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**Program for the Protection
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Institutional Review Boards

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PPHS Toolkit Updates

Document	Date	Change
HRP-388	08.01.2023	• Added language for PI change for IDS and RSC • Added language that added personnel must complete TE before COI can begin their review
HRP-452	08.01.2023	• Added language that added personnel must complete TE before COI can begin their review; submit once TE is completed by all parties; add TE# to mod summary
HRP-502p	07.31.2023	• Added "Authority of Authorized Representative" to signature block
HRP-502 (11.11.2022) (all Spanish versions)	08.15.2023	• Translated the footer
HRP-324	08.15.2023	• Added section for sponsor contact
HRP-061	08.15.2023	• Added sections 5.5-5.6 per AAHRPP review
HRP-511	08.17.2023	• Removed VA references per AAHRPP review
HRP-512B	08.17.2023	• Removed VA references per AAHRPP review
HRP-512C	08.17.2023	• Removed VA references per AAHRPP review
HRP-513	08.17.2023	• Removed VA references per AAHRPP review
HRP-515A	08.17.2023	• Removed VA references per AAHRPP review
HRP-515B	08.17.2023	• Removed VA references per AAHRPP review
HRP-517	08.17.2023	• Removed VA references per AAHRPP review
HRP-519	08.17.2023	• Removed VA references per AAHRPP review
HRP-527	08.17.2023	• Removed VA references per AAHRPP review
HRP-876	08.17.2023	• Removed VA references per AAHRPP review
HRP-877	08.17.2023	• Removed VA references per AAHRPP review
HRP-879	08.17.2023	• Removed VA references per AAHRPP review
HRP-232R	11.02.2023	• Added schedule 1 drug studies to the list of studies not eligible to use an external IRB • Other minor administrative changes
HRP-230	11.03.2023	• Expanded questions for sites to be more specific
HRP-098	04.01.2024	• Created document
HRP-822	05.30.2024	• Updated footer with J Kucera's title; • Updated Reviewing IRB #1, related to SmartIRB Section 3.4
HRP-524	06.04.2024	• Fixed Huron bug issue in merge fields
HRP-212b	07.03.2024	• Added all questions in the table format • Added a section specifically for questions relating to individuals that have turned 18 and/or regained capacity since their data/ specimens were collected and stored for future use.
HRP-503R	07.11.2024	• Changed format of instructional text to pink text.

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		- Added instruction to delete pink text in final document. - Removed mention of Sinai Central and IF# from header. - Clarified that the HRP-503R is not for record/ specimen review that require consenting. - Clarified location of checklists in the RUTH library - Added instructions for excluding special status patients in non-consented research. - Added Setting of Human Research, and Resources Available to Conduct research sections - Added instructions for excluding special status patients in non-consented research. - Changed Specimens to Samples. - Removed prospective data collection option - Removed option to provide information about consenting - Clarified CoC eligibility criteria - Combined Data Security with Data Storage
HRP-503E	07.11.2024	- Changed format of instructional text to pink text. - Added instruction to delete pink text in final document. - Removed mention of Sinai Central and IF# from header. - Changed the Introduction section to a Study Overview section. - Added a Study Procedures section. - Added instructions for excluding special status patients in non-consented research. - Changed Specimens to Samples.
HRP-503 Full	07.11.2024	- Changed format of instructional text to pink text. - Added instruction to delete pink text in final document. - Removed mention of Sinai Central and IF# from header. - Hyperlinked PPHS policies and checklists. - Added instructions for excluding special status patients in non-consented research. - Elaborated on the Specimen Banking session. - Clarified CoC eligibility criteria - Provided examples for who a prisoner is. - Added instructions for when an enrolled participant becomes vulnerable.
HRP-930	07.15.2024	Created Guidance for R2S Initial Study submission and Mount Sinai site activation
HRP-450	07.25.2024	- Added a link to eDMS website. - Added the need for only one appropriate role for all study team personnel listed on the study.

