4/1/15 Changes:
1. HRP-502 – TEMPLATE CONSENT DOCUMENT (all versions)
   Version Date 4/1/15 replaces Version Date 9/2/14

   Major Changes:
   • Revised header – must be customized for the study
   • Under What is a research study, 2nd paragraph, last sentence revised to reference
     the Mount Sinai Health System (MSHS)
   • Under Length of Time, revised to indicate that site within MSHS must be
     specified
   • Under Description, Added bullet to indicate which site (s) are involved for which
     study visits
   • Under Description, New birth control template language added – must be accurate
     for the study
   • Under Description, removal of NYS genetic testing instructions. Added reference
     to Guidance document for appropriate language and further instructions
   • Under Your Responsibilities, reference to the birth control methods in description
     section added, if applicable
   • Under Risks, revised risk of loss of private information bullet statement
   • Under Risks, added risk of blood draw template language
   • Under Risks, added reference to birth control methods in description section, if
     applicable (do not add all birth control requirements here in addition to the
     description section)
   • Under Ending Participation, revised to reference all hospitals within the MSHS
   • Under Contact Person(s), revised to reference MSHS
   • Under Maintaining Confidentiality – HIPAA Authorization: Numerous revisions
     to incorporate MSHS as appropriate
   • COC language, revised for additional clarity

   Additional minor changes have also been made to instructional text. See Adult
   Consent/Authorization Template Tracked Changes for all changes.

Previous Changes:
9/2/14 Changes:
2. 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

3. 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

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

5. **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

6. **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)

7. **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.

8. **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*

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

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**5/1/13 Changes:**

1. **HRP-213 - Modification of Approved Human Research**
   Version Date 4/8/13 replaces Version Date 8/16/10
   Changes:
   - 9. 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:
   - 10. 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:
   - 11. 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:
   - 12. 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.

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**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
   Changes: Revised instructions for added clarification in **Section B. Current Protocol Status.**

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**
   Version Date 10/19/12 replaces Version Date 7/08/11
   Changes: Reformatted and redesigned

10/10/12 Changes:
NEW
**Exempt Determination Form**
Version Date 10/10/12

7/20/12 Changes:
1. **HRP-212 - Continuing/Final Review Progress Report**
   Version Date 7/20/12 replaces Version Date 8/25/10
   Changes: Reformatting form for clarification; lettering of items for ease of reference; additional clarification regarding reporting harms/benefits.

2. **HRP-503-Template Protocol Instructions**
Version Date 7/20/12 replaces Version Date 11/21/11
Changes: Additional instructions under #12 referencing institutional policy on capacity
assessment and the consent process, additional clarification under #5i regarding the
standard for minimal risk studies.

3. **HRP-311-Worksheet – Criteria for Approval and Additional Considerations**
   Version Date 7/2/12 replaces Version Date 10/25/10
   Changes: Citations to direct regulatory sources added, numbering of items under section
   7 for ease of reference.

4. **HRP-211e-Standalone Personnel Section**
   Version Date 11/21/11
   Reposted

5. **HRP-422-Checklist – Research Involving Cognitively Impaired Adults**
   Version Date 7/20/12 replaces Version Date 8/16/10
   Changes: Clarification of criteria required by institutional policy A3-113 on Consent.

6. **HRP-211- Application for Human Research**
   Version Date 7/20/12 replaces Version Date 11/21/11
   Changes: Administrative changes only.

7. **HRP-503a- Template Protocol**
   Version Date 7/20/12 replaces Version Date 11/21/11
   Changes: Administrative changes only.

**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)