# IRB FORM 2: NEW PROTOCOL REVIEW REQUEST

**IRB Submission Checklist**

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| **LIST OF IRB SUBMISSION REQUIREMENTS (check all applicable)** |
| [ ]  IRB Form 2 (this form) **\*\*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\*\***  |
| [ ]  Current copy of CV for PI, CRC and Sub-Investigators |
| [ ]  IRB Form 2B Sub-Investigator Information and Signature Form (if applicable) |
| [ ]  Informed Consent Document(s) (if applicable) |
| [ ]  Parental Consent Document/Assent Document/ IC Waiver (IRB Form 8A) (if applicable) |
| [ ]  HIPAA Authorization **AND/OR** HIPAA Waiver (as applicable) |
| [ ]  Participant Education Materials and Questionnaires (if applicable) |
| [ ]  Recruitment Materials (if applicable) |
| [ ]  MHRI Investigational Product Information Sheet (drug/biologic or device) (if applicable) |
| [ ]  FDA Correspondence (IND/IDE acknowledgement letter) (if applicable) |
| [ ]  Investigator’ Brochure **AND/OR** Instructions for Use (if applicable) |
| [ ]  Tissue Repository Form (IRB Form 7) (if applicable) |
| [ ]  Other IRB/Required Committee Approvals (if applicable) |

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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**

**INITIAL SUBMISSION OF A RESEARCH PROTOCOL**

**TO THE INSTITUTIONAL REVIEW BOARD**

**This form must be utilized for all new protocol review requests except Social/Behavioral, Case Reports, Chart/Medical Record Review, and projects believed to be exempt from IRB review.** Social/Behavioral, Chart/Medical Record Reviews and Case Reports must be submitted on IRB Form 2D, 2C and 2A respectively. If it is believed that the research is exempt from IRB review, submit Form 3 entitled “Exempt Review Request Form” to the Office of Research Integrity (ORI).

**Complete the entire form electronically**, PRINT form and obtain appropriate signatures. Submit via InfoEd.

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: |       |
|  | a)Research Location: |        |
|  | b) To your knowledge, is this (or a substantially similar) study already being conducted at another MHRI institution? |
|  |        |
| 2. | Principal Investigator: |
|  | a) | Name (First, MI, Last): |       |
|  | b) | Title: |       | [ ]  If PI is a fellow/resident, please check box |
|  | c) | Address: |       |
|  | d) | Institution: |       |
|  | e) | Department: |       | f) | Telephone Number: |       |
|  | g) | Section: |       |
|  | h) | E-mail: |       |
|  | i) | PEER Number: |       |  j) | PEER Expiration Date: |       |
|  | k) | Is your conflict of interest form up to date according to your institutional policies/requirements?       |
|  | l) | 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 |
| 3. | 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: |       |
|  | i) | If any additional study-specific training has been provided, please describe:       | [ ]  None |
| 4. | Are there sub-investigators participating in this protocol? |
|  | [ ]  None | - OR - | [ ]  Yes (Complete Sub-Investigator Information and Signature Form – IRB Form 2B) |
| 5. | Expected Study Completion Date:       |
| 6. | a) | Is this study investigator-initiated? |   |
|  | b) | If investigator initiated, has this study received peer review (or Scientific Review Board (SRB)) from an external funding agency? |  |
|  |  |  i) | If “NO” has this study been submitted for SRB review? Please contact ORI for more information. |  |
|  |  |  ii) | If “NO” submit for SRB review and approval prior to submitting to the IRB. |
|  |  |  iii) | If “YES” submit SRB approval with the initial submission. |
| 7. | Protocol Risk Assessment (choose the **appropriate review/risk category** below): |
|  | [ ]  Expedited Review Eligible **(Minimal Risk or less studies) ONLY)** | [ ]  Full Board Review Required **(Greater than Minimal Risk studies and Minimal Risk studies involving) vulnerable populations)** |

