Selecting the IRB Application Form for Projects under Federal Regulation*

Project Type	IRB Application Type	Comments
Project to enhance or promote adoption of current best practices	Not research. Apply for a Quality Improvement Determination	
Analysis of data or specimens that already have been de-identified per HIPAA by individuals not associated with the study	Apply for a Not Human Subjects Determination	Study teams are allowed to get updated outcomes data, provided the data remain coded and team has no access to the code key.
Analysis of big data	Secondary Research if all data recipients are covered entities under HIPAA; If not, use the Expedited form	In parallel to the IRB submission, consult the KUMC HIPAA Program about the need for a data use agreement.
Chart reviews of EMR data or other source data with identifiers	Secondary Research	Data can be both retrospective and prospective. A data use agreement is required if data leave KUMC and can be arranged in parallel to the IRB submission.
Research on educational strategies	Exempt	
Minimal risk behavioral interventions	Exempt or Expedited, depending on study methods	For federal projects, refer to the limits of Exempt Category 3; Expedited Review is the alternative
Demonstration projects sponsored by a federal agency	Exempt	Projects in this category are only those posted on a federal website
Research on taste and food quality	Exempt	
Online surveys	Exempt	
Interviews and focus groups	Exempt for benign topics; Expedited for sensitive topics	Interviews may include video or audio recordings
Analysis of specimens labeled with one or more HIPAA identifiers	Expedited	
Non-invasive collection of biospecimens	Expedited	
Creation of a data registry to support multiple future projects	Expedited	Applicable when the future projects would involve either data analyses or recruitment into other new studies)
Creation of a biorepository to support multiple future projects	Expedited for non-invasive sample collection; Full board for invasive samples	
Development of a new diagnostic test	Full Board Application	Complete a Full-Board application unless the study has a letter from FDA saying it is IDE exempt; if so, complete an Expedited Application.
Invasive collection of biospecimens	Full board application	
Behavioral interventions that are more than minimal risk	Full board application	
Clinical trial of an FDA-regulated product	Full board application	
Compassionate use protocol	Full board application	
Emergency use of an investigational product	Emergency Use Notification within 5 days of the emergency use	Before emergency use, contact the IRB office for written acknowledgement (through email)

*KUMC research is reviewed under federal regulations when (1) it is greater than minimal risk; (2) it is federally funded or supported; (3) it involves delivery of an FDA-regulated product or collects data about FDA-regulated products