POLICY STATEMENT FOR DUKE FACULTY OR STAFF MEMBERS ENGAGED IN RESEARCH INVOLVING HUMANS SOLELY AT A SITE OTHER THAN WITHIN DUHS

12/19/2023

When a Duke faculty member or staff member, whether on sabbatical or not, proposes to do human subject research at a site other than within DUHS, but in connection with their Duke responsibilities, the conduct of the research must meet all applicable federal regulations governing the protection of human research subjects, this policy, and, if outside of the U.S., all relevant regulations in the applicable country. In order to ensure that these regulations and this policy will be met, limited DUHS IRB review will occur, as follows:

1) The faculty/staff member will provide the IRB, through its iRIS platform, a new protocol submission briefly describing the proposed research, where it will occur, the name of a local contact person, and the role of the faculty/staff member in the research.

2) The faculty/staff member will provide the DUHS IRB through iRIS with written confirmation from that site's IRB (or Ethics Committee) that the research protocol has been approved by that IRB.

3) The faculty/staff member will have completed all of Duke Health's required research ethics training (CITI modules) and provided documentation to the DUHS IRB. The IRB staff will confirm this.

4) The IRB reviewer (one who is designated to conduct reviews using the expedited procedure) will conduct an administrative review, and if appropriate, confirm the adequacy of the above information and approve the submission.

5) The faculty/staff member will receive notification from the IRB that the completion of items 1-3 above have been adequately documented. By way of this notification, the faculty/staff member will be informed that research data must not transported to, stored or accessed from any Duke facility for any reason unless the DUHS IRB confirms that one of the following two criteria is met:

    a) The research data are both anonymized (all direct and indirect links to subject identity are removed) and de-identified (all 18 HIPAA identifiers listed at 45 CFR 164.514(b) are removed) prior to arriving at Duke; or

    b) A DUHS IRB protocol has been submitted and approved prior to the data arriving at Duke.

Please note that the DUHS IRB has no oversight responsibility when research with human participants is performed at another site by DUHS faculty members who are on an unpaid leave of absence, or are otherwise not conducting research in connection with their Duke responsibilities, unless the faculty member brings identifiable private information, such as protected health information, back to Duke. In such a circumstance, the requirements in item # 5 above must be met.

Previous Version Date(s): 2/4/2008, 5/29/2011, 3/25/2021