Samuel Merritt University

Academic Affairs

General Information about Human Subjects Protections and Types of Review

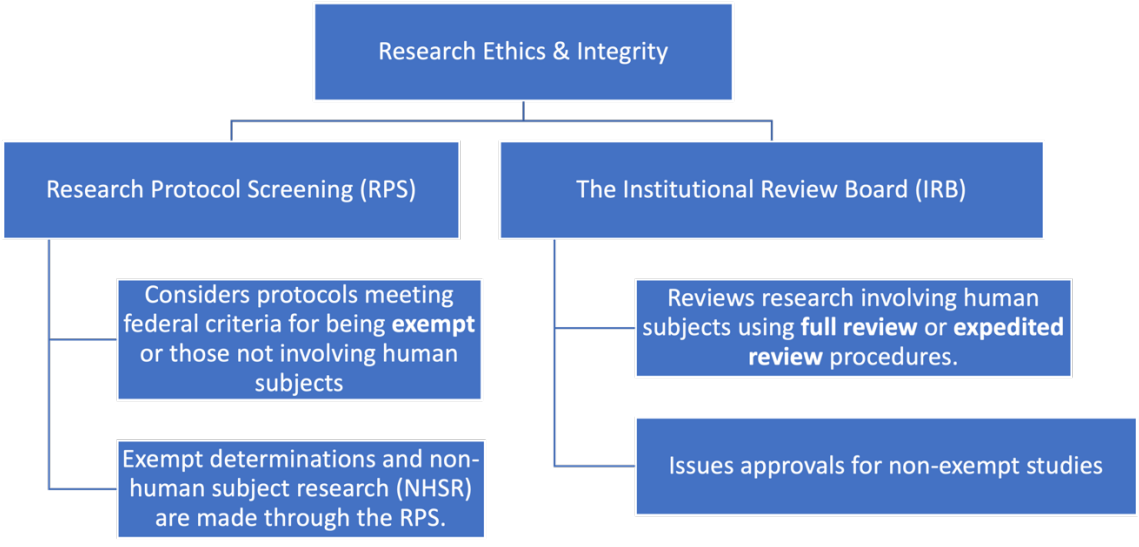
SMU holds a **Federalwide Assurance (FWA)** to protect human subjects and comply with the federal regulations. The U.S. Department of Health and Human Services published the revised **2018 Common Rule** in early 2017. The revised Common Rule offered the first revisions since 1991, providing several revisions that offered clarifications to ensure human protection but also with the intention of reducing administrative burden for organizations and researchers.

The **Office for Human Research Protections (OHRP)**

> *"provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research"*. (https://www.hhs.gov/ohrp/about-ohrp/).

The U.S. Department of Health and Human Services (HHS) **regulations for the Protection of Human Subjects** are found at **45 CFR Part 46**, including the two versions of the Common Rule (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/).

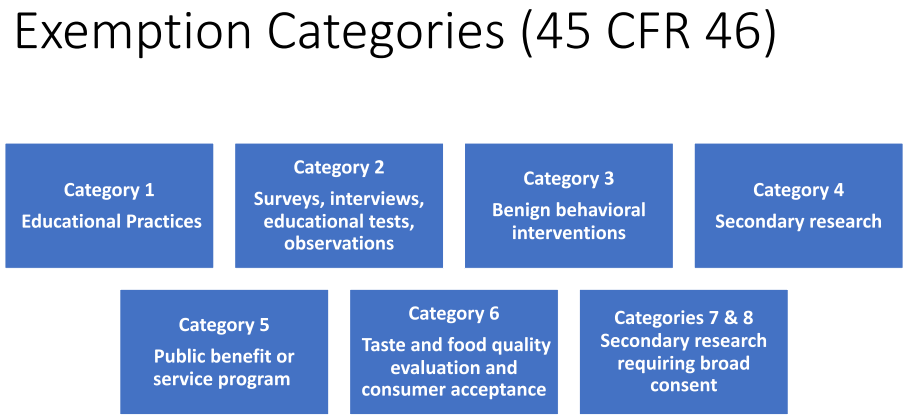
Within SMU, Academic Affairs supports two processes for the review of research activities conducted by SMU faculty, staff, and students.



Federal guidelines specify different classifications of research with different review processes.

Exempt Research

There are eight categories of research activities considered to be exempt. To qualify for exemption, the research must not be greater than minimal risk and must fall into one or more of the exempt categories. Exempt review is not allowed if the study involves vulnerable populations.



For full description of each category, refer to the Exempt Categories document.

Research qualifying for Expedited Review

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure involving two qualified IRB reviewers. Most commonly this will be the IRB chairperson and one other reviewer.

Expedited Categories

Category 1: Clinical studies of drugs and medical devices.
Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.
Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes *if research did not qualify as exempt*.
Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes *if research did not qualify as exempt.*
Category 7: Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies *if research did not qualify as exempt.*
Categories 8 & 9: Continuing review of research previously approved by the convened IRB.

For full description of each category, refer to the Expedited Categories document.

Research Requiring Full Review

Research not meeting criteria for exemption, or an expedited review process will undergo full review by a quorum of the IRB committee members during a convened meeting.