1. I received a call or letter from the OHRP/FDA. Who do I need to inform?

You will need to contact the following individuals at Temple:

- Chad Pettengill, IRB Director, Temple University
- Emily Weber, Associate Counsel, Temple University Health System, Inc.
- The Chair of the department where the inspection/audit will take place

Additionally, if your research is an industry sponsored clinical trial, you will need to contact:

- Arleen Wallen, Financial Administrator, Office of Clinical Research Administration

Please see Section 1 of “Conduct During FDA and OHRP Inspections: A Guide for Temple Researchers” for complete guidance on whom at Temple to inform if you have received notification of an audit by the FDA.

2. Do I have to answer all questions that an auditor or inspector asks me?

All questions should be answered honestly and completely, to the best ability of the person most knowledgeable about the particular topic. This person is most often the Principal Investigator. The PI should make every attempt to be available in person for the entire duration of an audit or inspection, or at minimum, be available at least once a day to debrief with the auditor and to answer any questions.

There might be instances where you do not know an answer. When this is the case, defer the question. Document the issues that cannot be resolved and the steps taken during the inspection to resolve them. Make every attempt to answers by the exit interview and before the audit is complete. If necessary, coordinate post-inspection follow up on any unanswered questions with the Temple IRB and Legal Counsel.

Please see Section 4 of “Conduct During FDA and OHRP Inspections: A Guide for Temple Researchers” for complete guidance on how to answer questions during an audit/inspection.

3. Is there any paperwork that I have to complete before an audit/inspection takes place?

You must complete the Pre-Inspection Checklist and Upcoming FDA or OHRP Inspection Form. Completing these internal Temple documents will help you prepare the necessary records and documents that will be reviewed during your audit. You might also find it helpful to review the FDA Compliance Program Guidance Manual 7348.811 in advance of your audit. The manual provides a list of information that will be requested during every FDA inspection.

Please see Section 2 of “Conduct During FDA and OHRP Inspections: A Guide for Temple Researchers” for complete guidance on how to prepare for an upcoming audit/inspection.

4. Following my inspection, I received an FDA Form 483 from the FDA. What do I do now?

If you receive an FDA Form 483 reporting audit findings, you should immediately forward the form to the appropriate Temple contacts found in the answer to Question 1 of these FAQs. We will work together to craft a response and ensure that proper follow up measures are taken. You should never respond to or contact the FDA without first consulting with the proper institutional contacts at Temple.

Please see Section 5 of “Conduct During FDA and OHRP Inspections: A Guide for Temple Researchers” for complete guidance on how to respond to audit findings.
5. I'm the PI. Do I need to be present during the audit?

The PI is ultimately responsible for the performance and supervision of their clinical trial. The PI must be available in person during an audit or inspection. While the FDA can and will complete an inspection without the PI present, this could present a problem for Temple, because it is the PI who can most often effectively and efficiently answer questions and provide information that could help to avoid unnecessary citations. The FDA has also been known to cite for supervision deficiencies when PIs are unavailable during inspections.

Ideally, the PI should serve as the liaison for the inspection. The liaison is the primary staff person escorting the inspector/auditor, serving as an institutional monitor, and acting as a guide and general contact study person. When that is not possible, at minimum, the PI must be available for the entrance and exit interviews. If the audit is conducted over more than one day, the PI should be available to meet with the inspector/auditor at the end of each day.

Please refer to Section 2 of “Conduct During FDA and OHRP Inspections: A Guide for Temple Researchers” for complete guidance on the PI’s involvement in audits and inspections.