REVISIONS IN THE 03/29/2019 (FROM 10/18/2018) HRPP MANUAL INCLUDE

Page	Section	Topic
Cover/Footers		Revised date
INSTITUTIONAL REVIEW BOARD STRUCTURE AND FUNCTION		
Table of Contents		Updated to correspond with revisions
Throughout the Manual		• Added references to pre2018 and 2018 Common Rule and updated CFR references accordingly; Updated description related to current quality assurance processes • Replaced Lubbock/Odessa IRB with Lubbock/Permian Basin IRB • Revised numbering as needed • Editorial corrections to federal regulatory references to be consistent with 2018 Common Rule
19-20	1.4.1	Added Section Titled 2018 Common Rule Requirements
21	1.4.2.1	• Added paragraph "*Collection and analysis…"* example of activities not deemed to be research. • Add IRB member as authorized to make determination regarding exempt status of a submission.
22	1.5	Provided clarification regarding the Authority of the Human Research Protection program (regardless of the funding source).
26, 110	1.9.1, 3.9.1	Removed reference to Recombinant DNA Biosafety Committee (these responsibilities will be assumed by the Institutional Biosafety Committee
33	2.3.5	Added the statement, "At this time TTUHSC IRBs do not have this representation, therefore no research specifically targeting prisoners may be reviewed by a TTUHSC IRB.
35, 37, 38	2.4.2.2, 2.4.4.1, 2.4.4.2	Replaced the title HRPP Education Coordinator with IRB Staff.
41-42	2.5	Updated the description of IRB minutes
42	2.6.1	• Added the term "serious" prior to "adverse event reports." • Added "as necessary" after "continuing review form…"
48	2.8.1.1 Item #8	Updated the examples of vulnerable subjects to be consistent with OHRP and FDA requirements.
49	2.8.1.3	Clarified to only address projects that require continuing review.
49	2.8.1.4	*Expiration Date* – added clarification regarding when this is assigned.
52	2.8.6.1	• Added the term "serious" prior to "adverse event or…" • Removed the clause, "for the purpose of continuing review" from the first sentence of the 4th paragraph.
55-58	2.9.1	Added the criteria for 2018 Common Rule Determination of Exempt Human Research – new section 45 CFR 46.104.
59	2.9.1.4	Removed the reference and hyperlink to the Human Subject Regulation Decision Charts.

64	2.10.2.1.1, 2.20.2.1.2	Revised the description of studies requiring continuing review to clarify difference between 2018 and pre2018 projects.
65	2.10.2.2	Added clause “which require continuing review” to the second sentence of the second paragraph.
66	2.10.2.5	Added the clause “processed or” to the second sentence.
	Prior 2.10.2.9, 2.10.2.10, 2.10.2.13	Deleted sections titled “Continuing review – Convened Meeting Review”, “Continuing review – Expedited Review” and “Exempt studies – Non Continuing Review Submission Required”
	Prior 2.10.4.3.4 & 2.10.4.3.5	Removed section related to “unanticipated adverse device effects (UADE)”
76	2.11.1.1	Inserted clause “and additional” to second sentence of the first paragraph describing template consent forms.
86	2.12.3	Deleted detailed information related to review of research targeting prisoner populations (consistent with section 2.3.5).
86	2.12.4.1	Inserted the clause “non-exempt” to the first sentence of the second paragraph.
97	2.16.4	Added the term “serious” prior to “adverse event or…”in the 3rd bullet at the top of the page.
97	2.17.1	Removed the term “approval”.
99	2.17.3.3	Added section “Whole Genome Sequencing”
103	2.19.2	Removed the duplicate paragraph, “If the initial….”
103, 104	2.19.3	• Added the term “serious” prior to “adverse event” – 6th bullet, fourth paragraph • Corrected title – “Senior Vice President for Research” in the fifth paragraph
107-108	3.4	Section rewritten to provide regulatory and institutional requirements and remove process information that is provided on the HRPP website.
118-122	3.18.1, 3.18.2	Added the term “serious” prior to “adverse events”

Glossary		• Removed the terms – Adverse Event and WEAVE
		• Updated the regulatory reference for Continuing Review
		• Updated the description of Study Status
		• Added terms
		  ○ Identifiable Biospecimen
		  ○ Identifiable Private Information
		  ○ Interaction
		  ○ Intervention
		  ○ Private Information
		  ○ Written or in Writing