



**DUKE TRAINEES* ENGAGED IN RESEARCH INVOLVING HUMAN
SUBJECTS
AT A SITE OTHER THAN WITHIN DUHS**

4/4/2021

When a Duke trainee proposes to do human subject research at a site other than within DUHS, the conduct of the research must meet all federal regulations that govern the protection of human research subjects. In order to comply with these regulations, the following will occur:

- 1) The trainee will create and submit a protocol in iRIS and provide documentation describing the proposed research, where it will occur, the name of the mentor, and the role of the trainee in the research. For assistance with preparing a submission in iRIS, contact the IRB Specialist responsible for research projects originating from Office of Curriculum: <https://irb.duhs.duke.edu/about-us/staff-and-chairs> .
- 2) The trainee will provide the DUHS IRB with written confirmation from the trainee's mentor of the trainee's role in the mentor's research project. An email from the mentor uploaded into iRIS will be suitable for this purpose.
- 3) The trainee will provide the DUHS IRB with written confirmation from that site's IRB that the research protocol has been approved by that IRB. The approval notice or letter from the site's IRB should be uploaded into iRIS.
- 4) The trainee will have completed all relevant DUHS Research Ethics educational modules (CITI modules). This will be confirmed by DUHS IRB staff.
- 5) 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.
- 6) The trainee will receive notification from the DUHS IRB that completion of items 1-4 above has been confirmed. By way of this notification, the trainee will be informed that he/she must not bring research data back to Duke 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 45CFR164.514(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.

A copy of this notification will be available to the School of Medicine Office of Curriculum or academic department office for inclusion in the trainee's record.

*This policy applies to Duke students, residents and fellows who do research involving human subjects while away from DUHS as a part of their training program. It also applies to DUSOM faculty members not on sabbatical or leave who do such research while away from DUHS.

Previous Version Date(s): 8/14/2008, 8/12/2010, 5/20/2011, 4/17/2013, 3/3/2016