

Guidance on Responding to Audit Findings

The purpose of this document is to provide Overall Principal Investigators and their research teams guidance on responding to audit findings.

For an internal audit conducted by the Office for Data Quality (ODQ), any major violation noted in the final audit report requires a formal written response from the Overall PI.

For an audit conducted by an external group, please see [AUD-OP-2: FDA and Other Regulatory Inspections](#).

Formulating an Appropriate Response:

- Carefully review the audit report and ensure that you understand and are familiar with any deficiencies cited. Think critically about each violation and what circumstances led up to its occurrence.
- For violations involving Regulatory Requirements or Data Management: it should be determined why this information is missing or discrepant and should be recovered and added when possible. The response to these types of violations should include information regarding how the violation was addressed and include a corrective action plan to ensure this type of violation will not be repeated in the future.
- If a violation involves failure to conduct protocol specific procedures (i.e., treatment administration, blood draws, recording vital signs, tissue sampling, drug accountability, etc.), investigate why the procedure was not completed and in addition to describing the circumstances that may have prevented protocol compliance, also provide a corrective and preventive action statement that will ensure systemic changes are implemented to prevent the problem from recurring.
- The response to audit findings is a formal communication. For an internal audit, the response is addressed to the Audit Committee representing DF/HCC and should be in memo or letter format.
 - Be clear and concise in your reply.
 - Use the audit report as an outline in formulating your response.
 - It is not acceptable to insert your response into the audit report.
 - Do not use shading of any kind in your response. It is photocopied for Audit Committee review and text will be obscured by highlighting.

For further information please refer to: [DF/HCC Website - ODQ Auditing Page](#)