**IRB Submission Checklist**

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| **LIST OF IRB SUBMISSION REQUIREMENTS (check all applicable)** |
| IRB Form 2A (this form) **\*\*REQUIRED\*\*** |
| IRB Form 2B Sub-Investigator Information and Signature Form (if applicable) |
| HIPAA Waiver **\*\*REQUIRED\*\*** |
| Protocol **\*\*REQUIRED\*\*** |
| Investigator Statement of Compliance **OR** FDA 1572 (if FDA regulated drug study) **\*\*REQUIRED\*\*** |
| ONLINE Conflict of Interest/Financial Disclosure (<https://medstar.coi-smart.com>) **\*\*REQUIRED\*\*** |
| Any other documentation pertinent to a complete and informed review of the research activity |

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| **A. INVESTIGATOR/COORDINATOR COMMENTS (below)** **NONE** |
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| **B. SIGNATURE OF PERSON MAKING SUBMISSION** | |
| Typed Name | Signature |

**MEDSTAR HEALTH RESEARCH INSTITUTE**

**OFFICE OF RESEARCH INTEGRITY**

**IRB FORM 2A: CHART/MEDICAL RECORD REVIEW REQUEST**

I**NITIAL SUBMISSION OF A RESEARCH PROTOCOL**

**TO THE INSTITUTIONAL REVIEW BOARD**

This form should be utilized to request review of chart/medical record review research activities. **Complete the entire form electronically**, PRINT form and obtain appropriate signatures. Submit to ORI following the submission instructions found on the website.

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.

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| **A. GENERAL INFORMATION** | | | | | | | | | | | | |
| 1. | | Study Title: | | |  | | | | | | | |
| 2. | | Research Location: | | |  | | | | | | | |
| 3. | | Is this research confined solely to a retrospective analysis of currently existing records? | | | | | | | | | | |
|  | |  | | | | | | | | | | |
| **B. STUDY PERSONNEL** | | | | | | | | | | | | |
| 1. | Principal Investigator: | | | | | | | | | | | |
|  | a) | | Name (First, MI, Last): | | | |  | | | | | |
|  | b) | | Title: | | | |  | | | | | |
|  | c) | | Address: | | | |  | | | | | |
|  | d) | | Institution: | | | |  | | | | | |
|  | e) | | Department: | | | |  | | f) | Telephone Number: | |  |
|  | g) | | Section: | | | |  | | | | | |
|  | h) | | E-mail: | | | |  | | | | | |
|  | i) | | PEER Number: | | | |  | | j) | PEER Expiration Date: | |  |
|  | k) | | Is the PI a staff member, treating physician, consultant, or otherwise affiliated with any of the following entities listed below? (Check all applicable institutions below. If none, check “None.”) | | | | | | | | | |
|  |  | | **NONE** | | | Johns Hopkins University | | | Georgetown University Hospital | | | |
|  |  | | Georgetown University or Georgetown University Medical Center | | | | | | | | Children’s National Medical Center (CNMC) | |
|  |  | | University of Maryland | | | | | Howard University | | | | |
|  |  | | George Washington University | | | | | | | | | |
|  |  | |  | | | | | | | | | |
| 2. | Are there sub-investigators participating in this protocol? | | | | | | | | | | | | |
|  | No | | | Yes (Complete Sub-Investigator Information and Signature Form – IRB Form 2B) | | | | | | | | | |

