Research Climate 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 (RCA), 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. This document outlines the OQC's Standard Operating Procedures (SOP) for conducting an RCA.

Definitions and Acronyms

CAPA: Corrective and Preventative Action Plan
ERICA: Electronic Research Integrity & Compliance Administration
OQC: Office of Quality Compliance
ORIC: Office of Research Integrity & Compliance
RCA: Research Climate Assessment
RIO: Research Integrity Officer
SOP: Standard Operating Procedures

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1. Research Climate Assessments are conducted by the OQC for research teams across the institution.
2. The purpose of an RCA is to (1) describe how well a research team is working together, (2) assess team communication, and (3) propose resources to support the team's activities and interactions.
3. Research Climate Assessments are a nuanced, qualitative approach to obtaining information about a research team through individual interviews with the members of the research team.
4. The RCA may be used to augment the quantitative information provided from compliance reviews and/or formal audits conducted by other compliance-related units.
5. Studies and research teams may be identified for an RCA through several mechanisms, which is not limited to but may include the following:

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5.1. The Office of Research Integrity & Compliance (ORIC) determines that an issue experienced by a study team crosscuts the units of the ORIC.
5.2. The ORIC receives a request for an RCA.
5.3. The Research Integrity Officer (RIO) requests an RCA after receiving a report of unprofessional behavior that is not specific to research misconduct.
5.4. The OQC receives a request for an RCA directly from the Principal Investigator (PI) or a member of a research team.

Other circumstances of a similar nature could provide the impetus for an RCA.

6. An RCA can be requested directly on the OQC website (https://qualitycompliance.research.utah.edu/forms/rca-request.php). The OQC will receive notification when the RCA Request Form is submitted. A representative from the OQC will review the submission within five (5) business days.
6.1. If the RCA Request Form is undergoing maintenance or cannot be completed for other reasons, the request for an RCA can be sent to the OQC by email at oqc@utah.edu.
6.2. Research teams will be notified of the RCA 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.
7. Following notification of the RCA the OQC will conduct an introductory meeting with the research team to introduce the RCA, outline the process, and answer any initial questions.
8. Requests for interviews with selected team members will be sent following the introductory meeting.
8.1. Standard interview questions have been developed for RCAs to guide the interview.
8.2. Additional interview questions may be tailored to the issues that originated the RCA request.
8.3. During the interview, the OQC team will collect detailed notes about the discussion.

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8.4. Each RCA interview will be scheduled for thirty (30) minutes.

8.5. Information from the discussions will be shared in an aggregate way so that the anonymity of interviewees can be maintained. The anonymity of interview responses is essential to ensuring that high-quality, accurate information is obtained during the RCA.

8.6. The OQC will archive interviews and aggregate information securely in the Compliance Store within ERICA.

9. At the conclusion of the RCA, the OQC will share an RCA Report of aggregate findings, accompanied by a list of resources and recommendations for team members, to obtain additional information and provide educational assistance. The OQC team will facilitate contact with resources, as needed. The final summary report will only contain aggregate information.

9.1. An RCA Report will be provided to the requestor.

9.2. A summary meeting will then be scheduled with the requestor to discuss the report, review recommendations for the research/research team, and if needed, propose a Corrective and Preventative Action Plan (CAPA).

9.3. The Department Chair or Dean may also be provided with a copy of the RCA Report and invited to attend the meeting.

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

9.5. At the conclusion of the meetings with the requestor and the principal investigator/lead researcher, a final RCA Report will be provided to those parties and the research team. The report will also be provided to other University entities, as necessary.

10. Research Climate Assessment findings and/or reports received may necessitate reporting to another entity within the institution.

11. It is anticipated that an RCA will take approximately thirty (30) business days to be completed, depending on research team availability and other factors.

12. A Follow-Up RCA may be required. Any follow-up and associated details will be outlined in the final RCA Report.

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13. Research Climate Assessments are an internal institutional process. Research teams should retain documents associated with the RCA, including the initial notification of review, completed self-assessment, the RCA Report, and other relevant correspondence. However, it is recommended that these documents **are not** filed in the official, external-facing regulatory record.

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Document Approval

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Revision History

Version Date	Change Summary
08/Mar/2021	Original Version
29/Oct/2021	Instructions for requesting an RCA through the OQC webpage added; additional clarifying edits made re: interview methods
17/Aug/2022	Clarified purpose of RCAs and added language re: CRSO monitors
12/Apr/2023	Definitions & Acronyms updated; CRSO reviewers removed; methods and process for initiating and completing an RCA updated; archived interviews and aggregate information within ERICA added; conclusion process updated; completion timeline added; CAPA details added; clarifications and formatting throughout

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