

**ADULT HEALTH
INSTITUTIONAL REVIEW BOARD
COMMONLY USED TERMS AND DEFINITIONS**

- IRB #:** Internal categorization of protocols follows OHRP and FDA guidelines. Protocols are denoted by year, followed by an internal tracking number. Those protocols labeled with an “E” are expedited; those labeled with “X” are exempt.
- Amendment:** Any revision or change to an originally approved document is considered an amendment. An amendment submission form signed by the principal investigator is required for EACH amendment request.
- Supporting documents include: a letter summarizing changes to be made; tracked changes; the original approved document being amended. One original hard copy with PI signature or Co-PI is required before a submission will be processed for review.
- Adverse Events:** A Serious Adverse Event Form is required for each SAE submitted. The SAE form must be signed by the principal investigator. Only one copy is required for submission.
- Supporting documents includes: One copy of the approved stamped Consent Form, a SAE summary form (if applicable), and sponsor documentation or internal hospital records with subject identification redacted if available. Please review what constitutes as an SAE at: [LINK](#)
- PI:** Principle Investigator
- CO-PI:** Co-principle investigator or Sub-investigator
- Progress Report:** Document requesting continuation or closure of your active IRB research study. A progress report is required one year after the initial IRB approval date. The IRB sends out reminder letters 90, 60 and 30 days before a review as a friendly reminder.
- The Progress Report **MUST** be signed by the PI or Co-PI
- Break down of participants by race is applicable only if you track this demographic. If you do not track this demographic for your research, please make a notation in your cover letter.
- Approval/** The date of approval/reapproval is the date of the Board meeting

Reapproval date: where the study submission/progress report was reviewed, minus one day.

Human Subject Certification: The IRB requires all persons involved in human subject research to complete an education course regarding ethical treatment of human subjects. The training course accepted by the UMKC IRB can be found at: <https://www.citiprogram.org/default.asp>
EXCEPTION: employees of CMH, VA and St. Lukes should contact the IRB for more information.

FDA: Food and Drug Administration

IND: Investigational New Drug: An IND protocol requires a 1572 form of authorization from the FDA.

HUD: Human Use Device: A human use device protocol requires a form of authorization from the FDA.

HIPAA: Health Insurance Portability and Accountability Act. All protocols will be reviewed for applicability of HIPAA either through Truman Medical Center or UMKC.

UMKC Dental School protocols will be provided with HIPAA review at time of submission and may be required to fill out a form for use during data collection.

COC: Certificate of Confidentiality. A COC is to be obtained from the National Institute of Health if you intend to obtain personal or confidential information (illicit drug use, sexual preference, etc.) from subjects during the course of your research. For more information, please review AH IRB FAQ or go to: <http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.pdf>