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1	**Document**	**Summary of Changes**
2	HRP-001 - SOP - Definitions	1) Added the definition of Artificial Intelligence, including a corresponding endnote referencing 15 USC 9401(3). 2) Expanded the definition of Non-Committee Review to include detemination re: engagement. 3) Added the definition of Staff Reviewer (to differentiate Staff Reviewers from Designated Reviewers), including the types of determinations that Staff Reviewers are permitted to make.
3	HRP-012 - SOP - Observation of Consent Process	Updated SOP to add additional details regarding the observation process and ensure observation findings are reported back to the IRB.
4	HRP-020 - SOP - Incoming Items	1) Added missing system text in the Procedures section to assign the submissions to IRB staff prior to the Designated Review for submissions involving emergency use of a test article and requests to continue subjects in expired research, consistent with ZOT IRB 2) Added HRP-024 - SOP - New Information in Materials section, consistent with the content in the Procedure section.
5	HRP-021 - SOP - Pre-Review	1) Modified the Procedures under 5.1 regarding the review of modifications to secure approval to be consistent with the ZOT IRB "Review Required Modifications" action/activity. 2) Revised the Procedures section, under 5.1, to clarify that submissions should be sent for convened board review, when the investigator refuses to make the modifications required to secure approval. 3) Updated the name of HRP-801 - SOP - Establishing Reliance Agreements in the Procedures section, consistent with revisions to HRP-801. Added HRP-801 to the Materials section. 4) Added steps to the Procedure section at 5.4 re: the review of submissions involving a Collaborating Independent Investigator or Collaborating Institutional Investigator, with instructions to follow HRP-311 and HRP-801 to determine engagement and, if engaged, to determine whether to establish an Individual Investigator Agreement.

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6	HRP-023 - SOP - Emerg and Device Comp Use Review	1) Revised "IRB" to "Designated Reviewer" in 1.2 to clarify when the process starts (consistent with the content of HRP-020 - SOP - Incoming Items). 2) Updated 5.1.1.1 to clarify that 5d reporting is not required when sufficient information is provided in advance to the IRB, consistent with FDA correspondence, and added an endnote to reference the correspondence. 3) Updated the ZOT IRB language to select IRB Chair concurrence for compassionate use of devices and non-emergency individual patient expanded access, consistent with ZOT IRB updates (v10.5.8). 4) Removed duplicative system step of documenting chair concurrence in the "Notes" section for determinations related to compassionate use of devices in 5.1.2.2. 5) Added 21 CFR §312.305 to Reference section (consistent with activities identified in Items 14 & 15 in HRP-105 - OHRP FDA Written Procedure Crosswalk). 6) Updated the link to FDA guidance on Form FDA 3926.
7	HRP-024 - SOP - New Information	1) Revised 5.1 to include system steps for executing "Request Pre-Review Clarifications" or complete the "Submit RNI Pre-Review" and added references to HRP-031 - SOP - Non-Committee Review Preparation & HRP-040 - SOP - IRB Meeting Preparation. Added HRP-031 & HRP-040 to Materials section. 2) Simplified "IRB chair or IRB manager" to "IRB" in 5.3 re: referencing HRP-025 - SOP - Investigations and added "if needed" to the statement in 5.4.4.2 re: confirming with the IRB chair or IRB manager. 3) Revised the Procedure section at 5.9 re: information that does not involve serious non-compliance, etc. to clarify ZOT IRB steps and remove reference to HRP-052. Removed reference to HRP-052 in the Materials section.
8	HRP-026 - SOP- Susp or Term Issued Outside of Conv IRB	1) Added ZOT IRB steps for suspension and termination. 2) Added 'and relevant agencies' to 5.4.5 re: reporting adverse events/outcomes. 3) Updated 5.7 re: sending HRP-515 - LETTER - Suspension to include reference HRP-515b - LETTER - Termination. Updated the Materials section to include HRP-515b. 4) Added 5.8 re: Sponsor-initiated suspension
9	HRP-027 - SOP - Emerg Use Comp Use Indiv Pt Access Post Rev	1) Updated 5.1.1.2 consistent with revisions to HRP-023 - SOP - Emerg and Device Comp Use Review re: 5d reporting requirements, revising to state "If a 5-day report is required…". 2) Added 21 CFR §312.305 to Reference section (consistent with activities identified in Items 14 & 15 in HRP-105 - OHRP FDA Written Procedure Crosswalk).

