

# Electronic Intake User Manual for Industry-Sponsored Contracts

## ADIS Entry Point

What is ADIS? ADIS stands for Academic Department Information System

Use the following steps to gain access to ADIS

Those using ADIS for the New Electronic Intake Process will need to contact Sponsored Programs Administration to be assigned appropriate security access for ADIS

**Note:** If you attended training sponsored by SPAdmin, your security access has been set up

## Steps for ADIS Login

Begin at UNMC's intranet home page (info.unmc.edu)



Click on the Quick Links button and the following screen will appear

## Quick Links

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>2007-2008 Campus Accomplishments Report</li> <li>Strategic Plan                         <ul style="list-style-type: none"> <li>- Detailed Plan</li> <li>- Chancellor's Retreat</li> <li>- Planning Info &amp; Quality Indicators</li> <li>- Prioritization of Academic Programs</li> </ul> </li> <li>Academic Services                         <ul style="list-style-type: none"> <li><b>ADIS - Academic Department Information System</b></li> <li>Announcements</li> <li>BlackBoard Online Courses</li> <li>BookStore (UNMC)</li> <li>Calendar of Events</li> <li>Center for Clinical and Translational Research</li> <li>Center for Continuing Education</li> <li>Center for Healthy Living</li> <li>Children's Hospital Affiliation</li> <li>Compliance                                 <ul style="list-style-type: none"> <li>- Access to Training</li> <li>- Clinical Research Billing</li> <li>- Conflict of Interest</li> <li>- Record Retention</li> </ul> </li> <li>DRC website</li> <li>Employee Self Service (Med Center)</li> <li>Employee Self Service (SAP)</li> <li>Employee/Students Discount Program</li> <li>Events Center</li> <li>Faculty Senate</li> <li>Firefly</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>General Supply Catalog</li> <li>Hand Hygiene</li> <li>Healthy U</li> <li>IDs/ Passwords</li> <li>Jobs@UNMC</li> <li>Library</li> <li>Media guide for faculty &amp; staff</li> <li>MercuryMD MData</li> <li>NCA-HLC reaccreditation process</li> <li>Ombuds Team</li> <li>Policies/Procedures</li> <li>Physician Carecast Training</li> <li>Printshop@UNMC</li> <li>Room Scheduling</li> <li>RSS (Research Support Systems)</li> <li>Software Downloads</li> <li>Sponsored Programs Administration</li> <li>Story Ideas</li> <li>Student Senate</li> <li>The Nebraska Medical Center</li> <li>The Nebraska Medical Center Intranet</li> <li>Travel Services</li> <li>UNeMed (Intellectual Property and Technology Transfer)</li> <li>UNMC Physicians</li> <li>UNMC Physicians Intranet</li> <li>Viruses - Current Computer Virus Threats</li> <li>WebOncall</li> <li>WebOncall Tutorial</li> </ul> |
|--|--|

Click on the ADIS link and the following screen will appear

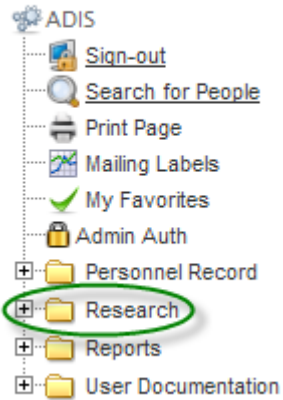
The screenshot shows the University of Nebraska Medical Center website. At the top, there is a navigation bar with 'UNMC' on the left and 'CONTACT US', 'DIRECTORY', and a search box on the right. Below this is the university's logo and name. A secondary navigation bar contains 'About Us', 'Education', 'Research', and 'News & Events'. The main content area features a large orange banner with the text 'ADIS - Academic Department Information System'. Below the banner, there is a login form with two input fields: 'Enter your UNMC NetID: [help?](#)' and 'Enter your password:'. A 'Continue' button is positioned below the password field. To the right of the form is a square logo with 'ADIS' in large white letters and 'University of Nebraska Medical Center' in smaller text below it. At the bottom of the page, there is a footer with the university logo on the left, copyright information in the center, and a red box on the right containing the text 'LOG IN: Blackboard, UNMC Intranet, Lotus Notes, Library'.

