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| **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:

* Fully-editable contract template
* Protocol
* Completed Questionnaire

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| **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  |

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

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| **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 |
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| **INTERNAL FORMS** |
| INTERNAL FORMS SUBMISSION |  STATUS | Choose an item. | ***Submit forms as soon as contract budget is final.*** |

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| **BUDGETED PERSONNEL**  | **ROLE ON STUDY** | **PRIVATE PRACTICE / ENTITY** | **COMMENTS** |
|       |       | [ ]        |       |
|       |       | [ ]        |
|       |       | [ ]        |
|       |       | [ ]        |
|       |       | [ ]        |
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*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)* |       |

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| **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 |

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| **PI-INITIATED** | **IF PI-INITIATED** | **SUB-SITES** |
| [ ]  Yes[ ]  NoIf no, did PI contribute to protocol?[ ]  Yes[ ]  No | [ ]  PI filed IND[ ]  PI filed IDE[ ]  PI requested IND exemptionIf no to all of the above, please explain.      | [ ]  Yes[ ]  NoPlease list sites: |

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| **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