9/2/14 Changes:

1. **HRP-211- Application for Human Research**  
   Version Date 9/2/14 replaces Version Date 10/19/12  
   Changes:  
   - Streamlined application form by reducing number of questions asked, added areas  
     for PI’s email and phone number in header, revised personnel section for clarity

2. **HRP-212- Continuing Review Progress Report**  
   Version Date 9/2/14 replaces Version Date 12/3/12  
   Changes:  
   - Clarification to questions in Section B and D, elimination of questions in Section  
     C, added space to provide summary progress report, clarification regarding need  
     to include status of active subjects and remaining research activities in progress  
     report

3. **HRP-213- Modification of Approved Human Research**  
   Version Date 9/2/14 replaces Version Date 4/8/13  
   Changes:  
   - Revised section A for clarity

4. **HRP-229A- Request to Rely on External IRB**  
   Version Date 9/2/14 replaces Version Date 9/27/11  
   Changes:  
   - Revised Section A to include NCI CIRB studies, revised section C for clarity,  
     revised personnel section to mirror revisions made to HRP-211

5. **HRP-229B – Request to Rely on External IRB BRANY**  
   Version Date 9/2/14 replaces Version Date 9/27/11  
   Changes:  
   - Revised Section B to include Appendix D (ionizing radiation)

6. **HRP-503 – TEMPLATE PROTOCOL INSTRUCTIONS**  
   Version Date 9/2/14 replaces Version Date 9/27/11  
   Changes:  
   - Revised #1 Objectives to specifically include the research question  
   - Revised instructions for #12 Consent process to make it clear that this section  
     always applies, and to indicate whether you will be obtaining consent or  
     requesting a waiver.

7. **HRP-502 – TEMPLATE CONSENT DOCUMENT (all versions)**  
   Version Date 9/2/14 replaces Version Date 3/26/13  
   Changes:  
   - Page one: spelled out Federal Drug Administration (FDA), page 2 instructions  
     clarified that unfunded studies should state “Mount Sinai”, Under Foreseeable  
     Risks, made statement about privacy risks mandatory, page 11 HIPAA
authorization paragraph revised “will” to “may” and added “When applicable”, under Certificate of Confidentiality, revised template language and provided substitute language to HIPAA authorization for studies with a certificate of confidentiality in keeping with NIMH’s requirements, signature page clarified use of Witness section

*Note: Other forms updated to include current logo in header*

**PREVIOUS CHANGES:**

3/24/14 Changes:

1. New Appendix launched. Appendix D for use in Research involving Ionizing Radiation

2/4/14 Changes:

1. HRP-224 –FORM – Reportable New Information
   Version Date 2/4/14 replaces Version Date 5/1/13
   Changes: Admin changes to IRB office use section

5/1/13 Changes:

1. HRP-213- Modification of Approved Human Research
   Version Date 4/8/13 replaces Version Date 8/16/10
   Changes:
   8. Revised questions in text box to better collect information regarding why the changes are being requested and the implications for currently enrolled subjects

2. EXEMPT DETERMINATION Form
   Version Date 4/11/13 replaces Version Date 10/10/12
   Changes:
   9. Additional fields added to collect department and funding source

3. HRP-224- Reportable New Information
   Version Date 5/1/13 replaces Version Date 2/1/11
   Changes:
   10. Revised questions on page one to better collect information required to evaluate the report

4. HRP-229A – FORM – Request to Rely on External IRB
   Version Date 5/1/13 replaces Version Date 9/27/11
   Changes:
   11. Added statement regarding HIV-testing consent and process for submitting HIV-testing consent to PPHS office when HIV-testing is occurring and an external IRB has approved the research.
3/26/13 Changes:
1. HRP-502 – Informed Consent Template series
   Version Date 3/26/13 replaces Version Date 2/1/11
   Changes:
   - Name Change from Mount Sinai School of Medicine to Icahn School of Medicine at Mount Sinai (header and throughout document)
   - Revision date updated from 2/1/11 to 3/26/13 (footer)
   - Under What is a Research Study: Added instructions regarding when ClinicalTrials.gov paragraph must be used (page 1)
   - Under Reasonably Foreseeable Risks and Discomforts: Added instructions for research involving use of genetic testing and required GINA language to be used (page 5)
   - In Case of Injury During this Research Study: Revised template language for studies posing greater than minimal risk to subjects to ensure template language is not exculpatory (page 6)
   - Under Ending Participation: Added instructional note for research involving use of genetic testing and future banking (page 8)
   - Under Ending Participation: Added to instructional note hyperlinks to consent language for blood/tissue banking or database repositories (page 8)
   - Under Can you change your mind: Revised information for research involving genetic testing (page 13)
   - Signature page: Separated out Date and Time to create separate lines for each and added instructions for when documenting time of signature is required