|  |  |
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| 8. | Protocol Type:  |
|  | This section **MUST** be completed for all drug/biologic and/or device studies **regardless** of FDA approval status. For studies that require an IND or IDE, the FDA acknowledgement/approval of the IND/IDE must be attached. For studies granted an IND/IDE exemption, attach the FDA letter granting the exemption. |
|  | a) |  |  | Drug #1 | Drug #2 | Drug #3 |
|  | i) | Drug/Biologic Study: |  |  |  |
|  | ii) | Drug/Biologic Name(if multiple, list:) |       |       |       |
|  | iii) | Is the agent FDA-Approved? |  |  |  |
|  |  | (1) | If yes, is it being used in accordance with approved labeling? |  |  |  |
|  | iv) | IND Required? |  |  |  |
|  |  | (1) | If yes, IND#IND holder |       |       |       |
|  | v) | Drug/Biologic Manufacturer: |       |       |       |
|  | vi) | Expected duration of treatment (drug/biologic administration): |       |       |       |
|  | vii) | Expected duration offollow-up: |       |       |       |
|  | viii) | Will MHRI participating institution’s pharmacist be dispensing the drug or biologic in association with this research activity?       |
|  |
|  | b) |  | Device #1 | Device #2 |
|  | i) | Device Study: |  |  |
|  | ii) | Type of Device Study: |  |  |
|  | iii) | IDE Required? |  |  |
|  |  | (1) | If yes, IDE# |       |       |
|  | iv) | CMS (Billing Category) |  |  |
|  |  | Device Name: |       |       |
|  | v) | Device Manufacturer: |       |       |
|  | vi) | Does this device require training and/or proctoring? |  |  |
|  | vii) | If yes, has training/proctoring been accomplished? |        |        |
| 9. | Other Type of Study: |        |
| 10. | Does this research involve nursing care or the nursing care process? If yes, Chief Nursing Executive (CNE) must sign. |  |
| **B. REGULATORY AND MONITORING INFORMATION** |
| 1. |  |
|  | a) | Does your study have a Data Safety Monitoring Board (DSMB) or Data Safety Committee (DMC)? |  |
|  |  | i) | What are the guidelines for meeting? |  |
|  |  | ii) | If date-specific – provide dates |       |
|  |  | iii) | If enrollment-specific – provide the number to be enrolled for each interim data analysis |       |
|  |  | iv) | Provide the section and page number of the protocol where the data and safety monitoring plan are discussed |       |
|  |  | v) | If this is a sponsored study, does the clinical trial agreement or contract include language requiring the sponsor to submit DSMB reports to the IRB in a timely manner? |  |
|  | b) | If the protocol does not have a data safety monitoring board, describe below how do you plan to monitor the study for safety issues and integrity of the data to be obtained? |
|  |  | i) | Who will monitor the participants? |       |
|  |  | ii) | Who will monitor the data? |       |
|  |  | iii) | What triggers will be used to alert the IRB of safety issues?       |
|  |  | iv) | How will you monitor the participants/data?       |
|  |  | v) | How often will you monitor the participants/data?       |
| 2. | Does this research involve Radiation Use?(Note: Research-indicated (required) radiation means that the subject will be receiving radiation specifically for research purposes and/or the subject will be receiving radiation doses that are not congruent with or outside of the standard of practice. If Research-required radiation is involved, a Radiation Safety Approval letter is required). |
|  |        |
| 3. | Does this research involve Recombinant DNA or gene transfer (manipulation of genetic material or bioengineering)? |
|  |  |
|  | a) | If yes, is an NIH Recombinant DNA Advisory Committee Approval Letter attached? |  |
|  | b) | If yes, is an MHRI Institutional Biosafety Committee (IBC) Approval Letter attached? |  |
| 4. | Does this research involve the use of Biohazardous Materials (known pathogens, infectious agents, hazardous chemicals, and other biological agents and materials potentially hazardous to humans or animals)? |
|  |  |
