**Submission Checklist**

**IRB Form 5**

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| **LIST OF IRB SUBMISSION REQUIREMENTS (check all applicable)** |
| IRB Form 5 (this form) **\*\*REQUIRED\*\*** |
| Tracked and Clean Copy of Study Materials (Protocol, ICF, Recruitment, etc.) **\*\*REQUIRED\*\*** |
| Current copy of CV for PI, CRC and Sub-Investigators (If applicable) |
| IRB Form 2B Sub-Investigator Information and Signature Form (if applicable) **\*\*REQUIRED\*\*** |

|  |  |
| --- | --- |
| **B. SIGNATURE OF PERSON MAKING SUBMISSION** | |
| Typed Name | Signature |

**MEDSTAR HEALTH RESEARCH INSTITUTE**

**OFFICE OF RESEARCH INTEGRITY**

**IRB FORM 5: REQUEST FOR AMENDMENT/MODIFICATION TO THE PROTOCOL**

This form must be submitted with all amendments/revisions/modifications to the protocol or supporting documents. **Complete the entire form electronically**, PRINT and submit to ORI. Ensure that all required attachments are enclosed with the submission.

If you require further assistance in completing this form or need additional information, please contact the Office of Research Integrity at (301) 560-2912 to speak with an ORI staff member.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **A. GENERAL INFORMATION** | | | | | |
| 1. | IRB Project # |  | 2. | Research Location: |  |
| 3. | Review Type: |  | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **B. STUDY INFORMATION** | | | | | | | | | | | | | | | | |
| 1. | Study Title | | |  | | | | | | | | | | | | |
|  | a) | | | Current Protocol Version Date *(if applicable, attach protocol)*: | | | | | | |  | | | | | |
|  | b) | | | Amendment Version *(if applicable, attach amendment)*: | | | | | | |  |  | | | N/A | |
|  | c) | | | Site Informed Consent Version Date *(if applicable)*: | | | | | | |  |  | | | N/A | |
| 2. | Principal Investigator: | | | | |  | | | | | | | | | | |
|  | a) | | | Contact Number: | |  | | | | b) | E-mail Address: |  | | | | |
|  | c) | | | PEER Number: | |  | | | | d) | PEER Expiration Date: |  | | | | |
| 3. | Clinical Coordinator: | | | | |  | | | | | | | | | | |
|  | a) | | | Contact Number: | |  | | | | b) | E-mail Address: |  | | | | |
|  | c) | | | PEER Number: | |  | | | | d) | PEER Expiration Date: |  | | | | |
| **C. TYPE OF AMENDMENT/MODIFICATION** | | | | | | | | | | | | | | | |
| Select all that apply; multiple drop-down boxes have been provided in the event of multiple types of changes. | | | | | | | | | | | | | | | |
| 1. | |  | Protocol Revisions: | |  | | | | | | | | | | |
|  | |  |  | |  | | | | | | | | | | |
|  | |  |  | |  | | | | | | | | | | |
| 2. | |  | Requested Change in MHRI site(s) Accrual Target (indicate new enrollment target): | | | | | | | | | | | (from       to      ) | |
| 3. | |  | **Modification** of Existing Material: | | | | | |  | | | | | | |
|  | |  |  | | | | | |  | | | | | | |
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| 4. | |  | **Addition** of New Material: | | | | |  | | | | | | | |
|  | |  |  | | | | |  | | | | | | | |
|  | |  |  | | | | |  | | | | | | | |
| 5. | |  | Change in Study Personnel: | | | | |  | | | | | | | |
|  | |  |  | | | | |  | | | | | | | |
|  | |  |  | | | | |  | | | | | | | |
| 6. | |  | Change in Sponsor (specify): | | | | |  | | | | | | | |
| 7. | |  | Other (specify): | |  | | | | | | | | | | |
| 8. | | Will the submitted changes affect the risk/benefit ratio of this protocol as it pertains to patient safety? | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | |
| **D. NARRATIVE SUMMARY OF AMENDMENT/MODIFICATION**  **(Sponsor-Generated generated summaries may also be attached)** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **F. PRINCIPAL INVESTIGATOR SIGNATURE** | | | | | | | | | | | | | | | |
| **I have reviewed the attached amendment or modification and request that it be approved for implementation at the MHRI participating site(s). To the best of my knowledge, the information presented on this form is complete and accurate.** | | | | | | | | | | | | | | | |
| Typed Name of Principal Investigator | | | | | | | Signature of Principal Investigator | | | | | | Date of Signature | | |