



Icahn School of Medicine at Mount Sinai  
 Mount Sinai Beth Israel  
 Mount Sinai Brooklyn  
 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*  
 Mount Sinai Health System  
 One Gustave L. Levy Place, Box 1081  
 New York, NY 10029-6574  
 T 212-824-8200  
 F 212-876-6789  
 irb@mssm.edu  
 icahn.mssm.edu/pphs

## PPHS Toolkit Updates

Document	Date	Change
HRP-388	08.01.2023	<ul style="list-style-type: none"> <li>Added language for PI change for IDS and RSC</li> <li>Added language that added personnel must complete TE before COI can begin their review</li> </ul>
HRP-452	08.01.2023	<ul style="list-style-type: none"> <li>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</li> </ul>
HRP-502p	07.31.2023	<ul style="list-style-type: none"> <li>Added "Authority of Authorized Representative" to signature block</li> </ul>
HRP-502 (11.11.2022) (all Spanish versions)	08.15.2023	<ul style="list-style-type: none"> <li>Translated the footer</li> </ul>
HRP-324	08.15.2023	<ul style="list-style-type: none"> <li>Added section for sponsor contact</li> </ul>
HRP-061	08.15.2023	<ul style="list-style-type: none"> <li>Added sections 5.5-5.6 per AAHRPP review</li> </ul>
HRP-511	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-512B	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-512C	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-513	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-515A	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-515B	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-517	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-519	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-527	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-876	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-877	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-879	08.17.2023	<ul style="list-style-type: none"> <li>Removed VA references per AAHRPP review</li> </ul>
HRP-232R	11.02.2023	<ul style="list-style-type: none"> <li>Added schedule 1 drug studies to the list of studies not eligible to use an external IRB</li> <li>Other minor administrative changes</li> </ul>
HRP-230	11.03.2023	<ul style="list-style-type: none"> <li>Expanded questions for sites to be more specific</li> </ul>
HRP-098	04.01.2024	<ul style="list-style-type: none"> <li>Created document</li> </ul>
HRP-822	05.30.2024	<ul style="list-style-type: none"> <li>Updated footer with J Kucera's title;</li> <li>Updated Reviewing IRB #1, related to SmartIRB Section 3.4</li> </ul>
HRP-524	06.04.2024	<ul style="list-style-type: none"> <li>Fixed Huron bug issue in merge fields</li> </ul>
HRP-212b	07.03.2024	<ul style="list-style-type: none"> <li>Added all questions in the table format</li> <li>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.</li> </ul>
HRP-503R	07.11.2024	<ul style="list-style-type: none"> <li>Changed format of instructional text to pink text.</li> </ul>



Icahn School of Medicine at Mount Sinai  
 Mount Sinai Beth Israel  
 Mount Sinai Brooklyn  
 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*  
 Mount Sinai Health System  
 One Gustave L. Levy Place, Box 1081  
 New York, NY 10029-6574  
 T 212-824-8200  
 F 212-876-6789  
 irb@mssm.edu  
 icahn.mssm.edu/pphs

		<ul style="list-style-type: none"> <li>• Added instruction to delete pink text in final document.</li> <li>• Removed mention of Sinai Central and IF# from header.</li> <li>• Clarified that the HRP-503R is not for record/ specimen review that require consenting.</li> <li>• Clarified location of checklists in the RUTH library</li> <li>• Added instructions for excluding special status patients in non-consented research.</li> <li>• Added Setting of Human Research, and Resources Available to Conduct research sections</li> <li>• Added instructions for excluding special status patients in non-consented research.</li> <li>• Changed Specimens to Samples.</li> <li>• Removed prospective data collection option</li> <li>• Removed option to provide information about consenting</li> <li>• Clarified CoC eligibility criteria</li> <li>• Combined Data Security with Data Storage</li> </ul>
HRP-503E	07.11.2024	<ul style="list-style-type: none"> <li>• Changed format of instructional text to pink text.</li> <li>• Added instruction to delete pink text in final document.</li> <li>• Removed mention of Sinai Central and IF# from header.</li> <li>• Changed the Introduction section to a Study Overview section.</li> <li>• Added a Study Procedures section.</li> <li>• Added instructions for excluding special status patients in non-consented research.</li> <li>• Changed Specimens to Samples.</li> </ul>
HRP-503 Full	07.11.2024	<ul style="list-style-type: none"> <li>• Changed format of instructional text to pink text.</li> <li>• Added instruction to delete pink text in final document.</li> <li>• Removed mention of Sinai Central and IF# from header.</li> <li>• Hyperlinked PPHS policies and checklists.</li> <li>• Added instructions for excluding special status patients in non-consented research.</li> <li>• Elaborated on the Specimen Banking session.</li> <li>• Clarified CoC eligibility criteria</li> <li>• Provided examples for who a prisoner is.</li> <li>• Added instructions for when an enrolled participant becomes vulnerable.</li> </ul>
HRP-930	07.15.2024	<ul style="list-style-type: none"> <li>• Created Guidance for R2S Initial Study submission and Mount Sinai site activation</li> </ul>
HRP-450	07.25.2024	<ul style="list-style-type: none"> <li>• Added a link to eDMS website.</li> <li>• Added the need for only one appropriate role for all study team personnel listed on the study.</li> </ul>



