



RESEARCH DEVICE AND EQUIPMENT CHECKLIST- VER. 2 24SEP2025

GENERAL IU HEALTH REQUIREMENTS

- ☐ If research study involves any study required devices, supplies or equipment, the [Research Device and Equipment Registration](#) is needed. This form is reviewed by the Clinical Research Charge Management team to determine whether a special charge code will be created for use in the charging and billing systems to ensure proper billing and/or pricing for the research related products. be completed. This form is reviewed by the Clinical Research Charge Management team to determine if a device requires a special charge code to be created for use in the charging and billing systems to ensure proper billing and/or pricing for the research related products. This form also records equipment brought into IU Health facilities to ensure all IU Health required reviews have taken place.
- ☐ Determine **location to store device(s)** and individuals responsible for device management.
 - Ideally, investigational devices will be managed by study team. Devices must be locked in a location with access limited to study team. Device shipping records, accountability records will be maintained by the study team.
 - If an implantable device or large device needs to be stored close to where device will be utilized, it may be appropriate to store somewhere within an IU Health location (i.e. close to a surgical location or radiology).
 - If anyone other than the study team will be responsible for device accountability, the study team is expected to provide training to IU Health team members on device accountability, maintenance of shipping records and appropriate storage conditions. The study team should document training and maintain in study records.
 - Device(s) should be stored in a locked storage unit, lockbox, or locked cage AWAY from normal IU Health stock and appropriately identified as investigational devices for use in clinical research only. Limit the number of non-study team members with access to devices.
 - Study provided Medical Equipment for clinical assessments (example: ECG machines, PFT machine, etc.) should be maintained by the study team unless it is difficult to bring equipment back and for to study visits. Work with IU Health team to determine if there is a location equipment could be stored within IU Health facility. Label the equipment to be used only as part of the research study.
- ☐ If the study will take place in an **IU Health Ambulatory Surgery Center (ASC)**, an IU Health ASC Research Acceptance Form will need to be completed. The form, a list of ASC locations can be found on the Office of Clinical Research website on [this page](#) and scroll down to IU Health ASC Research Acceptance Process.

STUDIES INVOLVING DEVICE IMPLANTS

- ☐ **Investigational Device Exemption (IDE) studies:**
 - Devices not currently approved for any use
 - Devices currently approved and marketed, but sponsor seeking new indication
 - Comparative effectiveness research involving approved devices
- ☐ **Clinical Trial Agreements**
 - IU Health should be a party to all clinical trial agreements involving investigational devices particularly when the device or the procedure will be billed by IU Health (with CMS approval)
- ☐ **Purchasing Agreements**



- IU Health must purchase devices that will be billed to third party payor or CMS
- Device Purchasing information may be included in the Clinical Trial Agreement. This is the ideal situation, but IU Health must be added as a party to the CTA
- The University should not go through purchasing or enter into a purchasing agreement for devices billed to a third-party payor.
- Contact clinicalresearchsupport@iuhealth.org and clinicaltrials@iuhealth.org to determine the appropriate contact for ordering/purchasing
- If there is a separate purchasing agreement, an IU Health attorney assigned to research will negotiate the purchasing agreement
 - Normally at IU Health, a request for purchase of equipment goes through the Lumere app for approval. Investigational devices will NOT go through the Lumere process.
 - If Vendor is not currently in the IU Health Oracle system, the vendor will need to register with IU Health. To identify the appropriate person to begin request, reach out to clinicalresearchsupport@iuhealth.org. Click [here](#) for more information about the Vendor registration process.
 - Tips for completion of contracts within either purchase agreement or purchasing information within Clinical trial agreement and/or purchasing agreement
 - Purchasing Contact: This would likely be an IU Health clinical coordinator at the location where the device is implanted (i.e. surgery clinical coordinator, radiology clinical coordinator)
 - Billing contact: CONFIRM that information has not changed: IU Health Accounts Payable, PO Box 7175, Indianapolis, IN, 46207, apinvoice@iuhealth.org , 317-962-4242. Always add the primary study coordinator email here also. If a specific IU Health contact is required, contact accounts payable to determine who is responsible for specific vendor.
 - Delivery Address: This should be worked out with the clinical staff in the location where study will take place.
 - If possible, delivery should be made to the research office for coordinator to maintain accountability of the device. Utilize the coordinator contact information.
 - There are circumstances where the devices should be shipped to clinical area. Ask clinical team to notify study team upon receipt and save all shipping documents. Ensure clinical team understands their responsibilities. Research team may need to provide locked storage options and signage. Follow instructions within GENERAL IU HEALTH REQUIREMENTS section for storage
- **Requesting Purchase Orders/Ordering Process**
 - Review of the purchasing language in the Clinical Trial Agreement or the purchase agreement to determine the type of Purchase Order (PO) needed for the study.
 - Work with your IU Health contact for obtaining PO numbers and ordering of devices (remember the vendor must be in the Oracle system prior to PO request)
 - Common PO Scenarios:
 - Sponsor Providing Device for Free: a no-charge PO may be required
 - Device is patient specific: A PO for each patient is requested once sponsor provides information about which components will be needed for the case.



- Sponsor requires certain amount of devices/in different sizes. CMS approval allows IU Health to bill to third party payor: Typically, a blanket PO is requested, and sponsor provides specific information regarding reordering process, etc.

