNotes and Discharge Summaries : ALL Chemo Orders : ALL Cardiac Notes : 5 Years
Immunizations	Discrete Immunizations (e.g. CVX) used in clinical decision support.	All	Reduplicated from SCM, AEHR and UHS
Allergies	Active allergies, including medication, food, and environmental.	Current and Active	
Ambulatory Medications	Active medications (e.g. NDD) prescribed in ambulatory visits.	Current and Active	Touchworks: All SCM ambulatory (Oncology, Transplant): All Inpatient: None
Ambulatory Problem List	Active problem list (e.g. ICD-9, ICD-10, SNOMED) associated with ambulatory visits.	Current and Active	Touchworks: All SCM ambulatory (Oncology, Transplant): All Inpatient: None
University Health Service	Employed health, and student health including student behavioral health.	Aligned with above	
Imaging Results	Textual reports for radiology, cardiology, and other studies, optionally includes study image links and scanned results.		Intellispace 3 years Synology low 5 years
Dental	Anatomical findings, existing procedures, planned treatments, periodontal data.	3	
Ambulatory Patient History	History of family, medical, surgical, and social conditions such as smoking history.	Current and Active	Touchworks: All SCM ambulatory (Oncology, Transplant): All Inpatient: None
Lab Results	Discrete or textual results for general chemistry, bloodbank, lab results, microbiology, pathology, and other lab tests and scanned results.	All	Gen Lab and Micro since April 2014
Discrete Mammography	Additional mammography data may include BIRAD assessments, follow up tracking, and pathology.		Text Results: 10 Years Discrete Data: 3 years
Transplant	Patient transplant: episodes, native grafts, graft organs, and other documentation.		Vitals from D1TR: 3 years Progress notes from OTTR: 5 years D1TR Labs and Path from Norton April 2014 Hand-entered labs (outside) April 2014 D1TR Red Results from Norton since 2016
Ophthalmology	Discrete ophthalmology measurements from Medflow, stored as Smart Data Elements.	3	
Scanned Documents	Reference pointers to a third party system (Hyland Onbase), for results, reference lab reports, transplant, and ultrasound.		Opti 3 years (5 for Kidney transplant patients) Hemodynamics 5 years Muse 10 years Synodynemics 10 years Provation 10 years Nextech 2/1/2020 - Current Axiom 3 years Magview 5 years Ge Viewpoint 3 years Vya/Vmax 5 years Provation MD 3-10 years Pacart 3 years Biotal 3 years AEHR Documents - Subset 3 years Medical - 1 Year

* Years of scope to be backdated from 1/1/2021