Enter your Lotus Notes user name and pass word to enter the ADIS application and click continue

### Navigation of the ADIS web site

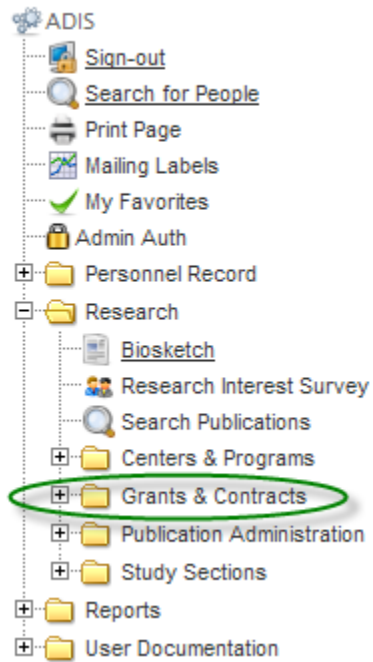
For navigation use the navigation tree on the left-hand side of the screen

[open all](#) | [close all](#) | [home](#)



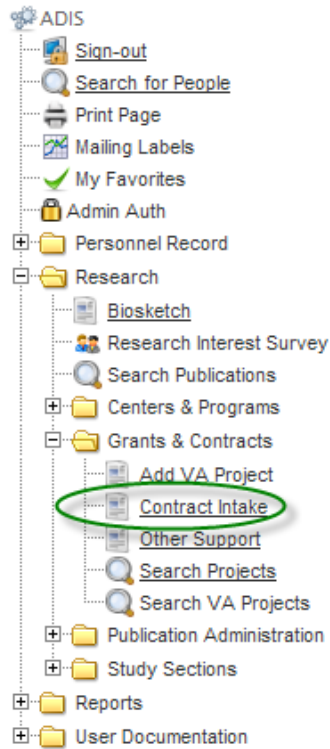
Click on the + sign in front of the research folder

[open all](#) | [close all](#) | [home](#)



Click on the + sign in front of the grants & contracts folder

[open all](#) | [close all](#) | [home](#)



Click on the Contract Intake button

## Begin Contract Intake Data Entry

Contract Intake Search appears

Before you can enter a new contract, it is essential to search for one that may already be in progress. Use the screen below for that search

A screenshot of a web form titled 'Sponsored Programs Administration Contract Intake Search'. The form has several input fields and buttons. The 'Last Name:' field is circled in green. The 'First Name:' field is empty. The 'Department:' field is a dropdown menu with a blue arrow pointing down. To the right of the 'Department:' field are 'Search' and 'Reset' buttons. Below these fields is a 'Contract Web ID: Sponsor:' label. The 'Contract Web ID' field contains the number '0'. The 'Sponsor:' field is a dropdown menu with a blue arrow pointing down. To the right of the 'Sponsor:' field is a checkbox labeled 'CRO'.

Enter Last Name of the investigator for the broadest search for that investigator's projects

	Contract Web ID	Sponsor	Title	Start Date	Status	PI Name
  	3	Seattle Genetics, Inc.	New CDA for Deborah Vetter with Novartis		In Process	Vetter, Deborah
  	4	Quintiles, Inc.	Sample Master		In Process	Vetter, Deborah
  	21	Accutec Testing Laboratory	This is a sample		In Process	Vetter, Deborah
  	15	Accutec Testing Laboratory	This is a sample CDA for Deborah		In Route	Vetter, Deborah
  	16	Novartis Pharma, Inc.	CDA between Novartis and UNMC		In Route	Vetter, Deborah
  	18	Quintiles, Inc.	cda		In Route	Vetter, Deborah
  	19	Pfizer, Inc.	New CDA		In Route	Vetter, Deborah
  	20	Pfizer, Inc.	Gobbledy Gook		In Route	Vetter, Deborah
  	22	UNL	education k- 12		In Route	Vetter, Joshua
  	23	Pfizer, Inc.	Test		In Route	Vetter, Deborah
   	5	NewLink Genetics Corporation	Research Agreement Sample	12/1/2009	In Route	Vetter, Deborah
   	6	Pfizer, Inc.	This is a sample contract	12/1/2009	In Route	Vetter, Deborah
   	8	Pfizer, Inc.	To be assigned	12/15/2009	In Route	Vetter, Deborah
   	2	Pfizer, Inc.	This is a special test contract	12/31/2009	In Route	Vetter, Deborah
   	7	NuvOx Pharma, LLC	Sample title	2/9/2010	In Route	Vetter, Deborah
   	9	Pfizer, Inc.	This is a sample contract	12/1/2010	In Route	Vetter, Deborah
 	14	Pfizer, Inc.	sample project	1/1/2009	Submitted	Vetter, Deborah

















### Status Meanings:

In Process – Contracts that you have entered part of the information – has not been submitted to PI for signature

In Route – Submitted to PI for signature – but not signed by PI

Submitted – Signed by PI and submitted to SPA for processing

### Icons Meanings:

-     - Trashcan – Delete
-     - Green Book – Edit General Contract Information
-     - Paper – View/Edit Questionnaire
-     - Red Book – Edit/View Contract Summary

### Other Search Functions:

**Sponsored Programs Administration Contract Intake Search**

Last Name:  First Name:  Department:

Contract Web ID, Sponsor:

Contract Web ID – Unique Identifier - creates a quick search

**Sponsored Programs Administration Contract Intake Search**

Last Name:  First Name:  Department:

Contract Web ID:  Sponsor:   CRO

Sponsor – Search by sponsor or check the CRO checkbox to the right and search by CRO

If contract is not already started – click the  button – It does not appear until you have done an initial search

**Contract General Information**

Please select the type of contract being entered.

