University Hospitals Clinical Research Center

UH CLINICAL RESEARCH CENTER

11100 Euclid Avenue, Lakeside 1400 Cleveland, Ohio 44106 ClinicalResearch@UHhospitals.org

New Researcher Checklist

Investigators, Study Staff, Residents, Fellows & Students

CREC Program Certification

- ✓ What: The CREC Program provides documented training in the protection of human subjects in research. To be entered into the CREC Program, you must complete CITI BASIC Training.
- Who: All study team members conducting research at University Hospitals listed on the IRB application.
- ✓ **How**: Visit <u>CREC.case.edu</u>. Instructions can be found in the "Initial Core Training for CREC Certification" section.
- Course: CITI BASIC Training fulfills your Human Subjects Protection (HSP) training requirement
 - User must select Group 1 Biomedical or Group 2 Social & Behavioral
 - Non-UH employees also need to complete the CITI HIPS course.
 - If you are in involved with NIH-funded research, you must complete the CITI GCP Course.
 - If you completed CITI Training within the last 2 years, affiliate your account to transfer credits.

UH Research Credentialing

- ✓ What: Research credentialing grants non-UH personnel a UH title and e-mail address. Skip if you're a UH Employee.
- ✓ Who: All non-employees of UH who plan to access UH PHI, patients, property, equipment, and systems
- ✓ How: Read SOP GA 103: Research Credentialing and review the UH Research Credentialing webpage for instructions
 - After credentialing is approved, manager must submit a Sailpoint request for user access to the EMR, the UH GPS to complete required training, and other systems.

UH Investigator Training

- What: UH Investigator Training is a series of videos across five modules that serves as an introduction and detailed overview of the research process at University Hospitals.
- Who: Required for all Principal Investigators and recommended for all others.
- ✓ How: Available via UH GPS.

Clinical Research Orientation

- How: Required Training Send an e-mail to ClinicalResearch@UHhospitals.org to register for one option below:
 - **OPTION 1 -** Principal Investigators (PIs) and Physicians (approx. 30 min.)
 - OPTION 2 Staff & credentialed non-employees involved in research (approx. five hours)
 - Medical Students, Residents, & Fellows are exempt from the options above unless specified by Research Integration & Education or your Department Administrator.

☐ Velos Training

- ✓ What: Velos is the clinical research management software system in which all clinical research projects are required to be entered and managed. Training is designed to instruct study teams on the use of the Velos application.
- Requesting Access: Complete the appropriate training in UH GPS. Once completed, a notification will be sent to Velos Support and you will receive instructions for initial login within 24 hours.
 - Velos for Principal Investigators 15-minute training via GPS.
 Velos for Study Coordinators 1 hour training via UH GPS

SpartalRB Account Setup

- What: SpartaIRB is the electronic IRB submissions system shared by UH and CWRU
- ✓ How: Visit the <u>SpartalRB Info page</u> and click on <u>SpartalRB New User Request</u>.

Resources

Sign up for the UH Research Listserv to receive research-related administrative and educational communications.
✓ How: Send an e-mail to <u>ClinicalResearch@UHhospitals.org</u> .

Use the **UH Research Roadmap** to navigate the **UH** research process.

- Accessing PHI for research requires IRB approval.
- Accessing PHI for preparatory to research requires Privacy Office approval per UH Research SOP GA-102: Use and Disclosure of Protected Health Information Preparatory to Research.
- All Chart Reviews require IRB approval before collecting data.
- All Case Reports with three(3) or less patients do not require IRB approval.
 - Four(4) or more patients will be considered a systematic chart review and requires IRB approval.
- All Quality Improvement (QI) projects and Case Reports with ≤ 3 patients must be submitted to the IRB for Non-Human Research (NHR) determination

	Check out our	Research	Education	<u>Cata</u>	log	to sign up	for c	lasses	via	UH	GPS	or	live.
--	---------------	----------	-----------	-------------	-----	------------	-------	--------	-----	----	-----	----	-------

- ✓ Reach out to schedule a group session that works with your team's schedule.
- ✓ We can also customize education based on your needs and interests.
- Go to IRB Walk-In Hours for one-on-one help or to ask about the SpartaIRB system. See schedule: IRB Webpage.
- Contact Carrie O'Neill, Manager, Research Integration & Education, for help developing a customized learning plan, or add a meeting to her outlook calendar to discuss.