

Examples of Items to Submit to HSC:

- À Outside Serious Adverse Events, use the HSC AE form
(Medwatch reports, letters from sponsors)
- À KUMC subject Serious Adverse Events, use the HSC AE
form
- À Data Safety Board Monitoring Reports
- À Revised Investigator Brochure
- À Advertisements
- À Re-Certifications
- À Revised Consents
- À Protocol Amendments/Clarifications
- À Protocol Deviations that affect subject safety
- À Principal Investigator Change
- À Termination of Study
- À Expired study drug given to subjects
- À Subject transfers