RELIANCE BY EXTERNAL SITES ON THE DUHS IRB

8/5/2021

The Duke University Health System Institutional Review Board (DUHS IRB) may act as the IRB-of-Record for research sites external to DUHS under the conditions defined in this policy. Herein, 'IRB-of-Record', 'single IRB' (sIRB), and 'central IRB' (cIRB) shall be used interchangeably. Examples of when such reliance may be permitted include: a multi-site research study in which a DUHS investigator is the overall PI; an external site that has an institutional conflict-of-interest and has previously arranged for the DUHS IRB to act as its IRB-of-Record for specific studies; and as part of master cooperative agreements to which the DUHS IRB has joined, in which the DUHS IRB may choose to act as an IRB-of-Record for other participating sites. These agreements may include, but are not limited to, the SMARTIRB agreement.

The DUHS Institutional Official (IO) or his/her designee has the ultimate authority regarding the decision to permit the DUHS IRB to function as the IRB-of-Record for external sites. Day-to-day reliance decisions will be made by the IRB Executive Director, or in the absence of the Executive Director, his/her designee.

In the rare instances when the NIH has given an exception from single IRB review for a multi-site NIH funded study, and when Duke is the primary award holder, the rationale for not relying upon a single IRB review (in accordance with NIH policy on exceptions from single IRB review) will be documented for that study in the iRIS system.

I. Considerations for Assuming the Role of IRB-of-Record

Before choosing to act as an IRB-of-Record for external sites, the IRB Executive Director shall consider the following:

1) the anticipated length of the study and the number of relying external sites are reasonable in proportion to DUHS IRB resources to guarantee appropriate oversight;
2) a DUHS IRB investigator has a prominent role in the multi-site study;
3) the risk/benefit of the study is reasonable, and reliance on the DUHS IRB does not result in unreasonable liability to the DUHS IRB or the institution; and
4) each relying site is in good standing with OHRP, FDA, and all applicable regulatory agencies.

Relying sites are encouraged to sign the joinder to SMARTIRB. However, if relying sites are unable or unwilling to sign the joinder, the DUHS IRB can execute DUHS' template IAA with an individual site.

II. Responsibilities of the DUHS IRB as an IRB-of-Record for External Sites

1) The DUHS IRB will be guided by all federal regulations and guidance applicable to research involving human participants in its review of research conducted by relying sites.
2) The DUHS IRB will ensure that convened IRB minutes pertaining to the relevant research study be made available to relying sites upon request. The DUHS IRB reserves the right to execute a Confidentiality Agreement with the relying site prior to providing minutes, as determined appropriate.
3) The reviewing IRB will be responsible for reporting serious or continuing noncompliance; unanticipated problems involving risks to subjects or others; and

suspensions or terminations of IRB approval. However, there may be cases in which the DUHS IRB reaches out to the relying institution to report these items jointly.

A written reliance agreement must define the responsibilities of the relying organization and reviewing IRB. When following DHHS and FDA requirements, ordinarily the reviewing IRB is responsible for obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners.

Responsibilities of the DUHS IRB as the IRB-of-Record for external sites are defined in the IRB Authorization Agreement (IAA), and in the terms of the Master SMARTIRB Agreement.

III. Responsibilities of a Relying Site

1) Each relying site must have adequate oversight processes in place to ensure compliance with the determinations of the DUHS IRB, and must be able to provide documentation of these processes to the DUHS IRB upon request.
2) Each relying site must be able to ensure that its researchers participating on the study are in good standing with the site's institutional policies and all applicable federal agencies.
3) Each relying site must inform the DUHS IRB of any relevant local context issues and protocol specific issues prior to initiation of any research activities at the site.
4) Each relying site must either: (i) ensure that its employees participating in the research study have met the ethics training requirements of the site; or (ii) ensure that its employees complete the Duke Health CITI training requirements as mandated by the DUHS IRB.
5) Each relying site must have processes in place to promptly report safety events, including adverse events and protocol deviations/violations, to the lead study team at Duke for reporting to the DUHS IRB.
6) Each relying site is responsible for meeting additional certification requirements, such as Certificates of Confidentiality or the NIH Genomic Data Sharing Policy.

