

EXEMPT, EXPEDITED AND FULL REVIEW PROJECTS

“Exempt” studies

- Exempt studies are low risk studies that fall into one of six categories delineated by the federal government.
- Only the Human Subjects Committee (HSC) may determine that a research project qualifies for Exempt status.
- After receiving Exempt approval, investigators are responsible for notifying the HSC office of any revisions to the research so that the HSC may determine whether or not the revisions to the research impact the risks to human subjects, thus affecting the project’s Exempt status.
- Exempt research cannot involve recording identifiers or using a coding scheme that links back to the individual’s identity.
- Generally, the Exempt studies at KUMC fall into two of the six federal categories:
 - Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, unless the information is obtained and recorded by the investigator in such a way that the subject can be identified, and any disclosure of the human subjects' response outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. Please note that this does not apply to research involving survey or interview procedures or observation of public behavior when children are the subjects.
 - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly, or through identifiers linked to the subjects.
- A full listing of categories is found on the Exempt application form at:
http://www2.kumc.edu/researchcompliance/forms/HSC_Application_for_Exemption_Class.pdf
- The request for Exempt status must be approved prior to initiation of the study.

Expedited Review

- Expedited review is a process through which certain kinds of studies are reviewed by the HSC chair, or one or more experienced reviewers designated by the chair, rather than the full HSC.
- Expedited review is permitted when the project is found by the reviewer(s) to involve no more than minimal risk. 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. Expedited review can also be used to review minor changes in previously approved research during the period for which approval is authorized.
- Expedited projects can be retrospective or prospective. Examples include:
 - Retrospective research that does not meet the Exempt criteria, i.e., identifiers or coding schemes are required to conduct the research
 - Prospective research that does not expose subjects to additional risk, such as research using data collected for clinical purposes
- Categories of Expedited research are summarized as follows:
 - Under certain conditions, clinical studies of drugs and medical devices.
 - Under certain conditions, the collection of blood samples.

- Prospective collection of biological specimens for research purposes by non-invasive means, e.g., hair and nail clippings, deciduous teeth, saliva, dental plaque, mucosal cells.
- Under certain conditions, the collection of data through non-invasive procedures routinely employed in clinical practice.
- Research involving materials collected for non-research purposes.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics employing survey, interview, oral history, focus groups (if not exempt).
- Research in which the primary risk is breach of confidentiality and the risk has been managed so that it is no more than minimal.
- A complete list of research categories that may be reviewed with an Expedited procedure is found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>
- The submission requirements for Expedited studies are identical to the requirements for research requiring Full Review. Submissions should include any applicable data collection tools or questionnaires. Additionally, requirements for written informed consent may apply.

Full Review Projects

- Any research involving human subjects that does not fall into an Exempt or Expedited category must be reviewed by the full Human Subjects Committee.
- Full review is required when there are identifiable risks to the subject or when an external granting agency requires full review.
- Research reviewed by the full committee usually involves significant physical, psychological, economic, legal or social risks. Common examples are clinical trials and behavioral studies.

The required submission paperwork for research studies is listed at:
<http://www2.kumc.edu/researchcompliance/forms/HSC.Submission.Req.05.19.2004.pdf>