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| ***Standard Operating Procedures*** | ***Worksheets*** |
| HRP-001 - SOP - Definitions | HRP-301 - WORKSHEET - Review Materials |
| HRP-012 - SOP - Observation of Consent Process | HRP-302 - WORKSHEET - Approval Intervals |
| HRP-013 - SOP - Legally Authorized Representatives, Children, and Guardians | HRP-303 - WORKSHEET - Communication of Review Results |
| HRP-020 - SOP - Incoming Items | HRP-304 - WORKSHEET - IRB Composition |
| HRP-021 - SOP - Pre-Review | HRP-305 - WORKSHEET - Quorum and Expertise |
| HRP-023 - SOP - Emergency and Device Compassionate Use Review | HRP-306 - WORKSHEET - Drugs |
| HRP-024 - SOP - New Information | HRP-307 - WORKSHEET - Devices |
| HRP-025 - SOP - Investigations | HRP-308 - WORKSHEET - Pre-Review |
| HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB | HRP-310 - WORKSHEET - Human Research Determination |
| HRP-027 - SOP - Emergency and Device Compassionate Use Post-Review | HRP-311 - WORKSHEET - Engagement Determination |
| HRP-030 - SOP - Designated Reviewers | HRP-312 - WORKSHEET - Exemption Determination |
| HRP-031 - SOP - Non-Committee Review Preparation | HRP-313 - WORKSHEET - Expedited Review |
| HRP-032 - SOP - Non-Committee Review Conduct | HRP-314 - WORKSHEET - Criteria for Approval |
| HRP-040 - SOP - IRB Meeting Preparation | HRP-315 - WORKSHEET - Advertisements |
| HRP-041 - SOP - IRB Meeting Conduct | HRP-316 - WORKSHEET - Payments |
| HRP-042 - SOP - IRB Meeting Attendance Monitoring | HRP-317 - WORKSHEET - Short Form of Consent Documentation |
| HRP-043 - SOP - IRB Meeting Minutes | HRP-318 - WORKSHEET - Additional Federal Agency Criteria |
| HRP-044 - SOP - Not Otherwise Approvable Research | HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent |
| HRP-050 - SOP - Conflicting Interests of IRB Members | HRP-320 - WORKSHEET - Scientific or Scholarly Review |
| HRP-051 - SOP - Consultation | HRP-321 - WORKSHEET - Review of Information Items |
| HRP-052 - SOP - Post-Review | HRP-322 - WORKSHEET - Emergency Use |
| HRP-054 - SOP - Institutional Conflicts of Interests | HRP-323 - WORKSHEET - Criteria for Approval HUD |
| HRP-055 - SOP - Financial Conflicts of Interests | HRP-324 - WORKSHEET - Contracts |
| HRP-060 - SOP - Annual Evaluations of the HRPP | HRP-325 - WORKSHEET - Device Compassionate Use |
| HRP-061 - SOP - Monthly Evaluations of the HRPP | HRP-330 - WORKSHEET - HIPAA Authorization |
| HRP-062 - SOP - Daily Tasks | HRP-331 - WORKSHEET - FERPA Compliance |
| HRP-063 - SOP - Expiration of IRB Approval | HRP-332 - WORKSHEET - NIH GDS Institutional Certification |
| HRP-064 – SOP - NIH GDS Institutional Certification | HRP-333 - WORKSHEET - Certificate of Confidentiality |
| HRP-070 - SOP - IRB Records | ***Checklists*** |
| HRP-071 - SOP - Standard Operating Procedures | HRP-401 - CHECKLIST - Pre-Review |
| HRP-072 - SOP - IRB Records Retention | HRP-402 - CHECKLIST - Non-Committee Review |
| HRP-080 - SOP - IRB Formation and Registration | HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process |
| HRP-081 - SOP - IRB Removal | HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent |
| HRP-082 - SOP - IRB Membership Addition | HRP-412 - CHECKLIST - Pregnant Women |
| HRP-083 - SOP - IRB Membership Removal | HRP-413 - CHECKLIST - Non-Viable Neonates |
| HRP-084 - SOP - IRB Meeting Scheduling and Notification | HRP-414 - CHECKLIST - Neonates of Uncertain Viability |
| HRP-090 - SOP - Informed Consent Process for Research | HRP-415 - CHECKLIST - Prisoners |
| HRP-091 - SOP - Written Documentation of Consent | HRP-416 - CHECKLIST - Children |
| ***General Documents*** | HRP-417 - CHECKLIST - Cognitively Impaired Adults |
| HRP-100 - Huron HRPP Toolkit Table of Contents | HRP-418 - CHECKLIST - Non-Significant Risk Device |
| HRP-101 - Human Research Protection Program Plan | HRP-430 - CHECKLIST - Investigator Quality Improvement  |
| HRP-102 - Flowcharts | HRP-431 - CHECKLIST - Minutes Quality Improvement  |
| HRP-103 - Investigator Manual | HRP-441 - CHECKLIST - HIPAA Waiver of Authorization |
| HRP-103p - Investigator Manual |  |
| HRP-104 - Brochure - Should I Take Part in Research? | ***Databases*** |
