POLICY STATEMENT ON ADMINISTRATION OF A STUDY DRUG OR STUDY PROCEDURE BY A RESEARCH PARTICIPANT'S LOCAL PHYSICIAN

11/20/2023

The Duke University Health System (DUHS) Institutional Review Board (IRB) has adopted the following policy governing the administration of study drug(s) or study procedure(s) by a research participant's local physician.

For the purposes of this document, a research participant's local physician is defined as a qualified treating or primary physician in the participant's home location who is familiar with the participant's medical history.

The DUHS IRB recognizes that in specific circumstances it may be beneficial to a research participant who lives elsewhere to receive study drug(s) or study procedure(s) in their home location. This policy can only be utilized under the following circumstances:

(A) the participant has received at least one administration of the study drug(s) or procedure(s) at Duke under the supervision of the Principal Investigator without experiencing serious adverse events, as defined in the study protocol; and
(B) the activities of the local physician will be strictly limited to administration of the study drug(s) or procedure(s), provision of supportive medical care, and standard medical/safety monitoring and reporting back to the Principal Investigator.

The DUHS IRB has determined that the activities described in (B) above do not constitute engagement in research as defined in OHRP guidance[1] and the site is not participating as a research site as described in FDA guidance[2]. Therefore, the local physician and the external institution do not require direct IRB oversight. However, the IRB recognizes that other institutions may differ with this interpretation, and, in these circumstances, the IRB will consider, if requested by the external institution, executing an appropriate IRB Authorization Agreement to govern the activities of the local physician.

The DUHS Principal Investigator who wishes to utilize this policy must adhere to the following requirements:

I. The Principal Investigator must first determine that it is in the best interest of the participant to return home to receive the study drug(s)/procedure(s). The research participant will provide to the Principal Investigator the contact information for the local physician

who is to administer the study drug(s)/procedure(s). It is the Principal Investigator's responsibility to determine through direct communication with the local physician that they have appropriate training, expertise and facilities with which to administer the study drug(s)/procedure(s) and that they are willing to administer the study drug(s)/procedure(s) as directed by the Principal Investigator.

II. The Principal Investigator will either describe these plans in the initial IRB submission, or submit an amendment to the IRB containing revisions to the protocol, protocol summary, consent form, if applicable, and any other relevant study documents describing the administration of the study drug(s)/procedure(s) by a local physician. The initial submission or amendment will also contain a justification for the request, a written statement from the study sponsor granting permission to transfer the study drug(s) to the local physician or for the local physician to perform the study procedure(s), and a copy of the cover letter described in section III below.

The initial submission or the amendment will be reviewed at the next available convened meeting of the DUHS IRB where the IRB will consider the appropriateness of the request, including the resulting risks and benefits to the research participant, the PI's assurance of qualifications of the local physician, and the PI's assurance of appropriateness of the facilities at which the administration of study drug(s)/procedure(s) will occur.

III. The Principal Investigator will provide the following items to the local physician:

- Cover letter explaining the purpose of the study and providing a signature line of agreement for the local physician and the physician's IRB-of-Record, if applicable
- Copy of the participant's signed and dated consent form for the study
- All relevant information related to the handling, storage, preparation and administration of the study drug(s) or performance of the study procedure(s) and necessary supportive medical care,
- All information related to anticipated adverse effects of the study drug(s)/procedure(s) as well as instructions for handling emergencies
- All relevant instructions regarding safety monitoring and reporting
- Contact information for the Principal Investigator, including a 24-hour number with area code

IV. When the Principal Investigator has received the cover letter signed by the local physician, a copy will be promptly forwarded to the DUHS IRB for the study record.

V. Once IRB approval of the new protocol submission or amendment has been obtained, and the signed cover letter has been returned to the Principal Investigator, the transfer and administration of study drug(s)/procedure(s) may occur.

The DUHS IRB may grant approval for all participants in a specific study to have study drug(s)/procedure(s) administered by a local physician; however, the Principal Investigator must follow steps I, III, IV and V above for each such research participant.

At the completion of the study or at the time the participant's involvement in the study has ended, any unused study drug(s) must be returned to the Principal Investigator for final disposition as per protocol.

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[1] "Engagement of Institutions in Research", dated January 26, 1999, found at: http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

[2] "Use of Investigational Products When the Subjects Enter a Second Institution", 1998 update, found at: http://www.fda.gov/oc/ohrt/irbs/investigational.html

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