Office of Sponsored Projects Award Acceptance and Negotiation - Contracts Team

GUIDE FOR INITIATING UNFUNDED AGREEMENTS IN MYRESEARCH

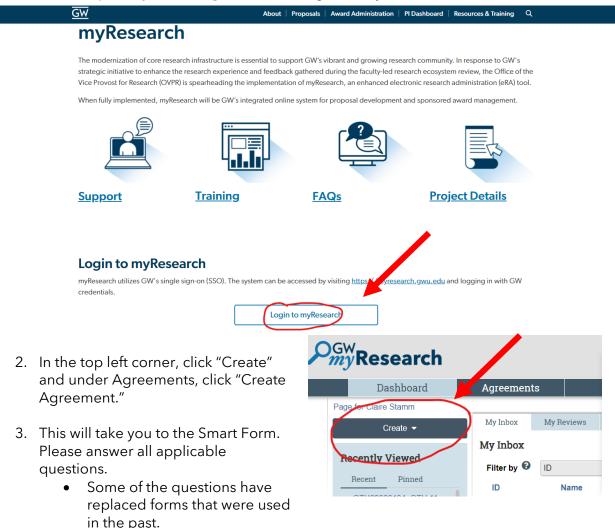
INTRODUCTION

- This guide contains the step-by-step process to properly input an unfunded agreement into myResearch.
- As part of inputting an unfunded agreement, there are Smart Form Questions about the agreement that aid and inform OSP's review and negotiation of the agreement. The four appendices attached to this guide offer specific guidance on answering the Smart Form Questions.
- This process and the questions replace the past forms that were required to send an unfunded agreement to OSP.

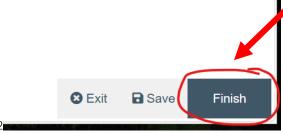
TABLE OF CONTENTS:	
NUMBER(S)	
<u>1</u>	
2-4	
5-7	
8-11	
12-13	
14-15	

myResearch Unfunded Agreements Step-by-Step Instructions

1. Go to https://myresearch.gwu.edu and log in with your GW credentials



- Answering all applicable questions allows us to do a quicker review of your file.
- For guidance on answering the Smart Form questions, please see the <u>Appendices.</u>
- 4. The questions may span several pages. The number of questions depends on the type of agreement that you have. Once you answer the questions on each page, click "Continue" in the bottom right corner of the page to navigate to the next page.
- 5. When you have finished answering all the questions, "Finish" will appear in the bottom right corner. Click "Finish."



6. When you click "Finish," you will be redirected to the main file page for this Agreement. To submit the Agreement to OSP for processing, click "Submit" on the left sidebar.

Next Steps Edit Agreement Printer Version View All Corr.spondence Submit Submit Manage Ancillary Reviews Email Agreement Log Correspondence Assign PI Proxies Discard

What Happens Next:

Once you click Submit, this Agreement is submitted to OSP. myResearch has a flow chart on the Agreement's page showing where your Agreement is in the review & negotiation process.

After clicking Submit, it will appear to be "Unassigned " in the flow chart.

If no clarification is needed by OSP, it will be assigned to a Contracting Officer on the Contracts Team. It will appear to be "In Review," as shown below. The Contracting Officer will (1) timely review the Agreement, (2) email you that this Agreement has been assigned and ask any additional questions, as needed, and (3) negotiate it.



Appendix 1: General Guidance on Answering Smart Form Questions

Page 1 #1 – *Agreement manager/Principal Investigator:

- To fill out this section, you can simply start typing a name, or if you click the three dots a list of faculty and staff will appear.
- Please choose the Principal Investigator. This person also serves at the Agreement manager.

Page 1 #2 – *Agreement creator:

• If this question did not automatically fill your name in, please add your name

Page 1 #3 – *Upload agreement draft:

- Please upload the template provided by the Sponsor.
- If the Sponsor does not provide one, no worries! We can internally generate it! We prefer internal generation. If this is the case, please click the box so that the system will let you move forward.

Page 1 #4 – Title or internal reference number:

- Does this Project have a title (aside from the Agreement Type title See #5 for guidance here)?
- Does this Project have an internal reference number already (this should be rare, if true)?
- If not, please feel free to leave this question blank.

Page 1 #5 – *Agreement type:

- If you choose a type of agreement and then hoover over it with your mouse, a definition of the agreement will pop up
- Other Agreement may be the correct answer if your unfunded Agreement is not an NDA, MTA, or Teaming Agreement.

Page 1 #6 – Description:

- Please include a description of what is being done under this Agreement.
- You are welcome to provide detailed responses, however, the crux of this section is to determine what is happening under this Agreement, the risk level of this Agreement, and possible compliance considerations.
- For instance,
 - For a NDA/CDA, "Sponsor confidential information will be shared with GW to determine the nature of potential future research."
 - For a MTA, "GW will provide a de-identified specimen to the Sponsor. This specimen does have a patent related to it. The patent number is XXXX."
 - For an MOU: "Sponsor would like to have an MOU in place to determine each party's role in the proposal development."

