

The Review Process

How do we notify investigators that their study has been selected for review?

First we will call and/or email to let you know that your study has been chosen and to set up a review date. The onsite reviews usually happen 2 to 6 weeks after that first phone call. We also may be in contact with you as we prepare for the review. We are, of course, always available by phone or email for researchers who have questions for us before the review.

What will we look at during the review?

In a study review, we will look at the study material on file with the IRB before we come to the study site, and we will send an email listing the records we expect to need. We typically review all consent forms (for all subjects), the study's regulatory binder, and study records for at least 10 percent of the subjects. We may also ask specifically for other records that we think we might need, such as laboratory sample logs. If you regularly use or create some study documentation that we have not specifically asked for, please volunteer it. That will help us get a better idea overall of how your study is run.

We do not expect PIs or their staffs to clear their calendars during the onsite review. Instead, we will want to meet with someone when we arrive to get oriented to the study and the records. We will ask that a responsible study team member be available by phone or email while we are there to answer any questions that might come up. Also, feel free to drop by occasionally while we are there. We can update you on our progress, and you can see if we need anything else from study staff.

It is important to note that ORC reviews focus on human subject protection compliance, and not on financial issues. We typically do not review financial records. If we note anything during our review that raises a question about a financial aspect, we will refer it to another office for further inquiry.

What happens at the end of the review?

When we finish up onsite, we will meet with the PI and any other available study staff to discuss our initial observations. We will also plan to meet with you about 2 weeks later to review our full, written report. This report will list the study strengths, recommendations, findings, and suggested remediation. We will send a copy to the IRB right after we present it to you, and you will have two weeks to respond in writing. The response and any supporting documents are to be uploaded directly into CLARA. After reviewing the report and response, the IRB will send you a letter through CLARA listing specific remediation requirements.