- CDA / NDA
- CTA
- MTA
- Master
- Other
- Registry
- Research
- Service / Lab
- Subcontract
- Testing
- Workorder

Select the type of contract you will be entering  
The information you will need to provide is determined on the type of contract

**Required and Optional Data Table:**

Contract Type	Questionnaire	Sponsor Contact	Redline Contract	Protocol or Workscope	Data Use Agreement
CTA	R	R	R	R	O
CDA/NDA		R	R		
Registry	R	R	R	R	O
MTA	R	R	R	R	
Subcontract	R	R	R	R	O
Testing	R	R	R	R	
Service/Lab	R	R	R	R	
Master		R	R		
Workorder	R	R	R	R	O
Research	R	R	R	R	
Other	R	R	R	O	O
	R = Required				
	O = Optional				
	Blank = Not Needed				



## CDA Data Entry:

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsor Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

### Search for the PI Name

- As you type a drop down of possible names will appear
- Select the appropriate name when it is available
- **Note:** If the person is new to UNMC and does not appear – Contact SPAdmin to have them added to the names list



Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsor Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

**Project Title:**

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

Enter the project title:

- CDAs may be titled with Protocol title or a title that easily identifies the study

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsor Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

Project Title:

**Sponsor Name Search:**

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

Search for the Sponsor

- Use the Legal Entity that UNMC will be contracting with
- **Note:** If the sponsor does not appear – contact SPAdmin to add a new sponsor to the drop down list

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsor Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

Project Title:

Sponsor Name Search:

Sponsor:

**CRO Name Search:**

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

### Search for the CRO

- Use the Legal Entity that UNMC will be contracting with
- **Note:** If the CRO does not appear – contact SPAdmin to add the new CRO to the drop down list
- **Note:** Only use the legal entities that the CDA will be with – so even if a CRO is involved, but we are not contracting with them, do not add them to the agreement at this point

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsor Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

**Sponsor Contact Information** Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

Enter the Sponsor Contact Information

- First Name
- Last Name
- Email
- Phone Number
- Is the contact with the Sponsor or the CRO – Check the appropriate one
- **Note:** This is the person the SPA negotiator is to contact to negotiate the contract – not the site administrator or a scientific contact

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsor Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

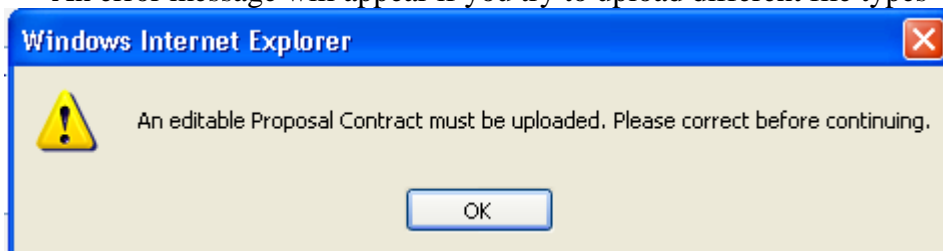
Email:

Phone:

Submitted:

### Upload the CDA (contract) document

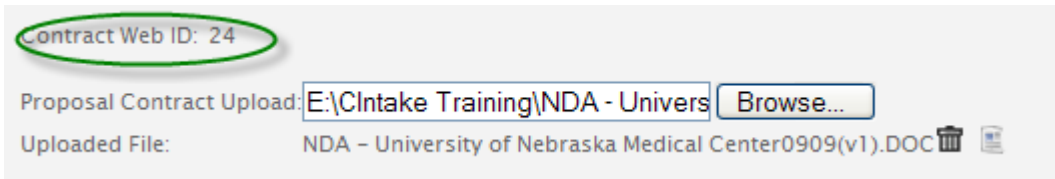
- Click the  button and look for the file where you have it stored
- **Note:** Must be in a Word or an RTF format
- An error message will appear if you try to upload different file types



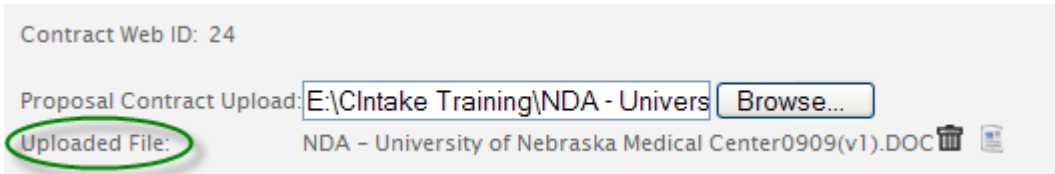
- **Note:** PDF or non-editable copies are not allowed

