## Sponsor Study Information Sheet

## *Sponsor-Initiated Studies*

 **Date form completed: Click here to enter text.**

|  |  |
| --- | --- |
| **Sponsor Protocol Number: Click here to enter text.** | **Sponsor Protocol Title: Click here to enter text.** |
| **Participant Information:**  **Gender:**  Male  Female  All  **Minimum Age:** **Click here to enter text.** **Maximum Age:** **Click here to enter text.**  **Accepts Healthy Volunteers?**  Yes  No | |

Sponsor/CRO Contacts:

*Legal Contact Information (responsible for contract terms)*

|  |  |
| --- | --- |
| Name **Click here to enter text.** | Email **Click here to enter text.** |

***Financial Contact Information*** *(responsible for budget and payment terms)*

|  |  |
| --- | --- |
| Name **Click here to enter text.** | Email **Click here to enter text.** |

***Invoicing Contact Information*** *(responsible for payments after agreement becomes effective)*

|  |  |
| --- | --- |
| Name **Click here to enter text.** | Email **Click here to enter text.** |

***Regulatory Contact Information*** *(responsible for receiving regulatory documents)*

|  |  |
| --- | --- |
| Name **Click here to enter text.** | E-mail **Click here to enter text.** |

***CRO Contact Information*** *(If applicable)*

|  |  |
| --- | --- |
| Name **Click here to enter text.** | Email **Click here to enter text.** |

External IRB contact:

|  |  |
| --- | --- |
| Name **Click here to enter text.** | Email **Click here to enter text.** |

|  |
| --- |
| ***Required Documents – All documents listed below – if applicable to the protocol - must be provided with the completed Study Information Sheet in order to begin the site activation process.*** |
| Final Protocol **Click here to enter text.** |
| Draft Clinical Trial Agreement (including payment terms) in Word editable format **Click here to enter text.**   1. Will biological specimens be sent to the Sponsor or a central lab as part of this study?  Sponsor  Central Lab  Not applicable    * If yes, for what purpose? **Click here to enter text.** 2. Will the Sponsor or central lab send samples and/or data to any other entity?  Sponsor  Central Lab  Not applicable  * Please provide names, addresses, and contact number for all entities receiving samples or data, and for what purpose (information required for IRB application):  |  |  |  |  | | --- | --- | --- | --- | | Organization | Contact Name, Address, Phone/Email | Please indicate if this contact will receive samples or data | Please indicate purpose for sharing samples/data | |  |  | Samples  Data |  | |  |  | Samples  Data |  | |  |  | Samples  Data |  | |  |  | Samples  Data |  |  * Please list what is being sent to whom and for what purpose: **Click here to enter text.** |
| Draft Budget   * Expected/actual start of global enrollment (date): **Click here to enter text.** * Expected end of global enrollment (date): **Click here to enter text.** * # of treatment cycles **Click here to enter text.** * # of budget periods **Click here to enter text.** * Is the drug/device provided at no cost?  Yes  No   + If no, please indicate cost to UMMC: **Click here to enter text.** * Non-standard of care procedures  Yes  No |
| Draft Informed Consent **Click here to enter text.** |
| Any Patient Contact Material (questionnaires, diaries, etc.) to be used in the study **Click here to enter text.** |
| Laboratory/Pathology Manual(s) |
| Investigator Brochure **Click here to enter text.** |
| Device Manual **Click here to enter text.**   * Has CMS approval been obtained?  Yes  No |
| Imaging Manual(s) **Click here to enter text.**   * Is Sponsor willing to accept UMMC standard imaging?  Yes  No * Is central review of images required?  Yes  No * Do you anticipate the transfer of images?  Yes  No * Will RECIST or additional non-SOC criteria be required?  Yes  No |
| ClinicalTrials.gov registration number **Click here to enter text.** |
| Pharmacy Manual(s). |
| **Equipment/Software:**   * 1. Are you providing equipment that requires electricity?  Yes  No   2. Are you providing a technology solution that could potentially connect to the UMMC network? (i.e. Laptop, iPad, lab equipment, ECG machines, CT, MRI, software, etc.) (This would include connecting for software updates, maintenance, or IT support)   Yes\*  No  If “Yes,” please provide specs and security information: **Click here to enter text.** |
| **Pregnancy:**   1. Pregnancy testing to be performed locally or central lab?  Local lab  Shipped to central lab 2. Is the company providing urine pregnancy test kits?  Yes  No |
| **Institutional Biosafety:**   1. Does the study involve recombinant DNA (rDNA), is classified as a Human Gene Transfer project, or uses a known infectious agent?    Yes     No |
| **Recruitment Materials**   1. Will the study use patient contact materials that will be submitted to the IRB?   Recruitment materials  Phone scripts  Patient letters  Advertising materials  Patient completed forms (pill diaries, questionnaires, etc.) |