**Sponsored Programs Administration Contract Questionnaire**

**Revised 12/15/2017**

**Purpose**

The contract questionnaire serves two purposes:

1. Guides SPA in negotiating contract terms and establishing workable timelines.
2. Certifies investigator compliance with FDA regulations per PI signature

**Instructions**

Submit the following to SPA, ideally in a single email to [spacontracts@unmc.edu](mailto:spacontracts@unmc.edu):

1. PDF of Contract Questionnaire, completed and signed by the PI
2. Protocol
3. Contract template (fully-editable)

**OR…check out the new user-friendly contract questionnaire in ADIS!**

Industry contract submissions to SPA just got easier. Based on user feedback, the “contract intake” has undergone a significant makeover:

* Navigation is now more intuitive.
* New mouse-over definitions have been added to guide users.
* Work-in-progress can be easily saved and re-accessed.

Unlike relying on a free-form system like email to submit new studies to SPA, the electronic questionnaire in ADIS **supports coordinators** by:

* Guiding users to provide what SPA needs for strong negotiations
* Serving as a parking lot for study documents during start-up
* Offering electronic signature capability so PIs can sign and route to SPA for negotiation, even when off-site.

Interested? Please email [spacontracts@unmnc.edu](mailto:spacontracts@unmnc.edu) or call 9-7456 to request user rights or one-one-one training.

If you have any questions, call 9-7456 for assistance.

**UNMC Contacts**

Principal Investigator       Department

Study Coordinator       Department

**Study Information**

Sponsor

CRO(if applicable)

Study Title

Protocol/Study ID

**Sponsor/CRO Contact for Contract Negotiations**

Name

Direct Line

Email Address:

**Timeline**

1. Is enrollment competitive?  Yes  No
2. When does enrollment close?
3. What is the status of budget negotiations?  Complete  In progress  Not started

**Study Type**

4. Is this study a clinical trial?  Yes  No

4a. If yes, please indicate study phase:  I  II  III  IV  Compassionate Use

4b. Please identify study participants:  Inpatient

Outpatient

Both inpatient and Outpatient

4c. If this is not a clinical trial, how would

you describe it?  Testing

Laboratory Research

Registry

Other (Describe)

1. Is this a device study?  No

Yes, device only

Yes, device and drug

1. Is this a PI-initiated study?  Yes  No

6a. If no, did you contribute to the drafting

of the protocol?  Yes  No

6b. If yes, have you or do you intend to file

an IND/IDE or seek IND exemption?  IND

IND exempt

IDE

Other (describe)

6c. If yes, does this study involve sub-sites?  Yes  No

6d. If yes, list sub-sites involved:

1. If you are receiving or have received federal funds

for research, are the funds related to this study?  Yes  No

**Study Conduct**

1. Does this study require use of non-UNMC facilities  Yes  No

or personnel?

8a. If yes, please identify the location of the facilities

to be used:  TNMC (if checked, please answer 8b.)

Bellevue Medical Center

VA

Children’s Hospital and Medical Center

Creighton University Medical Center

Grand Island - Saint Francis Medical Center

North Platte – Great Plains Regional Med Center

Village Pointe Medical Center

Other (please specify)

8b. What TNMC facilities/services will be required/utilized for this study?

Pharmacy  Clinical Research Center (CRC)

Biologics Production Facility  Surgery

Dialysis  Cath Lab

Radiology  CT/MR

GI  Other (be specific)

Infusion Center

8c. Please provide name, role on study, and contact information for all non-UNMC personnel involved in the conduct of the study.

9. Has this study been listed in a clinical trials registry?  Yes  No

9a. If yes, please specify: Registry name:

Registration number:

**Confidentiality and Intellectual Property**

1. Have you signed a confidential disclosure agreement

(CDA/NDA) related to this study?  No

Yes (signed by UNMC per Board of Regents policy)

Yes (signed by PI)

1. Do you have a relationship (e.g. consulting,

Data Safety Monitoring Board, Advisory Board) with

the sponsor/funding agency(ies) which would be

reportable in COI-SMART pursuant

to [UNMC Policy 8010](http://www.unmc.edu/policy/index.cft?L1_ID=18&L2_ID=20&CONREF=149)?  Yes  No

11a. If yes, please specify the type of arrangements:

1. Do you have an invention disclosure, patent filing, or any

IP agreement on file or pending with UNeMed?  No

Yes, related to subject matter of this study

Yes, unrelated to subject matter of this study

1. 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 = not at all likely and 5 = high likely)  1  2  3  4  5

1. Do you intend to publish the results of the study?  Yes  No
2. Will students be involved in the conduct of the study?  Yes  No
3. Are you willing to transfer ownership of all data

resulting from the study to the study sponsor?  Yes  No

**Regulatory Affairs**

1. Is an IRB required for this study?  Yes  No

17a. If yes, has protocol been submitted to IRB?  Yes  No

If yes, please provide IRB number.

17b. Does study include **children** as human subjects?  Yes  No

17c. Does study include **adults** as human subjects?  Yes  No

1. Will animals be used on this study?  Yes  No

18a. If yes, has protocol been submitted to IACUC?  Yes  No

If yes, please provide IACUC number.

1. Does your research use recombinant DNA and/or

microbiological agents in any assay?  Yes  No

19a. If yes, are your experiments covered by the

NIH guidelines for research involving recombinant

DNA molecules? (refer to section iii. Of the guidelines

available as a resource on the [IBC website](http://www.unmc.edu/ibc))  Yes  No

19b. Has protocol been submitted to the IBC?  Yes  No

If yes, please provide IBC number.

**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**

**Printed Name**

**Date**