Click the  button to complete the data entry process


- Note: The data can be saved without the document upload – but cannot be submitted for signature
- Two identifiers are added – to know that the file is saved
  - o Contract Web ID Number – a unique identifier




- Uploaded File – with icons at the end

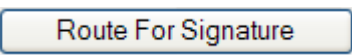


### Icons:

Trash Can – Delete the uploaded document - 


Paper – View the uploaded document 

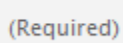
Click the  for a summary sheet of the CDA

Click the  to move to the Summary Page and proceed with routing to the Principal Investigator for signature

### Help Indicators:

Signature page contains help indicators to know if you have completed the data entry process or not

 - indicates that all information is provided

 - Indicates if data entry is required before routing for signature

 - Indicates if data entry is optional and only applies in certain circumstances

Go To  - Go To with a blue link – is a link directly to the page where the data can be entered

 - View the uploaded document link

## Sponsored Programs Administration Contract Intake Summary

### Instructions:

The Sponsor Programs Administration (SPAdmin) Contract Intake Process is designed to be completed and signed by the principal investigator, and is to accompany each contract submitted to Sponsored Programs Administration for negotiation. Please include a copy of the study protocol, a contact at the sponsor for contract negotiation, and an electronic copy (e.g. Word Document, it cannot be a .PDF) of the proposal contract.

### How Information Will Be Used:

Answers will guide Sponsored Programs Administration staff in negotiating contract terms and in establishing workable timelines. Signatures will certify investigator compliance with FDA department regulations.

Contract Web ID: 24 Contract Type: CDA / NDA

Title: This is a sample title for a sample CDA for samples in training

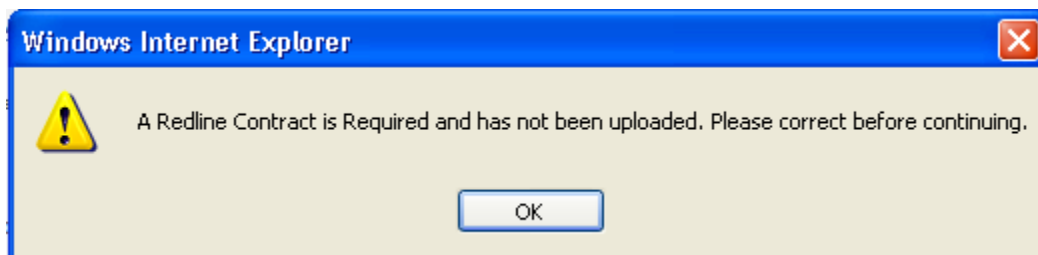
### Items Required to Submit to Sponsored Programs Administration

- Principal Investigator: (Required) Go To [Contract Principal Investigator Information](#)  
Vetter, Deborah K
- Sponsor: (Required) Go To [Contract Sponsor Information](#)  
NovaRx Corporation
- Sponsor Contact (Required) Go To [Contract Sponsor Contact Information](#)
- Redline Contract (Required) Go To [Redline Contract Upload](#)  
 NDA - University of Nebraska Medical Center0909(v1)

Submitted for Signature By:  
Submitted for Signature on:

[Route To PI](#)

If all the (Required) fields are not  then the agreement is not complete and cannot be forwarded to the PI for signature or to SPAdmin for negotiation. When all fields are not complete – the following message will appear as an error. Corrections will need to be made before the contract can be routed to the PI for signature.



When all fields are completed and all (Required) fields have a  then the contract can be routed to the PI for signature.

### **PI Signature step:**

The PI will receive an email from the “administrator” or “coordinator” who is completed the online Contract Intake information – which provides them with

### **Sample Email:**

**Your electronic signature is required for negotiation to begin on the following agreement entered by: Administrator/Coordinator Name**

**Contract Web ID:** 12  
**Sponsor:** Novartis  
**Title:** This is a sample

Please log into ADIS to review/verify the documents provided and to provide your electronic signature – which indicates:

- All the information provided is true, complete and accurate
- Provide certification of non-debarment

Follow the instructions below to:

- Verify information for this contract
  - Provide your electronic signature for this agreement.
1. Copy <https://edge.unmc.edu/adis/index.asp> into your default browser
  2. Login using your Lotus Notes ID and Password
  3. From the Navigation menu on the Left hand side of your screen – click the + symbol in front of the Research folder
  4. Click the + symbol in front of the Grants & Contracts folder
  5. Click Contract Intake
  6. To verify and sign the current contract – enter the number provided above into the Contract Web ID field
  7. Click on the red book icon to review/sign the contract
  8. Review the information by clicking on the blue links
  9. If all information provided is true, complete and accurate provide your electronic signature by clicking the box labeled 'I certify the above statement is true'
  10. Finalize the contract by clicking the Submit to SPA button