Responsibilities of the Relying Site are further defined in the template IAA and in the terms of the Master SMARTIRB Agreement.

IV. Responsibilities of the Lead Study Team

The Lead Study Team is defined as the study team at Duke that is acting under the direction of the Duke Principal Investigator for the study. The Lead Study Team will function as the conduit between the DUHS IRB and relying sites and will make all submissions to the DUHS IRB on behalf of relying sites as well as notify the relying sites of all study-wide DUHS IRB determinations and communications including those for initial review, continuing review, amendments and reportable events. The Lead Study Team will ensure that it:

1) obtains all required documentation to add on relying sites (e.g., reliance agreements, local context survey, protocol specific document, staff listings, etc.);
2) promptly collects safety events from relying sites and submits them to the DUHS IRB for review;
3) dispenses multi-site safety information to the relying sites if a formal coordinating center has not been established for the study;
4) relays questions and/or requests for modifications from the DUHS IRB to relying sites and submits site responses to the DUHS IRB for consideration;

5) provides IRB approval notices to the relying sites once DUHS IRB review is complete and provides the participating relying sites with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials);
6) ensures that Duke Health CITI credentialing is complete for relying site key personnel when the site does not have its own credentialing requirements and
7) provides the relying sites with the applicable DUHS IRB policies. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.

V. Electronic Process for Reliance on the DUHS IRB

1. The Lead Study Team must email the IRB Executive Director, with copy to the Vice Dean for Scientific Integrity, School of Medicine, to request that the DUHS IRB serve as the cIRB. The email must contain the following information:

   1.) A brief 3-4 sentence description of the study;
   2.) Duke's role in the study;
   3.) The PI's assessment of the risk level of the study;
   4.) The number of anticipated sites relying upon the DUHS IRB; and
   5.) The expected duration of the study.

2. A response will be returned to the study team within three (3) business days. If it is agreed that the DUHS IRB will serve as the sIRB, the email exchange will be forwarded to the Director, Extramural IRB Programs who will then interact with the Lead Study Team.

3. The Director, Extramural IRB Programs will determine whether or not the sites have joined a master reliance agreement, such as SMARTIRB, and proceed accordingly.

4. If a site has signed a master reliance agreement, a joinder to that agreement will be processed by the Director, Extramural IRB Programs in conjunction with the Duke lead study team. If a site has NOT signed such an agreement, the Director, Extramural IRB Programs will forward the appropriate IRB Authorization Agreement (IAA) to the Lead Study Team. In the latter case, follow steps 5-7 below. Otherwise, skip to step 8.

5. The Lead Study Team must complete the study-specific information on page 1 of either document and include as Attachment A, a brief (2-4 sentences) description of the activities to be conducted by the external individual(s).

6. The Lead Study Team will then forward the document to the relying institution for its review and signature. All requested changes should be returned via email to the cIRB manager for review by Duke's attorney.

7. Once terms are agreed, the relying site will email the partially signed IAA to the Director, Extramural IRB Programs to obtain signature on behalf of Duke.

8. The Director, Extramural IRB Programs will return the signed joinder, IAA to the Lead Study Team via email with the instructions to: (i) upload it into the study record via amendment in iRIS; and (ii) return a copy to the relying site representative. All Key Personnel at the relying site must be listed either in external Key Personnel within the iRIS application or a staff listing document must be uploaded in iRIS. Key

Personnel from relying sites who do not have institutional ethics training must complete the Duke Health CITI modules.

9. The external site's consent form must be submitted via amendment for watermarking. Generally, Duke's consent template is used; however, exceptions can be made to use the site's consent header. When the DUHS IRB is serving as the sIRB, this amendment must not only include (when applicable) the site specific consent form but also the fully signed reliance agreement, local context survey, protocol specific document and staff listing.

10. The external relying site's consent form must list the DUHS IRB's contact information.

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