OSU College of Medicine and Office of Health Sciences
<u>Accessing the Electronic Health Record for Research Purposes</u>

<u>Purpose and Scope</u>:
This document provides guidance to researchers within the College of Medicine (COM) or Office of Health Sciences (OHS) only who desire to establish new access to The Ohio State University Wexner Medical Center's (OSUWMC) electronic health record (EHR) system for research purposes. **This guidance does not apply to research conducted by departments/units outside of COM/OHS.** Researchers outside of COM/OHS are evaluated through a similar process with more emphasis on data security, and therefore may be subject to additional policies/procedures.

For the purpose of this document, the OSUWMC EHR is comprised of electronic patient health information contained within the Integrated Health Information System (IHIS) and other clinical systems. Access to aggregate health information outside of IHIS, such as data obtained through the Information Warehouse (IW), as well as requests for remote/off-site access to the EHR requires separate review and is not covered in this guidance. This process does not apply to research personnel who already have IHIS access for clinical or course purposes unrelated to research activities.

This document is the culmination of efforts in collaboration with the Health System and the Health Information Systems Access Review Committee (HISARC) and was approved by the HIPAA Steering Committee in December 2018.

<u>Requirements/Prerequisites</u>:
1. All research access requests will be vetted by the College of Medicine Office of Research (COMOR) and may be reviewed by others or HISARC as deemed necessary. HISARC will always review research access requests for personnel who do not fit into one of the categories in the table below.

2. Research personnel includes the Principal Investigator (PI), co-investigators, and other key personnel contributing directly to specific research protocols. Research personnel who are employees hired and employed under a COM/OHS cost center number and who are approved by the IRB or Privacy Board to access, use, and disclose PHI for research purposes may be granted access to the electronic health record (EHR) .

3. Research personnel also includes personnel who are not engaged in specific research protocols but are involved in research operations, such as scheduling, billing, grant management, routine laboratory analysis, specimen processing, etc. These research personnel are not required to be listed as key personnel on an IRB approved protocol, but they may be granted access to the EHR with appropriate justification.

4. The Principal Investigator or supervisor is responsible for the supervision of access to the EHR for research personnel.

5. Access to the EHR for research purposes is made pursuant to: (a) preparatory to research activities according to applicable policies and procedures; (b) a valid partial or full waiver of HIPAA authorization; and/or (c) participant authorization via a signed HIPAA research authorization form and participant consent to be in the study.

6. Access and use of the data is subject to compliance with all Medical Center and university policies and procedures. The access, use, and disclosure of PHI must be in alignment with the terms and conditions or the IRB and/or Privacy Board approval. **Failure to adhere to these policies may result in corrective action, up to and including termination.**

7. Access to the EHR for research purposes will be granted according to HIPAA regulations including being limited to the minimum necessary information (i.e., whether all patient charts are viewable and whether the research personnel may document in the chart) and the minimum required time. Accessible charts may be limited to those sent through IHIS inbasket, patients seen within a certain clinic, or other restrictions as appropriate.

8. Research Personnel must undergo appropriate security screening (i.e., background check and drug screen), vaccinations as appropriate for interaction with human subjects, and relevant training prior to being granted access.

9. Certain Research Personnel, especially those who do not go through the Medical Center Orientation, such as students, visiting scholars, and non-OSU medical students on a formal rotation, will be required to sign a statement of confidentiality
(**Attachment A**). HISARC will also request personal attestation (**Attachment B**) for the user. The attestation should come from a credentialed provider on the medical staff at OSUWMC. If the PI does not fulfill these requirements, the attestation can come from a supervisor or co-investigator who does meet these criteria. Personal attestation can be in the form of an email, letter, or documented conversation with at least one member of HISARC. The attestation shall address the user's needs and qualifications for accessing the EHR.

10. Staff with certain titles (Clinical Research Assistant/Associate/Coordinator/Manager and Research Nurse) hired and trained by certain management groups such as the College of Medicine Clinical Trials Management Organization (COM CTMO) and the Comprehensive Cancer Center Clinical Trials Office (CCC CTO) may be eligible for expedited review by COMOR staff. These agreements are subject to review and will be maintained separately.

11. Research monitors or auditors are eligible for expedited review by COMOR staff. These users will only be given inbasket access. Access to research patient records for research monitors or auditors may also be granted through DocLink.

12. Access as defined in the chart below is subject to the approval of HISARC and other Health System leaders as determined by HISARC.

Requirements for Gaining Access[1] to Electronic Health Record

Type of Research Personnel	Review Required	Signed Confidentiality Agreement Required	Personal Attestation Required
Faculty & Staff[2]	HISARC		
OSU Professional Student/Trainee[3]	HISARC		
OSU Undergraduate Student[3]	HISARC	Yes	Yes
Visiting Scholar[3]	HISARC	Yes	Yes
Non-OSU medical student on formal rotation[4]	HISARC	Yes	Yes
Staff eligible for expedited review[5]	COMOR		
Research monitor or auditor[6]	COMOR		

1. Only the minimum access necessary will be granted.
2. Excludes student staff. Student staff will be considered based on the type of student they are.
3. Regardless of pay status or receipt of course credit.
4. Will only be considered for limited access if they have a previous or future relationship with OSU.
5. Applies to staff hired and trained by the CCC CTO and COM CTMO with titles of Clinical Research Assistant/Associate/Coordinator/Manager and Research Nurse.
6. Research monitors or auditors will only be given inbasket access. Research charts may also be available through DocLink.