|  |  |
| --- | --- |
| **DEPT/SPONSOR TIMELINES** | |
| UNMC Target Enrollment | Enter date. |
| Enrollment Opened | Enter date. |
| Enrollment Closes | Enter date. |
| Add-on Site | Yes  No |

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**Industry-Sponsored Clinical Trial Questionnaire**

Phase:        Compassionate Use/Expanded Access  Emergency Use

**SUBMISSION INSTRUCTIONS**: Email following to [amanda.leingang@unmc.edu](mailto:amanda.leingang@unmc.edu):

* Fully-editable contract template
* Protocol
* Completed Questionnaire

|  |  |  |
| --- | --- | --- |
| **UNMC CONTACTS AND STATUS** | | |
| INVESTIGATOR |  | |
| STUDY COORDINATOR |  | |
| BUDGET NEGOTIATION | CRC  DEPT NAME: STATUS | Choose an item. |
| IRB SUBMISSION | CRC  DEPT NAME:  STATUS | Choose an item. |
| REGULATORY IRB # | UNMC Review  Chesapeake Review | |
| COVERAGE ANALYSIS SUBMITTED TO CRC IF REQUIRED:  Yes  No | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **SPONSOR INFORMATION** | | | |
| SPONSOR |  | | | |
| CRO |  | | | |
| NEGOTIATOR CONTACT  *Name and Email required* |  |  |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **STUDY INFORMATION** | | | |
| STUDY TITLE |  | | |
| PROTOCOL # |  | | |
| PET NAME IF APPLICABLE |  | | |
| OTHER NCT# IND #  IDE #  HUD # | [ClinicalTrials.gov](https://clinicaltrials.gov/)) | Drug only  Device only  Device and drug | Inpatient  Outpatient  Both |
| |  |  |  |  | | --- | --- | --- | --- | | **INTERNAL FORMS** | | | | | INTERNAL FORMS SUBMISSION | STATUS | Choose an item. | ***Submit forms as soon as contract budget is final.*** | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **BUDGETED PERSONNEL** | **ROLE ON STUDY** | **PRIVATE PRACTICE / ENTITY** | **COMMENTS** | |  |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | | | | |

*Please remind all personnel on budget to update COI-Smart as needed.*

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| **FACILITIES & DEVICE STORAGE** | | |
| *(check all that apply)* | Nebraska Medicine­–TNMC  Nebraska Medicine–Bellevue  VA  Children’s Hospital  Creighton Medical Center  Grand Island–Saint Francis  North Platte–Great Plains  Village Pointe Medical Center  Internal Med Associates of Grand Island  Other: | Nebraska Medicine Services:  Biological Production Facility  Cath Lab  Clinical Research Center (CRC)  CT / MR  Dialysis  GI  Infusion Center  Pharmacy  Radiology  Surgery  Other: |
| DEVICE STORAGE LOCATION  *(See NE Medicine Policy MI29)* |  | |

|  |  |
| --- | --- |
| **CONFIDENTIALITY AND INTELLECTUAL PROPERTY** | |
| Has investigator signed CDA/NDA? | No  Yes, signed by investigator only  Yes, signed by institutional signatory |
| Does investigator have relationship with sponsor that’s reportable in COI-SMART? (See [UNMC Policy 8010](http://www.unmc.edu/policy/index.cft?L1_ID=18&L2_ID=20&CONREF=149)) | No  Yes |
| Does investigator have invention disclosure, patent filing or IP agreement on file or pending with UNeMed? | No  Yes, related to subject matter  Yes, unrelated to subject matter |

|  |  |  |
| --- | --- | --- |
| **PI-INITIATED** | **IF PI-INITIATED** | **SUB-SITES** |
| Yes  No  If no, did PI contribute to protocol?  Yes  No | PI filed IND  PI filed IDE  PI requested IND exemption  If no to all of the above, please explain. | Yes  No  Please list sites: |

|  |
| --- |
| **OTHER INFORMATION** |
| *Please tell us anything else you or the investigator would like us to know for contracting purposes.*  *Example: Are there preferences regarding data protection? How about publication rights? Are students participating who need to publish? Can you think of other important information we should know?* |

Submitted by:       Date:

cc: Department Administrator