Mount Sinai

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Mount Sinai Beth Israel
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The Mount Sinai Hospital
Mount Sinai Queens
New York Eye and Ear Infirmary
of Mount Sinai
Mount Sinai St. Luke's
Mount Sinai West

Program for the Protection of Human Subjects
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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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