



*Office of Quality Compliance
Standard Operating Procedures*

SOP #: OQC-SOP-03
Version Date: 17Mar2022

Best Practice Review

Introduction and Purpose

The Office of Quality Compliance (OQC) was established to facilitate ethical, efficient and high-quality research, and protect overall data integrity. To accomplish this goal, three different types of reviews are performed by the OQC: Self-Assessment, Research Climate Assessment, and Best Practice Review. The aim of all three reviews is to support research teams in assessing, implementing and maintaining compliance with local and federal regulations, University of Utah research standards, and Good Clinical Practice, where applicable. This document provides the OQC's Standard Operating Procedures (SOP) regarding Best Practice Reviews.

Definitions and Acronyms

IRB:	Institutional Review Board
OQC:	Office of Quality Compliance
ORIC:	Office of Research Integrity and Compliance
SOP:	Standard Operating Procedures

Best Practice Review

1. A Best Practice Review is a triggered investigation of any research study involving human subjects that has been identified by the Office of Research Integrity & Compliance. Other compliance entities on campus may request a Best Practice Review, if needed.
2. An investigation may be triggered by one of the following reasons, but could include other unlisted reasons:
 - 2.1 Whistleblower Complaint
 - 2.2 Research Subject Complaint
 - 2.3 Employee Complaint
 - 2.4 IRB request due to new information that has the potential to negatively impact the rights and welfare of research participants
3. The purpose of a Best Practice Review is to investigate complaints and/or concerns about study activities and/or potential research misconduct, as defined under University of Utah Research Policy 7-001: Policy for Research Misconduct.
4. Participating in these reviews is not voluntary. However, the OQC intends that these reviews will provide fruitful discussions about studies involving human participants.
5. Overall goals of the review include:
 - 5.1 Ensure that the specific components and conditions of the IRB approval are being implemented in research practices and are being appropriately documented



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- 5.2 Ensure that information submitted in the IRB application and study activities are congruent with funded and approved grant proposal documents and methods (applicable to grant-funded studies)
 - 5.3 Ensure that information submitted in the IRB application and study activities are congruent (applicable to sponsor-funded studies)
 - 5.4 Assure the continued protection of human subjects and their rights when they are taking part in a research study
 - 5.5 Develop an action plan to address misconduct and/or study quality and effectiveness issues, as necessary
6. Best Practice Reviews will be conducted in a timely manner, based upon the OQC receipt of complaint from the Office of Research Integrity & Compliance or other requesting compliance entity.
 7. These reviews will take precedence over all other reviews being conducted by the OQC.
 8. Study teams will receive notification of a Best Practice Review, as well as follow-up communications, through a combination of (1) scheduled meeting(s) with the OQC team, (2) e-mail correspondence, and/or (3) email notifications through the ERICA system. Additionally, study teams may be notified from the Director of the Office of Research Integrity & Compliance and/or Director of the Human Research Protections Program (HRPP) that a Best Practice Review is required and being undertaken by the OQC.
 9. Upon notification of a Best Practice Review, the study team will be asked to complete a self-assessment checklist to provide the OQC reviewers an overview of their study activities. The study team will be provided five business days to complete the self-assessment. A copy of the checklist is available to investigators/researchers on the OQC website, here:
https://qualitycompliance.research.utah.edu/_resources/documents/investigator-self-assessment-checklist.pdf.
 10. Reviews are designed to provide a comprehensive review of a study's activities, as well as monitoring the quality and effectiveness of protocol adherence. A Research Climate Assessment may occur, if the OQC deems it necessary to provide more information about the activities for the study and the study team.
 11. It is anticipated that a Best Practice Review will be completed within 90 days, although this may be extended as needed.
 12. A final Best Practice Review Report will be reviewed with and provided to an investigator/researcher and study team once the review is completed. This report will also be provided to the departmental chair or dean of the PI/lead researcher, Associate Vice President for Research Integrity & Compliance's Office and other entities, as necessary.
 13. If there are concerns that highlight the need for corrective action, a corrective action plan will be created. The OQC will work with the study team to develop



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specific actions to address the compliance issues and timeline for when they should be addressed. The OQC will check in with the study team to ensure that deadlines are being met as established in the corrective action plan.

14. Best Practice Reviews are an internal institutional process. Study teams should internally retain documents associated with these reviews, including the initial notification of review, completed self-assessment, final letter and findings report, list of resources and recommendations, and other relevant correspondence. However, it is recommended that these documents **are not** filed in the official, external-facing regulatory record.

Materials Required

- Self-Assessment Checklist:
https://qualitycompliance.research.utah.edu/_resources/documents/investigat-or-self-assessment-checklist.pdf.

References:

- University of Utah Research Policy 7-001: Policy for Research Misconduct - <https://regulations.utah.edu/research/7-001.php>

Document Approval

DocuSigned by:

Caren Frost

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3/18/2022

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Revision History

Version Date	Change Summary
08/Mar/2021	Original Version
17/Mar/2022	Changed name of review type to "Best Practice"

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