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
Click on the ADIS link and the following screen will appear

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

Click on the + sign in front of the research folder

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

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

Contract Web ID – Unique Identifier - creates a quick search
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

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:**

<table>
<thead>
<tr>
<th>Contract Type</th>
<th>Questionnaire</th>
<th>Sponsor Contact</th>
<th>Redline Contract</th>
<th>Protocol or Workscope</th>
<th>Data Use Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTA</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>CDA/NDA</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Registry</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>MTA</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Subcontract</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Testing</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Service/Lab</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Master</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Workorder</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Research</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Other</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

R = Required
O = Optional
Blank = Not Needed
CDA Data Entry:

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
Enter the project title:
- **CDAs may be titled with Protocol title or a title that easily identifies the study**

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
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
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
Upload the CDA (contract) document

- Click the **Browse** 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

![Windows Internet Explorer error message]

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

Click the **Save** 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
  - 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 Print for a summary sheet of the CDA

Click the Route For Signature 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 Contract Principal Investigator Information - Go To with a blue link – is a link directly to the page where the data can be entered

- View the uploaded document link
If all the 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.

Windows Internet Explorer

A Redline Contract is Required and has not been uploaded. Please correct before continuing.

OK

When all fields are completed and all 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
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

<table>
<thead>
<tr>
<th>Contract Type</th>
<th>Questionnaire</th>
<th>Sponsor Contact</th>
<th>Redline Contract</th>
<th>Protocol or Workscope</th>
<th>Data Use Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDA/NDA</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Registry</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>MTA</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Subcontract</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Testing</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Service/Lab</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Master</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Workorder</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Research</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
</tr>
<tr>
<td>Other</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

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
Search for the Principal Investigators by last name and select from the drop down that appears to the right of the Name search box.
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
Enter the Project Title in the box provided

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

Upload the Contract document

- Click the **Browse** 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 **Save** 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
  - 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 Print button for a summary sheet of the Contract

Click the Questionnaire button to continue the data entry process
Time Line Information:

Project Type Information:

Question 1:

Yes

1. Is this project a clinical trial?
   1a. Please indicate the study phase:
       - [ ] Yes
       - [ ] No
       - [ ] 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:

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

3a. Registry initiated by:
   - Yes
   - No
   - Principal Investigator
   - Sponsor
   - Other (please specify)

3b. Please indicate the Registry:
   - ClinicalTrials.gov

Question 4:

Sponsor

4. Who initiated this project?  
   - PI  
   - Sponsor

PI

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
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

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)?
   (Please specify in detail, e.g. 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

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)?
   (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? [Circle one]

Yes

(Please specify)

Question 4:

No

4. Are there drugs or devices that are being provided by someone other than the sponsor? [Circle one]

Yes

(Please specify)
Question 5:

No

5. If this is a renewal or continuing project, were any inventions previously conceived or reduced to practice?  
   (Please specify in detail)

Yes

5. If this is a renewal or continuing project, were any inventions previously conceived or reduced to practice?  
   (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?  
   (Please specify in detail)

Yes

6. Do you have an invention disclosure, patent filing, or any IP agreement on file or pending with the IPO?  
   (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)

Question 8:

8. Do you want to publish or use the research results on other projects?  
   (Please specify in detail)
Question 9:

No

Yes

9. Will students be involved on the project?  
(Addresses need of students to publish.)

Question 10:

10. Are you willing to transfer ownership of all data resulting from the study to the study sponsor?  
Please explain.

Regulatory Affairs:

Question 1

No

1. Is an IRB required for this project?  

Yes

1a. Has your protocol been submitted to the IRB?  

1b. Does this project include children as human subjects?  

1c. Is there a time for recruitment of human subjects, after which the sponsor will unilaterally terminate the contract if none have been enrolled?

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

Yes

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

Question 3:

No

Yes

Note: If No to 3b – then no IBC number is required
Click the Save 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.

![Invalid answer to who initiated the contract. Please correct before continuing.](image)

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

Click the Submit for Signature button to move to the Contract Intake Summary Page
**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:
The Sponsor Programs Administration (SAPAdmin) Contract Intake Process is designed to be completed and signed by the principal investigator, and 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: 32  Contract Type: CTA
Title: Sample Project Title

Items Required to Submit to Sponsored Programs Administration

☑ Principal Investigator: Miller, Crystal C
☑ Sponsor: Novartis Pharma, Inc.
☑ Contract Questionnaire
☑ Sponsor Contact
☑ Redline Contract
☑ Protocol/Workscope
☑ Data Use Agreement

(Required) Go To Contract Principal Investigator Information
(Required) Go To Contract Sponsor Information
(Required) Go To Contract Questionnaire
(Required) Go To Contract Sponsor Contact Information
(Required) Go To Redline Contract Upload
(Required) Go To Protocol/Workscope Upload
(Optional) Go To Data Use Agreement Upload

Sample Proposal Contract.doc
Sample Study Protocol.doc
Sample Data Use Agreement.doc

Submitted for Signature By:
Submitted 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 1992 (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