**Sponsored Programs Administration Contract Intake**

To initiate the contract review process, email the following to spacontracts@unmc.edu:

* This form, signed & dated by the PI
* Fully editable contract template
* Protocol/Scope of Work

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| **UNMC CONTACTS & STATUS** |
| Principal Investigator:        | Department:       |
| Study Coordinator:        |

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| **SPONSOR INFORMATION** |
| Sponsor:       |
| Cooperative Group/CRO:       |
| Sponsor Contact for Contract Negotiation  | Name:        | Email:       |

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| **STUDY INFORMATION**  |
| Study Title:       | Anticipated start date:       |
| Select all study types that apply: | [ ]  Clinical [ ]  Phase:       | [ ]  Data Registry  | [ ]  Laboratory research |
| [ ]  Inpatient only | [ ]  Drug only | [ ]  Chart review  |
| [ ]  Outpatient only | [ ]  Device only | [ ]  Data analysis |
| [ ]  Inpatient & outpatient  | [ ]  Device & drug | [ ]  Consulting |
| [ ]  Other, Please Describe:       |

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| **PI-INITIATED**  |
| Is this Study PI-initiated? [ ]  Yes [ ]  No If no, did PI contribute to protocol? [ ]  Yes [ ]  No |
| Are there Sub-sites (Subcontracts)? [ ]  Yes [ ]  No  |  If yes, list sites/contacts:       |

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| **BUDGET**  |
| Who is negotiating the budget?  |  [ ]  Department [ ]  CRC [ ]  UNeMed  | Name:       |
| Is study fully funded by Sponsor? [ ]  Yes [ ]  No  | Please identify other sources of funding:       |
| Will any federal funds be used for this study? [ ]  Yes [ ]  No |
| The budget must incorporate the appropriate direct and indirect costs, which are available at <https://www.unmc.edu/spa/about/institutional.html>.  |

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| **REGULATORY**  |
| Is an IRB required? [ ]  Yes [ ]  No  | IRB number:        | [ ]  UNMC Review [ ]  External Review |
| Is an IACUC required? [ ]  Yes [ ]  No  | IACUC number:       |
| Is an IBC required? [ ]  Yes [ ]  No  | IBC number:       |

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| **FACILITIES**  |
| Select all sites that apply to this study:  | [ ]  UNMC  | [ ]  Nebraska Medicine  | [ ]  Children’s Hospital  |
| [ ]  CHI/Creighton | [ ]  Biologics Production Facility  | [ ]  Methodist |
| [ ]  VA | [ ]  Other       |

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| **CONFIDENTIALITY & INTELLECTUAL PROPERTY** |
| Is there an executed Confidentiality Disclosure Agreement (CDA) or Nondisclosure Agreement (NDA) for this project? | [ ]  No [ ]  Yes, signed by PI [ ]  Yes, signed by institutional signatory |
| Does PI have an invention disclosure or patent filing on file with UNeMed that is related to subject matter? | [ ]  No[ ]  Yes |
| Does PI have a relationship with sponsor/funding agency that is 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 |
| How likely is it that a new discovery, invention, process, biological material, or research tool will result from **your personal contribution or the contribution of other UNMC personnel** on this study? | [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 *(1 = not at all likely and 5 = high likely)* |
| Does PI intend to publish the results of the study? | [ ]  No[ ]  Yes, independent of sponsor [ ]  Yes, in collaborative with sponsor |
| IS PI willing to transfer ownership of all data resulting from the study to the study Sponsor? | [ ]  Yes [ ]  No |
| Will students be involved in the conduct of the study? | [ ]  Yes [ ]  No |

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| ADDITIONAL COMMENTS:       |

**Principal Investigator Certification**

I certify that I am not under investigation by the FDA for debarment action or presently debarred pursuant to the generic drug enforcement act of 199 (21 U.S.C. § 335(a) and (b), as amended from time to time). Additionally, I represent that I have not been disqualified from participating in a clinical trial pursuant to 21 CFR § 312.70, as amended from time to time.

PI Signature: Date: