

Audit Steps (Overview)

Step One: Protocol is selected for audit.

Step Two: IRB notifies research team.

The NC State University IRB will email the principal investigator (PI) or faculty point-of-contact a questionnaire to complete and onsite or virtual visit scheduling information.

Step Three: PI completes and returns questionnaire.

After reviewing the completed questionnaire, the NC State IRB may ask the PI questions or for study documents to be provided.

Step Four: Onsite or virtual audit visit conducted by two IRB full board members.

The PI must be present during the visit. If the PI is a student, their faculty advisor must also be present. Other members of the research team members are welcome but not required to attend the onsite or virtual audit visit.

During or after the audit visit, the full board members may ask the PI or research team members who are present questions or for study documents to be provided.

Step Five: IRB sends audit findings to PI or the PI and the faculty

point-of-contact. Results of the audit findings will be sent to the PI and (if the PI is a student) the faculty point-of-contact. If changes or next steps are required because of the audit findings, go to Step Six. If no changes or steps are required, go to Step Seven.

Step Six: The appropriate party (the PI and research team OR the NC State University IRB) will implement all required changes resulting from the audit findings. Some of the changes may include additional steps to ensure the changes are implemented.

Step Seven: Audit is complete.