Routine Audit Overview

Why is my protocol being audited?
Your protocol was randomly selected to be audited as part of our routine audit process. Routine audits give the NC State University IRB a chance to ensure the continued protection of human subjects and assess compliance within the research community and to identify areas for growth, improvement, and correction within our own IRB processes.

What happens during the routine audit process?
First, the IRB will email all researchers listed on the approved IRB protocol that their study has been selected for audit. This email will include a questionnaire for the research team to complete and a request for a meeting for the IRB to conduct an onsite or virtual monitoring visit. The visit will be conducted by two IRB full board members. We expect the principal investigator and, if they are a student, their faculty advisor to attend the visit. Other members of the research team are welcome to attend as well.

Researchers can expect the onsite or virtual visit to take up to an hour. During the visit, the IRB members may

- ask for a walkthrough of the procedures.
- review implemented study measures, stimuli, or devices.
- observe participant interactions.
- observe a demonstration of any study processes (e.g., consent, administration of the activities participants experience).
- discuss experiences with participants.
- discuss participant compensation.
- discuss or see study documentation.
- discuss or view how data and other research records are stored.
- discuss the progress and status of the study itself.
- discuss other relevant study concerns.

During this time, researchers are welcome to ask questions, but the members will not be able to discuss specific observations or determinations related to the audit.

Before, during, or after the visit, the IRB members may request the researchers to send them copies of study related materials via NC State University's secure google drive or ask questions of research team members.

When will I find out the results of the audit?
Within 10 business days after the onsite or virtual visit, unless otherwise notified. The IRB members will send the research team their findings, along with any required or recommended next steps. The convened full board membership will be notified of routine audits conducted.

The audit findings may include:

- Observations made during the site visit.
- Whether any issues or noncompliance are found regarding the research team actions throughout the study or from the IRB review and approval processes. If any issues or noncompliance are found, then the report will include the following:
    - Severity of issues found.
    - Whether any consequences, next steps, or corrective action is needed.
    - Deadline for required next steps or corrective action for the research team.
    - Any corrections needed to the IRB review and approval process, procedures, and previous determinations.
- Any recommended (suggested) next steps for the researchers.
- Any other relevant information.

What if serious issues are found?
If there are any risks that pose an immediate danger to research participants, then the IRB will work with the researcher to prevent these risks from occurring, which may include stopping some or all research activities.

Serious issues and serious noncompliance may be reported to the IRB Director, IRB Chair, convened full board, Institutional Official, or relevant entities or regulatory bodies within or outside of NC State. The IRB will follow procedures for reporting noncompliance (opens in a new window) findings (Word document), unanticipated problems and adverse events (Word document), and participant concerns (Word document) as appropriate.

What if I have questions about or disagree with the findings, believe a required next step/action is not feasible, or would like to correct any information in the report?
Please inform the IRB within 30 business days of when you were sent the routine audit findings.

You can respond to the IRB auditor who sent you the report or connect with one of the below individuals:

- IRB Coordinator for Post-Approval Monitoring (irb-coordinator-post@ncsu.edu)
- IRB Director (irb-director@ncsu.edu)
- IRB Chair, Tom Birkland (tabirkla@ncsu.edu)

If we are unable to resolve your concerns or if you have a serious grievance that you would like to take straight to the convened full board, you can submit an [Audit Determination Appeal Form] (Word document). Submitting a formal appeal request will petition the NC State University IRB's convened full board to reconsider the determinations, required next steps, or corrective actions you identify in the routine audit report. After the convened full board reviews the petition, you will be notified in writing of their decision within 14 days of the review, unless otherwise notified.

Do I have to participate in the routine audit?
Yes, researchers are required to participate in the audit if their study is selected. IRB members will attempt to connect with the Faculty Point of Contact before involving their Department Chair.

Researchers who do not cooperate with or fail to engage with any post-monitoring activities or required actions will be reported to the NC State University IRB Full Board.

What if I have questions about the routine audit process?
You can contact the IRB Coordinator for Post-Approval Monitoring (irb-coordinator-post@ncsu.edu) or the IRB Director (irb-director@ncsu.edu).