DGHI RESEARCH OVERSIGHT PLAN
(for human subjects research conducted by DGHI faculty and students) approved 10/16/2014

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An Oversight Plan is required to ensure the integrity, financial accountability, regulatory compliance, and quality of clinical research. Certain functions will be the responsibility of DGHI (noted below) or DOCR (noted below), but the primary responsibility for maintaining research integrity remains with the Investigator. During the proposal and protocol development, please feel free to contact Kelly Deal (Kelly.deal@duke.edu) and/or schedule a research planning meeting with Rebecca Brouwer at DOCR (rebecca.brouwer@duke.edu).

Submission to the DUHS IRB is required for SOM faculty conducting human subjects research with health outcomes. If no DUHS patients or locations will be used, DGHI can be listed as the Owning Organization. If any DUHS patients or locations will be used, A Clinical Research Unit (CRU) must be used. The guidelines below currently only apply to protocols submitted through the DUHS IRB (eIRB) system.

DOCR Responsibilities

- Review eIRB protocol and approve once DGHI Research approval is received
- Offer study planning meetings to interested faculty/study teams
- Serve as a resource to DGHI
- Compile regular reports on faculty & staff training compliance
    - DGHI (Kelly Deal) will contact faculty & staff whose training needs to be completed

DGHI Responsibilities

- Review research protocols as part of the eIRB submission process
    - Protocols reviewed to ensure study scientific merit, feasibility (clinical, financial, etc.) and to ensure investigators are supported to conduct high quality research.
        - Student projects are reviewed and approved by Thesis Committees
        - DGHI Research will review faculty projects via pre-submission peer review when possible, or individual review when necessary
    - RDSP data security review (Kelly Deal, Research and Patrick Daniels, IT)
        - Investigators will be made aware of online data security training module
        - DGHI encourages that any data from international collaborators be de-identified (remove all PHI indicators) prior to data transfer

if applicable and possible
        - Patrick Daniels is available to study teams to discuss secure data transfer, storage, etc.
- Take part in coordination of contract negotiation (ORA, ORS, or DGHI Finance & Grants team, according to Duke Institutional policies, if applicable)
- In accordance with institutional policies, DGHI Finance & Grants team members work directly with Principal Investigators to ensure that they are filing internal and external regulatory submissions and tracking study-specific expenses/revenues.
- Kelly Deal works with the Finance & Grants team to ensure that internally-funded projects have identified fund codes in accordance with the Internally Funded Project Fund Code Guidance document.
- In concert with Investigators, Kelly Deal and John Bartlett will review annual reports of regulatory audits, provided by the study team.

Investigator Responsibilities

- Ensure that for each protocol, the research activities are understood and fully resourced.
- In accordance with institutional policies, Principal Investigators will work with DGHI Finance & Grants team members to file internal and external regulatory submissions and verify study-specific expenses/revenues.
- Ensure that study team members receive study-specific training, and are qualified to carry out research activities.
- Ensure compliance with guidance, policies and good clinical practice (GCP) related to:
    - subject identification/screening (in person, phone, chart abstraction)
    - consent
    - enrollment
        - ensure that study team understands key milestones, expected timeline, etc.
        - ensure ongoing monitoring
    - subject retention and re-contact
- Ensure compliance with guidance, policies and GCP related to:
    - 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)
- Track effort of personnel (Effort tracking is expected to follow institutional policy)
- 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.

To ensure compliance, **Investigators should maintain a Regulatory File**. Whether this is a physical binder or online storage of files may depend on the complexity of the study. File examples are available, and options can be discussed in a Research Planning meeting with Kelly or Rebecca as mentioned above. Recommended contents of a Regulatory Binder can be provided by DOCR, and should include documents such as a project staff list and training updates, all IRB communications, a copy of the protocol and consent templates.

1) *Retrospective studies* (secondary data analysis)
   a) Must maintain and audit their regulatory file at least annually

2) *Prospective data collection and/or intervention* – international work only
   a) Must maintain and audit regulatory files annually.
   b) Intervention studies shall have at least 10% of study participant files reviewed, including informed consents, adverse event reporting, and outcome ascertainment.

Regulatory files should be audited according to standard operating procedure.

a) Whenever possible, audits should be performed by an independent and knowledgeable party. If existing audits are performed routinely by site monitors, then these reports will suffice.
b) If site monitors do not routinely audit study records, then faculty may wish to hire clinical research staff from outside of their project to perform the audit. If funds are not available, then they may utilize their own staff to conduct the audit. The Duke Ethics and Compliance Office (DECO) is a knowledgeable resource for all study teams and may be willing to conduct an educational audit if requested.
c) An annual report of audits should be provided to Kelly Deal and John Bartlett.

RESOURCES:

- General questions about DUHS research oversight, resources, training or IRB process– DGHI (Kelly Deal) or DOCR (Rebecca Brouwer)
- DOCR policies http://docr.som.duke.edu/policies-procedures/policies
- RDSP: Patrick Daniels – resource for questions regarding secure data transfer, storage, collection, etc.
- Master Regulatory File checklist (available)
- Templates attached: Consent Process, Recruitment and enrollment monitoring, draft specimen collection, signatures and delegation of authority log