

Research Climate Assessment

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 Research Climate Assessments.

Definitions and Acronyms

OQC:	Office of Quality Compliance
RCA:	Research Climate Assessment
SOP:	Standard Operating Procedures

Research Climate Assessment Review

1. A Research Climate Assessment (RCA) is a nuanced, qualitative approach to obtaining information about a study from study team members and/or researchers.
2. Assessments are conducted by trained members of the Office of Quality Compliance (OQC) and include discussions with study teams, researchers, scholars, and investigators in Health Sciences or on Main campus.
3. The purpose of an RCA is to augment the quantitative information provided from compliance reviews and/or formal audits conducted by other compliance-related units.
4. Studies for an RCA will be identified through several mechanisms, which may include the following:
 - The Director of the Human Research Protections Program (HRPP) determines that an issue experienced by a study team crosscuts the units of the HRPP.
 - The Director of the Office of Research Integrity & Compliance (ORIC) receives a request for an RCA.
 - The Research Integrity Officer (RIO) requests an RCA after receiving a report of research misbehavior that is not specific to research misconduct.
 - The OQC receives a request for an RCA directly from the Principal Investigator (PI) or a member of a research team.

There may be other circumstances of a similar nature that could provide the impetus for an RCA.

5. An RCA can be requested directly on the OQC website, here: <https://qualitycompliance.research.utah.edu/forms/rca-request.php>. The OQC

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will receive notification when the *Research Climate Assessment (RCA) Request Form* is submitted, and a representative from the OQC will be in contact within 5 business days.

- 5.1 In the event that 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. Study teams will receive initial notification of the RCA, 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.
7. The RCA is conducted through individual interviews with members of the study teams.
 - 7.1 Standard interview questions developed for RCAs by the OQC will be used to guide the RCA.
 - 7.1.1 Additional interview questions will be tailored to the issues that originated the RCA request.
 - 7.2 During the interview, the OQC team will collect detailed notes about the discussion.
 - 7.3 Data from the discussions will be shared in an aggregate way so that the anonymity and confidentiality of study team respondents can be maintained.
 - 7.4 The OQC will archive the interview and aggregate data on UBox, and only members of the OQC team will be able to access the interview data and documents.
8. Data collected during the RCA will be used to (a) determine how well a study team is working together and (b) propose resources to support the work of the team.
9. At the conclusion of the RCA, aggregate findings will be shared, accompanied by a list of resources to direct team members (including team leads, scholars, investigators, and researchers) to obtain additional information and educational assistance.
 - 9.1 The OQC team will facilitate contact with resources, as needed.
 - 9.2 In some instances, department chairs and/or deans may also receive a copy of the RCA findings.
10. A typical interview being performed as part of the RCA will take about 15 to 20 minutes per study team member.
11. It is anticipated that an RCA will take approximately two weeks to be completed, depending on interviewee availability.

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12. The confidentiality of interview responses is essential to ensuring that high-quality, accurate data is obtained during the RCA. Interview respondents are assured that the RCA is completed independently of any other monitoring activities, and their responses will be kept confidential and secure. Additionally, the final summary report will only contain aggregate data.
13. After the interviews are completed and the data are analyzed, a final report (with aggregate information only) will be provided to the study team and other parties, as deemed appropriate.
14. 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 any identified compliance issues and a timeline for addressing these actions. The OQC will check in with the study team to ensure that deadlines are being met as established in the corrective action plan.
15. The RCA is an internal institutional process. Study teams should internally retain documents associated with these reviews, including the initial notification of review, aggregate findings, 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.

Document Approval



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11/1/21

DATE

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

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