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| **FORM:** Application for Initial Review | | |
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| **Use for newly proposed research**  *(Make copies of pages as needed)* | | | |
| **Grant/Protocol Number:** |  | | |
| **Protocol Name:** |  | | |
| **Investigator:** |  | | |
| **Primary Contact:** |  | | |
| **Clinicaltrials.gov NCT Number: (if applicable)** |  | | |
| **Funding Sources** | | | |
| **Name of Funding Source** | | **Funding Source ID** | **Grant Office ID** |
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| **Parent Protocol** | | | |
| **Protocol Name** | | | **IRB Number** |
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| **All Individuals listed below are required to complete the “FORM: Contact Information (HRP-201)”.** | | | |

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| **Name of Research Personnel (Other than PI)** | **Name of Research Personnel (Other than PI)** |
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Provide the following documents: *(Omit starred (\*) items if this is the activation of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those*

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*sites.)*

Point-by-point response *(When in response to modifications to secure approval, deferral, or disapproval)*

For any financial interest related to the research, Conflict of Interest Committee’s determination.

FORM: HRP-201, Contact Information – is to be completed for each research personnel on the study

FORM: Application for Initial Review (HRP-211), including as applicable:

o Appendix A: External Site Approvals

o Appendix B: Drugs and Device (include associated attachments, such as package insert, investigator

brochure, or labeling, verification of IND/ IDE number)\*

 Investigator Protocol **with Version Date** (See TEMPLATE PROTOCOL (HRP-503) for instructions)

• Written material to be provided to or meant to be seen or heard by subjects

o Evaluation instruments and surveys\*

o Advertisements (printed, audio, and video)

o Recruitment materials and scripts

o Consent documents *(The IRB does not require an informed consent document for HUD use.)*

o If consent will not be documented in writing, a script of information to be provided orally to subjects

o Foreign language versions of the above

Complete sponsor protocol including DHHS-approved protocol, if any\*

DHHS-approved sample consent document, if any \* Grant application, if any

If the research is conducted or funded by the Department of Energy (DOE), a completed “Checklist for IRBs to Use in

Verifying that HS Research Protocols are In Compliance with Department of Energy (DOE) Requirements”

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| **Department Chair or Supervisor Approval** | |
| As the Department Chair, the Principal Investigator is qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. The PI meets all the qualifications specified by the applicable regulatory requirement(s), and can provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authority(ies).  The Department Chair agrees to accept responsibility for the scientific review and the principal investigator’s conduct of the project and will ensure the Principal Investigator provides the required progress reports if a grant is awarded as a result of the application.  I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research in terms of time, facilities, staff, access to a subject population, and resources for care than subjects may need. | |
| Departmental Chair or Supervisor Signature | Date |
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| Drexel University College of Medicine Vice Dean for Research Signature  (**Required for College of Medicine faculty and staff when protocol has NO external funding**) | Date |
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| **Investigator Acknowledgement** | |
| As the Principal Investigator, you are qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. You meet all the qualifications specified by the applicable regulatory requirement(s), and can provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authority(ies).  The Principal Investigator agrees to accept responsibility for the scientific review and conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.  By signing below you are verifying that:  You have obtained the financial interest status (“yes” or “no”) of each research staff member.  You have obtained the agreement of each research staff to his/her role in the research.  You will conduct this Human Research in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103). | |
| Investigator Signature | Date |
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**Appendix A: External Sites**

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**Complete for each external site at which the investigator will conduct or oversee the research**

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| **Site name:** |  |
| **Contact name:** |  |
| **Contact phone or email** |  |
| Yes  No | Will the site’s IRB review the research? |
| Yes  No | Will the site rely on this institution’s IRB? |

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| **Site name:** |  |
| **Contact name:** |  |
| **Contact phone or email** |  |
| Yes  No | Will the site’s IRB review the research? |
| Yes  No | Will the site rely on this institution’s IRB? |

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| **Site name:** |  |
| **Contact name:** |  |
| **Contact phone or email** |  |
| Yes  No | Will the site’s IRB review the research? |
| Yes  No | Will the site rely on this institution’s IRB? |

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| **Site name:** |  |
| **Contact name:** |  |
| **Contact phone or email** |  |
| Yes  No | Will the site’s IRB review the research? |
| Yes  No | Will the site rely on this institution’s IRB? |

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| **Site name:** |  |
| **Contact name:** |  |
| **Contact phone or email** |  |
| Yes  No | Will the site’s IRB review the research? |
| Yes  No | Will the site rely on this institution’s IRB? |



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| **Appendix B** | | | | | | |
| **Drugs** | | | | | | |
| **List all (1) Unapproved drugs being used; (2) Approved drugs whose use is specified in the**  **protocol; (3) Foods or dietary supplements being evaluated to diagnose, cure, treat, or mitigate a disease or condition:** | | | | | | |
| **Generic Name** | | | **Brand Name** | | | **IND #**  **(or none)** |
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| For each approved drug include a copy of the package insert.  For each drug with an IND number, ensure that the application includes one of the following: Current investigator brochure  Sponsor protocol with the IND number  Communication from the sponsor with the IND number | | | | | | |
|  |  | Communication from the FDA with the IND number | | | | |
| **Devices** | | | | | | |
| **List all (1) devices being evaluated for safety or effectiveness or (2) HUDs being used:** | | | | | | |
| **Name** | | | | **IDE/HDE # (or none)** | **Claim of an Abbreviated IDE** | **Humanitarian Use Device (HUD)** |
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| For each approved include a copy of the product labeling.  For each device with an IDE/HDE number, ensure that the application includes one of the following: Sponsor protocol with the IDE/HDE number  Communication from the sponsor with the IDE/HDE number  Communication from the FDA with the IDE/HDE number | | | | | | |