When compared we have made 1,752 changes. (Most of these were editorial/formatting changes to provide clarification and ease of reading.)

Section	Revision
	Added list of Acronyms
ORGANIZATION OF THE PROGRAM	
1.1	Assistant Vice President-Research Integrity (term changed throughout the manual)
	Clarification of reports and reporting
1.2	Added Quality Improvement Board as a component program
1.4.11	Add a more thorough description of non-research activities distinguishing between QI activities
	Removed the AVP-RI from role of determination of exempt projects
1.9.1	Added QIRB and ESCRO as compliance committees
1.9.3	Added entire section on Cooperative Research Activities involving other entities
INSTITUTIONAL REVIEW BOARD STRUCTURE AND FUNCTION	
2.2.1	Removed link and reference to knowledge of local research conduct (non-working) Clarified when adding another site and amendment must first be submitted and approved by IRB
2.2.3	Removed Collaboration between TTUHSC and TTU (addressed in new 1.9.3)
2.2.6	Clarified aspects of international research
2.3.1	Added “former employee who is receiving financial benefits from TTUHSC” to be considered as “affiliated with TTUHSC”
2.4.2	Clarified annual requirement for COIC training and disclosure for all IRB members
2.4.3.2	Clarified “encouraged” continuing education vs “mandatory” continuing education
2.4.4.1 (this is the first reference)	Clarified the Institutional Compliance Office is responsible for maintaining the list of up to date disclosures for all IRB members
2.4.7	Added clarification to description of IRB member evaluation process
2.6.1	Specifically cited TTUHSC Compliance Committee Letters as an approval item
2.7.2	Added documents necessary for multisite studies
2.7.3	Revised wording and order to be consistent with IRB member checklist
2.7.4	Removed reference to continuing review “not less frequently than once per year”
2.8.1.3	Removed reference to continuing review “no case will the interval between CR be more than 11 months”
2.8.1.4	Provided clarification regarding approval and expiration dates allowing for minimal risk projects with no external source of funding who met the criteria for expedited review to no longer require continuing review
2.9.1.1	Added a to the second exempt category from 45 CFR 46 NOTE: Surveys or questionnaires involving children may not be considered exempt.
2.9.1.2	Added entire list of exempt categories for research **without external funding**
2.9.3.2	Added entire section titled Conduct of the [IRB] Meeting
2.9.3.3	Added clarification to IRB duties to assure congruency between funding and project design Added requirement for IRB checklist completion
2.10.2	Revised wording to allow for new categories of research that do not require annual review
2.10.2.1	Added last 2 bullets re: funding sources and type of initial review to items used to determine frequency of review
2.10.2.9	Added several bullets to provide guidance re: continuing review and assigned frequency of review

2.10.3	Revised wording to clearly state amendments are still required for changes to projects that do not require annual IRB review
2.10.4.2.2	Added clarification re: protocol deviations. If a reported UPIRSO is the result of a protocol deviation, the UPIRSO report will be accepted in lieu of a protocol deviation report
2.10.5.1	Added clarification regarding IRB requirements for completed studies – no further research activity are permitted
2.10.5.2	Same as 2.10.5.1
2.10.5.3	Added clarification regarding IRB requirements for studies that are temporarily closed. Activity occurring during this time is to be reported (ie: amendments, UPIRSOs, SAEs with subjects previously enrolled)
2.11.1.1	Added clarification regarding valid consents and the requirement for ALL signatures
2.11.1.4	Added clarification regarding expiration stamp on studies that do not require continuing review (no expiration stamp will be placed)
2.11.3.1 & 2.11.3.2	Added clarification to assure the witness is an "impartial" witness – see new definition in glossary
2.11.3.3	Added clarification regarding waiving informed consent
2.11.5.2	Replaced the term "Decisionally Impaired" with "Persons with Impaired Decision – Making Capacity"
2.12.8	Added reference to Reviewer Checklist for vulnerable population additional safeguards
2.16.4	Added affiliate requirements for very limited instances of non-TTUHSC Physicians and Emergency Use Drugs/Devices
2.17.3.1	Wording clarified
RESEARCHER AND RESEARCH STAFF INFORMATION	
3.4.1.2	Added clarification regarding training requirements and lapses
3.4.2	Revised to comply with current conflict of interest and financial disclosure requirements
3.9.2	Added entire section on Indirect Cost Rate for Industry Sponsored Clinical Trials
3.12	Added statement regarding scanned documents becoming the source document and allowing for paper document to be destroyed
3.12.3	Added clarification regarding studies that do not require continuing reviews
3.13	Added a statement that over enrollment is to be submitted as an Unanticipated Event.
GLOSSARY	
Administratively Closed Status	Added clarification to definition
WEAVE	Added definition
WITHDRAWN	Added **(STUDY STATUS)** to word
WITHDRAWN (STUDY SUBJECT)	Added
WITNESS, IMPARTIAL	Added