CAMPUS OVERSIGHT PLAN
(for DUHS IRB protocols from Campus-based researchers)
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Campus Oversight Organization for DUHS IRB Protocols
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Duke University Health System Institutional Review Board (DUHS IRB) approval is required for all studies involving human subjects that utilize Duke University Health System (DUHS) patients, patient information, resources (equipment or personnel), or services that generate a Maestro Care charge. The operating business units responsible for the integrity, financial accountability, regulatory compliance, quality, and academic productivity of clinical research studies are the School of Medicine's site-based Clinical Research Units [CRU; per the Duke Office of Clinical Research (DOCR) policy: Scope of Oversight and Responsibility of Clinical Research]. Campus investigators who wish to conduct studies using any of the Duke Medicine resources listed above must receive DUHS IRB approval; however, depending on the nature of the study, a CRU may not be the appropriate operational home for the proposed research. In some cases, an Oversight Organization may provide the necessary guidance.

This Oversight Plan outlines the steps necessary to allow for efficient protocol approval and start-up for studies submitted through the DUHS IRB that fall outside of CRU oversight. Certain functions (detailed below) will be the responsibility of the Oversight Organization, the associated Content Area Review Committees, or DOCR; however, the primary responsibility for maintaining research integrity shall remain with the Investigator.

During proposal and protocol development, please feel free to contact the manager of the **Campus Oversight Organization for DUHS IRB Protocols** (Marissa Stroo, marissa.stroo@duke.edu) and/or schedule a study-planning meeting with DOCR staff (email docr-studyplanning@dm.duke.edu).

DOCR Responsibilities

- Assist with determining whether CRU oversight is required.
    - If CRU oversight is not required, DOCR will contact the Campus Oversight Organization Manager to ensure that the protocol is included in the Campus Oversight Organization portfolio.
    - If CRU oversight is required, DOCR will communicate with the study PI and request the change. The protocol will then fall under the oversight of the selected CRU.
- Approve the protocol in eIRB once the following items are complete:

    - All members of the study team have completed mandatory training.
    - The Campus Oversight Organization has approved the protocol in eIRB.
    - No other major outstanding issues exist that may hinder institutional approval.
- Serve as a resource to:
    - The Campus Oversight Organization Director and Manager
    - Campus faculty and staff
- Offer study planning meetings to interested faculty/students/study teams
- Compile regular reports and share with Campus Oversight Organization and others

Campus Oversight Organization Responsibilities

- Responsibilities related to review of protocols:
    - Identify a recipient in each Content Area Review Committee that will receive relevant study protocols, when appropriate.
    - Be aware of each Committee's processes to assist with navigation and timely processing of study protocols.
    - Identify reviewers in each Committee that will review study protocols. Maintain current contact information.
    - Identify ad-hoc scientific reviewers to whom identified protocols can be sent when they fall outside of an identified Committee's organization.
- Training:
    - Ensure faculty and staff training compliance and provide guidance as needed.
    - Disseminate information to faculty and staff as training requirements change.
    - Create and serve as resource for all protocol reviewers and subgroup organization contacts. Provide training for protocol reviewers as necessary.
- Conduct Research Data Security Plan (RDSP) review (Note: All RDSP reviewers shall take RDSP training offered by the IT Security Office)
    - Investigators will be made aware of data security training offerings.
    - Campus Oversight Organization Manager recommends that any data sent to or received from external collaborators be de-identified (remove all PHI indicators) prior to data transfer if applicable and possible.
    - Connect the Chief Information Security Officer, Richard Biever, with study teams to discuss secure data transfer, storage, etc., as needed.
- Ensure maintenance of regulatory documentation (see PI responsibilities for regulatory file guidance)
    - In concert with Investigators, the Campus Oversight Organization Manager will review reports of regulatory reviews, provided by the study team. These reviews may be conducted by the study teams themselves or by external services such as the Duke Office of Audit, Risk and Compliance (OARC).
- Financial/contract oversight
    - Campus Oversight Organization Manager will contact the appropriate department business manager to confirm financial feasibility and oversight within the department, when appropriate.

Content Area Review Committees Responsibilities

- Identify a primary contact for general questions that come from the Campus Oversight Organization Manager.
    - **Scientific review committees - protocols reviewed to ensure study scientific merit** (See DOCR policy: Scientific Review of New Clinical Research Proposals)
        - Student projects are reviewed and approved by thesis committees or other appropriate body as necessary
        - Faculty projects will be reviewed via pre-submission peer review committees when possible, or individual review when necessary
    - **Business manager or department – study reviewed to ensure feasibility (financial, etc.)** and to ensure investigators are supported to conduct high quality research.
        - In accordance with institutional policies, work directly with PIs and study teams to ensure that they are filing internal and sponsor-required reports and tracking study-specific expenses/revenues.
        - May provide internal review/audit of regulatory documents for research studies
        - May provide guidance in the preparation of monitoring/review visits (e.g., from OARC)
        - Take part in coordination of budget development or effort estimation.