□ **Device Research Billing Plan**

- During the coverage analysis process, the appropriate billing responsibility will be determined based on the study and research billing compliance rules and regulations.
- Upon completion of **Research Device and Equipment Registration**, Clinical Trials and Research Charging team will determine whether a special research code needs to be built for the study. This is called an SNX Code. You will be provided instructions for the clinical team to enter the charges.
- The SNX code includes the actual price of the device. If sponsor provides device for free, a \$1 dollar charge is entered, otherwise the charge will be based on U Health's purchase price. The SNX code also includes the CMS required elements for billing (i.e. claims modifiers and NCT number.) The NCT number alerts Patient Financial Services to complete further processing requirements.
 - IU Health device charge should not exceed the cost of what is necessary to recover costs of manufacture, research, development, and handling.
- Work with clinical staff in the area where device will be implanted. Provide appropriate training and outline the workflow for the study case. Communication with the clinical team is crucial.
 - Identify contact for scheduling the procedure. Ask clinical team if additional information would be helpful for them on schedule or within an order if needed.
 - Identify the group in charge of procedure preauthorization
 - If sponsor is paying for entire procedure, no preauthorization will be needed. Develop a workflow to be ensure the team is aware.
 - If the procedure and/or device will be billed to a third-party payor, preauthorization will be required for all payors (except for Medicare—must have CMS approval in place to bill to Medicare)
 - Have a plan in place for getting the device to the case. Communication with the clinical team prior to the implant is imperative. The coordinator is also responsible for ensuring that the clinical team on the day of the case understands the charge entry process.
 - The implanted device/associated equipment will be scanned by the clinical staff. This is part of the clinical documentation and will be recorded within the EMR operative records.
 - Work with clinical team on charge entry process. Provide instructions given to you by the Clinical Trials and Research Charging Team.
 - If using IU Health stock supply, ensure that the SNX code is used for charge entry-NOT the Oracle number. This may involve working with a charge entry specialist outside of the surgical team.
 - If the sponsor will be sending a representative to assist with the implant, they will need to register in [Vendormate](#) and sign in, obtain a badge on the day of the procedure. For questions, please contact VendormateCred@IUHealth.org

- When **study completed**, all devices should be returned to the sponsor. If FDA approval of the device is received, the provider will need to follow IU Health Lumere process to request device purchase for the IU Health system and subsequent entry into the Oracle system



- ☐ If a Research charge code is built for a study device, notify clinicaltrials@iuhealth.org **immediately** so the code can be discontinued. There have been several circumstances where the clinical team charged the research code instead of the Oracle code with lost IU Health revenue.

STUDIES INVOLVING DEVICES OR EQUIPMENT REQUIRING AN IT RISK ASSESSMENT

- ☐ If study equipment or devices involves any of the following scenarios, an IU Health IT Risk Assessment will be required:
 - Connection to an IU Health network, either via ethernet or wi-fi
 - Integration with Cerner or other clinical system (ex. MUSE, synapse, PACS, etc.)
 - Automated extraction of data from an IU Health system (Cerner, Muse, Synapse, etc.)
 - Entry of Personal Health Information (PHI) into the Device
- ☐ To complete an IT Risk Assessment (ITRA), email ISclinicalresearchsupport@iuhealth.org. An analyst will initiate the process for you. A scoping document will be provided and will need to be completed by study team and vendor supplying the device. The information security team will review the scoping document to determine if a full ITRA will be required. Please submit as early as possible to not delay study start up.
- ☐ ITRA is the first step in reviews. Other reviews may be required as noted below.

STUDIES INVOLVING SOFTWARE OR ARTIFICIAL INTELLIGENCE

- ☐ Studies or software involving Artificial Intelligence will need to be reviewed by the AI/ML (Artificial Intelligence/Machine Learning team. You will be notified of this requirement as part of the ITRA process. For questions reach out to ISClinicalResearchSupport@iuhealth.org.

STUDIES INVOLVING CLINICAL SYSTEM INTEGRATIONS OR AUTOMATED DATA EXTRACTION

- ☐ This work may utilize multiple IS teams and will typically require funding for the IU Health resources used. You will be notified of this requirement as part of the ITRA process. For questions reach out to ISClinicalResearchSupport@iuhealth.org.

MEDICAL EQUIPMENT PROVIDED SPECIFICALLY FOR STUDY'S CLINICAL ASSESSMENTS

Many studies provide medical equipment to standardize clinical assessments for multi-site studies (ex. ECG machine, spirometry, fibroscan etc.)

- ☐ If the medical device will be used in an IU Health clinical space, clinical engineering will need to check the equipment
 - IU Health contracts with Trimedx to check medical equipment for most hospitals in the system.
 - To find more information about the service request process, review this [page](#) on the IU Health team portal. Additional information is available [here](#). You may also call 317-962-8044 to reach Trimedx team directly.



- ☐ If the medical equipment will require IU Health clinical staff to use the equipment, work with the appropriate IU Health team to provide training.
 - If the IU Health team member is utilising the equipment along with standard of care procedures and taking time away from IU Health duties, consider working with team to reimburse for their research related time.
- ☐ If medical equipment requires Cerner Integration, access to IU Health network, involves Artificial intelligence or entry of Personal Health Information (PHI) into device review, please follow applicable instructions above.