

Administrative Information

Q: Why do I need to include the pager and mail code for key study contacts?

A: Sites need to know pager numbers and best mail location for communicating with key contacts on the study.

Q: What if a key contact does not have a pager number?

A: Alternatively you may enter the cell phone number or other best contact number. Otherwise, simply record N/A in the box.

Research Participants

Q: What do I put in the annual accrual rate if recruitment might vary per year or by performance site?

A: Record the expected annual accrual across all performance sites. Of note, the eIRB asks for the total number for the entire study, not annually.

Q: Does the exact number of subjects/charts to be reviewed need to be known at the time of the “NR3” application submission?

A: No. However, the approximate number should be included in the initial application.

Q: Should requests for audits/monitors be included in this number?

A: No. Refer to the policies of the individual performance sites for requesting access to medical records.

Services/Locations

Q: What is meant by “obtain physician referrals”?

A: In order for performance sites to anticipate resources we need to know if you are planning on obtaining physician referrals only and not performing other activities or requesting other services from ancillary departments such as lab or pathology. If you are only obtaining referrals, performance sites consider this a “recruitment” only study.

Q: If the only activity to be performed at a performance site is obtaining informed consent, is that considered a study activity requiring performance site approval?

A: Yes, consenting is a study activity and should be recorded in Services/Location question 3.

Q: Why do you need to know where the tests will be performed?

A: Performance sites need to anticipate resources and applicable approvals for each location (e.g., department leaders for each clinical area need to approve plans for study activities in their clinical areas).

Supplies/Equipment/Devices

Q: What additional information is needed under “Please describe under the HUD section”?

A: Performance sites need to understand the financial impact on the patients and the organization. If the sponsor is not paying for the device, please provide information on cost as well as who is paying for the device. All other study tests and procedures should be outlined in the Clinical Trial Coverage Analysis (CTCA).

Q: What are some examples of non-standard medical equipment?

A: Examples of non-standard medical equipment may include special tubing for infusions, special infusion pumps, dynamometers, or EKG machines. *Note- With the exception of Children's HealthSM, vacutainer tubes and lab kits supplied by the study sponsor are NOT considered non-standard medical.*

Performance sites need to understand how the medical equipment will enter the institution and where the equipment/supplies/devices will be securely stored and how they will be transported to and from the site. Non-standard equipment requires additional reviews and safety checks by the respective performance sites biomedical department.

Q: What are some examples of non-standard medical devices?

A: Examples of non-standard medical devices may include non-FDA approved devices, cardiac stents, orthopedic devices, cardiac defibrillators or ocular lens.

Q: If a laser is to be used and is FDA approved and considered standard of care, do I still need to list it on the Performance Site Review Form?

A: Yes. If a laser will be used, state if it is standard of care and if it is FDA approved or not. The use of lasers requires notification of Environmental Health and Safety.

Q: Where do I record instruments such as autoclaves or surgical instruments?

A: Record instruments being brought into the institution under the "Other Equipment" section.

Study Team Credentials at the Site

Q: What is the purpose of this section?

A: Performance sites need to know who will be in their institution and determine credentialing requirements based on role.

- **Parkland** requires all non-physician research staff to be credentialed through the Office of Research Administration. For questions regarding credentialing email: Research.credentialing@phhs.org.
- **University Hospitals** require all personnel listed as study team members in the IRB submission be credentialed through Medical Services.
- **Children's HealthSM** requires all researchers not employed by Children's Health be credentialed through Medical Staff Services at Children's Health.

Q: In the Study Team Credential Section, do I need to include all study team members?

A: Only those research staff members who will be involved in research activities at the performance site or who will have contact with patients (such as consenting, enrollments, blood draws, need EPIC access. etc.) need to be included.

Q: I don't know if the key contacts are credentialed at the performance site, how should I complete that box?

A: You may leave the “Need Credentialing” box blank and the performance sites will contact you should follow up action be required. If you know the study team member is not credentialed but will require credentialing, indicate that by checking “Yes” on the Site Performance Review Form.

Q: If the research staff members are also employees of the performance site, do they need to go through the credentialing process?

A: This varies by performance site and may be confirmed by each site:

- **Parkland** – employees of the institution are already credentialed at the site.
- **University Hospitals** – the employee status will be verified
- **Children’s HealthSM** – employees do not need to go through the credentialing process, however there are other research specific modules that must be completed by research staff members.

Q: Can the study coordinator and other study team members perform blood draws at the performance site?

A: Each site has their own policies regarding performance of clinical functions. Please refer to the policies of the respective performance site.

Pharmacy

Q: What is the purpose of this section?

A: Performance sites need to anticipate resources. FDA approved drugs used for a non-FDA indication are considered “investigational”. If dispensation of investigational medications will occur after hours or on weekends, the IDS will need to plan for coverage.

NOTE: ONLY licensed research team members performing within the scope of their individual licensure are allowed to administer medications in a clinic or hospital.