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| **C. REQUEST FOR WAIVER OR ALTERATION OF INFORMED CONSENT REQUIRED ELEMENTS** | | | | | | |
| Request for Waiver or Alteration of the Informed Consent Required Elements: | | | | | | |
| * The **information must include** a brief specific description of the procedure(s) involving the human subjects in sufficient detail to demonstrate that the research protocol meets the requirements of the waiver category claimed. | | | | | | |
| **Request for Waiver or Alteration of Informed Consent Required Elements – 45 CFR 46.116 (c & d):** | | | | | | |
|  | 1. | RESEARCH or DEMONSTRATION PROJECT CONDUCTED BY OR SUBJECT TO APPROVAL OF STATE OR LOCAL GOVERNMENT OFFICIALS, AND designed to study or evaluate, or otherwise examine the following: | | | | |
|  |  |  |  | | i) | Public benefit of service programs; |
|  |  |  |  | | ii) | Procedures for obtaining benefits or services under those programs; |
|  |  |  |  | | iii) | Possible changes in or alternatives to those programs or procedures; or |
|  |  |  |  | | iv) | Possible changes in methods or levels of payment for benefits or services under those programs |
|  | If checked | | | | | |
|  |  | a. | Explain how the research fits the checked criteria above. | | | |
|  |  |  | ▪ |  | | |
|  |  | b. | Explain why the research cannot practicably be carried out without the waiver or alteration. | | | |
|  |  |  | ▪ |  | | |
|  | | | | | | |
|  | 2. | ALL OTHER RESEARCH FOR WHICH A WAIVER OR ALTERATION OF INFORMED CONSENT REQUIRED ELEMENTS IS SOUGHT: | | | | |
|  | If checked | | | | | |
|  |  | a. | Explain why the research involves no more than minimal risk to subjects. | | | |
|  |  |  | ▪ |  | | |
|  |  | b. | Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects. | | | |
|  |  |  | ▪ |  | | |
|  |  | c. | Explain why the research could not be practicably carried out without the waiver or alteration of informed consent requirements. | | | |
|  |  |  | ▪ |  | | |
|  |  | d. | Is it appropriate to provide the subjects with a written statement regarding the research or additional pertinent information after participation, and if not, why? | | | |
|  |  |  | ▪ |  | | |

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| **D. IDENTIFIABLE INFORMATION/CONFIDENTIALITY/HIPAA** | | | | |
| 1. | Will you be accessing any Protected Health Information (PHI) specifically for the purposes of this Chart Review? (If yes, indicate where the information is stored, i.e., from where it will be accessed.) | | | |
|  |  | | | |
| 2. | At any time, will you be recording subject’ identifiable information? (If yes, indicate what identifiers will be recorded.) | | | |
|  |  | | | |
|  | a) | Will the subjects’ identifiers be used in publications of the research activity? | | |
|  |  |  | | |
|  | b) | Will any identifiable information be disclosed? | | |
|  |  |  | | |
|  | c) | Will any identifiable information be entered into a database? | | |
|  |  |  | | |
| 3. | Will this research activity require a Waiver or Alteration of HIPAA Authorization for Research Use/Disclosure of Protected Health Information or a HIPAA Authorization for Use/Disclosure of Protected health Information for Research Purposes? (Note: Please contact ORI regarding HIPAA if you have questions.) | | | |
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| 4. | Will this research require a HIPAA Authorization? | | | |
|  |  | | | |
| **E. PRINCIPAL INVESTIGATOR SIGNATURE** | | | | |
| As Principal Investigator of the aforementioned protocol, I certify that:   1. To the best of knowledge, the information provided in this form is accurate. I have submitted any necessary attachments to provide the IRB with a complete overview of the intended research activity (including the current version of the protocol/chart review proposal). 2. I understand that as Principal Investigator, I am ultimately responsible for the conduct of research involved with this study. **I will not begin any research activities until final written IRB approval is received.** Unless immediately required for the protection of subject safety, I will obtain ***prior* written approval from the IRB for any amendment or modification to the protocol** or supporting materials. 3. I understand that I, as well as all Sub-Investigators involved in this study, must obtain a MedStar PEER number before performing any Human Subject research. 4. I will comply with all IRB policies and procedures. 5. I will comply with all IRB requests to report on the status of the study and **I will maintain an active IRB approval**. I understand that I am to submit annual reviews to the Institutional Review Board (IRB) and I agree to submit all requests for Continuing Review no later than *forty-five (45) days* prior to the annual expiration of the project. 6. **I will maintain accurate and complete regulatory records** in association with this study. 7. **I understand that I am required to file a final report upon conclusion of the research** with the Institutional Review Board (IRB).   I understand that if my research is under a sponsored research agreement, additional requirements may apply. | | | | |
| Typed Name of Principal Investigator | | | Signature of Principal Investigator | Date of Signature |

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| **F. DEPARTMENT CHAIR SIGNATURE**  The Department Chairman of the respective administrative unit MUST sign this application.  I have read this completed form and endorse the aforementioned research to be conducted. | | |
| Typed Name/Title of Department Chair or designee | Signature of Department Chair or designee | Date of Signature |