NEW:
1. HRP-502x – Informed Consent Template
   Informed Consent Template for adults provided with instructions limited to HIPAA section.
   (Version Date 3/26/13)

12/3/12 Changes:
2. HRP-212 - Continuing/Final Review Progress Report
   Version Date 12/3/12 replaces Version Date 7/20/12

10/19/12 Changes:
1. HRP-211- Application for Human Research
   Version Date 10/19/12 replaces Version Date 7/20/12
   Changes: Changes to Appendix B

2. HRP-211b Standalone Appendix B
NEW:

1. **HRP-215-Comparative Review**
Version Date 7/20/12
Use this form in response to a “approved pending funding” letter from the IRB once the notice of award has been received, or when adding a funding source (or changing a funding source) to an already approved project.

2. Investigator Information Sheet: Comparative Review
Version Date 7/20/12.
Information sheet explaining when to use the Comparative Review Form

3. HRP-229C-Request to Utilize NCI CIRB
Version Date 4/27/12
This form is ONLY for use by investigators conducting NCI Cooperative Group research at MSSM. Investigators must first be enrolled and have access to the Participants Area of the NCI CIRB website – contact the CCTO or the PPHS office to begin the process.

11/21/11 Changes:
1. HRP-503a – Template Protocol
Version Date 11/21/11 replaces Version Date 2/1/11
Substantive change: Additional section for Brief Summary of Research (250-400 words) before Objectives

Administrative changes:
- Overall Instruction text box: Clarification regarding what source materials can/cannot be referenced in the Template Protocol
- Administrative change: #19 Control of Drugs, Biologics or Devices: Added information regarding IDS and the requirement to complete separate IDS forms for review by IDS prior to obtaining signature on Appendix B

2. HRP-503-Template Protocol Instructions
Version Date 11/21/11 replaces Version Date 2/1/11
Substantive change: Additional section for Brief Summary of Research (250-400 words) before Objectives

Administrative changes:
- Overall Instruction text box: Clarification regarding what source materials can/cannot be referenced in the Template Protocol
- #12 Consent Process: Clarification regarding information to be provided if SOP HRP-090 will be followed
- #19 Control of Drugs, Biologics or Devices: Added information regarding IDS and the requirement to complete separate IDS forms for review by IDS prior to obtaining signature on Appendix B

3. HRP-211 Application for Human Research
Version Date 11/21/11 replaces Version Date 7/8/11
Administrative change:
Section B: “Use of Clinical Research Centers” – correction to name of office requiring application submission (from “CTSA” to “CRC”).

4. HRP-220-Application for Humanitarian Use Device
Version Date 12/29/11 replaces Version Date 8/16/10
Administrative change: Requires evidence of qualifications to be submitted for all personnel.

7/8/11 Changes:
1. HRP-211 Application for Human Research
Version Date 7/8/11 replaces Version Date 8/16/10
Substantive change: Appendix B: Revised significantly to simplify information required by the IRB.

Administrative changes:
- Section B: Revised to include “Use of Investigational Drug Service” and “Use of Clinical Research Centers”
- Section E: Clarification regarding inclusion of CRC/CRU and Ruttenberg Cancer Center Nurses on this form
- Appendix C: Minor revision to wording of question #8 for added clarity.

Note: The Pharmacy Investigational Drug Services (IDS) requires the submission of IDS forms and relevant information prior to submission to the IRB. For additional information, please visit their webpage at: http://www.mountsinaihospital.org/for-medical-professionals/pharmacy-services/investigational-drug-service

2. HRP-211b Standalone Appendix B
Version Date 7/8/11 replaces Version Date 8/16/10
Substantive change: Appendix B revised significantly to simplify information required by the IRB about the drugs/biologics being used in the research.

Note: Pharmacy Investigational Drug Services (IDS) now requires the submission of IDS forms and relevant information prior to submission to the IRB. Please follow the link to the Pharmacy IDS webpage for additional information (http://www.mountsinaihospital.org/for-medical-professionals/pharmacy-services/investigational-drug-service).

Previous Changes:
HRP-502 Consent Template
Version Date 2/1/11 replaces Version Date 8/16/10
• Under Description of What’s Involved: Additional information required if the research involves genetic testing (page 2-3).
• Under Description of What’s Involved: Added paragraph (final paragraph in section) about clinical trials and clinicaltrials.gov registration (page 3).
• Under Ending Participation in the Research Study: Added instructions “notes” to investigator under “For clinical trials under FDA jurisdiction”: Added statements about not removing data if a subject discontinues participation in clinical trials under FDA jurisdiction; added statement about follow-up data collection (pages 6-7).
• Under Ending Participation: Added information for research involving genetic testing (page 7).
• Under Can you change your mind: Added information for research involving genetic testing (page 12)