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| **MHRI IRB External Site Questionnaire** |
| **THIS FORM MUST BE TYPED. THE IRB WILL NOT ACCEPT HANDWRITTEN APPLICATIONS.** |
| **When to Use This Form:** This form should be used when a MedStar Health Investigator is requesting the MHRI IRB be the IRB of record for a site external to MedStar Health. This form should be submitted in conjunction with an Initial Submission Application or Modification. |

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| MedStar Health Principal Investigator | |
| Name: | **Phone #:** |

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| **External Site Investigator** | **External Site Study Coordinator** |
| **Name:** | **Name:** |
| **Phone #:** | **Phone #:** |
| **Email:** | **Email*:*** |
| Person/Address to which correspondence should be mailed: | |
| *List additional study personnel on next page* | |

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| **Protocol Title:** |

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| 1. | Where will the study be conducted? (List all locations.) |  |
| 2. | Applicant Organization’s Federal Wide Assurance (FWA) # (required for all federally funded studies): |  |
| 3. | Does your organization have its own IRB? | Yes  No |

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| **Facility/External Site Approval** |
| By signing below, I acknowledge that I have reviewed this protocol for scientific validity, and confirm that the investigators have the appropriate credentials to perform the research procedures. I have read the attached protocol submission and the execution of the project has my endorsement. I understand that it is **my responsibility** as to closely supervise research to ensure continued protection of human research subjects at my facility including compliance with 45CFR46, and 21CFRParts 50 and 56.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed Name Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title Date |

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| **Study Personnel Requirement - Attach CVs in the eIRB system for all personnel listed** | |
| Required Education - All investigators are required to be trained in Human Subjects Research. If the external site does not have its own training requirements, investigators from that site should follow the training requirements of MedStar Health.  The Human Subjects Training CITI Date is the date of most recent completion of the CITI tutorial program for the basic or refresher human subjects’ research course.  The COI Training CITI Date is the date of most recent completion of the Conflict of Interest Training Course. | |
| Please check one of the following: | |
|  | My Institution has human subjects research training requirements and all staff listed on this protocol have completed those requirements |
|  | My Institution does not have our own human subjects training requirements. The requirements of MedStar Health are being followed for staff listed on this study. Dates of training are provided in grid below. |

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| **External Interest (COI) Disclosures for Research** | |
| Each site is responsible for reviewing the protocol and determining whether a conflict of interest exists in accordance with the site’s institutional policies. It is the relying site’s responsibility to manage or eliminate any conflict. The conflict and the management plan must be disclosed to the MHRI IRB. The MHRI IRB will have the final determination whether it is appropriate for the site’s IRB to assume IRB review responsibilities given any disclosure and management plan. | |
| Does the protocol present any potential conflicts of interest as defined in the relying Site’s institutional policies? | |
|  | Yes |
|  | No |
|  | External Site will be relying on MHRIs Conflict of Interest Management Process |
| If Yes, is marked, please fully describe the conflict: | |

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| **Please attach and describe the Management Plan including any language that should be in the consent document:** |
| For organizations without their own conflict of interest review process, investigators can complete the MHRI disclosure form. Please contact the ORI office to discuss. |

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| **Study Personnel Requirements (Continued)** | | | | | | | | | |
| **A.**  **Obtaining Informed Consent?** | **B.**  **Study Personnel** | **C.**  **Email** | **D.**  **Role on**  **Project** | ***REQUIRED EDUCATION*\*** | | External Interest (COI) Disclosures for Research**\*** | | | |
|  |  |  |  | Human Subjects Training **Date** | COITraining(CITI) **Date** | **Date of Disclosure** | Management Plan Required? | Disclosures for **all personnel listed** have been reviewed & are accurate as of the date of this submission? |
| Yes  No |  |  |  |  |  |  | Yes  No | Yes  No |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| Yes  No |  |  |  |  |  |  | Yes  No |  |
| **\* Required Education and COI Disclosure information only needs to be completed if your site is relying on MHRIl’s education and COI policies. If your institution is relying on its own policies for education and External Interest Disclosures, only complete columns A – D on this chart.** | | | | | | | | | |

