KUMC Policy for Flexible IRB Review

Purpose:

The purpose of this policy is to reduce administrative and regulatory burdens for minimal risk research that is not under federal purview while maintaining core ethical principles that protect the rights and welfare of research participants. In January 2018, KUMC updated its Federalwide Assurance to apply only to research that is conducted or supported by any US federal agency. For research not conducted or supported by a federal agency, KUMC has the flexibility to apply IRB review standards that differ from federal regulations provided research participants are afforded equivalent protections. This policy implements a flexible IRB review process.

Applies to:

This policy applies to the KUMC HRPP and KUMC researchers conducting minimal risk research that is not federally funded or supported and is thus not covered by our Federalwide Assurance FWA00003411.

Definitions:

Federalwide Assurance means an agreement by a research institution to comply with the requirements of HHS Protection of Human Subjects regulations at 45 CFR 46. The assurance is filed with the federal Office for Human Research Protections. Compliance with 45 CFR 46 is required for all research that comes under federal purview.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Federally funded or supported is defined at KUMC as any of the following:

- Funded by a direct federal grant
- Funded through a sub-award or pilot grant associated with federal dollars
- Includes personnel on a federally-funded training grant
- Research conducted under a no-cost extension
- Data will be used to support an application for FDA approval or a grant application (e.g., data collection in response to a scored grant submission with plans to re-submit)
- Involves delivery of an FDA-regulated product or dietary supplement
- Involves registries about FDA-regulated products
- Conducted under a contract that requires the investigator to adhere to federal human subjects regulations (e.g., 45 CFR 46, 34 CFR 97 or other references to the HHS Common Rule)
- Involves any services that could be billed to a federal program

Flexible IRB review means a review and oversight process that applies human subjects protections commensurate with risk while reducing administrative burdens for researchers and the IRB. Flexible IRB review allows abbreviated consent forms, streamlined review process and elimination of the continuing review requirement.

Policy:

This policy creates flexible IRB review options for minimal risk research projects that meet the required criteria specified below. While the policy allows for greater flexibility in the review process, it does so while ensuring equivalent protections for research participants. All research reviewed at KUMC, regardless of research type, will be guided by the core ethical principles of respect for persons, beneficence and justice. Equivalent protections include the requirement for IRB approval, expertise of the reviewers, human subjects training and financial disclosures from study teams, agreement by participants for research involving direct interactions, provisions for confidentiality and security if data are identifiable, HIPAA protections when applicable, and reporting of unanticipated problems. This policy applies to all research under the jurisdiction of the KUMC IRB.

Required Criteria for Flexible Review:

- Minimal risk research, as defined above
- Does not involve federal funding or support, as defined above
- Does not involve reliance on KUMC's IRB by collaborating institutions or organizations that apply federal regulations to all research regardless of funding source

The KUMC institutional review board (IRB) is responsible for making the final determination of eligibility for flexible review.

Investigator Responsibility

In the course of requesting flexible review, the principal investigator will provide attestation that the research meets all eligibility criteria. IRB review will be conducted based on the attestation. The principal investigator is responsible for notifying the IRB if there is a change in funding or any other change in status that would cause the project to no longer qualify for flexible review.

IRB Submission and Review:

Research that qualifies for IRB review under this policy is submitted in the electronic IRB system for review and prior approval in the same manner as other human subjects research projects. However, there are separate application forms and review process. Research proposed under this policy may be reviewed by the IRB Chair, IRB members with relevant expertise, HRPP Director or experienced IRB staff members.

Types of Research

The types of research qualifying for flexible review are listed in the IRB Standard Operating Procedure (SOP) 20 and outlined in IRB submission documents. These types may be updated as

needed to reflect federal guidance about minimal risk research, institutional policy or consultation with the KUMC research community.

Reporting Requirements
Research projects that qualify for flexible review are not subject to federal reporting requirements when an unanticipated problem, suspension or termination occurs or when the IRB makes a finding of serious or continuing non-compliance. However, all requirements for submitting reportable events to the KUMC IRB remain in effect. Unanticipated problems and non-compliance are reported and reviewed as described in SOP 5.3 and 17.1 respectively.

Exclusions to the policy:
Minimal risk projects that are under the jurisdiction of an external IRB must meet all requirements of the external IRB. They are not eligible for flexible review.

Related Procedures:
Standard Operating Procedure 20.0 – Flexible IRB Review