Investigator Responsibilities

- At time of submission, select appropriate organization and, if applicable, CRU that correctly aligns with scope of research.
    - Studies that utilize Duke School of Medicine research equipment, resources, or patient data, but not patients or DUHS chargeable services, may select the Campus Oversight Organization (listed in the eIRB as: *Oversight Organization – Campus*).
    - If any DUHS patients or facilities/resources will be used, a CRU must be designated.
- Ensure that for each protocol, the research activities are understood and fully resourced.
- Ensure that study team members receive study-specific training and are qualified to carry out the proposed research activities. This includes training related to the informed consent process. (See IRB policy: Appropriate Study Personnel to Conduct the Consent Process). In accordance with institutional policies, work with the departments to file internal and external regulatory submissions and verify study-specific expenses/revenues.
- Ensure compliance with guidance and policies related to the following (contact DOCR if there are questions about anything below):
    - Subject identification/screening/consent
    - Enrollment/accrual/retention/re-contact (as appropriate)
        - Ensure that study team understands key milestones, expected timeline,

etc.
        - Ensure ongoing maintenance of an enrollment log that includes at minimum: participant identifier, date of consent, whether participant was accrued*, and date of accrual (*accrual is a dichotomous variable that indicates whether participant has evaluable data).
    - Sample collection, processing and storage
    - Data collection
    - Data integrity (accuracy and consistency of the data over time)
    - Data transfer and/or receiving data from other institutions (agreements in place as needed)
    - Data retention (how stored, how long)
    - Storage of Social Security Numbers, even if just for payment, per the guidance from the Information Security Office entitled Guidance on Duke Social Security Number (SSN) Storage Approval Process
- Ensure compliance with guidance and policies related to scope of work that can be conducted by students. This includes issues related to sharing of data with students who may leave the institution, informed consent conducted by undergraduate students, and export control issues of international students.
- Ensure that the effort expended by personnel matches the effort for which employees are compensated. Effort tracking is expected to follow institutional policy. This is accomplished via the annual ECRT process.
- Ensure that published results are appropriately reported, depending on funder or other existing requirements.
- Ensure compliance with Federal requirements for entry of http://clinicaltrials.gov/ results, or other appropriate registries depending on funding source.
- Maintain a regulatory file for each study. Whether this is a physical binder or online storage of files will depend on the complexity of the study. File examples are available, and options can be discussed in a study-planning meeting with DOCR as mentioned above. Recommended contents of a regulatory binder can be provided by DOCR, and should include documents such as a Delegation of Authority Log, all IRB communications, and a copy of the protocol and consent templates. Here is some general guidance:

    1) Retrospective studies (secondary data analysis)
        a) Delegation of authority log
        b) IRB communications, including approvals
        c) Study protocols
        d) Must maintain and audit regulatory file at least annually
    2) Prospective data collection
        a) Delegation of authority log
        b) IRB communications, including approvals
        c) All versions of study protocol, consent, recruitment documents

d) Intervention studies shall have at least 10% of study participant files reviewed, including informed consents, adverse event reporting, and outcome ascertainment.
e) Must maintain regulatory files, and provide a completed "Regulatory File Checklist" to the manager at the time of continuing review. The checklist will show that the team has ensured that the regulatory file is updated, and reviewed concordance of the enrollment log and consent forms.

- Regulatory files should be reviewed/audited according to standard operating procedure.
  - Whenever possible, reviews/audits should be performed by an independent and knowledgeable party.
  - Faculty may wish to hire research staff from outside of their project to perform the review or assist with preparing for the review. DOCR has capable, experienced coordinators who can perform this function. If funds are not available, then they may utilize their own staff to conduct the review. OARC is a knowledgeable resource for all study teams and may be willing to conduct an educational review at the request of the study team or the Campus Oversight Organization. In addition, DOCR offers free classes on study documentation that can assist all study teams.
  - An annual report of any external audits/reviews should be provided to the Campus Oversight Organization manager. If the PI is aware that an outside agency is intending to conduct a review or audit, s/he must notify the Campus Oversight Organization manager and OARC prior to the audit/review.

Appendix materials:

- General questions about DUHS research oversight, resources, training or IRB process– DOCR (docr.help@dm.duke.edu)
- DOCR policies http://docr.som.duke.edu/policies-procedures/policies
- RDSP: Richard Biever, Chief Information Security Officer, OIT and Holly Benton, Privacy Compliance Director, OARC resource for questions regarding secure data transfer, storage, collection, etc.
- Review process documentation and checklists.