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

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 Cl 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 (nonworking) 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 annual requirement for COIC training and disclosure for all IRB members of up to date disclosures for all IRB members 2.4.3.1 (this is the first reference) 2.4.7 Added clarification to description of IRB member evaluation process 2.6.1 Specifically cited TTUHSC Compliance Officies is responsible for maintaining the list of up to date disclosures for all IRB members 2.7.2 Added documents necessary for multisite studies 2.7.3 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.	Section	Revision	
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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	
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	
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 &	Added clarification to assure the witness is an "impartial" witness – see new
2.11.3.1 &	
2.11.3.2	Ů ,
2.11.5.2	l '
0.40.0	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	Added clarification to definition
Closed Status	
WEAVE	Added definition
WITHDRAWN	Added (STUDY STATUS) to word
WITHDRAWN	Added
(STUDY	
SUBJECT)	
WITNESS,	Added
IMPARTIAL	