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10	HRP-030 - SOP - Designated & Staff Reviewers	1) Modified the SOP to define the process for identifying and documenting Staff Reviewers; including: a) Updating the SOP title; b) Modifying the Purpose statements to be inclusive of Staff Reviewers; c) Identifying the use of HRP-602 - DATABASE - Staff Reviewer Roster in the Policy section; d) Adding instruction in the Procedure section to add Staff Reviewers to the corresponding roster, as identified by the IRB manager; and e) Adding HRP-602 to the Materials section. 2) Modified the Procedure section to clarify how Designated Reviewers are identified in the ZOT IRB.
11	HRP-031 - SOP - Non-Committee Review Preparation	1) Modified the SOP to accommodate revisions related to the role of Staff Reviewers, including: a) Modifying Section 1.3 to include Staff Reviewers; b) Adding a Policy statement to indicate that Staff Reviewers are maintained via HRP-602 - DATABASE - Staff Reviewer Roster (consistent with revisions to HRP-030 - SOP); c) Adding reference to HRP-601 (for ZOT IRB only) and HRP-602 in the Procedure section and clarified the types of Non-Committee reviews that can be conducted by reviewer role (Designated vs. Staff Reviewer); d) Adding reference to HRP-001 and HRP-602 in the Materials section; and e) Adding 45 CFR 46.164.512(i) to the References section. 2) Added a statement in the Policy section to specify that only Designated Reviewers and Privacy Board designees can issue waivers/alterations of HIPAA authorization reviewed via Non-Committee Review (for ZOT IRB v12, the existing statement was modified to include reference to Privacy Board designees).
12	HRP-032 - SOP - Non-Committee Review Conduct	1) Modified the SOP to accommodate revisions related to the role of Staff Reviewers, including: a) Revising purpose statement at 1.1 to generically refer to Non-Committee reviews (removing "Designated Reviewers"); b) Revising "Designated Reviewer" to "Designated Reviewer or Staff Reviewer" throughout the document; and c) Adding new content in the Procedure section to clarify when re-assignment, based on role, may be necessary. 2) Added statement in the Policy section to reference HRP-301 - WORKSHEET - Review Materials to clarify what documents are used to conduct the review (consistent with activities identified in Items 2 & 20 in HRP-105). Added "Modifications required to secure approval..." as potential determination in the Procedures section, consistent with federal regulations (and activities identified in Item 2 of HRP-105). Added HRP-301 to the Materials section. Added HHS & FDA criteria for approval citations in the References section (consistent with Item 3 of HRP-105). 3) Removed "for approval" from Section 3.5 regarding exemption determinations. 4) Added language to the Procedure section to clarify appropriate selection of review categories for follow-on submissions

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13	HRP-040 - SOP - IRB Meeting Preparation	1) Added a statement in the Policy section re: HRP-301 - WORKSHEET - Review Materials consistent with HRP-031 - SOP - Non-Committee Review Preparation (also consistent with activities identified in Item 1 in HRP-105). 2) Added a statement in the Procedures section re: preparing the expedited report (consistent with activities identified Item 2 in HRP-105). 3) Corrected FDA citation in references from 21 CFR §56.108(b) to 21 CFR §56.108(c) (consistent with activities identified in Item 1 in HRP-105).
14	HRP-041 - SOP - IRB Meeting Conduct	1) Modified the statement in the Policy section re: HRP-301 - WORKSHEET - Review Materials to add the word 'documents' and remove 'and listed below in Section 6: Materials' to make HRP-301 the single source for identifying the documents, worksheets, and worksheets provided to IRB members for the purpose of conducting the review (consistent with revisions to HRP-032 - SOP - Non-Committee Review Conduct). 2) Similarly, removed all worksheets and worksheets in the Materials sections that are not directly referenced in this SOP (but instead, are listed in HRP-301). 3) Moved the statement in the Procedures section at 5.5.6.1 re: the approval period and level of risk to a separate bullet (5.5.7). The statement was further revised to clarify that the approval period and risk should also be made with motions of "Modification Required to Secure Approval" (in addition to approval) and to address considerations to take into account re: the approval interval (consistent with activities identified in Items 12 & 17 in HRP-105). 4) Added HHS criteria for approval citation in References section (consistent with Item 3 in HRP-105). 5) Add that Director or Designee will be responsible for onboaring an external consultant.*
15	HRP-043 - SOP - IRB Meeting Minutes	Modified section 3.3 to include turnaround times and removed turnaround times defined in the Procedure section.
16	HRP-051 - SOP - Consultation	Added reference to Staff Reviewer in 4.2.
17	HRP-052 - SOP - Post-Review	1) Added steps in the Procedures section to execute the NIJ Privacy Certificate. 2) Added 45 CFR §46.109(d) and 21 CFR §56.109(e) re: notifications to the References section (consistent with activities identified in Item 13 in HRP-105). 3) Updated OHRP incident reporting form link in endnotes.