## Sponsored Programs Administration Contract Intake Summary

### Instructions:

The Sponsor Programs Administration (SPAdmin) Contract Intake Process is designed to be completed and signed by the principal investigator, and is to accompany each contract submitted to Sponsored Programs Administration for negotiation. Please include a copy of the study protocol, a contact at the sponsor for contract negotiation, and an electronic copy (e.g. Word Document, it cannot be a .PDF) of the proposal contract.

### How Information Will Be Used:

Answers will guide Sponsored Programs Administration staff in negotiating contract terms and in establishing workable timelines. Signatures will certify investigator compliance with FDA department regulations.

Contract Web ID: 25 Contract Type: CDA / NDA

Title: Test from a PI perspective

### Items Required to Submit to Sponsored Programs Administration

- Principal Investigator: (Required) Go To [Contract Principal Investigator Information](#)  
Miller, Crystal C
- Sponsor: (Required) Go To [Contract Sponsor Information](#)  
Novartis Pharma, Inc.
- Sponsor Contact (Required) Go To [Contract Sponsor Contact Information](#)
- Redline Contract (Required) Go To [Redline Contract Upload](#)  
 NDA - University of Nebraska Medical Center0909(v1)

Submitted for Signature By:  
Submitted for Signature on:

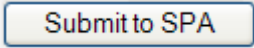
### Principal Investigator Certification

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.

I certify the above statement is true.

Submit to SPA

When the Principal investigator checks the box this provides the electronic signature and verification for the current agreement

The final step is for the Principal Investigator to check the  button. Checking this button sends a notification to SPAdmin that there is a contract to process and begin negotiation.



## CTA Data Entry

Contract Type	Questionnaire	Sponsor Contact	Redline Contract	Protocol or Workscope	Data Use Agreement
CTA	R	R	R	R	O
CDA/NDA		R	R		
Registry	R	R	R	R	O
MTA	R	R	R	R	
Subcontract	R	R	R	R	O
Testing	R	R	R	R	
Service/Lab	R	R	R	R	
Master		R	R		
Workorder	R	R	R	R	O
Research	R	R	R	R	
Other	R	R	R	O	O
	R = Required				
	O = Optional				
	Blank = Not Needed				

Please select the type of contract being entered.

- CDA / NDA
- CTA
- MTA
- Master
- Other
- Registry
- Research
- Service / Lab
- Subcontract
- Testing
- Workorder

Select CTA and the General Contract Information screen will appear

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator:

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

Search for the Principal Investigators by last name and select from the drop down that appears to the right of the Name search box

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator: **Vetter, Deborah K** Sponsored Programs Administration

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

Once selected – the Principal Investigator’s Home department will appear in the drop down box to the right of their name

- If the contract will be administratively managed in the investigators home department – leave it as the default
- If the contract will be administratively managed in a department other than the investigators home department, change the department to the department where the contract will be managed

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator: **Vetter, Deborah K**

**Project Title:**

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

Enter the Project Title in the box provided

**Note:** The project title, IRB title and Protocol title must match exactly

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator: **Vetter, Deborah K**

Project Title:

**Sponsor Name Search:**

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

### Search for the Sponsor

- Use the Legal Entity that UNMC will be contracting with
- **Note:** If the sponsor does not appear – contact SPAdmin to add a new sponsor to the drop down list

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator: **Vetter, Deborah K**

Project Title:

Sponsor Name Search:

Sponsor:

**CRO Name Search:**

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

### Search for the CRO

- Use the Legal Entity that UNMC will be contracting with
- **Note:** If the CRO does not appear – contact SPAdmin to add the new CRO to the drop down list
- **Note:** Only use the legal entities that the CDA will be with – so even if a CRO is involved, but we are not contracting with them, do not add them to the agreement at this point

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator: **Vetter, Deborah K**

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

**Sponsor Contact Information:** Contact Type:  Sponsor  CRO

First Name:

Last Name:

Email:

Phone:

Submitted:

### Enter the Sponsor Contact Information

- First Name
- Last Name
- Email
- Phone Number
- Is the contact with the Sponsor or the CRO – Check the appropriate one
- **Note:** This is the person the SPA negotiator is to contact to negotiate the contract – not the site administrator or a scientific contact

You can Save the Contract at this point

## Proposal Contract Upload

Contract Web ID: 0

Proposal Contract Upload:

Uploaded File:

If the needed name does not appear when searching please contact Sponsored Programs Administration (SPAdmin) for further assistance.

