School of Medicine

Clinical Research

OFFICE OF CLINICAL RESEARCH

November 2025

Investigational Device Management & Research Study Supplied Equipment

As a result of an IU Health internal audit, a remediation plan was put in place to identify medical devices and equipment brought into IU Health facilities. It is crucial that equipment and devices go through appropriate reviews for the protection of our systems and patients.

Device and Equipment Registration

IU Health requires registration of all investigational devices and research supplied equipment brought into its facilities as part of a clinical research study. This allows IU Health to build

research charge codes for investigational devices when appropriate and identify if any additional IU Health reviews are required such as:

- IT risk assessments (Required if device and/or equipment will be connected to an IU Health network or equipment OR if PHI will be entered into the device)
- Artificial Intelligence /Machine Learning reviews (required for studies where data will be used to train artificial intelligence or uses machine learning).
- Interoperability reviews (required for studies requiring integrations with EHR or other IU Health systems)
- Clinical Engineering Reviews (required for medical diagnostic equipment)

Both investigational devices and equipment are registered via *Research Device and Equipment Registration* (this replaces the previous RCS Charge Request form for IDEs)

Examples of devices and equipment that should be registered when used within an IU Health facility (not purchased by IU Health):

- All investigational devices
- ECG machines
- Spirometry Machines Fibroscans
- Any equipment that will be connected to an IU Health network
- Medical equipment

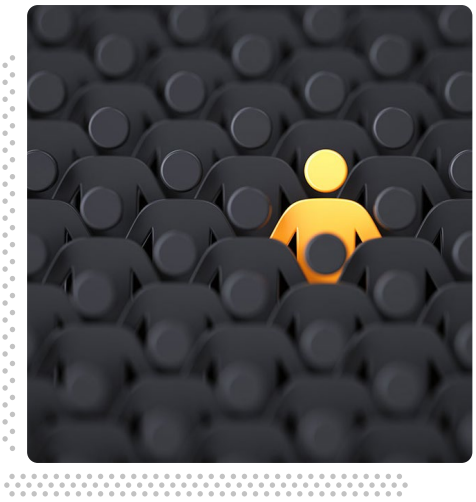
Equipment that does NOT need to be registered:

- Sponsor provided equipment sent home with patients (e.g. wearables, tablets, thermometers, glucose monitors, etc.)
- IU laptops
- IU tablets (not connected to the IU Health network)
- Equipment that will not be used within IU Health
- Small medical equipment not requiring clinical engineering reviews (e.g. thermometers, scales, finger oximeters)

The survey will be reviewed and you will receive a notification if further reviews are required and how to proceed.

Additional Resources can be found on the *Office of Clinical Research Website*:

- *IU Health Research-Related Policies*
- *Requirements for Device, Equipment, and Software in Research*



OneStudy Team

Enhancing Study Recruitment

OneStudyTeam: Enhancing Study Recruitment

IU Health is excited to announce that OneStudyTeam is now able to be used when offered by study sponsors. OneStudyTeam is a platform designed to streamline the recruitment process for clinical studies. This tool will enhance our ability to connect with potential study participants. IU Health has entered into an agreement with OneStudyTeam to obtain referrals from marketing campaigns for study recruitment. It is important to note that no additional agreements should be entered into by study teams. All access to OneStudyTeam will be managed through the IU Health process, ensuring a centralized and secure approach.

Process for Access

If a sponsor offers OneStudyTeam as a resource for recruitment, study teams should email *clinicalresearchsupport@iuhealth.org*. We will work with OneStudyTeam to add the study to the appropriate IU Health location. You will then receive an email from OneStudyTeam with a link to IU Health OneStudyTeam User Access Request REDCap Survey . You will be unable to log in until the IU Health Single Sign-On (SSO) process is activated. By completing the Access Request survey, you will attest that you will follow IU Health-specific requirements for using OneStudyTeam (including not entering IU Health patients PHI into the system) and one of our team will put in the SOLAR to activate SSO for you.

Other tools like OneStudyTeam are also used by industry sponsors. If you are offered a system that allows a user to enter IU Health patient data into the platform, it must be approved by IU Health for use. If the platform ONLY sends self-referred patients from a marketing campaign to the study team, you can use that system. When in doubt, please reach out to *clinicalresearchsupport@iuhealth.org*

Services Available Through the Indiana CTSI

A wealth of services are available to researchers through the Indiana CTSI. Please find a sampling of these services below and feel encouraged to check the CTSI website for further services.

Project Development Teams

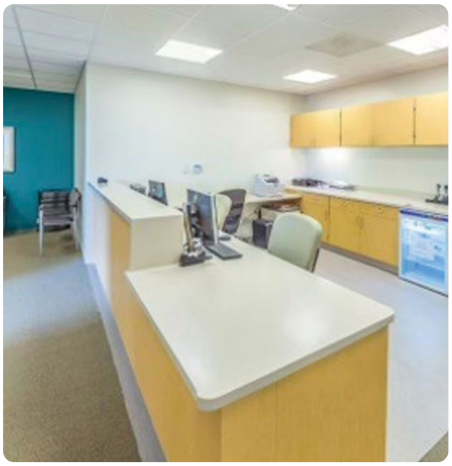
Project Development Teams (PDTs) are multi-disciplinary teams of experts who assist researchers in crafting proposals on multiple topics such as general research, community engagement, implementation, or device or drug development. There are specialized development teams to assist with commercialization and research projects, helping researchers go from an early concept to clinical use or grant submission.

Research Jam

Research Jam is a team of healthcare, research and design professionals using human-centered design to collaborate with doctors, patients and community members to ensure that health research, interventions and communications are more relevant to the community they serve. Services include facilitating in-person or virtual sessions with stakeholders, creating physical or virtual workbooks and toolkits and more.

Grant Writing Office Hours

The Indiana CTSI holds regularly-scheduled *office hours* with experts on specific topics such as Biostatistics, career development, community engagement and more. Keep an eye on the CTSI website for more information to come on 2026's office hours.



Clinical Research Center Update

Outpatient space and support will be provided by the Clinical Research Center (CRC) at Goodman Hall.

It is currently planned for the CRC space in Goodman Hall to be included on the hospital license, meaning that standard of care billing will be incorporated.

Discussions are ongoing as to how best to support studies that require overnight stays in the new hospital. But rest assured support for overnight stays will be available.

Changes have been made to the CRC approval process which has resulted in increased efficiency.

The CRC's strategic refresh remains in progress. This process has included convening small groups, conducting listening sessions with individuals regarding their CRC experience and conducting a survey to gauge how many groups have heard of or used the CRC and which services they used. This process is designed to best enable the CRC to meet the needs of researchers as we prepare for the move to the new hospital campus.

Indiana Biobank Data Portal for Researchers

On the May 1st OCR Community Call, we introduced the new OCR Clinical Research The Indiana Biobank has launched a new self-service researcher portal designed to support IU researchers and their collaborators. This portal provides secure access to browse genetic and de-identified clinical data from all Indiana Biobank participants.

Researchers can:

- Explore data to identify cohorts of interest
- **Request access to approved cohorts** in a secure cloud computing environment
- **Conduct analyses directly within the portal**

Analytical support (including genetics, and phenotyping) is available through the Biobank Analyses Core. Through the Indiana Biobank team, participants can also be recontacted for additional de-identified clinical data, biological samples, or new study opportunities.

Visit the Indiana Biobank Data Portal

IU School of Medicine
340 W 10th St
Indianapolis, IN 46202