| **C. LAY SUMMARY OF THE RESEARCH PROTOCOL****Please answer the following in simple (lay terms), non-technical language. The entire summary (Questions 1-5) should total 300 words or less. Please DO NOT copy from the protocol or informed consent documents. This is intended to be a summary of the research activity in layman’s terms.** |
| 1. | List primary objectives and aims: |
|  | *
 |
| 2. | Describe the research design and methods: |
|  | *
 |
| 3. | Describe any potential risks to subjects and how these risks will be minimized: |
|  | *
 |
| 4. | List potential benefits that may accrue to the study subjects/society as a result of their participation: |
|  | *
 |
| 5. | How will study data be collected?All instruments, surveys, and questions must be submitted with this application. (Choose as many as apply from the lists below. If not listed below, include in ‘Other means’ the additional procedures). |
| **[ ]**  | **Surveys**  | [ ]  | **Focus Groups** | **[ ]**  | **Questionnaires** |
| **[ ]**  | **Other means including computerized tasks (e.g. electronic case report forms). Describe**:       |
| 6. | Does the research activity involve any of the following procedures (Choose as many as apply from the drop down lists below. If more than 3, choose “multiple” from the third drop-drop list and list the additional procedures). |
|  |                    |
| **D. STUDY POPULATION**If the protocol research is limited to the use of discarded materials AND there are no identifiers associating the specimens with the donors, **SKIP Section D.** |
| 1. | Please indicate which, if any, of the following populations are involved |
|  | **[ ]**  | **Employees of the Sponsor, Investigator(s), MedStar Health Research Institute, or MedStar Health facilities** |
|  | **[ ]**  | **Non-English Speaking People** (Attach the informed consent form and all applicable materials in the native language(s) of the subjects in the research OR attached the original English consent, back-translated English consent and certifications of translation. Consult ORI staff for guidance.) |
|  | **[ ]**  | **Adults competent to consent for themselves (non-MHRI Staff)** |
|  | **[ ]**  | **Adults that may require a legally authorized representative (LAR) if so, justify below:** |
|  |  |       |
|  | **[ ]**  | **Mentally Incapacitated** (answer question 1a) |
|  | [ ]   | **Children** [Ages 0-17 years] (If children ages 7-17 are involved, you must utilize an assent document unless subjects are deemed incapable of providing assent or otherwise waived by the IRB. Answer question 1a) |
|  | **[ ]**  | **Pregnant Women, Fetuses, or In Vitro Fertilization** |
|  | **[ ]**  | **Prisoners** |
|  | **[ ]**  | **Genetic Research** (Answer question 1b) |
|  | **[ ]**  | **Other vulnerable population (explain:)**  |
|  | a) | Will an assent document(s) be used for children or mentally incapacitated persons? |
|  |  |        |
|  | b) | If this project involves genetic research, is it an optional portion of the research protocol? |
|  |  |  |
| 2. | Inclusion/Exclusion criteria. Please indicate which, if any, of the following populations are **EXCLUDED**. |
|  | **[ ]**  | **Male** |
|  | **[ ]**  | **Female** |
|  | **[ ]**  | **Native American (American Indian)/Alaskan Native** |
|  | **[ ]**  | **Asian or Pacific Islander** |
|  | **[ ]**  | **Black (not of Hispanic origin)** |
|  | **[ ]**  | **White (not of Hispanic origin)** |
|  | **[ ]**  | **Hispanic** |
|  | a) | Provide a brief justification below (in lay terms) for all excluded study populations. (**\*\*REQUIRED\*\***) | [ ]  N/A |
|  |  |       |
| 3. | Total number of subjects to be enrolled in the protocol **(includes all study centers)**: |       |
| 4. | Total number of subjects to be enrolled at MHRI facility(ies) under this submitting PI: |       |
| 5. | **Subject recruitment:** Provide a summary of how subjects will be recruited. Indicate if any medical records or databases will be screened to identify prospective participants. Include location of recruitment and enrollment. (Please attach a copy of all recruitment flyers, advertisements, telephone scripts, etc.) |
