UT Graduate School of Medicine IRB Submission Flowchart

http://gsm.utmck.edu/irb/main.cfm

CITI training for Human Subjects Protection **MUST** be completed by everyone involved with the research at the time of IRB Submission.

WHAT IS MY LEVEL OF SUBMISSION?

Projects of Non GSM / Non UHS Investigators must be approved by UHS Director of Research Compliance

→ Contact Janet Parkey

Exempt Review

Less than "minimal risk"* to human subjects

Example:

•Anonymous response survey, focus group or questionnaire, case reports

•Working with a completely deidentified (anonymous) secondary data set

Expedited Review

"Minimal risk"* to human subjects

Examples: Prospective or retrospective chart review, surveys/questionnaires collecting limited personal identifiers or health information, any intervention or interaction with the subject

Full Review

▪More than "minimal risk"* to participants
▪Any research project involving human subjects not covered under other review categories
▪Contact with vulnerable populations
▪Working with data that can be traced or linked to individual participants
▪Interventions involving physical or emotional discomfort

WHAT FORMS DO I NEED?

Application for Exemption [Form 5]

Exempt Categories most commonly used include:

Category 2 - Research on educational tests, survey/interview procedures, subjects must be deidentified, must be "benign research" (no risk of liability or damage due to release of data)

Category 4 - Collection or study of existing data or specimens where NO identifiable information is collected.

*See page 3 of Form 5 for additional Categories

Exempt and Expedited studies may be submitted any time.

See the IRB Meeting Schedule for pre-review and submission deadlines for Full Board Reviews

Exempt Submissions:

One copy each:

Research Proposal

Form 5

Data Collection Instruments (surveys, questionnaires, advertisements etc.)

Expedited and Full Review:

Full Board: Submit original and 28 copies of all forms

Expedited Review: original and 1 copy of all forms

•IRB Submission Checklist
•IRB Application [Form 1, Form 1a or Form b]
•Research Proposal/Protocol (3 copies for Full Board)
•Informed Consent
•Assent Form for participation of minors (if applicable)
•Request for Consent Waiver (to waive or alter consent) [Form 8]
•Budget
•Investigators brochure or pertinent information (3 copies for Full Review, 2 for Expedited) Patient Information or Instructions for Use if research involves the use of a drug, device or interventional procedure
•Copy of Grant Application & Approval Letter if applicable

IMPORTANT

▪Review all paperwork carefully before submitting to IRB

*"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical and physiological examinations or tests (noninvasive examples, physical, blood pressure, EKG). Note that all proposals must include a risk/benefit assessment to identify whether the research will pose more than a "minimal risk" to the subject.

**"Vulnerable Populations" include those whose interests require special protection, e.g., Pregnant women/fetus, prisoners, minors, subjects with psychiatric/mental disorders, etc.