Self-Assessment

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. 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 (GCP). This document outlines the OQC's Standard Operating Procedures (SOP) for conducting a Self-Assessment.

Definitions and Acronyms

CAPA: Corrective and Preventative Action Plan
ERICA: Electronic Research Integrity & Compliance Administration
GCP: Good Clinical Practice
IRB: Institutional Review Board
OQC: Office of Quality Compliance
PI: Principal Investigator
SOP: Standard Operating Procedures

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1. A Self-Assessment is a valuable resource provided by the OQC to assist investigators and research teams conducting research. Completing a Self-Assessment guides teams in evaluating and improving study conduct, compliance, and adherence to Institutional Review Board (IRB)-approved research protocols, federal and local regulations, GCP standards, and University policies.
2. A Self-Assessment may be initiated by one of the following methods:
   - **2.1.** Voluntarily created or requested by a member of the research team seeking information regarding study conduct and recommendations for improving study activities.
   - **2.2.** Selection by the OQC to participate.
   - **2.3.** Required by the OQC in conjunction with, or because of, a separate OQC review/assessment for the purpose of preparing study records for

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formal OQC review (i.e., Best Practice Review, Research Climate Assessment) and/or supplementary information collection.

3. A Self-Assessment may utilize on-site and remote evaluation and monitoring practices.

4. The OQC uses an educational framework for discussions with research teams to:

4.1. Verify that the components and conditions of the IRB approval are being correctly implemented in research practices, and ensure these practices are appropriately documented.

4.2. Ensure that the information submitted in the IRB application and study activities are congruent with grant proposal documents and methods (applicable to grant-funded studies).

4.3. Provide support to research teams in assessing, implementing, and maintaining compliance.

4.4. Offer recommendations and educational resources to assist research teams in identifying areas for improvement.

5. The Self-Assessment is completed within the Electronic Research Integrity & Compliance Administration (ERICA) system.

5.1. The assessment contains questions on regulatory documentation, IRB documentation, problem and event reporting, subject selection criteria, informed consent, source documentation and case report forms, study recruitment procedures, drug and/or device dispensing accountability, record keeping, allocation of responsibilities, staff training, and other study information.

5.2. A Self-Assessment may be completed by any member(s) of the research team and requires submission by the Principal Investigator (PI).

6. As indicated above, a Self-Assessment may be initiated voluntarily, selected by the OQC, or in association with a separate OQC review/assessment.

6.1. A Self-Assessment may be voluntarily initiated by following the steps outlined in OQC-SOP-01 Supplement A.

6.2. When a study is selected, or required, by the OQC to complete a Self-Assessment the OQC will create the Self-Assessment within the IRB study profile and send a letter of notification to the PI and study contacts through the ERICA system.

6.2.1. The invitation will include a link to the Self-Assessment, which will automatically navigate the user to the Self-Assessment within ERICA.

6.2.2. The Self-Assessment is due within ten (10) business days of notification.

7. Once a Self-Assessment is completed by the research team and submitted, the OQC will contact the PI and research team to schedule a meeting to review the Self-Assessment, discuss any findings, and provide recommendations and resources for the team.

8. It is anticipated that each Self-Assessment, comprised of completion of the Self-Assessment, OQC review, and team meeting, will be completed within thirty (30) business days.

9. A final report will be provided to, and reviewed with, the PI and research team, where appropriate.

10. If there are compliance issues identified that require corrective action, a Corrective and Preventative Action Plan (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.

11. A "Certificate of Self-Assessment" will be provided to the PI and research team after completing the Self-Assessment.

12. The Self-Assessment is an internal institutional process. Research teams should retain documents associated with these reviews, including the completed Self-Assessment in ERICA and Self-Assessment Report. 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

References

- OQC-SOP-01 Supplement A

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Document Approval

DocuSigned by:
Caren Frost
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Caren J. Frost, PhD, MPH — Date

Associate Vice President for Research Integrity and Compliance, University of Utah

Revision History

Version Date	Change Summary
08/Mar/2021	Original Version
17/Aug/2022	Definitions & Acronyms updated; CRSO reviewers added; methods and process for initiating a Self-Assessment updated
12/Apr/2023	Definitions & Acronyms updated; CRSO reviewers removed; methods and process for initiating a Self-Assessment updated; purpose of a Self-Assessment updated; completion timelines of a Self-Assessment updated; ERICA instructions for completion of a Self-Assessment have been removed and Supplement A created; clarifications and formatting throughout

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