Self-Assessment 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 For-Cause 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) for Self-Assessment Reviews.

Definitions and Acronyms

ERICA: Electronic Research Integrity & Compliance Administration system
IRB: Institutional Review Board
OQC: Office of Quality Compliance
SOP: Standard Operating Procedures

Self-Assessment Review

1. A Self-Assessment Review is a voluntary review, conducted at the request of a study principal investigator or researcher, to obtain recommendations regarding improving study activities involving human participants.
2. Information obtained during this review will describe how well the study is meeting federal, industry-sponsored, and University regulations and policies.
3. Recommendations and education will be provided by the OQC to improve study team performance, compliance, and interaction with study participants.
4. The review may utilize on-site and/or remote evaluation and monitoring techniques. The OQC uses an educational framework for discussions with research teams to:
    - 4.1 Ensure that the specific components and conditions of the IRB approval are being implemented in research practices and are being appropriately documented
    - 4.2 Ensure that the information submitted in the IRB application and actual 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
5. A "Self-Assessment Checklist" is used to facilitate the review. The assessment contains questions on regulatory documentation, IRB documentation, problem and event reporting, informed consent process, subject selection criteria, source documentation, case report forms, study recruitment procedures, drug and/or device dispensing accountability, record keeping, allocation of responsibilities,

staff training, and other study information. 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.

6. An investigator/researcher can initiate a self-assessment through the IRB's online application system, ERICA, here: https://erica.research.utah.edu/.
   - 6.1 After opening the desired study, navigate to the "Assessments" tab and select the "Create Self Assessment" button.
   - 6.2 The user will automatically be routed to an ERICA application containing an electronic version of the "Investigator Self-Assessment Checklist". Note that the content of the electronic checklist is identical to the content of the self-assessment checklist discussed in section 5, above.
     - 6.2.1 After completing the "Intro Section" and selecting "Continue" in the lower right-hand corner, the user will be able to advance through all remaining sections of the application by providing the requested data and selecting "Continue" in the lower right-hand corner of each page. Users can also navigate the Investigator Self-Assessment Checklist using the left-hand menu.
     - 6.2.2 After selecting "Finish" on the last page of the application the user will be returned to the "Assessment" page in ERICA. The principal investigator/researcher will be able to submit the self-assessment by selecting "Submit" under the "Activities" menu on the left-hand side of the page.
       - 6.2.2.1 A pop-up window will appear allowing for the addition of any comments, if desired. If not, leave the comments field blank. In either case, final submission will occur after selecting "Submit" on the pop-up window.
7. Once a Self-Assessment is completed by the study team, the OQC team will have five business days to contact the study team to schedule a meeting for the Self-Assessment review of findings and discussion of recommendations and resources for the study team.
8. It is anticipated that each Self-Assessment Review will be completed within 30 days.
9. A final report of findings will be provided to and reviewed with the investigator/researcher and study team, where appropriate.
10. 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 specific actions to address the compliance issues and timeline for when they should

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be addressed. The OQC will check in with the study team to ensure that deadlines are being met as established in the correct action plan.

11. A "Certificate of Self-Assessment Review" will be provided to the investigator/researcher and study team after completing the Self-Assessment Review.
12. The Self-Assessment is a voluntary, internal institutional process. Study teams should internally retain documents associated with these reviews, including the completed self-assessment application in ERICA, final letter and report, list of resources/recommendations, 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
- Self-Assessment Checklist: *https://qualitycompliance.research.utah.edu/_resources/documents/investigator-self-assessment-checklist.pdf*.

Document Approval

DocuSigned by:
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Caren J. Frost, PhD, MPH — DATE
Director, Office of Research Integrity & Compliance, University of Utah

Revision History

Version Date	Change Summary
08/Mar/2021	Original Version

Printed or photocopied versions are considered unofficial copies unless it is the original signed document.