Human Research Protection Program (HRPP) Manual Revisions
(Updates to 1.12.15 version manual from 8.25.14 version)

Section 1.3.1 (page 4)—Added a section regarding communication between various components of the Human Research Protection Program (HRPP).

Section 1.4.1—Definitions (pages 4-5):
  a) Added a definition of generalizable knowledge
  b) Added information about deciding and communicating whether a project meets the definition of research involving human subjects
  c) Added the FDA definition of a human subject

Section 2.11.1 Deadlines (page 40)—Established a deadline of 10-days before convened meeting (for both Amarillo and Lubbock/Odessa IRBs) for submissions to be reviewed by the full board.

Section 2.13.3.5 Exception from Informed Consent Requirements for Emergency Use of a Test Article (page 61)—Added information regarding the consent process and limited conditions in which consent can be waived. Also, clarified the difference between “emergency use of a test article” and “planned emergency research” in this section.

Section 2.14.3 Prisoners (page 67):
  a) Added information to clarify that IRBs reviewing prisoner research must include a member with knowledge or experience with the population.
  b) Added the definition of “minimal risk” as it applies to prisoners

Section 2.14.7 Decisionally Impaired participants (page 72):
  a) Added information regarding additional IRB review requirements
  b) Added information regarding obtaining consent and assent in this subject population.

Section 2.18.5 Planned Emergency Research (page 80)—this section was added to clarify the distinction between planned emergency research and emergency use of a test article.

Section 2.21.2 Reporting Non-compliance (page 85)—Provided clarification regarding the reporting and review processes

Section 3.10 Compensation for Research related injury (page 94)—added new section based on TTUHSC OP 73.17.

Section 3.15.3 Storage, Handling and Dispensing of Investigational Agents (page 99)—Clarified storage requirements and PI responsibilities regarding communication and assurance that only eligible subjects will receive investigational agents stored in or outside of a pharmacy setting.

Section 3.18.1 PI Responsibilities (checklist) (page 103)—added information to regarding storage and dispensation of investigational agents to the section titled “Assures the proper use and storage of investigational Agents.”