REVISIONS IN THE 10/8/2019 (FROM 10/24/2016) HRPP MANUAL INCLUDE

Page	Section	Topic
Cover/Footers		Revised version and date
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INSTITUTIONAL REVIEW BOARD STRUCTURE AND FUNCTION		
2	1.1	Introduction and Organizational Summary-Clarified use of IRB review fees.
4-6	1.4.1	Definitions-Updated with the revised Common Rule
8	1.5.5	State Authority - Clarified language
9-10	1.8	Institutional Conflict of Interest – Added wording to more clearly describe institutional conflict of interest
11	1.10.2.1	Cooperative Research Activities Involving Other Entities – Revised to more clearly describe activities and process
13	2.2.1	Research Conducted by Students/Residents with IRB Approval from Another Institution – clarified notice to the TTUHSC IRB office and Student Affairs, is required prior to student resident participation in a project
14	2.2.3	Community Based Participatory Research - Revised wording regarding process
15	2.2.4	International Research – Revised wording regarding process
16-17	2.3.1.6	Consultants - Added clarification
17	2.4.1	Liability Coverage – Revised wording
18	2.4.2	IRB Staff Education – Added wording on requirements
19	2.4.3	IRB Member Conflict of Interest – Revised wording
19-20	2.4.4	IRB Member Education - Clarified wording
23	2.4.7	IRB Alternate Members – Clarified wording
24	2.6	IRB Meeting Minutes – Clarified wording
24-25	2.6.1	File Composition – Clarified wording
25	2.6.2	Record Retention – Clarified wording
25-26	2.7.1	Submission Mechanism – Clarified wording
26	2.7.2	Documents – Removed requirement for grant applications or funding proposals
27-28	2.7.4	PI Sign Off-Revised wording to include recordkeeping requirements
28	2.7.5	Department Signatory Sign Off – Revised wording to include recordkeeping requirements; Process for sign off when PI is also the Department Signatory
29	2.7.7	Agenda – Clarified wording
29	2.7.8	Notification to Investigators – Clarified Wording

32	2.8.1.4	IRB Approval and Expiration Dates – Clarified requirements for projects requiring continuing review and added “no expiration date” information
33	2.8.3	Disapproval – Clarified wording
37-39	2.9	Determination of Exempt Human Research – Revised with new regulation categories and information; who to call with questions and about the written notice
42	2.10.2	Deadlines – Clarified wording
43	2.11.2	Conduct of the Meeting – Added section
44	2.12.2	Added IRB Determination for continuing review - revised sections to clarify when continuing review is and is not required; clarified frequency
45-46	2.12.2.4	Required information – Addition of an updated complete protocol
46	2.12.2.5	Submission screening – Additional section
46	2.12.2.6	Duties of IRB Members – Clarification of wording
47	2.12.2.10	Continuing Review-Expedited Review – clarified wording
48	2.12.2.13	Exempt Studies-No Continuing Review Submission Required – Added a note regarding ongoing requirement for submission of study changes, unanticipated events and study closures; removed yearly notices
48	2.12.3	Amendments – Clarified wording
48	2.12.3.1	Minor Amendments – Clarified wording
50-51	2.12.4.1.2	Reporting to IRB – Clarified wording
54-55	2.12.4.4	Adverse Events – Added section
57-58	2.12.4.7	Sponsor Monitoring Reports – Added section
58	2.12.5.1	Study Status-Completed – Clarified wording
58	2.12.5.2	Study Status-Cancelled – Clarified wording
59	2.12.5.3	Study Status-Temporarily Closed – Clarified wording
59	2.13.1.1	Informed Consent-Templates – Clarified wording
60	2.13.1.2	Informed Consent-English Document – Clarified wording
60	2.13.1.4	Clarified the approval date description and removed the requirement for an expiration date associated with assigned review time frame on consent documents
62-63	2.13.2.3	Waiver of the Informed Consent Process – Clarification regarding review criteria
64	2.13.2.6	Legally Authorized Representative – Updated wording for statutes
65	2.13.4.1	Child or Minor – Clarification of wording on waivers of assent
66	2.13.4.2	Updated section title
70	2.14.3.3	Approval criteria for Prisoner Research – revised wording; only applies if prisoner advocate/representative is a member of the board.
71	2.14.3.4	Special Considerations for Participants who become prisoners- Added section; only applies if prisoner advocate/representative is a member of the board.

71-72	2.14.4.4	Age of Majority and Reconsenting as an adult-Added section
73-74	2.14.5	Employees as participants – Clarified language regarding recruitment of subordinates
74	2.14.7	Participants with Impaired Decision-Making Capacity - Revised title and language
80	2.18.2	IND Application – Revised wording
80	2.18.3	Expanded Access – Revised wording regarding the three categories of expanded access
80	2.18.4	IDE Application – Clarified IDE process
81	2.18.5	Emergency Use of Investigational Drug/Device – Clarified wording for submission request by physicians credential through affiliated entity
83	2.18.6	Planned Emergency Research – Clarified wording
83	2.18.7	Humanitarian Device Exemption – Revised wording to include documents needed for review
85	2.19.3.1	Human embryonic stem cells – Clarified wording on TTUHSCEP compliance
87-88	2.21	Research Compliance – Revised section; removed detailed information which will be located in the research compliance manual
89	2.21.2	Reporting Non-Compliance – Revised section; removed detailed information which will be located in the research compliance manual
89-90	2.21.3	Regulatory Compliance Audits – Revised section; ; removed detailed information which will be located in the research compliance manual
90-91	2.21.4	IRB Review of Audit Reports – Revised section to include clarification on the review process
93	3.4.1.1	Human Subject Protection Training and Financial Conflict of Interest Training – Clarified training requirements
93	3.4.1.2	New CITI Account Instructions – Clarified wording on instructions
93-94	3.4.1.3	CITI Renewal Training – Clarified wording on training requirements
94	3.4.3	Investigator Conflicts of Interest – Clarified wording that the IRB must approve a CMP prior to enrollment of human subjects
94-95	3.4.4	iRIS Access – Clarified instructions

RESEARCHER AND RESEARCH STAFF INFORMATION		
95	3.6	Who can be a PI from an affiliated entity? – Clarified that outside collaborators may not be PI's, but may be listed in other roles and must comply with TTUHSCEP policies
95	3.8	Non-TTUHSC EP Research Personnel – Clarified activities that may not be conducted by volunteers
97	3.10.1	Relation to Other Committees – Revised the committee list
97	3.11	IRB Fee Policy – Revised language regarding Reviewing IRB designation
97	3.11.2	Indirect Cost Rate for Industry Sponsored Clinical Trials – Added section
98	3.13	Clinical Trial Registration – Revised language to include new mandates
98-99	3.14	Informed Consent – Revised to include language regarding electronic documents
100	3.15	Recruitment and Advertising – Clarified that over-enrollment should be reported as an unanticipated event; clarified recruitment methods
102	3.17.1	IND/IDE Application – Clarification on required documentation
103	3.18	Packaging and Shipment of Infectious Materials – Revised to include the requirement of an IBC license
104	3.19.1	Recordkeeping – Clarified paper and/or electronic records; records includes specimens; storage by PI/PI's department
109-110	3.20.2	Special Considerations for Clinical Trials that are Required to Follow ICH-GCP (E6) – Added section regarding adherence to standards
110-112	3.20.3	Removed sample documents in subsequent sections. Will now be found in the research compliance manual
114	Chapter 4	Glossary – Updated