

 <p>UNIVERSITY OF Cincinnati</p> <p>Category: CoM- Office of Clinical Research (OCR)</p> <p>Applicable for: CoM Clinical Research Professional Faculty and Staff</p>	<p>COLLEGE OF MEDICINE Operating Procedure/Guideline</p> <p>UC Health Research Access and Authorization (Formerly Research Credentialing) to Access UCH Facilities and Epic for the Purpose of Clinical Research</p> <p>Effective Date: 06/01/2023</p> <p>Prior Effective Date: 06/01/2023</p>	<p>Document Owner: CoM Office of Clinical Research Compliance Administrator</p> <p>Responsible Office(s): CoM Office of Clinical Research</p> <p>Disseminated: Office of Clinical Research 06/01/2023</p>
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Background

This document details the process for applying for research access and authorization (formerly known as research credentialing) at UC Health (UCH) for the purpose of clinical research. This is a system-wide standard operating procedure that applies to clinical research conducted in the facilities of University of Cincinnati (UC) and affiliated facilities (UC Health, LLC, University of Cincinnati Physicians Company {UCPC}, LLC) and all University of Cincinnati and UC Health Clinical Research Professional Staff that conduct clinical research in these facilities.

Guidelines

Before any individual interacts with UCH patients or private health information or enters UCH patient care facilities for research purposes, the appropriate checks to ensure the proper protections for patients, UCH personnel and property must be conducted. Clinical Research Professionals and volunteers are not permitted to access UCH facilities or data without having approved UCH Research Access and Authorization. Other than physicians, all personnel undergo an Access and Authorization process for research. Personnel with approved Research Access and Authorization may have access to UCH electronic medical records, patients, and other research related staff and facilities.

This SOP applies to all persons wishing to interact with patients or their private health information, or who wish to access an outpatient or inpatient setting for which the facility, resources, or personnel are owned, leased to, or managed in part or in whole by UCH for the purposes of conducting research. Research may involve patients, persons who are not registered patients, staff, facilities or resources, human tissue or samples, and identified or de-identified data.

DEFINITIONS:

- **Research Access and Authorization:** The permissions granted to a researcher allowing access to UCH facilities and interactions with patients or their private electronic health information for the purposes of clinical research.

- **New Provider/CRP Form:** Electronic form used by University of Cincinnati College of Medicine (UC COM) for new providers. It is now also used for clinical research professionals when hired or in need of UCH and initiates the request to begin the Access and Authorization process with UCH.
- **Affiliate Researcher:** is an individual who is employed by a partnering entity. This can include a full-time employee or student worker.
- **Volunteer Researcher:** is an individual who volunteers to perform research work without any expectation of or receipt of compensation.
- **Epic:** UC Health's electronic medical records (EMR) system.
- **One Touch Training:** UCH institutional online training platform.
- **Exclusion check:** the process of verifying that an employee or research affiliate is not classified as an excluded individual who is prohibited from participation in any Federal health care program.

Process

- Depending on employment status, researchers who wish to conduct research at UCH must either contact the UCH Access and Authorization administrator research-credential@uchealth.com or the UC COM. Please note, UCH and UC are two separate entities and access is a process required by the institution of UCH to ensure UCH is aware of research at UCH and who is accessing UCH systems.
 - If employed by or affiliated with the UC COM, the researcher will seek access through the New Provider/CRP form, initiated and completed by the hiring or business manager within the researcher's department.
[New Provider/CRP Form](#)
 - If the researcher is employed by UCH, outside of the UC COM, is a volunteer or an external affiliate, the Research Access and Authorization packet must be completed and submitted.
[Access Application](#)
 - Physicians who are credentialed to provide clinical services at UCH have research included in their scope of practice and additional credentials are not required.
 - Physicians who are no longer credentialed but require access to Epic to continue research activities may be eligible to be reactivated and should reach out to UCH OCR.

UC COM RESEARCHERS SEEKING ACCESS TO UCH FACILITIES AND EPIC FOR THE PURPOSES OF CLINICAL RESEARCH

- The New Provider/CRP form should be completed by the hiring department manager/supervisor or their assigned human resources consultant team.

