REVISIONS IN THE JUNE 2023 (FROM JULY 2022 vsn) 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 • Replaced 'iRIS' with Cayuse (and updated instructions accordingly) • Revised numbering as needed • Editorial corrections to federal regulatory references to be consistent with 2018 Common Rule
20	1.4.1	Added Section Titled 2018 Common Rule Requirements
21	1.4.2	Case series - in manual a single case doesn't have to be submitted to IRB, created Internal policy to allow case series. Page 20 revision → [i.e., single case report, case series (n=3)]
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.
23	1.4.2.3	• in reference to the 3rd bullet say "TTUHSC patients' identifiable non-public information
23	1.5	Provided clarification regarding the Authority of the Human Research Protection program (regardless of the funding source).
26-27	1.7.1	Added acronym for ICOI
27, 113	1.9.1, 3.9.1	Removed reference to Recombinant DNA Biosafety Committee (these responsibilities will be assumed by the Institutional Biosafety Committee
35	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.
38	2.4.3.2	Added the statements, "alternate member, and consultants" and "in accordance to institutional policy and OHRPP Policy".
37, 39, 40	2.4.2.2, 2.4.4.1, 2.4.4.2	Replaced the title HRPP Education Coordinator with IRB Staff.
43	2.5	Updated the description of IRB minutes
44	2.6.1	• Added the term "serious" prior to "adverse event reports." • Added "as necessary" after "continuing review form…"
49	2.8.1.1 Item #8	Updated the examples of vulnerable subjects to be consistent with OHRP and FDA requirements.

51	2.8.1.3	Clarified to only address projects that require continuing review.
51	2.8.1.4	*Expiration Date* – added clarification regarding when this is assigned.
54	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.
57-61	2.9.1	Added the criteria for 2018 Common Rule Determination of Exempt Human Research – new section 45 CFR 46.104.
61	2.9.1.4	Removed the reference and hyperlink to the Human Subject Regulation Decision Charts.
66	2.10.2.1.1, 2.10.2.1.2	Revised the description of studies requiring continuing review to clarify difference between 2018 and pre2018 projects.
67	2.10.2.2	Added clause "which require continuing review" to the second sentence of the second paragraph.
68	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)"
78	2.11.1.1	Inserted clause "and additional" to second sentence of the first paragraph describing template consent forms.
88	2.12.3	Deleted detailed information related to review of research targeting prisoner populations (consistent with section 2.3.5).
88	2.12.4.1	Inserted the clause "non-exempt" to the first sentence of the second paragraph.
90	2.12.7	Added statement below to the end of the section (1/30/2022) based on AAHRPP requirements for reaccreditation. "When providing information, the available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial."
97	2.16.4	Added the term "serious" prior to "adverse event or…"in the 3rd bullet at the top of the page.
99	2.17.1	Removed the term "approval".
101	2.17.3.3	Added section "Whole Genome Sequencing"
104	2.19.2	Removed the duplicate paragraph, "If the initial…."
105-106	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
109	3.4	Section rewritten to provide regulatory and institutional requirements and remove process information that is provided on the HRPP website.

109	3.4.1	Clarification of 'clinical' research staff in the NOTE section.
109	3.4.3	Updated/revised the instructions for this section due to the change from iRIS to Cayuse.
110-111	3.5	Revised title of section to "Individual Conflicts of Interest', and added the following as the first sentence – "In order to minimize the actual or potential conflicts of interest in Human Research, the IRB requires that all individuals involved in the design, conduct, or reporting of the research disclose financial interests related to the research. Of note, in addition to the PI and coinvestigators, individuals involved in the design, conduct, or reporting of the research may include study coordinators, research nurses, data coordinators, and other support staff." Section below added: "A financial conflict of interest in research is any financial interest related to the research. This can refer to, but is not limited to, any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family (spouse, unmarried domestic partner, dependent children): • Ownership interest of any value including, but not limited to stocks and options. • Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income (TTUHSC salary paid by a sponsor is excluded). • Proprietary interest of any value including, but not limited to, patents, trademarks, copyrights, and licensing agreements. • Board or executive relationship, regardless of compensation. • Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center. With regards to intellectual property, patents, technology development, proprietary ownership, commercial or manufactured products, etc., the IRB recommends disclosure of intent to commercialize or license intellectual property, as it relates to the research, in the consent documents. This disclosure should include plans for any development, licensure, commercialization, and/or patentability of any intellectual property, technology, commercial or manufactured products, etc., and indicate how participant identifiers are used in this process, if at all. The disclosure should include a statement about if/when the PI would profit or benefit financially, and indicate what additional compensation will be awarded to participants, if any, if/when the intellectual property results in commercialization."

111	3.6	PI definitions for EM faculty. → TTUHSC PI must meet requirements of (link to OP 73.08) exceptions may be granted on a case by case basis by the assistant vice president for Research Integrity
112	3.9	Updated/revised the instructions for this section due to the change from iRIS to Cayuse. iRIS link removed from first paragraph. Link at end of section updated to https://www.ttuhsc.edu/research/divisions/integrity-office/review-board/default.aspx
117	3.15.2	Payments processed through TTUHSC MUST (changed "Musty" to "Must"
119	3.17.1	Removed statement re: subject management.
121-125	3.18.1, 3.18.2	Added the term "serious" prior to "adverse events"
121	3.18.1	Statement added under 'Protects the rights and welfare of subjects by:' - • acts in accordance with all applicable laws, regulations, and/or their professional licensing board in regards to protecting the rights and welfare of research participants during an emergency.
120	3.18.1	Added second and third bullet (1/30/2022) shown below based on AAHRPP requirements for reaccreditation. "• reporting new information that might affect adversely the safety of the subjects or the conduct of the clinical trial • reporting any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects"
125	3.18.4	Removed 'subject management' from Delegation of Authority
129	4	Section 4 Glossary was moved to Section 5 New Section 4 – Emergency Preparedness - The Institution routinely assesses potential emergency scenarios and threats to the Institution, its faculty, staff, employees, residents, and students to improve its emergency preparedness and response plan. The VPR/IO, or their designee, collaborates with Institutional leadership to develop, implement, and assess emergency preparedness procedures for the HRPP. Depending on the nature of the event, the SVPRI/IO, or their designee, may collaborate with Institutional leadership and PIs to determine the types of research that might continue and the types that the Institution may need to temporarily postpone under applicable laws, regulations and/or Institutional policies. The Institution may identify external IRBs on which it can rely on temporarily during an emergency. The IRB staff will work with applicable departments, resources and/or vendors to ensure continuity of operations. In addition to this HRPP manual and Institutional policies, PIs will be instructed, and will be expected, to act in accordance with all applicable laws, regulations, and/or their professional licensing board in regards to protecting the rights and welfare of research participants during an emergency.

129	4	New Section 4 – Replaced old section information with completely new revisions (1/30/2022) based on AAHRPP requirements for reaccreditation.
133	5	Department of Defense Added entire section (01/30/2022) based on AAHRPP requirements for reaccreditation.

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