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18	HRP-060 - SOP - Annual Evaluations of the HRPP	1) Updated Section 5.2 to directly reference HRP-065 - SOP - Continuity Planning for HRPP Disruptions. 2) Added HRP-065 to the Materials section. 3) Revised 'IRB staff' to 'IRB Manager or designee' in the Responsibilities section. 4) Modified statements re: IRB registration and FWA status to reference HRP-080 - SOP - IRB Formation and Registration. 5) Added statements to verify the IRB roster is up-to-date and assess outstanding toolkit updates. 6) Added HRP-071 and HRP-601 to the Materials section.
19	HRP-061 - SOP - Quarterly Evaluations of the HRPP	Revised 'IRB staff' to 'IRB Manager or designee' in the Responsibilities section. Modified the Procedures section to combine statements at re: reviewing results/examining for trends identified via HRP-430 - worksheet - Investigator Quality Improvement and HRP-431 - worksheet - Minutes Quality Improvement into one statement, thereby removing duplicative content. Additional editorial corrections.
20	HRP-064 - SOP - NIH GDS Institutional Certification	Updated NIH hyperlinks in References re: Institutional Certification.
21	HRP-065 - SOP - Continuity Planning for HRPP Disruptions	Revised SOP to more broadly address business continuity (i.e., include scenarios such as mass funding cuts and/or loss of facilities). Specific updates include: 1) Updated SOP title; 2) Expanded list of disruptive event examples in 1.1; 3) Additional content in 5.1.2 re: circumstances that may warrant postponing study activities by the IO/OO; 4) Clarification in 5.2.2.1 re: prioritization of IRB reviews; 5) Clarifications and editorial revisions throughout to accommodate the broadened scope; and 6) Updates to the Materials section consistent with remainder of the document, as well as updates to other related Toolkit documents.
22	**HRP-066 - SOP - Institutional Review Board Federal Inspections**	**New SOP to support IRB inspections conducted by a federal agency.**
23	HRP-071 - SOP - Toolkit Management	1) Added instructions to update HRP-100 - Huron HRPP Toolkit Table of Contents, HRP-105 - OHRP FDA Written Procedure Crosswalk and all other applicable documents at 5.3.3, when necessary (consistent with Item 26 in HRP-105). 2) Added HRP-100 and HRP-105 to Materials section.

