**Office of Quality Compliance**

**Standard Operating Procedures for Routine Reviews**

**Draft**

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This document provides the Office of Quality Compliance’s (OQC) Standard Operating Procedures (SOP) for routine reviews of research studies. A **“Routine Review”** is an evaluation of a research study that is non-exempt involving human subjects and approved by the U of Utah’s IRB. This type of review may involve studies that have federal, industry, or foundation funding. These reviews will include a grant fidelity consideration as well.

Routine reviews will be structured using the four-tiered system described below:

* Tier 1 = more than minimal risk studies that are federally funded, industry-sponsored, or foundation funded
* Tier 2 = more than minimal risk studies that use investigational drugs and/or devices
* Tier 3 = minimal risk studies that are federally, industry-sponsored, or foundation funded
* Tier 4 = minimal risk studies that are not funded

The purpose of these reviews is to provide on-site evaluation of a study to improve investigator performance through monitoring, education, and measurement of quality and effectiveness of protocol management. These reviews are designed to assist Principal Investigators (PI) and their study teams in improving their research processes. Participating in these reviews is voluntary, but the OQC intends that these reviews will provide fruitful and positive discussion about studies involving human participants. By using an educational framework for discussion, 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 the activities of the study are congruent with approved grant proposal documents and methods, if this is a funded study,
* Provide support to research teams in assessing, implementing, and maintaining compliance, and
* Assure the continued protection of human subjects and their rights when they are taking part in a research study.

Routine Reviews will be conducted based on a random selection of studies. Units with the most studies will be identified, and a selection of studies from PIs these units will be selected for routine reviews. The OQC will focus on Tier 1 and Tier 2 reviews annually. For Tier 3 and Tier 4 reviews, the OQC will complete reviews, as needed.

For these reviews, study teams will be asked to complete self-assessment documents to provide the OQC reviewers an overview of their study and the issues they have identified for themselves. Each Routine Review will take up to 10 days to complete and a report of findings will be provided to and reviewed with the PI and study team.