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| **Study Personnel Requirements (Continued)** | |
| **1.** | Confirm that all investigators on this application have the adequate resources to protect human subjects: |
|  | Yes  No |
| **2.** | Explain how staff is qualified; include any training and expertise specific to the conduct of this study. Include information about relevant licenses/medical privileges, as applicable: |
|  |  |
| **3.** | Detail processes to inform staff of the protocol and their duties and functions for this study: |
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| **4.** | Have any of these individuals been sighted for noncompliance by a Federal Agency, in the past 3 years? If so, explain: |
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| **5.** | Have any of these individuals been debarred as a clinical investigator, by the FDA or ORI, in the past 3 years? If so, explain: |
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| **1. Study Population  N/A** | |
| **Only complete this section if local study population differs from that of the MedStar site. If local study population is not different, mark “N/A.”** | |
| **A.** | Study population will include: |
|  | Males  Females   Children (<18 years)  Minorities  *(If the study is not gender/ethnic/racial/age group specific, the protocol must include justification for excluding women, and/or minorities or specific age groups).* |
| **B.** | Vulnerable Populations: |
|  | Students  Institutionalized Persons  Employees  Educationally/economically disadvantaged  Children (<18 years)  Fetuses  Children who are wards of the state  Decisionally impaired persons  Pregnant women  Prisoners (See note)  Abortuses  None of the above  **Prisoners:** In addition to individuals involuntarily confined or detained in penal institutions, the term “prisoner” includes those detained in other facilities as alternatives to criminal prosecution or incarceration in penal institutions (i.e., drug treatment facilities, etc.). **Please note, if a research subject is incarcerated or detained in an alternative facility after enrolling in a study, the PI must notify the IRB immediately.**  *(The protocol must include rationale for recruiting any vulnerable populations and details regarding the additional protections in the protocol.)* |
|  | If vulnerable populations are included, what additional protections are in place to ensure their safety? |
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| **C.** | Expected number of subjects at this site: |
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| **2. Drugs/Placebos/Biologics/Other Agents  N/A** | | |
| **Only complete this section if local drug/placebo/biologic management differs from that of the MedStar site. If there is no difference, mark “N/A.”** | | |
| **A.** | Name of drug(s) (generic and, if applicable, trade) and/or placebos, biologics, radioisotopes, other agent: | |
|  |  | |
| **B.** | Are any of these agents investigational new drugs (i.e., not used in a manner consistent with its labeling, not on the market, not FDA approved)? | Yes  No |
| **C.** | **If yes**, has a formal IND filing been made with the FDA? | Yes  No |
| **D.** | Date submitted to the FDA:  FDA/IND number, if available:  Sponsor: | |
| **E.** | **If no**, is the drug FDA approved for the use indicated in this submission? | Yes  No |

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| **3. Minors or Decisionally Impaired Adults  N/A** | | | |
| **Only complete this section if local study population differs from that of the MedStar site. If local study population is not different, mark “N/A.”** | | | |
| **A.** | Do you anticipate enrolling minors who are wards of the state? | | Yes  No |
|  | If yes (wards of the state *will* be included in the study), and the category of research falls under category 46.406 or 46.407 described above: | | |
|  | Is the research related to the subjects’ status as wards? | | Yes  No |
|  | Is the research conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as subjects are not wards? | | Yes  No |
| **B.** | If adult subjects will be included, are they: | | |
|  | **Temporarily Decisionally Impaired**  If temporarily decisionally impaired, will consent be sought from the subject  once competency is regained? | | Yes  No |
|  | **Chronically Decisionally Impaired**  Who will provide consent for these subjects? | |  |
| **C.** | Do you plan to assess the competency of the subjects? | | Yes  No |
|  | If yes, how? | Comprehension Assessment Form  Other (explain): | |
| **D.** | Do you plan to obtain the assent of the subject? | Yes  No  Yes, if appropriate, based on maturity/competence | |
|  | **If yes:** *Include the “Assent for Minor Subjects or Decisionally Impaired Adults” section of the consent form (see “Guidelines for Preparing Research Consent Forms”) as the last page of the Informed Consent for*m.  **If no:** Are you requesting a waiver of the assent requirement?  Yes, Why: | | |

