CONDUCT OF LIMITED, SPECIFIC STUDY RELATED ACTIVITIES AT EXTERNAL SITES

3/9/2021

External sites that enroll and consent subjects and/or are involved in more than limited study-directed activities will be considered to be investigators in the research and will need either to secure their own IRB approval for their conduct of the research or facilitate a written agreement for their own IRB to cede oversight to the DUHS IRB. This policy has been developed by the DUHS IRB to facilitate participation in research by patients who: (1) do not live near enough to Duke Hospital/clinics to make frequent travel possible; (2) have no reasonable clinical treatments locally available to treat their disease; and (3) could experience direct medical benefit from study participation.

Personnel at sites external to DUHS may conduct specific, limited study activities which are part of an IRB-approved research protocol, when approved by the DUHS IRB. Activities must be limited in scope but occurring on more than a short term basis, such as the planned periodic administration of a study drug, conducting study-directed follow up evaluations, or conducting study-directed laboratory tests and involve a limited number of study subjects who were enrolled and provided informed consent at DUHS. The personnel at the external site will be considered "agents" of DUHS regarding their performance of the IRB approved activities as they will be performing DUHS designated activities. In the case of administration of an investigational drug, it is possible that the IRB will require the first administration of the drug to occur at Duke under the direct supervision of the Duke Principal Investigator. If no adverse events occur, then subsequent administrations of the drug may occur at the external site, as the DUHS IRB determines appropriate.

In order for the DUHS IRB to consider whether approval is appropriate, the DUHS Principal Investigator will provide the following documentation for each site:

1) A listing of the specific activities to be conducted at the site
2) The names and credentials for all personnel at the site who will be delegated to conduct any of the study related activities
3) Designation of the site physician who will have overall site responsibility
4) Declaration by the site physician that the personnel who will be conducting the study-related activities are licensed to perform those activities
5) The personnel who will be conducting the activities have the training and experience required to perform the activities

6) The site is an appropriate and adequate facility for the conduct of the specific activities
7) The plan for monitoring activities at the site
8) The plan for communicating with the site

The DUHS IRB will determine whether the scope of activities is appropriate and the monitoring and communication plan is adequate.

If the DUHS IRB approves the external site, the DUHS Principal Investigator must submit a packet containing the following elements to the site physician designated with overall responsibility for the site performing the study activity:

1) Cover letter detailing the activities to be performed and who (by name) is delegated to oversee those activities;
2) Copy of the subject's signed DUHS consent form;
3) Copy of the DUHS IRB Notification of Approval for the most recent initial/continuing review;
4) Copy of DUHS IRB Notification of Approval for the site's conduct of this activity, if different from (3) above;
5) Copy of full protocol;
6) Copy of protocol summary;
7) Copy of the Investigator's Brochure if applicable; and
8) Copy of all other relevant study documentation relating to study activities to be performed at the site, as determined by the DUHS Principal Investigator and approved by the IRB.

The cover letter will provide for a countersignature of acceptance by the site physician on behalf of the site personnel and must be signed and returned to the Duke Principal Investigator prior to the start of any study related activities at the site. A copy of the acceptance letter will be placed in each applicable subject's research file at DUHS, and a copy will be uploaded into the iRIS study file at the time of periodic continuing review of the study.

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