**Office of Quality Compliance**

**Standard Operating Procedures for For-Cause Reviews**

**Draft**

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This document provides the Office of Quality Compliance’s (OQC) Standard Operating Procedures (SOP) for reviews of study information. A **“For-Cause Review”** is a triggered investigation of any research study involving human subjects that has been identified through the Assistant Vice President for Research Integrity & Compliance’s Office. Reasons for triggering an investigation are due to

* Whistleblower Complaint,
* Research Subject Complaint,
* Employee Complaint,
* IRB request due to new information that has the potential to negatively impact the rights and welfare of research participants.

# The purpose of these reviews is to investigate complaints about study activities and/or potential research misconduct, as defined by U of Utah 7-001: Policy for Research Misconduct. These reviews are designed to provide a full review of a study's activities as well as monitoring the quality and effectiveness of protocol management. Participating in these reviews is not voluntary, but the OQC intends that these reviews will provide fruitful discussions about studies involving human participants. The overall goals of these reviews are to

* Ensure that what was approved by the IRB is being implemented in a PI's research practices and is appropriately documented,
* Ensure that information submitted in the IRB application and study activities are congruent with funded and approved grant proposal documents and methods, if this is a funded study,
* Ensure that information submitted in the IRB application and study activities are congruent, if this is a non-funded study,
* Assure the continued protection of human subjects and their rights when they are taking part in a research study,
* Determine if the complaints about study activities and/or potential research misconduct are accurate, and
* Develop an action plan to address misconduct and/or study quality and effectiveness issues.

For-Cause Reviews will be conducted based when a complaint is made to the Assistant Vice President for Research Integrity & Compliance’s Office. These reviews will take precedence over all other reviews being conducted by the OQC.

For these reviews, study teams will be asked to complete self-assessment documents to provide the OQC reviewers an overview of their study activities and links to the IRB application as well as any grant funding that supports the research team's work on the study in questions. There is no time limit for completing a For-Cause Review. A report will be provided to and reviewed with the PI and study team once the review is completed. This report will also be provided to the Assistant Vice President for Research Integrity & Compliance’s Office and other entities, as necessary.