**Office of Quality Compliance**

**Definitions of Terms for Standard Operating Procedures**

**Draft**

**January 2019**

This document provides definitions of terms that will be used in the Office of Quality Compliance’s (OQC) Standard Operating Procedures (SOP). The work of the OQC is to review studies that involve human subjects. Studies using animal subjects are not subject to review by the OQC. See other documents for SOPs for each of the review types mentioned below.

A **“Best Practice Review”** is a review requested by a study principal investigator (PI). These reviews are to provide recommendations on-site about how to improve study activities involving human participants and approved by the U of Utah’s IRB. These reviews will provide information to the PI and study team about how well their study is meeting federal, industry-specific, and university regulations as well as university policies.

##### 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 usually include a grant fidelity review as well. Routine reviews will be structured using the four-tiered system described below:

* Tier 1 = more than minimal risk studies that are federally, 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

##### A “Grant Fidelity Review” is an evaluation of a research study that is non-exempt involving human subjects and approved by the U of Utah’s IRB. These reviews will involve studies that have federal, industry, or foundation funding. The purpose of these reviews is to check on grant congruency for studies involving human participants. These reviews will be a narrow component of Best Practices and Routine Reviews, and a broad component of For-Cause Reviews.

A **“For-Cause Review”** is a triggered investigation of a research study 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.