Selecting the IRB Application Form when Federal Regulations Do Not Apply*

Project Type	IRB Application Type	Notes/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	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.
Analysis of specimens labeled with one or more HIPAA identifiers	Secondary Research	
Research on educational strategies	Flexible Review	
Minimal risk behavioral interventions	Flexible Review	
Research on taste and food quality	Flexible Review	
Online surveys	Flexible Review	
Interviews and focus groups	Flexible Review	Interviews may include video or audio recordings
Non-invasive collection of biospecimens	Flexible Review	
Creation of a data registry to support multiple future projects	Flexible Review if the study involves interaction with subjects	If the registry involves only data already being collected clinically, use the Secondary Research form instead of Flexible Review
Creation of a biorepository to support multiple future projects	Flexible Review for non-invasive collection of samples; 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)

*This chart covers research that is **not** subject to federal regulations: (1) it is low or minimal risk; (2) there is no federal funding or support; (3) it does not deliver an FDA-regulated product or collect data about FDA-regulated products. If the three criteria are met, the study is reviewed for ethical considerations and institutional policy. If any of the three criteria are not met, then please refer to the chart on projects under federal regulations.