Best Practice Review

Introduction and Purpose

The Office of Quality Compliance (OQC) was established to promote ethical, efficient, and high-quality research while safeguarding data integrity. The OQC conducts three types of reviews to achieve these goals: Self-Assessment, Research Climate Assessment, and Best Practice Review (BPR). The three assessments/reviews aim to assist research teams in evaluating, implementing, and maintaining compliance with federal and local regulations, University of Utah research standards, and, where applicable, Good Clinical Practice. This document outlines the OQC's Standard Operating Procedures (SOP) for conducting a BPR.

Definitions and Acronyms

BPR: Best Practice Review
CAPA: Corrective and Preventative Action Plan
ERICA: Electronic Research Integrity & Compliance Administration
IRB: Institutional Review Board
OQC: Office of Quality Compliance
ORIC: Office of Research Integrity and Compliance
SOP: Standard Operating Procedures

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1. The OQC is requested to conduct a BPR by the Office of Research Integrity & Compliance (ORIC) for any research that has been identified as requiring additional review. Other compliance entities on campus may request a BPR, if needed.
2. A BPR may be prompted by one of the following, but not limited to:
   - **2.1.** Whistleblower complaints
   - **2.2.** Research participant complaints
   - **2.3.** Employee complaints
   - **2.4.** Request from any entity within ORIC
3. The objectives of a Best Practice Review are to:
   - **3.1.** Review concerns and/or complaints about research activities and/or potential unprofessional behaviors/conduct in research.

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3.2. Verify that the specific components and conditions of Institutional Review Board (IRB) approval are being implemented in research practices and are being adequately documented.

3.3. Verify that information submitted in an IRB application and study activities are consistent with funded and approved grant proposal documents and methods (applicable to grant-funded research).

3.4. Verify that information submitted in an IRB application and study activities are consistent (applicable to sponsor-funded research).

3.5. Ensure the continuous protection of human participants and their rights when participating in a research study (applicable to human participant research).

3.6. Develop an action plan to address unprofessional behaviors/conduct and/or research quality and integrity issues, as necessary.

4. Participation in a BPR **is not voluntary**. However, the OQC intends that these reviews will facilitate productive discussions and provide education that improves the quality of research.

5. The BPR will be conducted in a timely manner and given priority over all other reviews being conducted by the OQC.

6. Research teams will be notified of the BPR and receive follow-up communications through a combination of scheduled meetings and email correspondence with the OQC, as well as email notification through the Electronic Research Integrity & Compliance Administration (ERICA) system.

6.1. Research teams may also receive notification from the ORIC that a BPR is required and will be conducted by the OQC.

7. Upon notification of a BPR, the research team may be asked to complete a Self-Assessment. The Self-Assessment provides the OQC reviewers with an overview of research activities and helps prepare research records for review.

7.1. The OQC creates the Self-Assessment within the IRB profile for the study, and a notification letter is sent to the PI and contacts through the ERICA system.

7.1.1. The invitation includes a link to the Self-Assessment, which automatically navigates the user to the Self-Assessment in ERICA.

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7.2. The research team is provided ten (10) business days to complete the Self-Assessment.

7.2.1. If multiple studies are included in the BPR, the research team may be required to complete a separate Self-Assessment for each study, with an additional timeline provided for each Self-Assessment.

8. Once the research team completes the Self-Assessment, the OQC will conduct the BPR. The review may be conducted either remotely or on-site, as determined by the OQC.

8.1. On-site reviews: OQC staff will require dedicated workspace (e.g., office space or conference room) and access to all study documents including regulatory and participant study documents.

8.2. Remote reviews: OQC staff will require unrestricted electronic access to all study documents (i.e., regulatory documents and participant study documents). In case of technical issues, a research team member needs to be available by email and/or phone.

8.3. Interviews will be requested with identified research staff. Previous team members may be invited to participate in the interview portion of the BPR. Each individual will be asked a standard set of questions determined by the OQC. The information provided during the interviews is aggregated to provide anonymity for those who agree to participate.

9. At the conclusion of the BPR:

9.1. The BPR Report will be provided to the requestor, and a summary meeting will be scheduled to discuss the report, review recommendations for the research/research team, and if needed, propose a Corrective and Preventative Action Plan (CAPA).

9.1.1. The Department Chair or Dean may also receive a copy of the BPR Report and be invited to attend the summary meeting.

9.2. Following the meeting with the requestor, the BPR Report will be provided to the principal investigator/lead researcher for review, and a meeting will be scheduled to review the BPR Report.

9.3. Once the meetings with the requestor and the principal investigator/lead researcher conclude, a final BPR Report will be provided to those parties and the research team. The report will also be shared with the Associate

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Vice President for Research Integrity & Compliance's Office and other necessary University entities.

10. In some cases, BPR findings and/or information from interviews may necessitate reporting to another entity within the institution.
11. It is anticipated that a BPR will be completed within 90 business days, although the timeline may be extended as needed.
12. If there are compliance issues identified that require corrective action, a CAPA will be created. The OQC will collaborate with the research team to develop specific actions to address the concerns and establish a timeline for their completion. The OQC will monitor the research team's progress in meeting the deadlines outlined in the CAPA.
13. A Follow-Up BPR may be required. Any follow-up and associated details will be outlined in the final BPR Report.
14. Best Practice Reviews are an internal institutional process. Research teams should retain documents associated with the BPR, including the initial notification of review, completed self-assessment, the BPR Report, and other relevant correspondence. However, it is recommended that these documents **are not** filed in the official, external-facing regulatory record.

Materials Required

- An active ERICA account and access to the desired study

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Document Approval

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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"
17/Aug/2022	Extended self-assessment completion window; added self-assessment details; added language re: CRSO monitors; added provisions for conducting Best Practice Reviews remotely and on-site; clarifications and formatting throughout
12/Apr/2023	Definitions & Acronyms updated; CRSO reviewers removed; methods and process for initiation, notification, and completion of a BPR updated; BPR objectives updated; decreased self-assessment completion window; interviews with identified research staff updated; CAPA details added; details concluding a BPR updated; reporting BPR findings to other institution entities added; clarifications and formatting throughout

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