- Once the New Provider/CRP form is submitted, it will go to the University of Cincinnati College of Medicine HR team (UC COM HR team).
- The UC COM HR Team will send out a welcome email along with onboarding instructions and requirements.
- The UC COM HR Team will coordinate all pre-employment requirements, including health screening and the background check process.
- The Office of Clinical Research (OCR) will send a welcome email along with instructions for obtaining UC Health research access requirements for badging and EPIC purposes. Requirements include:
 - Generation of an employee identification number (EIN) and username (UID).
 - Exclusion check completed by the UCH OCR.
 - UCH required OneTouch Training automatically assigned to researcher and will be sent by email. Once the UID and EIN are generated, the UC OCR will email the researcher with log in information and instructions for accessing OneTouch training. After completing all assigned OneTouch training, the researcher must submit a copy of his or her training transcript for verification to research-credential@UCHealth.com.
 - Epic research training if Epic access is required. UC OCR will schedule the researcher for a 4-hour session specific to Epic Research training.
- Once all requirements have been met, badging and/or Epic access will be approved. The researcher and direct supervision will receive an email with approval and directions to pick up badge.

UCH EMPLOYEES, EXTERNAL AFFILIATES AND/OR OUTSIDE OF THE UC COM, and VOLUNTEERS SEEKING ACCESS TO UCH FACILITIES AND EPIC FOR THE PURPOSES OF CLINICAL RESEARCH

- The Research Access and Authorization application must be completed in its entirety prior to submission to the UCH OCR for processing. Send the completed application with appropriate signatures via email to research-credential@UCHealth.com
- The Access and Authorization packet includes:
 - Appendix A: Research Personnel Application
 - Appendix B: Consent and Release (Researcher)
 - Appendix D: Confidentiality and Data Security Agreement
- The application must include the name, signature, and contact information of a direct supervisor/manager, physician, or EDDBA.

- By signing the application, the direct supervisor/manager, physician, or EDBA are responsible and accountable for the oversight of the applicant's execution of his or her tasks and responsibilities.
- The application must also include specific access requested, UCH cost center and billing contacts (the department is charged for background check and employee health screening)
- Once the application is received, the OCR will send a welcome email. In addition to information regarding what steps will be initiated by the OCR, the email will also include information for the applicant to initiate.
 - Information to initiate the required background check. Initiated by the applicant.
 - Employee Health appointment information to be scheduled by the applicant for a drug test and vaccination screening. Individuals with a lapse in employment greater than 30-days will again be required to complete drug testing.
 - Exclusion check. Please refer to UC Health Policy: UCH-CMP-ADMIN-009-02: Exclusion and Sanction Checking.
 - UCH required OneTouch training to be completed once the username number (UID) and employee identification number (EIN) are generated. An email from UCH OCR will be sent with this information. After completing all assigned OneTouch training, the researcher must submit a copy of his or her training transcript for verification to research-credential@UCHealth.com.
 - Epic research training information and schedule, if applicable will be sent by UCH OCR via email, once the UID and EIN are generated.
- Individuals experiencing a change in status (e.g. any change in department, part/full-time employment status, volunteer/staff employment status, or dual compensation status) should only submit Appendix A of the Research Access and Authorization application to research-credential@uchealth.com.
- Researchers who have not accessed the system for some time and have been removed from the UCH system, will need to complete Appendix A, B and D.
- If a research applicant transfers to another department or leaves and no longer requires UC Health research access, it is the department manager's responsibility to contact the OCR, UC and UC Health Human Resources representatives to update employee records.
- Once all requirements have been met, badging and/or Epic access will be approved. The researcher and direct supervisor will receive an email with approval and directions to pick up badge.
- Researchers who hold a professional license to practice within his or her discipline within the United States may be required to provide evidence of active licensure to the Medical Credentialing Office and receive UCH access via the Medical Credentialing Office.

Organizational units may institute policies more, but not less, restrictive than these guidelines if desired.

Related Forms/Links

- Appendix A: Research Personnel Application
- Appendix B: Consent and Release (Researcher)
- Appendix D: Confidentiality and Data Security Agreement
- <https://ucpapps.uchealth.com/apps/epicchangerequests/myrequests.aspx>

KEY WORDS

- Access
- Authorization
- Research
- Affiliate
- Volunteer Researcher
- External Researcher
- One Touch Training