

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

When IRB review is ceded to an outside single IRB (sIRB), 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. Request an [IRBManager](#) account, if needed, by emailing [IRB@adventisthealthcare.com](mailto:IRB@adventisthealthcare.com). Once the IRB Office has added you to IRBManager, you will receive an email titled “IRBManager Password Reset Request – Adventist HealthCare”. Click on the link in the email to reset your password and establish an IRBManager account.
3. Complete and submit the [Research Evaluation by Leadership xForm](#) in IRBManager.
4. Revise the sIRB-approved consent form for use at Adventist HealthCare.
  - a. The consent must be inclusive of applicable Adventist HealthCare boilerplate language, as seen in the [Required ICF Boilerplate Language](#).
5. Complete the [Reliance Agreement Application](#) in IRBManager.
  - a. Submit the completed [Reliance Agreement template](#) with sIRB signatory designee sign-off in the Reliance Agreement Application referenced above.
6. The IRB Office will review submitted documents and coordinate Adventist HealthCare Institutional Official sign-off of the Reliance Agreement template.
7. Once the agreement has been signed off by both organizations, the IRB Office will issue the fully executed Reliance Agreement and a Reliance execution letter to the Principal Investigator indicating that Adventist HealthCare has ceded review to the sIRB. Study activities may not begin until the letter and agreement is issued.

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

1. All translations of the informed consent form being used at Adventist HealthCare should be on file with the Adventist HealthCare IRB.
2. Any Adventist HealthCare study staff changes or study changes requiring additional institutional approvals should be submitted as a reliance amendment in IRBManager to ensure compliance with institutional policy.
3. All reportable events, deviations, suspensions, and terminations occurring at Adventist HealthCare should be reported to the overall Principal Investigator. The overall Principal Investigator is responsible for reporting these events to the sIRB, who will notify Adventist HealthCare, as appropriate.
4. Any unanticipated problems or unresolved subject complaints should be reported to Adventist HealthCare IRB and the sIRB.
5. Completion of the Reliance Check-In Form, which will be prompted annually, is required to ensure that the most up-to-date study information is on file.
6. Site must maintain compliance with all Adventist HealthCare policies.