External (Non-Duke) Sites

What are the DUHS IRB requirements for external (non-Duke) sites?

If an external (non-Duke) site is determined to be engaged in research and added to a Duke-based study, the DUHS IRB requires the following:

- Notice of approval from the site’s IRB; OR
- A completed IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA) to extend DUHS IRB coverage to the site

Sometimes a site will provide a letter stating that they are deferring to the DUHS IRB, but that is not sufficient. Duke must have a fully signed IAA or IIA that clearly defines site responsibilities and liability for both parties.

Contact Minna Pak in the IRB office for the templates for either agreements. Please upload your fully signed IAAs or IIAs as documentation with your protocol in iRIS.

Multi-Site Studies: What is the process for keeping the IRB approvals from external sites up-to-date?

If you have a multi-site study, please pay attention to keeping the IRB approvals from the external sites current. When a DUHS investigator plans to conduct research at a site or sites external to DUHS, and the site(s) will be engaged in research according to OHRP guidance (October 16, 2008), the investigator must submit to the DUHS IRB documentation of current IRB approval at all external sites in a timely manner. This documentation belongs in the "Multi-site Research" section of your iRIS submission.

Click Here for Process for Reliance on the DUHS IRB by External Institutions or Individuals on Multi-site Studies

Click Here for iRIS Process for Reliance on an External IRB