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| **4. Local Site Participation** | |
| **A.** | Describe the organization’s human subject protection training and education requirements for researchers and study staff. Include initial and continuing education requirements. |
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| **B.** | Describe the process your organization uses to address conflicts of interest in the conduct of human subjects research – specifically, how information about potential conflicts of interest are identified, reviewed and processed by the HRPP: |
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|  | Please confirm that your organization has assured compliance with federal laws and regulatory requirements concerning potential financial COI by obtaining certification from the Federal Demonstration Partnership Institutional Clearinghouse. |
|  | Yes  No  *(Note: If this is not true, researchers at your site will have to follow the MedStar Health Conflict of Interest Disclosure Procedure)* |
| **C.** | Describe the role of your site in this study (i.e. describe what you believe your role is on the study and what study related procedures will be performed at your site): |
|  |  |
| **D.** | Describe the selection and recruitment of subjects for this study, at this site, if it differs from the procedures described in the main study application and/or protocol. |
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| **E.** | Does the master application and/or protocol adequately describe the consenting process to be used at your institution, including the plans to compensate subjects? |
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| **F.** | Does the consenting process outlined in the main application and/or protocol, as well as local consent form, comply with all of your local institutional consent policies and local law? Are there any issues you would like to specifically highlight for the MedStar IRB which would help the Committee in their evaluation of the local consent process or form? |
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| **G.** | Does the information in the main study application regarding privacy and confidentiality adequately describe the provisions at your location? Are there any areas where your location will deviate from the main study procedures? |
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| **H.** | Are there any other areas of the application where your local institution will differ from what is described? |
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| **I.** | Identify areas where there are unique state, local or institutional requirements; for example:   1. Legally authorized representatives 2. Age of majority in your state 3. State laws regarding assent for children 4. State laws regarding confidentiality of specific types of health information |
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| **J.** | Are there any special characteristics of your institution or community of which the reviewing IRB should be made aware? |
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| **K.** | Have there been any recent events in the community that have created positive/negative attitudes towards human subject research? |
|  |  |
| **L.** | Describe any governmental inquiries or investigations over the past three years that may be material to the activities that would be conducted under the proposed IRB Authorization Agreement. Include, without limitation, research compliance problems (e.g. OHRP or FDA inquiries or investigations and corrective actions). Provide the status of such matters, including how there were resolved, if resolved. |
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| **M.** | Are there any additional comments you would like to add? |
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| **Institutional Official for Research** | **IRB Administrative Contact** | **IRB Chair** |
| **Name:** | **Name:** | **Name:** |
| **Position:** | **Position:** | **Position:** |
| **Contact Information:**  **Mailing Address:**  **Email:**  **Phone:**  **Fax:** | **Contact Information:**  **Mailing Address:**  **Email:**  **Phone:**  **Fax:** | **Contact Information:**  **Mailing Address:**  **Email:**  **Phone:**  **Fax:** |

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| **Statement of Compliance** | | |
| If the Institutional Review Board approves this project, I agree to:   1. Ensure that all staff involved in the project at my site have received and reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; 3) relevant institutional policies and procedures for the protection of human subjects. 2. Execute the research plan as described in this application, including obtaining informed consent from all subjects as deemed appropriate by the IRB. 3. Accept responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this application 4. Comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this application. 5. Abide by all determinations of the MedStar Health Institutional Review Board (IRB) and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities. 6. Complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this application MedStar Health utilizes the Collaborative Institutional Training Initiative (CITI) [http://www.citiprogram.org](http://www.citiprogram.org/) to meet our federal human subject protections educational requirements. 7. Report promptly to the IRB any proposed changes in the research conducted under this application. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects. 8. Report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this application 9. When responsible for enrolling subjects, obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the IRB. 10. Cooperate in the IRB’s responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion. 11. Not enroll subjects in research under this application prior to its review and approval by the IRB.   There will be random audits of research protocols by Research Compliance and/or the IRB. Failure to comply with any of the above regulations may result in CLOSURE OF THE STUDY by the IRB.  I hereby assure compliance to the above and assume responsibility for all activities and investigators involved in this project. | | |
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| **Date** | **Signature of Local Site Investigator** | **Title** |