University Hospitals Clinical Research Center

UH CLINICAL RESEARCH CENTER
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FAQs for Industry Sponsors

1. **How extensive is your health care organization?**
   University Hospitals (UH) is one of the nation's leading health care systems providing the highest quality of patient-centered care and patient safety. UH has received numerous awards and recognitions from some of the most prestigious institutions in the country for our leadership and exceptional patient outcomes. The UH system has 50+ ambulatory health centers. UH conducts 11 million outpatient procedures and discharges more than 142,000 inpatients annually. UH covers approximately 2.1 million patients' lives. More than 28,000 physicians and employees constitute UH and its partnership hospitals, making it Northeast Ohio's second-largest private-sector employer.

   UH Seidman Cancer Center, the region's only freestanding cancer hospital, is devoted to treating cancer and hematologic disorders. UH Seidman is a founding member of the National Cancer Institute-designated Case Comprehensive Cancer Center. Fourteen disease teams focus on each type of cancer spanning Northeast Ohio, with 18 community-based cancer centers that cover the region.

2. **What is your experience in clinical research?**
   UH has a rich history of conducting clinical research. In 1962, UH was the first of 5 hospitals in the U.S. to have a hospital-based Clinical Research Unit allowing investigators to see their research patients on a nursing floor. The Clinical Research Center (CRC) was founded in 1996 and has become one of the largest biomedical research centers in Northeast Ohio, and one of the top 15 in the country. Currently, more than 3,400 active clinical research studies are encompassing all specialties; more than 300 of these studies are cancer clinical trials.

3. **Does your site(s) support inpatient and outpatient research?**
   Most University Hospitals Medical Centers are able to support both inpatient and outpatient research visits, as they are fully comprehensive hospitals. Most University Hospitals Health Center are able to support outpatient research, with laboratory, radiology, and specialty clinics. For other satellite locations, we are able to utilize the Mobile Research Unit to complete outpatient research visits.

   In addition, UH Cleveland Medical Center has a dedicated-research inpatient and outpatient facility which supports pediatric and adult patients, research staffing services for departments without dedicated research study teams, and numerous clinical trials unit spread across locations.

4. **What services does the Clinical Research Center offer?**
   UH Cleveland Medical Center is a comprehensive site, with a Clinical Research Center (CRC). The CRC adds additional support to all types of studies at UH in addition to the support that comes from the departmental/specialty level. The CRC offers support throughout the research process, from pre-development to study close-out and

publication. We have research education offerings, an internal IRB, recruitment services, study budget services, grants accounting, contract agreement and legal services, and research study team support. Some of these services include fee-for-service study support, with study coordinators, nurse coordinators, and FDA submission support. There is the Dahms Clinical Research Unit available to use for research patient visits. Services include nursing, bionutrition, and lab processing services. Additionally, the CRC has a Mobile Research Unit that assists with increasing accessibility and convenience to improve patient participation and engagement while enrolled in a study. See a complete list of services on our website.

5. **What experience do the different UH departments have?**
   Check out each department conducting research to see where their expertise lies. If you do not see the department you are looking for, please contact ClinicalResearch@UHhospitals.org to verify.

6. **Can you support all phases of clinical research projects?**
   Yes, our research site supports all study phases.

7. **Do you work with CROs?**
   Yes, our site has been establishing Master Confidentiality Agreements, and Master Clinical Trial Agreements with CROs to help streamline the process.

8. **Does University Hospitals require any training prior to conducting research?**
   Yes, we have a New Researcher Checklist for all levels of researchers. All researchers are required to be CREC certified which is checked by our IRB prior to approval of the study. Review the Clinical Research SOP GA-105 Investigator Responsibility for Study Team Training and Documentation for more details.

9. **How do you facilitate recruitment?**
   The CRC offers assistance with the recruitment for all studies. We have a comprehensive recruitment workshop and toolkit available to all investigators and study teams to teach and assist them with the recruitment of research participants. We also offer free study population querying through TriNetX, which gives us the ability to re-identify patients within our system who meet the study criteria.

10. **Do you offer clinical services outside of a medical setting?**
    The Research Support Core personnel and resources are dedicated to ensuring our patients and communities have access to clinical research opportunities by bringing research directly to the patients. Services include mobile research support, home health services, and virtual health services. In addition, study teams can utilize the Mobile Clinical Research Unit to conduct clinical services for research at other locations.

11. **Do you offer dedicated pharmacy services?**
    Yes, we have an Investigational Drug Services Pharmacy with services including procurement, inventory, and dispensing of investigational and non-investigational drugs for research protocols across the UH system.

12. **Can you store investigational drugs at different temperatures?**
    The Investigational Drug Services Pharmacy consists of 12 refrigerators, 5 freezers (20 C Freezer) and (70 C Freezer) and an ambient temperature and humidity monitor (ISENSIX). Readings by ISENSIX are performed every 5 minutes and are recorded for review.

13. **Are monitors allowed to review drug accountability logs, temperature logs, and other regulatory documents in the Investigational Drug Services?**
    Yes, there is dedicated monitoring space for monitors to review all documents.

14. **Do you have an Electronic Medical Records (EMR) System to generate and store source data for research projects?**
    University Hospitals utilizes EPIC as their electronic medical/health records system.

15. **Do you have an available local lab to perform routine blood test?**
    Yes, most medical/health centers within the system have one or more laboratories to draw specimens.

16. **Does your site have its own eConsent system?**
    We have the REDCap eConsent Framework to utilize for the entire system. This framework is not 21 CFR Part 11 compliant.

17. **Do you have an internal IRB Administration?**
    Yes, our Clinical Research Center has a Human Research Protection Program division with our internal IRB. The IRB Administration is supported by IRB Specialists who pre-review all submitted studies before going to the full board. This service ensures all study materials are submitted correctly before having the committee review for the final determination.

18. **What is the meeting schedule and process of the IRB?**
    Three committees meet on a bi-weekly basis. The M and J committees meet on rotating Tuesdays and review all non-cancer research studies. The C committee meets every other Thursday and reviews all cancer research studies.

19. **Does your site allow IRB submissions in parallel with negotiations of contracts?**
    Yes, it is possible to do both at the same time.

20. **Does your site allow studies to rely on another IRB?**
    The UH IRB has entered into reliance agreements with various institutions, as well as with independent central IRBs, including Advarra and Western IRB (WIRB). The UH IRB has also entered into agreements to participate in the national reliance platform, SMART IRB. The UH IRB will continue to consider new opportunities to rely on external IRBs accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

21. **Does the IRB approval for primary site cover all satellite sites?**
    When completing the IRB Application, users are allowed to list all sites they wish to conduct the research. IRB has to approve the sites before conducting research at them.

22. **On average, how long does IRB Approval process take?**
    On average, 4-6 weeks.

23. **On average, how long does the contract negotiation and signature process take?**
    On average, 6-8 weeks.

24. **Can your site provide, CAP and CLIA information from labs providing services to the study patients?**
    Yes, the research study team will provide these for you for the specific labs they will use on the research study. We have access to view all information throughout the system on our website for study teams.