

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

When IRB Review is ceded to an outside Reviewing IRB, the following steps must be completed by the Principal Investigator:

- 1) Notify the Adventist HealthCare IRB Office with the request to rely on a sIRB.
- 2) Complete Research Operations Evaluation Review.
- 3) Request an account in [IRBManager](#), if needed. Once the IRB Office has added you to IRBManager, you will receive an email titled “IRBManager Password Reset Request - AdventistHealthCare”. Click on the link in the email to reset your password and establish an account in IRBManager.
- 4) Revise the Relying IRB approved consent form for use at Adventist HealthCare.
 - a. The consent must be inclusive of Adventist HealthCare’s [Required ICF Boilerplate Language](#).
- 5) Complete the [Reliance Agreement Application](#) in IRBManager.
- 6) If the Reviewing IRB is not a member of SMART IRB, submit the completed [Reliance Agreement Template](#) in the [Reliance Agreement Application](#) referenced above.
- 6) If the Reviewing IRB is a member of SMART IRB and utilizes their online reliance system, request investigator access at <https://smartirb.org/reliance/>. The Relying IRB’s required information will be uploaded here.
- 7) IRB Office will review submitted documents and coordinate Adventist HealthCare Institutional Official sign-off of the reliance agreement.

If the relying IRB does not utilize the SMART IRB online reliance system, consult the Reviewing IRB regarding their submission process.
- 8) The Principal Investigator will then coordinate sIRB Institutional Official sign-off on the Adventist HealthCare reliance agreement.
- 7) Once the study has been signed off, the Adventist HealthCare IRB will issue a letter to the Principal investigator indicating that Adventist HealthCare has ceded review to the external IRB. Study activities may begin once this letter has been issued.
- 9) Once the agreement has been signed off by both Institutional Officials, the Adventist HealthCare IRB will issue a letter to the Principal investigator indicating that Adventist HealthCare has ceded review to the external IRB. Study activities may begin once this letter has been issued.

Principal Investigator Responsibilities to the Adventist HealthCare IRB During the Study:

1. Any study staff changes should be submitted as an amendment in IRBManager to ensure compliance with institutional policy.
2. Completion of a Reliance Check-In Form is required annually to ensure that the most up-to-date study information is on file.

All reportable events, deviations, suspensions and terminations should be reported to the overall Principal Investigator. The overall Principal Investigator will be responsible for reporting these to the Reviewing IRB, which will notify Adventist HealthCare IRB, as appropriate.