Q: Do I need to supply the Investigators Brochure (IB) to Investigational Drug Service (IDS) directly?

A: This varies between performance sites:

- **Parkland** - upload to Velos and/or eIRB and the Office of Research Administration will send the IB to IDS.
- **University Hospitals** - contact IDS directly to contract services for studies.
- **Children’s HealthSM** - submit the IB and pharmacy manual to the Children’s HealthSM IDS at IDSRx@childrens.com

Q: What box do I chose if the medication is an FDA approved drug used in an off label manner?

A: Choose the investigational medication box.

Q: The protocol requires dispensation of medication after 5pm. Where should I indicate that the protocol requires staffing resources to administer after hours?

A: Record in the “Who will administer study medications” question under “Additional Comments”.

Imaging

Q: What is the purpose of this section?

A: Performance sites need to anticipate resources. All research protocols that involve imaging procedures conducted on clinical imaging equipment must be formally reviewed by the Radiology Research Committee. This committee is separate from the Sub-Committee for the Human Use of Radiation (SHUR). This applies to research protocols that involve standard of care imaging procedures as well as protocols that involve research imaging procedures. The purpose of the review is to determine the feasibility and rigor of the study from an imaging prospective, based on protocol requirements and equipment/resource availability. The committee determines the location(s) where the study will be conducted based on these criteria. The study may require a consultation between the investigator and a radiologist and/or scientist for the purposes of protocol development or modification. When deemed appropriate, the Radiology Research Committee may recommend inclusion of members of the Department of Radiology with specific expertise as co-investigators to support the research study. Similarly, the Radiology Research Committee will review and respond to request from investigators looking for collaborators within the Department of Radiology that can support the study.

Q: What does professional read for imaging mean?

A: This varies between performance sites.

- **Parkland** - This means the images will be read at a central location and not read locally at Parkland. This will not generate a professional read fee and may require additional study start up time to create an order set in Parkland EPIC. Please see Final Study Requirements Approval Email for specific study requirements.
- **University Hospitals** - A professional read means the study requires a clinical interpretation by the Radiologist and this interpretation will be reported in the medical record. When a study indicates that images will be sent to a central imaging lab for interpretation it does not mean that a local read will not be required. If the study site is responsible for evaluating incidental findings, then a local read may be required. It will be up to the Radiology Research Committee to determine if a local read is required.
- **Children’s HealthSM** – Procedures performed on hospital owned equipment usually require a professional read and therefore result in a physician fee being generated that will be routed to UT Southwestern to be billed. When reading fees are paid for by the study, the researcher must ensure the professional fees are billed to the UT Southwestern research account and not to the patient.

Q: What information is required in the “additional comments section under imaging”?

A: All sites -Please include specific locations for imaging procedure(s) since they are done at a variety of locations.

- **University Hospitals** - Please indicate if there is a separate imaging or operations manual for the study. This will need to be sent to the Radiology Research Committee along with the protocol to review.
- **Children’s HealthSM** - Please indicate if there are specific imaging requirements and/or operations manual for the study. Indicate if the images will need to be de-identified prior to data transfer.

Pathology

Q: What is the purpose of this section?

A: Performance sites need to anticipate use of resources, staffing (e.g. hospital staff, physicians, nurses, therapists and others not on study team), and fees if applicable.

Q: How would I record if the labs per protocol are sent and resulted by an outside laboratory and drawn along with the standard of care labs?

A: If a study is only collecting laboratory data, this section of the application should not be completed. This section only applies when a study is requiring a billable procedure. Answer “No” to “Will any pathology or laboratory services be needed”. However, if you need the performance site to draw the samples, mark “Yes”.

Performance Site Staff Resources

Q: What is the purpose of this section?

A: Performance sites need to anticipate use of resources, staffing (e.g. hospital staff, physicians, nurses, therapists and others not on study team), and fees if applicable.

Data Requests

Q: What is the purpose of this section?

A: Performance sites need to anticipate use of resources, staffing, and fees if applicable.

Q: What additional information is needed to complete a data request? Are there additional fees associated with data requests?

A:

- **Parkland** - requires a separate data request form to be completed. After you submit the Performance Site Review Form, a member of the Office of Research Administration team will contact regarding the data request.
- **University Hospitals** – When all record reviews will be performed by study team members and only from electronic medical records (rarely will any additional fees or paperwork be imposed). When you require assistance from medical record staff members and hard copy charts – additional paperwork and fees apply.
- **Children’s HealthSM** - There are no fees associated with Electronic Medical Record reviews performed by credentialed study team members. Paper chart reviews may have an associated fee for record retrieval from long term storage. Requests for building electronic data reports for research purposes may have an associated fee.

Performance Site Approval

Q: Will the study team receive notification of the outcome of the performance site review?

A: Yes. Once the request is approved, the performance site reviewer will add the status “Performance Site – Approved” if approved, or “Performance Site – Disapproved” if not approved. These status changes will generate an email notification to the PI, Primary Research Coordinator, and Study Author.