

IRB Updates

September 19, 2023 Research Matters

Modification Holds



CHANGES IN PROCESS: Modifications on studies which have a Coverage Analysis (CA) regardless of whether we are the reviewing IRB or an external IRB is responsible for the study will have approved documents held until SPA provides clearance that the CA has been approved or confirms that no changes are required



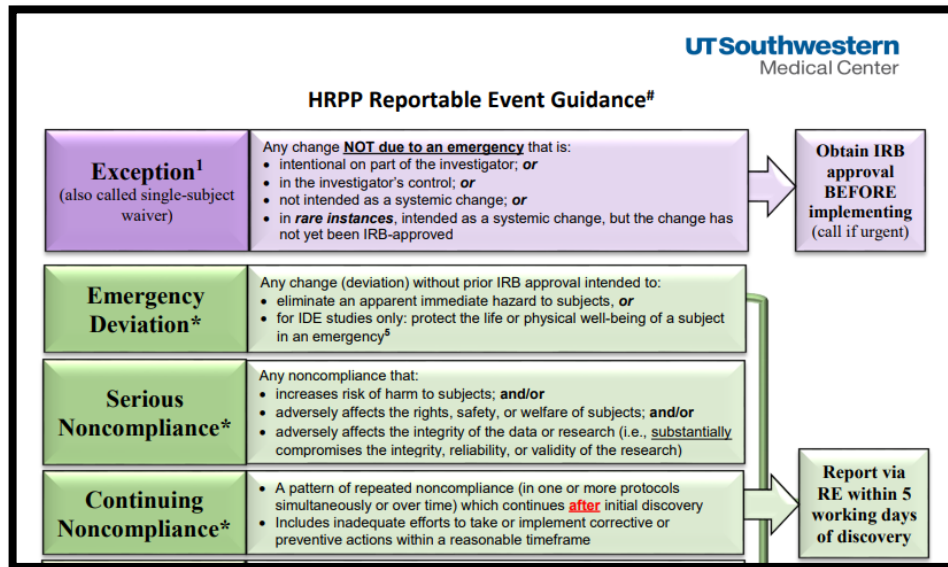
PURPOSE: Update to allow for changes to the CA to be made where necessary to studies in which we are the IRB of record and when we are not the IRB of record (Reliance Studies)



EXCEPTIONS: Exceptions to this process include Modifications made due to safety reasons

Other Updates on the Horizon

- RE Guidance Table



- Developing a Reportable Event Decision Tree

