# *Summary of Changes – HRPP Policies and Procedures 2016 to 2017*

| Explanation of Change | Policy Section | Page |
|---|---|---|
| ***Update: Elimination of Department of Navy Addendum to the FWA***<br>As of February 1st, 2016, DoN no longer requires or issues the Navy Addendum to the FWA. | 3.2 Department of Defense (DOD) and Department of the Navy DON) | 31 |
| ***Clarification: "Not Engaged" in research***<br>Overview of conditions necessary for institution employees or agent to be considered "not engaged" in research. | 4.5 Engagement in Research | 52 |
| ***Clarification: Types of Reliance Agreements***<br>Definition of types of Reliance Agreements and Authorization Agreement submission process<br>***Addition: Ceded Review Submission***<br>Expansion of policies and procedures for submission. Moved to Section 4.6 from Section 7.10 | 4.6 IRB Reliance Agreements | 61 |
| ***Addition: Transfer of IRB Oversight***<br>Considerations for transferring clinical investigation oversight to another IRB | 4.7 Transfer of IRB Oversight | 68 |
| ***Addition: Just-in-Time (JIT)***<br>Priority processing for IRB approval requested via NIH Just-in-Time process. | 7.0 Types of IRB Submissions | 96 |
| ***Addition: Guidance for International Research***<br>Considerations for research conducted outside of the U.S. | 7.11 International Research | 111 |
| ***Addition: IRB Response Verification***<br>The IRB evaluates the submission application to determine that the study will be conducted in accordance with applicable regulations and requirements.<br>***Addition: Review of Scientific Merit***<br>Non-cancer, investigator-initiated clinical trials that have no prior scientific review are forwarded to the CTSI for scientific review committee.<br>***Clarification: Review of Research Funds/Budget***<br>In the submission, the PI must assure that there are adequate financial resources for the study and provide supporting documentation. | 8.2 Criteria for IRB Approval of Research | 121 |
| ***Addition: Exempt Study Review by UPIRB***<br>UPIRB will no longer review ICF and/or recruitment materials for Exempt studies | 8.3 Review of Exempt Research | 125 |
| ***Addition: Revised HSIRB ICF Model Templates***<br>HSIRB informed consent templates have been updated. One template is suitable for Investigator-initiated studies, or studies where no template is provided. Another is to be used with model consent forms provided by industry, cooperative sponsors or external IRBs. | 10.2 Required Elements of Informed Consent | 164 |
| ***Addition: IRB Directors Signature Authorization***<br>Provost Signature Authorization provides that IRB directors are authorized to sign IRB Authorization Agreements, Certificates of Confidentiality, and Individual Investigator Agreements. | 11.4 Provost Signature Authorization letter | 199 |
| ***Updated: Mandate for GCP Refresher Course***<br>2016 regulations mandate that a GCP "refresher course" is to be completed every three years after completion of initial GPC training. | 13.3 Educational Requirements – Good Clinical Practice (GCP) Course | 219 |

# *Summary of Changes – HRPP Policies and Procedures 2016 to 2017*

| Explanation of Change | Policy Section | Page |
|---|---|---|
| ***Clarification: Investigators Role and Responsibilities in Multi-Site Research for studies using a Centralized IRB or NIH Single IRB***<br>***Addition: IRB review process for studies using a Centralized IRB***<br>***Clarification: Resource Adequacy***<br>The PI has the responsibility to assure that sufficient resources and necessary approval are obtained to conduct the study. | 13.5 USC Investigators Conducting Multi-Site Research | 221 |
| ***Clarification: Investigators Responsibility to Identify All Entities Involved in The Conduct of Research***<br>***Clarification: Resource Adequacy***<br>The PI has the responsibility to assure that sufficient resources and necessary approval are obtained to conduct the study | 13.11 Resources Allocation and Ancillary Approvals | 230 |
| ***Addition: OHRP Definitions for Parolees and Probationers in Research***<br>***Addition: The PI requirements to abide by The California Department of Corrections and Rehabilitation Title 15 (California Code of Regulations)*** | 14.3 Prisoners in Research | 261 |
| ***Clarification: Case Studies***<br>Case Studies where PHI is not recorded does not need HIPAA authorization. | 15.1 Chart Reviews/Case Studies | 272 |
| ***Clarification and Addition: Safety of Recombinant or Synthetic Nucleic Acid Molecules***<br>Updated NIH Guidelines reference. Protocol evaluation by an IRB and/or Biosafety Committee now must determine whether a human gene transfer study will be referred for NIH Recombinant DNA Advisory Committee (RAC) review. | 15.6 Human Gene Transfer Research ("Gene Therapy") | 293 |
| ***Addition: FDA Guidelines for In Vitro Diagnostic (IVD) Studies***<br>FDA will exercise enforcement discretion on the need for informed consent for IVD research studies using leftover human specimens that are not individually identifiable. (FDA Guidance) | 18.3 Investigational Medical Devices | 336 |
| ***Clarification: Responsibilities of Sponsor-Investigator for IND/IDE***<br>Requirements for IDE and IND protocols with reference links | 18.4 Sponsor-Investigator Responsibilities (IND/IDE) | 340 |
| ***Clarification: Physician responsibilities for the Compassionate Use of a medical device*** | 18.5 Compassionate Use of Medical Device | 341 |
| ***Addition: Submission of Planned Emergency Research***<br>Requirements for Planned Emergency Research will be evaluated by the IRB. | 18.8 Planned Emergency Research with Exception from Informed Consent | 351 |
| ***Clarification: Reliance agreements and their purpose*** | Appendices - F. IRB Reliance Agreements | 415 |
| ***Addition: NIH Requirement for Centralized IRB Oversight***<br>NIH funded research requirement of centralized IRB oversight for multi-site studies beginning September 25, 2017 | Appendices - N. Requisites for Single IRB | 416 |