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24	HRP-080 - SOP - IRB Formation	Revise responsibility to reflect IRB Director or designee.*
25	HRP-081 - SOP - IRB Removal	1) Clarified system steps for removing a Committee in the system. 2) Revise responsibility to reflect IRB Director or designee.*
26	HRP-082 - SOP - IRB Membership Addition	1) Added endnote at 5.4 to reference OHRP and FDA guidance re: scientific vs. non-scientific reviewers (consistent with activities identified in Items 34 & 35 in HRP-105). 2) Replaced IRB staff with IRB Director or designee in 4.1.* 3) Specified IRB staff is responsible for new member training in 5.12.2.*
27	HRP-083 - SOP - IRB Membership Removal	1) Clarified system steps for removing Committee Members in the system. 2) Replaced IRB staff with IRB Director or designee in 4.1.*
28	HRP-100 - Huron HRPP Toolkit Table of Contents	1) Updated the names of HRP-030, HRP-065, HRP-108, HRP-351, HRP-352, HRP-515, HRP-540, HRP-542, HRP-801, HRP-806. Added HRP-066, HRP-329, HRP-334, HRP-515b, HRP-602, HRP-603 and HRP-870a. 2) Added HRP-852. 3) Added UCI specific documents that have been incorprated into toolkit.*
29	HRP-101 - Human Research Protection Program Plan	Updated heading and content re: Emergency Preparedness to be consistent with updates made to HRP-065 - SOP - Continuity Planning for HRPP Disruptions. Simplified and removed duplicative content re: records and electronic systems management.
30	HRP-103 - Investigator Manual	1) Revised "How do I submit... to the IRB?" to provide general details on the contents of an IRB submission, consistent with updates made to HRP-105 (consistent with activities identified in Items 1 & 2 in HRP-105). Additional editorial revision to non-ZOT IRB (paper) and ZOT IRB text to accommodate additional content. 2) Revised "How do I write an Investigator Protocol?" section to clarify intent behind each protocol template and provide additional guidance on when to use each template. 3) Added instruction under "What are my obligations when relying on an external IRB?" re: submitting study updates and site modifications. 4) Updated Appendix A-12 consistent with revisions to HRP-065 - SOP - Continuity Planning for HRPP Disruptions. Revisions includes updated references to HRP-108 and HRP-351 and editorial revisions consistent with the broadened scope of HRP-065. 5) Included OHRP training for those researchers who do not have access to the internet.* 6) Added timelines for non-response and administrative closure.*

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31	HRP-105 - OHRP FDA Written Procedure Crosswalk	Revised introduction to directly reference OHRP/FDA guidance on IRB written procedure formatting and flexibility and added a description of Toolkit components.
32	HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning	Revised consistent with HRP-065 - SOP - Continuity Planning for HRPP Disruptions revisions. Specific revisions include an updated title, updated references to HRP-351, and updated structure to accomodate the broadened scope of HRP-065, as well as provide clarification on when detailed, study-specific risk mitigation plans are required.
33	HRP-109 - IRB Member Manual	1) Corrected the reference to HRP-032 - SOP - Non-Committee Review Conduct (from HRP-302) in Q4. 2) Added content to 'How do I conduct Committee Review as a Primary Reviewer?' (Q9) re: including the approval period and risk level in th emotion (consistent with activities identified in Item 17 in HRP-105). 3) Modified the statement re: loss of quorum to state "if quorum is lost and a submission cannot be voted on…" (removing reference to recusal and abstention) Q11. 4) Modified Q14 to clarify section content is limited to modifications and continuing reviews (instead of referencing follow on submissions, generally). 5) Added a new at Q15 on the review of reports of new information. 6) Updated the Table of Contents to include the new section on RNIs.
34	HRP-301 - WORKSHEET - Review Materials	1) Modified the purpose statement to clarify the purpose of the document (consistent with updates to HRP-032 - SOP - Non-Committee Review Conduct, HRP-040 - SOP - IRB Meeting Preparation, and HRP-041 - SOP - IRB Meeting Conduct). 2) Added reference to Staff Reviewer, where appropriate, throughout the document. Added reference to HRP-310, HRP-311, HRP-312, HRP-314a, and HRP-319 where appropriate, to accomodate all types of non-committee reviews. Additional editorial edits to group all worksheets accordingly and improve consistency throughout the document. 3) Added reference to HRP-334 - WORKSHEET - AI to sections on initial review, continuing review and modifications. 4) Revised all sections to include references to applicable SmartForms and corresponding documents included (attached) within a SmartForm to clarify materials provided to reviewers. Additional editorial edits to simplify/re-group content and improve consistency throughout the document. 5) In the RNI section, removed 'Add when the problem involves…' and all corresponding worksheets from this grouping as changes in determinations, resulting from the RNI, would be made via a modification.

