**IRB Submission Checklist**

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| **LIST OF IRB SUBMISSION REQUIREMENTS (check all applicable)** |
| IRB Form 3 (this form) **\*\*REQUIRED\*\*** |
| IRB Form 2B Sub-Investigator Information and Signature Form (if applicable) |
| HIPAA Waiver (if applicable) |
| Protocol **\*\*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 3: EXEMPT STATUS REQUEST**

**Complete the entire form electronically**, PRINT form and obtain appropriate signatures. Submit to ORI.

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. | Type of Study: | | | | |  | | | | | | |
| 2. | Study Title: | | | | |  | | | | | | |
| 3. | Research Location: | | | | |  | | | | | | |
| 4. | Does this research involve nursing care or the nursing care process? | | | | |  | | | | | | |
| **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 institutions 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. | Clinical Research Coordinator: | | | | | | | | | | | |
|  | a) | Name (First, MI, Last): | | |  | b) | | | Telephone Number: | | |  |
|  | c) | Department: | | |  | | | | | | | |
|  | d) | Section: | | |  | | | | | | | |
|  | e) | Address: | | |  | | | | | | | |
|  | f) | E-mail: | | |  | | | | | | | |
|  | g) | PEER Number: | | |  | h) PEER Expiration Date: | | | |  | | |
|  |  | | | | | | | | | | | |
| 3. | Are there sub-investigators participating in this protocol? | | | | | | | | | | | |
|  | None | | - OR - | | Yes (Complete Sub-Investigator Information and Signature Form – IRB Form 2B) | | | | | | | |
| **C. HIPAA** | | | | | | | | | | | | |
| 1. | Will this research activity require a Waiver or Alteration of HIPAA Authorization for Research Use/Disclosure of Protected Health Information?  *(Note: Review the HIPAA Decision Matrix to ensure that all HIPAA requirements have been met)* | | | | | | | | | | | |
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| **D. EXEMPT CATEGORY** | | | | | | | | | | | | |
| Exempt Category Requested: | | | | | | | | | | | | |
| 1. | Address the critical elements of your exemption categories as indicated. | | | | | | | | | | | |
| 2. | **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 for the category of exemption claimed in this human subject research. | | | | | | | | | | | |
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| **EXCEPTIONS to the EXEMPT Categories even though it meets the criteria of one of the categories below:** | | | | | | | | | | | | |
| 1. | Research involving vulnerable populations such as the mentally or cognitively impaired, prisoners, parolees, pregnant women, and fetuses, **CANNOT** be exempt from review. | | | | | | | | | | | |
| 2. | Research using survey procedures or interview procedures upon children **CANNOT** be exempt from review. | | | | | | | | | | | |
| 3. | Research involving observation of children’s behavior **CANNOT** be exempt from review if the investigator is a participant in the behaviors observed. | | | | | | | | | | | |
| 4. | Research involving subjects who are students of the investigators. | | | | | | | | | | | |
| **Exemption Categories – 45 CFR 46.101(b)** | | | | | | | | | | | | |
|  | 1. | Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: *(check applicable subcategory)* | | | | | | | | | | |
|  |  |  | (i) | research on regular and special education instructional strategies, or | | | | | | | | |
|  |  |  | (ii) | research on the effectiveness of or the comparison among instructional techniques, curricular or classroom management methods. | | | | | | | | |
|  |  | If checked, | | | | | | | | | | |
|  |  |  |  | a. | Briefly explain how subcategory (i) or (ii) applies: | | | | | | | |
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|  | 2. | Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing ,employment or reputation. Research which deals with sensitive aspects of the subject’s own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol, **cannot** be exempt from review. | | | | | | | | | | |
|  |  | If checked, | | | | | | | | | | |
|  |  |  |  | a. | Briefly explain how category 2 applies and confirm that copies of test/survey/interview questions or items are attached. | | | | | | | |
|  |  |  |  |  |  | | | | | | | |
|  |  |  |  | b. | Assure that conditions 2(1) and 2(ii) are not jointly present. Specify any precautions taken to ensure that research personnel are not recording information in an identifiable manner (directly or through identifiers). Confirm and explain how any planned disclosure of subjects’ responses outside the research ***will not*** reasonable place the subjects at risk, as described in (ii) above. | | | | | | | |
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|  | | | | | | | | | | | | |
|  | 3. | Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 (above) if: *(check applicable subcategory)* | | | | | | | | | | |
|  |  |  | (i) | the human subjects are elected or appointed public officials or candidates for public office; or | | | | | | | | |
|  |  |  | (ii) | federal state(s) require(s) without exception that the confidentiality of the personally indentifiable information will be maintained throughout the research and thereafter. | | | | | | | | |
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|  | 4. | Research involving the collection or study of **existing** data, documents, records, pathological specimens or diagnostic specimens, if: | | | | | | | | | | |
|  |  |  | (i) | these sources are publicly available; or | | | | | | | | |
|  |  |  | (ii) | the information is recorded by the investigator in such a manner that subjects cannot be identified, directly, or through identifiers linked to the subjects. | | | | | | | | |
|  |  | If checked: | | | | | | | | | | |
|  |  |  |  | a. | Specify how subcategory (i) or (ii) applies: | | | | | | | |
|  |  |  |  |  |  | | | | | | | |
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|  | 5. | Research and demonstration projects which are conducted by or subject to the approval of **federal** department or agency heads and which are designed to study, evaluate, or otherwise examine: | | | | | | | | | | |
|  |  |  | (i) | public benefit or 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 change in methods or levels of payment for benefits or services under those programs. | | | | | | | | |
|  |  | If, checked: | | | | | | | | | | |
|  |  |  |  | a. | Specify how subcategory (i), (ii), (iii), or (iv) applies: | | | | | | | |
|  |  |  |  |  |  | | | | | | | |
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|  | 6. | Taste and food quality evaluation and consumer acceptance studies, if: | | | | | | | | | | |
|  |  |  | (i) | wholesome foods without additives are consumed; or | | | | | | | | |
|  |  |  | (ii) | a food is consumed that contains a food ingredient at or below the level and for use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food and Safety and Inspection Service of the U.S. Department of Agriculture (USDA). | | | | | | | | |
|  |  | If, checked: | | | | | | | | | | |
|  |  |  |  | a. | Specify how subcategory (i) or (ii) applies: | | | | | | | |
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| **E. PRINCIPAL INVESTIGATOR SIGNATURE** | | |
| As Principal Investigator, I certify that:  To the best of my knowledge, the information provided in this form is accurate.  I understand that the IRB has the authority to determine and confirm “Exempt Status” of this protocol/research activity, and I will not begin any research or research-related activity until written confirmation, granting “Exempt Status” to this protocol is received from the IRB.  I will maintain accurate and complete regulatory records in association with this study.  I will comply with all IRB policies and procedures.  I will submit any amendment or modification to the protocol to the IRB for confirmation that the amendment/modification does not in any way alter the “Exempt Status” of the protocol. I will not implement any amendment or modification to the protocol until a letter granting approval for continued “Exempt Status” of the protocol is received from the IRB.  I agree to comply with any and all applicable informed consent and HIPAA requirements and I understand that the IRB’s granting of “Exempt Status” for this protocol/research activity does not in any ay negate the requirement for informed consent or HIPAA authorization, where applicable.  I understand that the IRB has the authority to require Expedited or Full Board Review of this protocol, if deemed appropriate. | | |
| 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 |