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		• Added information about the Admin non-FCOI role. • Added GCO information about industry funded studies with FACTS – managed contracts submitted after January 1 2024. • Updated PI proxy information. • Added information about the primary contact role.
HRP-451	07.25.2024	• Added a link to eDMS website. • Updated PI proxy information.
HRP-452	07.25.2024	• Added a link to eDMS website. • Added the need for only one appropriate role for all study team personnel listed on the study. • Added information about the Admin non-FCOI role. • Updated PI proxy information. • Added information about the primary contact role.
HRP-928	08.05.2024	• Removed the need for consent or a waiver of consent in certain screening procedures. • Removed mention of how to count enrolled participants at the time of continuing review. • Removed mention of how to report screen failures at the time of continuing review.
HRP-917	09.09.2024	• Added types of submissions that use the "site modification" submission type. • Added clarification on the type of submissions using the "update study details" submission type.
HRP-212b	10.02.2024	• Changed title from "Progress Report for Continuing Review Specimen or Data Banking" to "Annual Activity Report for Continuing Review Specimen or Data Banking". • Updated header with revised title. • Added clarification on when Question #2 is applicable.
HRP-503R	10.14.2024	• Added clarification to the Instruction section on when this template can be used. • Added further instruction regarding the review period in Section 6. • Removed reference to retrospective data and the definition of retrospective data in Section 6. • Added instruction for when data is obtained from Mount Sinai in Section 9. • Removed the case-series box from page 5. • Added new instructions for requesting Waiver of Alterations in Section 12.
HRP-935	10.22.2024	• Created guidance to provide instructions for the continuing review progress report

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Document	Date	Changes
HRP-451	10.22.2024	• Added reference to the HRP-935 guidance document
HRP-904	12.09.2024	• Added clarification that consent form does not need updating when the study is closed to enrollment and to use good judgment for which documents need updating. • Removed outdated reference to FCOI Investigator Form.
HRP-451	12.18.2024	• Added reference for R2S forms for continuing review (HRP-820 and HRP-812).
HRP-450	12.18.2024	• Added section for the study team to include the Flesh-Kincaid Grade Level and the Flesch-Kincaid Reading Ease Score for the consent summary section.
HRP-452	12.18.2024	• Added statement that submissions in Clarification Request State for four weeks will be withdrawn by PPHS • Added instructions for using the "compare" tool in RUTH • Added instructions for assigning FCOI Ancillary Review in RUTH
HRP-450	01.15.2025	• Revised to clarify that the grant proposal must be included win the RUTH submission but cannot serve as the standalone protocol • Revised to clarify that either the Flesh-Kincaid Grade Level **or** the Flesch-Kincaid Reading Ease Score will need to be included (both are not required)
HRP-936	01.15.2025	• Created guidance to provide instructions for the use of an honest broker.
HRP-902	01.15.2025	• Added language throughout the document to clarify what constitutes a case report and a case series; and when IRB approval is needed.
HRP-454	02.24.2025	• Created document.
HRP-935	03.10.2025	• Reformatted the document. No new information added.
HRP-451	03.10.2025	• Added language to clarify how to report enrollment numbers. • Added language to clarify when a GCO submission is needed. • Added instructions for selecting FCOI as an ancillary review.
HRP-904	03.10.2025	• Added instructions to also select "Study Team Member Information" as part of the modification scope. • Added instructions to update the Local Study Team Members section of the RUTH SmartForm to reflect changes in the study team.
HRP-925	03.20.2025	• Update the point of contact for obtaining institutional clearance.
HRP-917	04.14.2025	• Updated to include guidance for submitting final reports for R2R submissions • Document name changed from 'HRP-917-Guidance-R2R Continuing Review Submissions in RUTH' to 'HRP-917-Guidance-R2R Continuing Review-Final Report Submissions'

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HRP-451	04.14.2025	• Removed reference to the HRP-919-Guidance – R2R Closeout Submissions document
HRP-502 (all versions)	01.16.2026	• Updated the reporting threshold from $600 to $2,000 under the Costs or Payments section • Updated for payments issued using the Greenphire ClinCard, the funds are available within 1-3 business days
HRP-415	01.28.2026	• Clarified on page 3 the DHHS regulated refers to projects conducted, supported, or funded by a federal agency
HRP-502 (all versions)	02.03.2026	• Greenphire language in Costs or Payments section has been modified to reflect more general language for debit cards.
HRP-450, HRP-452	02.10.2026	• Added language requiring fund numbers be added in study applications.
HRP-916	02.10.2026	• Added language requiring fund numbers be added in study applications. • Added language pertaining to requirements for using the designated single IRB in multi-site research.