Adventist HealthCare

Institutional Review Board (IRB)
Reliance Agreement: Principal Investigator Guidance

Even after the external single IRB (sIRB) has approved the research, no human subjects research may begin at AHC until a number of steps are completed. The AHC IRB must agree to cede review to the sIRB, the AHC IRB must confirm that the consent form aligns with AHC's requirements, and the AHC Institutional Official must sign off on the agreement.

When IRB Review is ceded to an outside Reviewing IRB, the Principal Investigator will complete the following steps:

1) Notify the AHC IRB Office with the request to rely on a sIRB.
2) Complete Research Operations Evaluation Review.
3) Complete the **AHC Site Protocol Application when relying on an outside reviewing IRB**
4) Revise the Relying IRB approved consent form for use at AHC
    a. The consent form approved by the Reviewing IRB for the main site must be adapted for use at AHC and must conform to institutional requirements (see **AHC boilerplate language**).
5) Contact IRB Office to create a new study in IRBANA.
6) Upload study documents into IRBANA.
    a. All Relying IRB study documentation, including approval letter, protocol, recruitment materials, etc.
    b. Relying IRB approved consent form inclusive of AHC boilerplate language
    c. Research Operations Evaluation Review
    d. AHC IRB Site Protocol Application when relying on an outside reviewing IRB
    e. Research Team Conflict of Interest disclosures
    f. Principal Investigator Certification Form
    g. Sub-investigator Certification Form, as applicable
    h. Unaffiliated Investigator agreement, as applicable
7) The Principal Investigator will then coordinate sIRB Institutional Official sign-off on the AHC reliance agreement.
8) IRB Office will review submitted documents and coordinate AHC Institutional Official sign-off of the reliance agreement.
9) Once the agreement has been signed off by both Institutional Officials, the AHC IRB will issue a letter to the Principal investigator indicating that AHC has ceded review to the external IRB. Once this letter has been issued, study activities may begin.
10) During the Study
    a. Although the AHC IRB does not provide any oversight when an external IRB is the Reviewing IRB, the AHC IRB Office remains responsible for all research activities that take place at AHC, thus the AHC IRB Office requires that all amendments, reportable events, and continuing reviews be uploaded into IRBANA to ensure that study approval has not lapsed and that only the most current and IRB approved documents are being used.