| ***Forms*** | HRP-601 - DATABASE - IRB Roster |
| HRP-202 - FORM - IRB Member Information |  |
| HRP-211 - FORM – Basic Study Information |  |
| HRP-212 - FORM - Continuing Review |  |
| HRP-213 - FORM - Modification |  |
| HRP-214 - FORM - Reportable New Information |  |
| ***General Templates*** |
| HRP-500 - TEMPLATE BROAD CONSENT DOCUMENT  |
| HRP-501 - TEMPLATE MINUTES |
| HRP-502 - TEMPLATE CONSENT DOCUMENT |
| HRP-503 - TEMPLATE PROTOCOL |
| HRP-503a - TEMPLATE SBS PROTOCOL |
| HRP-504 - TEMPLATE LETTER - School Permission to Conduct Research |
| HRP-505 - TEMPLATE SOP |
| HRP-506 - TEMPLATE CONSENT DOCUMENT - Emergency Use |
| HRP-507 - TEMPLATE CONSENT DOCUMENT - Short Form |
| HRP-508 - TEMPLATE Site Supplement to Sponsor Protocol |
| ***Template Letters – Post-Review*** |
| HRP-510 - TEMPLATE LETTER - Approval |
| HRP-511 - TEMPLATE LETTER - Closure |
| HRP-512 - TEMPLATE LETTER - Modifications Required to Secure Approval |
| HRP-513 - TEMPLATE LETTER - Not Human Research Determination |
| HRP-514 - TEMPLATE LETTER - Exemption |
| HRP-515 - TEMPLATE LETTER - Suspension or Termination |
| HRP-516 - TEMPLATE LETTER - Deferral |
| HRP-517 - TEMPLATE LETTER - Disapproval |
| HRP-518 - TEMPLATE LETTER - Tabled |
| HRP-519 - TEMPLATE LETTER - Information Item |
| HRP-520 - TEMPLATE LETTER - External Report |
| HRP-521 - TEMPLATE LETTER - Significant Risk Device |
| HRP-522 - TEMPLATE LETTER - Certification of Prisoner Research |
| HRP-523 - TEMPLATE LETTER - Not Otherwise Approvable Research |
| HRP-524 - TEMPLATE LETTER - Acknowledgement of Personnel Update |
| HRP-526 - TEMPLATE LETTER - External Report to DoD |
| HRP-528 - TEMPLATE LETTER - NIH GDS Institutional Certification |
| HRP-529 - LETTER - AAHRPP Notice of Information Item |
| ***Template Letters – Reminders*** |
| HRP-530 - TEMPLATE LETTER - Continuing Review Reminder |
| HRP-531 - TEMPLATE LETTER - Training Reminder |
| HRP-532 - TEMPLATE LETTER - Continuation of Subjects in Expired Research |
| HRP-533 - TEMPLATE LETTER - Expiration of IRB Approval |
| HRP-534 - TEMPLATE LETTER - Investigator Quality Improvement Assessment |
| HRP-535 - LETTER - Annual Reminder |
| ***Template Letters – IRB Review*** |
| HRP-540- TEMPLATE LETTER - Designated Reviewer Materials |
| HRP-541 - TEMPLATE LETTER - IRB Member Review Materials |
| ***Template Letters – Failure Notifications*** |
| HRP-550 - TEMPLATE LETTER - Failure to Submit Continuing Review |
| HRP-551 - TEMPLATE LETTER - Failure to Submit Emergency Use Report |
| HRP-553 - TEMPLATE LETTER - Failure to Submit Emergency Use Protocol |
| HRP-554 - TEMPLATE LETTER - Failure to Undergo Training |
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| ***Template Letters – Committee Management*** |
| HRP-560 - TEMPLATE LETTER - IRB Member Appointment |
| HRP-561 - TEMPLATE LETTER - IRB Member Thank You |
| HRP-562 - TEMPLATE LETTER - IRB Member Appreciation |
| ***Template Letters – Emergency Use*** |
| HRP-570 - TEMPLATE LETTER - Pre-Review of Emergency Use - Criteria Met |
| HRP-571 - TEMPLATE LETTER - Pre-Review of Emergency Use - Criteria Not Met |
| HRP-572 - TEMPLATE LETTER - Review of Emergency Use - Criteria Met |
| HRP-573 - TEMPLATE LETTER - Review of Emergency Use - Criteria Not Met |
| ***Single IRB (sIRB) Documents*** |
| HRP-801 - SOP - Establishing Authorization Agreements |
| HRP-802 - SOP - Institutional Profile Management |
| HRP-803 - SOP - Site Validation |
| HRP-804 - SOP -Site Pre-Review |
| HRP-805 - SOP - Site Updates |
| HRP-811 - FORM - Basic Site Information |
| HRP-812 - FORM - Site Continuing Review |
| HRP-813 - FORM - Site Modification |
| HRP-814 - FORM - Site Reportable New Information |
| HRP-815 - FORM - Institutional Profile |
| HRP-830 - WORKSHEET - Communication and Responsibilities |
| HRP-851 - LETTER - Invitation Decision |
| HRP-857 - LETTER - Acknowledge External IRB |
| HRP-859 - LETTER - Acknowledge External IRB Update |
| HRP-861 - WORKBOOK - Institutional Profiles |
| HRP-870 - LETTER - Site Approval |
| HRP-872 - LETTER - Site Modifications to Secure Approval |
| HRP-876 - LETTER - Site Deferral  |
| HRP-877 - LETTER - Site Disapproval |
| HRP-879 - LETTER - Review of Site Information Item |