Icahn School of Medicine at Mount Sinai  
 Mount Sinai Beth Israel  
 Mount Sinai Brooklyn  
 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*

Mount Sinai Health System  
 One Gustave L. Levy Place, Box 1081  
 New York, NY 10029-6574  
 T 212-824-8200  
 F 212-876-6789  
 irb@mssm.edu  
 icahn.mssm.edu/pphs

		<ul style="list-style-type: none"> <li>Added information about the Admin non-FCOI role.</li> <li>Added GCO information about industry funded studies with FACTS – managed contracts submitted after January 1 2024.</li> <li>Updated PI proxy information.</li> <li>Added information about the primary contact role.</li> </ul>
HRP-451	07.25.2024	<ul style="list-style-type: none"> <li>Added a link to eDMS website.</li> <li>Updated PI proxy information.</li> </ul>
HRP-452	07.25.2024	<ul style="list-style-type: none"> <li>Added a link to eDMS website.</li> <li>Added the need for only one appropriate role for all study team personnel listed on the study.</li> <li>Added information about the Admin non-FCOI role.</li> <li>Updated PI proxy information.</li> <li>Added information about the primary contact role.</li> </ul>
HRP-928	08.05.2024	<ul style="list-style-type: none"> <li>Removed the need for consent or a waiver of consent in certain screening procedures.</li> <li>Removed mention of how to count enrolled participants at the time of continuing review.</li> <li>Removed mention of how to report screen failures at the time of continuing review.</li> </ul>
HRP-917	09.09.2024	<ul style="list-style-type: none"> <li>Added types of submissions that use the “site modification” submission type.</li> <li>Added clarification on the type of submissions using the “update study details” submission type.</li> </ul>
HRP-212b	10.02.2024	<ul style="list-style-type: none"> <li>Changed title from “Progress Report for Continuing Review Specimen or Data Banking” to “Annual Activity Report for Continuing Review Specimen or Data Banking”.</li> <li>Updated header with revised title.</li> <li>Added clarification on when Question #2 is applicable.</li> </ul>
HRP-503R	10.14.2024	<ul style="list-style-type: none"> <li>Added clarification to the Instruction section on when this template can be used.</li> <li>Added further instruction regarding the review period in Section 6.</li> <li>Removed reference to retrospective data and the definition of retrospective data in Section 6.</li> <li>Added instruction for when data is obtained from Mount Sinai in Section 9.</li> <li>Removed the case-series box from page 5.</li> <li>Added new instructions for requesting Waiver of Alterations in Section 12.</li> </ul>
HRP-935	10.22.2024	<ul style="list-style-type: none"> <li>Created guidance to provide instructions for the continuing review progress report</li> </ul>



**Mount  
Sinai**

Icahn School of Medicine at Mount Sinai  
Mount Sinai Beth Israel  
Mount Sinai Brooklyn  
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*

Mount Sinai Health System  
One Gustave L. Levy Place, Box 1081  
New York, NY 10029-6574  
T 212-824-8200  
F 212-876-6789  
irb@mssm.edu  
icahn.mssm.edu/pphs

HRP-451	10.22.2024	• Added reference to the HRP-935 guidance document
---------	------------	--