PI Name Search:

Principal Investigator: **Vetter, Deborah K**

Project Title:

Sponsor Name Search:

Sponsor:

CRO Name Search:

CRO: (if applicable)

Sponsor Contact Information: Contact Type:  Sponsor  CRO

First Name:

Last Name:

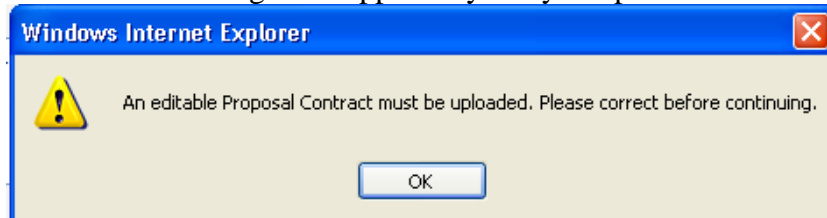
Email:

Phone:

Submitted:

### Upload the Contract document

- Click the  button and look for the file where you have it stored
- **Note:** Must be in a Word or an RTF format
- An error message will appear if you try to upload different file types



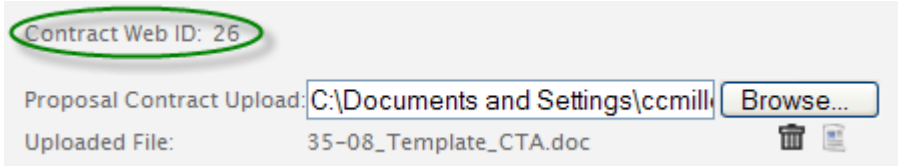
- **Note:** PDF or non-editable copies are not allowed

Click the  button to complete the data entry process

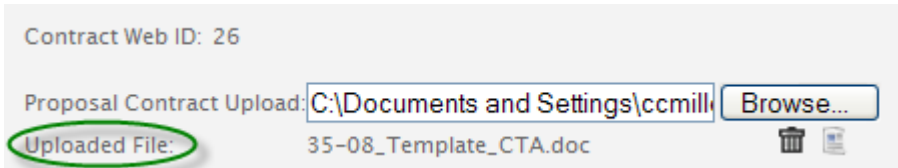
- **Note:** The data can be saved without the document upload – but cannot be submitted for signature



- Two identifiers are added – to know that the file is saved
  - o Contract Web ID Number – a unique identifier




- o Uploaded File – with icons at the end

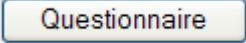


**Icons:**

Trash Can – Delete the uploaded document - 

Paper – View the uploaded document 

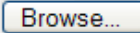
Click the  for a summary sheet of the Contract

Click the  button to continue the data entry process

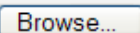
### Sponsored Programs Administration Contract Questionnaire

**Instructions:**  
 The Sponsor Programs Administration (SPAdmin) Contract Questionnaire is designed to be completed and signed by the principal investigator, and is to accompany each contract submitted to Sponsored Programs Administration for negotiation. Please include a copy of the study protocol, a contact at the sponsor for contract negotiation, and an electronic copy (e.g. Word Document, it cannot be a .PDF) of the proposal contract.

**How Information Will Be Used:**  
 Answers will guide Sponsored Programs Administration staff in negotiating contract terms and in establishing workable timelines. Signatures will certify investigator compliance with FDA department regulations.

**Study Protocol/Workscope Upload:**  

Uploaded Study Protocol/Workscope:

**Data Use Agreement Upload:**  

Uploaded Data Use Agreement:

Contract Web ID: 26

Time Line Information:

**Timeline:**

1. What is the anticipated start date of this project?(Date Format: mm/dd/yyyy)

2. Is this a sponsor imposed start date?  Yes  No

Project Type Information:

Question 1:

**Project Type:**

1. Is this project a clinical trial?  Yes  No

Yes

1. Is this project a clinical trial?  Yes  No

1a. Please indicate the study phase:

Phase I  
 Phase II  
 Phase III  
 Phase IV  
 Compassionate Use

1b. Please identify the study participants:

Inpatient  
 Outpatient  
 Both Inpatient and Outpatient

1c. Please provide the name of the Nurse Coordinator or other staff member to whom SPA may direct any project-related questions:

Contact Name:	Contact Email:	Contact Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

No

1a. If this is not a Clinical Trial, how would you describe it?