|  |  |       |
|  | a) | Type of subject recruitment (check ALL that apply): |
|  |  | [ ]   | Direct person to person solicitation per consent form |
|  |  | [ ]   | Telephone scripts (attach oral presentation) |
|  |  | [ ]   | Letter (attach finalized copy) |
|  |  | [ ]   | Notices (attach finalized copy) |
|  |  | [ ]   | Internet (attach finalized copy) |
|  |  | [ ]   | Subject pool |
|  |  | [ ]   | Database (HIPAA waiver required) |
|  |  | [ ]   | Other (Explain and/or attach finalized copy if applicable): |
| 6. | What rewards, remuneration, or other incentives, if any, will be provided to subjects? |
|  |        |
| **E. INFORMED CONSENT**Written documentation of informed consent from the subject or from the subject’s legally authorized representative is normally required. The finalized informed consent document (in all applicable languages) should be included with the materials submitted to the IRB unless the PI is requesting a waiver or alteration of informed consent requirements. Investigators must keep all signed informed consent documents in a locked and confidential location for a period of six (6) years after termination of the research. |
| 1. | Is a waiver/alteration of informed consent requirement(s) being requested?(If applicable, attach IRB Form 8A, as indicated) |
|  |        |
| 2. | What native languages, other than English, is the study population expected to speak?(If none, then SKIP Questions 3 and 4) | [ ]  None |
|  |       |
| 3. | Do you plan to make consent forms available in the native language for all subjects involved in the research? |
|  |  |
|  | a) | If no, explain your procedures in determining the primary language spoken by the subjects and how you plan to deliver the informed consent process to subjects who do not speak English: |
|  |  |       |
| 4. | Will research staff be fluent in this/these language(s) or will a professional interpreter be available for the informed consent process? | [ ]  None |
|  |       |
| **F. INTERNAL/EXTERNAL FUNDING**Please specify the source of any funding for the research. Check all that apply and provide specific information where requested. If funding is not yet obtained, please specify intended source(s) and indicate pending). |
| 1. | Funding Source: |
|  | [ ]   | FEDERAL (Specify Agency:      ) |
|  | [ ]   | INDUSTRY SPONSORED (Specify Company:      ) |
|  | [ ]   | MHRI Intramural Grant (Specify Grant No.      ) |
|  | [ ]   | Local Department (Specify Department:      ) |
|  | [ ]   | GHUCCTS (CTSA) |
|  | [ ]   | Other:       |
|  | [ ]   | None |
| 2. | Is the study budget being processed through MHRI Office of Contracts and Grants Management (OCGM)? |
|  |        |
| 3. | Will the study require a procedure? |  |
|  | a) | If yes, is the procedure reimbursable? (Choose all that are applicable) |
|  |  | [ ]   | Yes, by Sponsor |
|  |  | [ ]   | YES, by Commercial Insurance |
|  |  | [ ]   | Yes, by Medicare |
|  |  | [ ]   | No |
|  |  | [ ]   | Study involves multiple procedures (specify whether or not each procedure may be reimbursed and how): |
|  |  |  |       |
| 4. | Will the study require a hospital stay? |  |
|  | a) | If yes, is the hospital stay reimbursable? (Choose all that are applicable) |
|  |  | [ ]   | Yes, by Sponsor |
|  |  | [ ]   | Yes, by Commercial Insurance |
|  |  | [ ]   | Yes, by Medicare |
|  |  | [ ]   | No |
| 5. | Does this study involve a drug or device? |  |
|  | a) | Is the drug/device provided free of charge? |  |
|  | b) | Does the drug/device require purchase by the MHRI Institution? |  |
|  | c) | Is the drug/device reimbursable? (Choose all that apply) |
|  |  | [ ]   | Yes, by Sponsor |
|  |  | [ ]   | Yes, by Commercial Insurance  |
|  |  | [ ]   | Yes, by Medicare |
|  |  | [ ]   | No |
|  |  | [ ]   | Study involves multiple drugs/devices (specify whether or not each product may be reimbursed and how) |
|  |  |  |       |

