**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:

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 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**