Testing  
 Laboratory Research  
 Registry

Other: (Describe)

## Question 2:

2. Please identify the location of the study facilities to be used and appropriate contact information for all non-UNMC parties involved with this project:

UNMC/NMC  
 VA  
 Children's Hospital  
 Creighton University Medical Center  
 Other (please specify)

Non-UNMC Contact: Name:   
Phone Number:   
Email:

## Question 3:

No

3. Has this project been listed in a clinical trials registry?  Yes  No

Yes

3. Has this project been listed in a clinical trials registry?  Yes  No

3a. Registry initiated by:  
 Principal Investigator  
 Sponsor  
 Other (please specify)

3b. Please indicate the Registry:  
Name:   
Address:   
Registration Number:

## Question 4:

Sponsor

4. Who initiated this project?  PI  Sponsor

PI

4. Who initiated this project?  PI  Sponsor

4a. If this is a PI-initiated clinical trial, have you or do you intend to file an IND or seek IND exemption:  
 IND  IND Exemption

Question 5:

5. Who wrote the protocol?

Sponsor  
 Investigator  
 Sponsor and Investigator

Question 6:

6. Is the study?

Multicenter  Single Site

Question 7:

7. What are the sources of funding that will be used to support this project?

Sponsor  Other

Question 8:

8. What funding sources will be used to contribute to this work in the future?

Question 9:

9. If you are receiving or have received federal funds for research, are any of the funds related to this project?

Yes  No

Question 10:

No

10. Will this project require the use of non-UNMC personnel for the conduct of the project?

Yes  No

Yes

10. Will this project require the use of non-UNMC personnel for the conduct of the project?

Yes  No

10a. If yes, please provide names(s), role on project, and appropriate contact information:

## Confidentiality and Intellectual Property

### Question 1:

No

1. Have you signed a confidentiality agreement (CDA) with the Sponsor that relates to this project (e.g. has the Sponsor provided you with confidential information for your evaluation of the project that must be held in confidence under the terms of the CDA)?  Yes  No

Yes

1. Have you signed a confidentiality agreement (CDA) with the Sponsor that relates to this project (e.g. has the Sponsor provided you with confidential information for your evaluation of the project that must be held in confidence under the terms of the CDA)?  Yes  No  
(Please specify in detail, e.g. effective date of CDA)

Detail and effective date of CDA

### Question 2:

No

2. Have you signed a material transfer agreement (MTA) with the Sponsor that relates to this project (e.g. has the Sponsor provided you with materials for your evaluation of the project that must be held in confidence under the terms of the MTA)?  Yes  No

Yes

2. Have you signed a material transfer agreement (MTA) with the Sponsor that relates to this project (e.g. has the Sponsor provided you with materials for your evaluation of the project that must be held in confidence under the terms of the MTA)?  Yes  No  
(Please specify in detail, e.g. effective date of MTA)

Question 3:

No

3. Outside of this study, have you signed a consulting agreement for which this science or technology is the subject?  Yes  No

Yes

3. Outside of this study, have you signed a consulting agreement for which this science or technology is the subject?  Yes  No  
(Please specify)

Question 4:

No

4. Are there drugs or devices that are being provided by someone other than the sponsor?  Yes  No

Yes

4. Are there drugs or devices that are being provided by someone other than the sponsor?  Yes  No  
(Please specify)

Question 5:

No

5. If this is a renewal or continuing project, were any inventions previously conceived or reduced to practice?  Yes  No

Yes

5. If this is a renewal or continuing project, were any inventions previously conceived or reduced to practice?  Yes  No  
(Please specify in detail)

Question 6:

No

6. Do you have an invention disclosure, patent filing, or any IP agreement on file or pending with the IPO?  Yes  No

Yes

6. Do you have an invention disclosure, patent filing, or any IP agreement on file or pending with the IPO?  Yes  No  
(Please specify in detail)

Question 7:

7. 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 project? (1 = Not at all likely, 5 = Highly Likely)  1  2  3  4  5

Question 8:

8. Do you want to publish or use the research results on other projects?  Yes  No

Question 9:

No

9. Will students be involved on the project?  Yes  No

Yes

9. Will students be involved on the project?  
(Addresses need of students to publish.)  Yes  No

Question 10:

10. Are you willing to transfer ownership of all data resulting from the study to the study sponsor?  Yes  No  
Please explain.

Regulatory Affairs:

Question 1

No

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

Yes

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

1a. Has your protocol been submitted to the IRB?  Yes  No  
IRB Number:

1b. Does this project include children as human subjects?  Yes  No

1c. Is there a time for recruitment of human subjects, after which the sponsor will unilaterally terminate the contract if none have been enrolled?  Yes  No

Weeks:

Months:

Cut-off date: (Date Format: mm/dd/yyyy)

Note: If No to 1a – then no IRB number is required

Note: If No to 1c then cut-off dates are not required



Question 2:

No

2. Will animals be used on this project?  Yes  No

Yes

2. Will animals be used on this project?  Yes  No  
2a. Has your protocol been submitted to the IACUC?  Yes  No  
IACUC Number:

Note: If No to 2a – then no IACUC number is required

Question 3:


No

3. Does your research use recombinant DNA and/or microbiological agents in any assay?  Yes  No

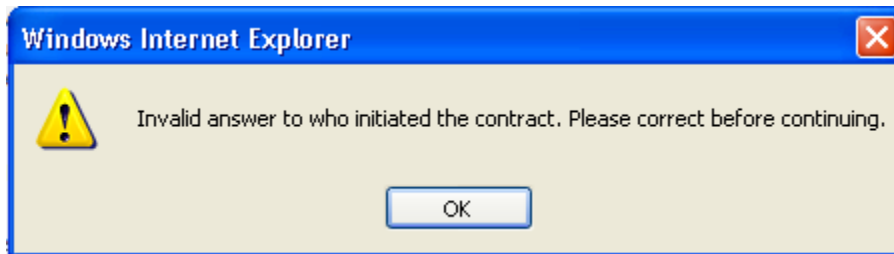
Yes


3. Does your research use recombinant DNA and/or microbiological agents in any assay?  Yes  No  
3a. Are your experiments covered by the NIH Guidelines for Research Involving Recombinant DNA Molecule? (Refer to section II of the Guidelines available as a resource on the [IBC website](#))  Yes  No  
3b. Has your protocol been submitted to the IBC?  Yes  No  
IBC Number:

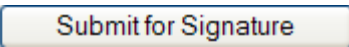
Note: If No to 3b – then no IBC number is required

Click the  button to save all data entered in the contract questionnaire.

**Note:** If questions are answered incorrectly error messages will appear – telling which question is not answered



When the questionnaire is finalized and will save you can click the  button to get a hard copy of the questionnaire.

Click the  button to move to the Contract Intake Summary Page



### Sponsored Programs Administration Contract Intake Summary

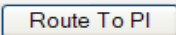
**Instructions:**  
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**How Information Will Be Used:**  
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Contract Web ID: 26 Contract Type: CTA  
Title: This is a sample proposal

#### Items Required to Submit to Sponsored Programs Administration

<input checked="" type="checkbox"/>	Principal Investigator: Vetter, Deborah K	(Required)	Go To <a href="#">Contract Principal Investigator Information</a>
<input checked="" type="checkbox"/>	Sponsor: Novartis Pharma, Inc.	(Required)	Go To <a href="#">Contract Sponsor Information</a>
<input checked="" type="checkbox"/>	Contract Questionnaire	(Required)	Go To <a href="#">Contract Questionnaire</a>
<input checked="" type="checkbox"/>	Sponsor Contact	(Required)	Go To <a href="#">Contract Sponsor Contact Information</a>
<input checked="" type="checkbox"/>	Redline Contract  35-08_Template_CTA.doc	(Required)	Go To <a href="#">Redline Contract Upload</a>
<input checked="" type="checkbox"/>	Protocol/Workscope  SGN35-008_Protocol_A00.pdf	(Required)	Go To <a href="#">Protocol/Workscope Upload</a>
<input type="checkbox"/>	Data Use Agreement Submitted for Signature By: Submitted for Signature on:	(Optional)	Go To <a href="#">Data Use Agreement Upload</a>



## Help Indicators:

Signature page contains help indicators to know if you have completed the data entry process or not



- indicates that all information is provided

(Required)

- Indicates if data entry is required before routing for signature

(Optional)

- Indicates if data entry is optional and only applies in certain circumstances

Go To [Contract Principal Investigator Information](#)

- Go To with a blue link – is a link directory to the page where the data can be entered



- View the uploaded document link

PI Signature Step is the same as outlined in the CDA

## Sponsored Programs Administration Contract Intake Summary

### Instructions:

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### How Information Will Be Used:

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Contract Web ID: 32 Contract Type: CTA  
Title: Sample Project Title

### Items Required to Submit to Sponsored Programs Administration

- Principal Investigator: (Required) Go To [Contract Principal Investigator Information](#)  
Miller, Crystal C
  - Sponsor: (Required) Go To [Contract Sponsor Information](#)  
Novartis Pharma, Inc.
  - Contract Questionnaire (Required) Go To [Contract Questionnaire](#)
  - Sponsor Contact (Required) Go To [Contract Sponsor Contact Information](#)
  - Redline Contract (Required) Go To [Redline Contract Upload](#)  
 Sample Proposal Contract.doc
  - Protocol/Workscope (Required) Go To [Protocol/Workscope Upload](#)  
 Sample Study Protocol.doc
  - Data Use Agreement (Optional) Go To [Data Use Agreement Upload](#)  
 Sample Data Use Agreement.doc
- Submitted for Signature By:  
Submitted for Signature on:

### 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.

I certify the above statement is true.

Submit to SPA