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| **G. CLINICAL TRIALS.GOV REGISTRATION** |
| Potential risks associated with failure to register with [clinicaltrials.gov](http://clinicaltrials.gov/ct2/manage-recs/background):* Loss of funding (National Institute of Health)
* Financial penalty levied against the PI
* Denial of publication (ICMJE)
* Denial of payment to healthcare providers.

The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Behavioral interventions and behavioral treatments include behavioral treatments such as an experimental treatment design. Research projects that meet the ICMJE definition may not be accepted for publication if they are not registered in a registry that is electronically searchable and accessible to the public at no charge. For more information on this requirement see <http://www.icmje.org> Note that retrospective registration of projects is not allowed.**Please contact ORI for additional information and registration assistance.** |
| **CLINICALTRIALS.GOV REGISTRATION DETERMINATION** |
| 1. **Is this project registered with clinicaltrials.gov?**
 |
| [ ]  Yes [ ]  No | **Clinicaltrials.gov registration number:**If registration is pending enter “pending” in the space provided. After review, the IRB may determine that clinicaltrials.gov registration is required. The PI will be notified of this decision along with resources to assist with the registration process. |

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| **H. PRINCIPAL INVESTIGATOR SIGNATURE** |
| As Principal Investigator of the aforementioned protocol, I certify that:1. To the best of my 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, but not limited to: design study and plan, recruitment and screening strategies and material, investigational product information (as applicable), informed consent procedures, and applicable HIPAA documentation).
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, including (but not limited to) changes in inclusion/exclusion criteria, procedures, sub-investigators, sponsor, funding agencies, informed consent documentation or procedures, recruiting materials, patient education materials, etc.
3. I will comply with all IRB policies and procedures.
4. I am aware that the signed consent forms need to be filed in a secure area with limited and documented access for a period of six (6) years upon termination of the research per MedStar Health Record Retention Policy. These consent forms will be available for inspection by an IRB designee, monitors and/or auditors of the Sponsor or agents from Federal Agencies.
5. I will **promptly report** any serious, unexpected events, unanticipated problems, or significant new findings that arise throughout the course of the research. Congruent with MHRI policy, **I will report any serious and unexpected adverse events and/or unanticipated problems within 24 hours** of knowledge of the event (per MHRI policy).
6. I will comply with all IRB requests to report on the status of the study and **I will maintain an active IRB approval**. I agree to submit all requests for Continuing Review no later than *forty-five (45) days* prior to the annual expiration of the project. Furthermore, I understand that I am required to file a final report upon conclusion of the research with the Institutional Review Board.
7. I will maintain accurate and complete regulatory records in association with this study.
8. I understand that if my research is under a sponsored research agreement, additional requirement may apply.
9. I understand that the Institutional Review Board has the authority to place on administrative hold or to administratively terminate any research project for which the aforementioned conditions are not met.
 |
|      Typed Name of Principal Investigator | Signature of Principal Investigator | Date of Signature |
| **I. DEPARTMENT CHAIR/ADMINISTRATOR SIGNATURES**The Department Administrator and Department Chairman of the respective administrative unit MUST sign this application. If the research activity involves an investigational drug or biologic, the signature of the Research Pharmacist must be obtained. Signatures of Alternate Authorities: in the event an Alternate Administrator/Chair has the authority to approve research projects in the absence of the Administrator/Chair, a memo acknowledging or granting the Alternate Administrator/Chairman authority to approve new research protocol applications should be placed on file with the ORI. |
| I have read this completed form and endorse the aforementioned research to be conducted. |
|      Typed Name/Title of Research Pharmacist | Signature of Research Pharmacist | Date of Signature |
|      Typed Name/Title of Department Administrator | Signature of Department Administrator | Date of Signature |
|      Typed Name/Title of Section Chair | Signature of Section Chair | Date of Signature |
|      Typed Name/Title of Department Chairman/Dean/Director | Signature of Department Chairman/Dean/Director | Date of Signature |
|      Typed Name/Title of Chief Nursing Executive (CNE) | Signature of Chief Nursing Executive | Date of Signature |
|      Typed Name/Title of Vice President Medical Affairs | Signature of Vice President Medical Affairs | Date of Signature |