**Sponsored Programs Administration Contract Intake**

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