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35	HRP-303 - WORKSHEET - Communication of Review Results	1) Added missing references to HRP-514 - LETTER - Exemption , HRP-574 - LETTER - Device Compassionate Use & HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access (consistent with activities identified in Item 13 in HRP-105). 2) Added new template letters HRP-515b - LETTER - Termination and - LETTER - Site Approval - CR NOT Req. Updated reference to HRP-515 - LETTER - Suspension to remove termination language. 3) Updated OHRP incident reporting form link provided in the endnote to HRP-520a and hyperlink to prisoner certification form linked with HRP-522. 4) Combined HHS and DoD notifications re: prisoner certifications (HRP-522) into one line. Removed duplicate listings of HRP-523. 5) Added HRP-852 as a notification sent at the IRB's discretion.
36	HRP-305 - WORKSHEET - Quorum and Expertise	(For VA only) Revised text and added endnote re: VA representation in Section 2 to clarify that representation should be considered but is not required to meet quorum.
37	HRP-306 - WORKSHEET - Drugs and Biologics	Added endnote to IND Exemption Category 1 to reference FDA guidance on IND exemptions for cancer trials.
38	HRP-307 - WORKSHEET - Devices	1) Updated Category 1 in Section 7 to include Class I in 'The device is FDA-approved/cleared or is a Class I or Class II 510(k) exempt device'. 2) Add determination flowcharts.*
39	HRP-308 - WORKSHEET - Pre-Review	Added a checkbox and corresponding endnote in the Initial Review and Modification section to confirm the protocol includes information re: the inclusion of women and minorities consistent with NIH policy (NOT-OD-25-131).
40	HRP-311 - WORKSHEET - Engagement Determination	Revised "Designated Reviewer" to "Designated/Staff Reviewer" in the purpose statement to accomodate the Staff Reviewer role.
41	HRP-312 - WORKSHEET - Exemption Determination	1) Revised "Designated Reviewer" to "Designated/Staff Reviewer" in the purpose statement to accomodate the Staff Reviewer role. 2) Under Section 3, added endnote VII to 3(i)(C)(ii) noting that, per OHRP correspondence, eye-tracking can be considered for data collection under this exemption. 3) Revised to reflect that only Category 4i is eligible for self-determination. 4) Revise Category 3 eligibility for self-determination for accuracy.

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42	HRP-314a - WORKSHEET - Criteria for Consent	1) In the ICH GCP section: a) Removed 'approval of the IRB'; b) Combined statements re: reasonably foreseeable risks and benefits to partner, etc. into 1 sentence; and c) Added statement re: benefits/risks of alternative procedures back into ICH-GCP section, which was removed in error in 5.3. 2) Re-organized elements, fixed broken links, and added more endnotes.*
43	HRP-315 - WORKSHEET - Advertisements	Revised "Designated Reviewer" to "Designated/Staff Reviewer" in the purpose statement to accomodate the Staff Reviewer role.
44	HRP-316 - WORKSHEET - Payments	1) Revised "Designated Reviewer" to "Designated/Staff Reviewer" in the purpose statement to accomodate the Staff Reviewer role. 2) Updated IRB threshol dto $2k.
45	HRP-318 - WORKSHEET - Additional Federal Agency Criteria	Clarified NIJ Privacy Certificate criterion to state the IRB Chair or representative should sign as the authorized institutional representative consistent with NIJ FAQs and Privacy Certificate template. Added an endnote linking to the Privacy Certificate (see endnote 1 within the Privacy Certificate re: chair signature).
46	HRP-321 - WORKSHEET - Review of Information Items	Added additional consideration re: no further action, when CAPA is adequate.
47	HRP-322 - WORKSHEET - Emergency Use	Added 'when necessary' to references to 5d reporting requirements, consistent with updates to HRP-023 - SOP - Emerg and Device Comp Use Review, in Sections 1, 3 and 4.
48	HRP-325 - PI WORKSHEET - Expanded Access	Added section to identify type of subjects.
49	**HRP-329 - WORKSHEET - HIPAA Applicability**	**New worksheet to support determinations regarding HIPAA applicability.**

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50	HRP-333 - WORKSHEET - Certificate of Confidentiality	Revised "Designated Reviewer" to "Designated/Staff Reviewer" in the purpose statement to accomodate the Staff Reviewer role.
51	HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disruption Risk Mitigation Planning	Revised consistent with HRP-065 - SOP - Continuity Planning for HRPP Disruptions revisions. Specific updates include: 1) Revised introduction to refer to HRP-108 to determine whether a risk mitigation plan is needed, note that the the list of considerations provided is intended to serve as a starting point, and that all actions taken must comply with broader institutional/HRPP requirements pertaining to the emergency; 2) Eliminated Section 1 to avoid duplication with HRP-108; 3) Added content related to modifying the DSMP & DMP, documenting impact on research records, and notification to subjects in the "General Considerations..." section; 4) Added a section on additional notification considerations; and 5) Additional editorial revisions to provide clarification, minimize duplication and improve consistency.
52	HRP-352 - WORKSHEET - Additional Emergency-Disruption Review Considerations	Revised consistent with HRP-065 - SOP - Continuity Planning for HRPP Disruptions revisions. Specific updates include: 1) Removed content duplicative with HRP-411 in Section 1; 2) Added reference to Pre-Review determination in Section 3, when considering whether or not the research is covered by federal regulations; and 3) Additional editorial revisions to provide clarification.
53	HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent*	1) Added NA option for retrospective research. 2) Added endnote to SACHRP guidance for retrospective research.
54	HRP-416 - PI WORKSHEET - Children*	1) Reworked Section 2 California considerations for clarity. 2) Added NA option for retrospective research.
55	HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization	1) Revised the purpose statement to accomodate review by either IRB or privacy board and clarify review pathways. 2) Added endnote to reference 45 CFR 164 to sentence 2 re: waivers/alterations.

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56	HRP-502 - CONSENT TEMPLATES	1) Under "What happens to the information collected for the research?", added disclosure statement for NIJ-funded studies involving a Privacy Certificate covered by DOJ statute (34 USC 10231(a)). 2) Added statement regarding return of device to study team.* 3) Study Info Sheets assigned HRP-502f & HRP-502g.* 4) HRP-502F Study Info Sheet updated to reflect $2k IRS threshold.* 5) Assent forms assigned HRP-502h & HRP-502i.* 6) HRP-502h Assent updated witness box.*
57	HRP-503 - PROTOCOL NARRATIVES*	1) Revised NA statement for pre-screening for clarity. 2) Added NA option for section re: Secondary Data Analysis
58	HRP-506 - CONSENT - Expanded Access	Add witness box to account for short form process.*
59	**HRP-507 - CONSENT - Short Form Expanded Access***	**New Short Form for Expanded Access.**
60	HRP-801 - SOP - Establishing Reliance Agreements	1) Revised title to 'Establishing Reliance Agreements'. Under 5.1.2.4, removed instruction to file HRP-815 - FORM - Institutional Profile, as is duplicative with instructions in HRP-802 - SOP - Institutional Profile Management. 2) In 5.2, revised "unaffiliated individual or individual affiliated with an organization that does not have an FWA" to "Collaborating Individual Investigator or Collaborating Institutional Investigator', consistent with OHRP guidance and the terms defined in HRP-001. 3) Removed HRP-815 from the References section.
61	HRP-805 - SOP - External IRB Updates	Revised Policy statements to direct the submission of reportable events as RNI (instead of via Update Study Details), with corresponding removal of section 5.2.5-5.2.8.
62	HRP-806 - SOP - Review Request to Rely on External IRB	1) Clarified steps for confirming reliance, including adding reference to the use of - LETTER - Permission to Rely on an External IRB when documentation needs to be submitted to the external IRB confirming permission to rely. 2) Added HRP-852 to Materials section.

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63	HRP-832 - PI WORKSHEET - Considerations for Relying on an External IRB*	Revised 2.1 to calrify eligibility criteria.
64	HRP-833 - PI WORKSHEET - Considerations for Serving as the Reviewing IRB*	Added option for pSite to serve as their own privacy board.
65	Recruitment Material Master Template*	1) Updated format to be consistent with Toolkit 2) Updated links