Appendix 1: General Guidance on Answering Smart Form Questions

Page 1 #7 – Supporting Documents:

- Please attach any additional documents in your possession related to this agreement (there is no need to reattach the agreement draft, though, as that is included per #3).
- These documents may be any of the following, but not limited to the following:
 - Emails with the Sponsor (made into PDF files the system does not accept email files)
 - o Internal Emails regarding the Agreement (if they exist)
 - o Any other letters or documents provided by the sponsor
 - o Scope or Statement of Work (if any unfunded research will be done)

Page 1 #8 – Responsible department / division / institute:

- To fill out this section, you can simply start typing a name, or if you click the three dots a list of departments, divisions, and institutes will come up.
- Please choose the department / division / institute that has submitted this Agreement request. Likely, this is the department/ division/ institute that the Principal Investigator/Agreement manager works in.
- However, if the Principal Investigator/Agreement manager has dual appointment, please ask PI what department / division/ institute this Agreement is for. Please see Appendix II for email terms that may be copied and pasted.
- With the exception of MTAs, the Contracts Team assignments come from the department / division / institute. Thus, this is why this question is in here.

Page 1 #9 – If this agreement is related to an existing proposal or sponsored project, type in the proposal or project number, if known:

- Is this project related to a SPA or FP or other file in myResearch? If so, please provide it here.
- This information helps the Contracts Team if you provided this information here, as contractual terms can overlap, and we check related agreements to ensure they do not conflict each other.

Page 1 #10 - Will this project involve export control? For additional guidance and next steps related to Export Controls, please visit <u>https://research.gwu.edu/export-controls-gw-policy</u>

- *Please note this question may not appear on the Smart Form if you have an MTA
- Please review the link above to determine whether to choose yes or no for this question.
- If the Sponsor is a foreign entity, the Contracts Team must seek Export Review. Therefore, if the Sponsor is a foreign entity, please check yes.

Page 1 # 11 - Do you (the requesting researcher), or any immediate or close family member, have any conflicts of interest as described in GW's Policy on Conflicts of Interest for Faculty and Investigators <u>https://compliance.gwu.edu/conflicts-interest-and-commitment-faculty-and-investigators-policy</u> with the provider or recipient of the material, as applicable?

- Please review the link above to determine whether to choose yes or no for this question.
- If there is a potential conflict of interest, the Contracts Team will seek an Ancillary Review from ORIC prior to signing the Agreement.

Appendix 1: General Guidance on Answering Smart Form Questions

Page 2 #1 – *Select an organization:

- To fill out this section, you can simply start typing a name, or if you click the three dots a list of organizations will come up.
- If the organization does not come up, you can manually input where it states: Contracting Party Name.
- You are also able to add this organization to the drop down list here: https://forms.gle/3dCZ7AYuFXmaBygGA
- *Please make sure to pick the exact same name as on the agreement itself as the sponsor / other contracting entity.

Page 2 #2 – Contracting party contact name:

- Please provide the contact party name
- This information is crucial, as it will be used when we reach out to the sponsor.

Page 2# 3 – Contracting party contact e-mail:

- Please provide the contact party email address
- This information is crucial, as it will be used when we reach out to the sponsor.

Page 2# 4 – Contracting party contact phone:

- Please provide the contact party phone, if known
- This information is helpful, as it will be used if we have trouble reaching out the sponsor by e-mail.

Page 2 #5 – Agreement collaborators: (institutional staff given read/edit permissions for this Agreement)

- To fill out this section, you can simply start typing a name, or if you click the three dots a list of faculty and staff will come up.
- Filling in someone for this question will allow that person to access, read, and edit this myResearch file.
- There is no requirement to put someone here, but it may help to add a Co-PI here or Departmental Administrator here.

***If you have an MTA, DUA, or NDA please continue reading for guidance on additional questions

- > Appendix 2 MTA Guidance Appears on Pages 8-11
- > Appendix 3 DUA Guidance Appears on Pages 12-13
- Appendix 4 NDA/CDA Guidance Appears on Pages 14-15

Please first review Appendix 1 for answering the general questions related to the MTA (Pages 1 & 2)

MTA Direction of Transfer Page - Question: *Are you receiving or sending materials?

• Please provide whether we are sending another entity materials or receiving materials from another entity

If you are SENDING Materials, please review the Green Sections below. If you are RECEIVING Materials, please review the <u>Yellow</u> Sections below (see page 11)

MTA Material Recipient Information Page -Questions for <u>SENDING</u> materials:

- 1. *Are you exporting material outside the United States?
 - This question is asking whether we are sending material to a foreign place or entity.
 - Note: If you check yes, additional questions on Export Control will be presented on the next page. Please answer them to the best of your ability by reviewing: <u>https://research.gwu.edu/export-controls-gw-policy</u>
 - i. They are the following:
 - 1. Can the material be purchased in the public domain?
 - 2. Is there a military application for the material?
 - 3. Do you have any reason to believe the end user may intend to use the material for military or defense systems?
 - 4. Does the end user intend to re-export the material?
 - 5. Is the material listed as a select agent in the US Patriot Act?
 - 6. Select one of the following:
 - a. ITAR
 - b. EAR
 - c. Unknown
- 2. *Is GW charging any fees in addition to shipping?
 - If GW is only charging shipping, please click no here.
 - If GW is charging shipping with additional fees (for collection or packaging or time and effort to gather and send the materials), please click yes here.
- 3. *What is the total amount, excluding shipping, to be reimbursed?
 - If you clicked yes to #2, please provide the total amount for the additional fees. Please do NOT include the shipping.
 - If you clicked no to #2, please write "0" in this line.

MTA Material Description- Questions for <u>SENDING</u> materials:

- 1. *Identity the material:
 - Please provide a brief description of the material
 - Examples of property identifications are: "unmodified proteins or "DNA molecule" or "chromosomal DNA" or "pharmaceutical compound or drug"
- 2. *What is the origin of the material?
 - This question asks where did the material come from?
 - Please review the list and choose the right origin. The origin may be "Other" when it is not from an animal, plant, human, or plasmid. When you click "Other" please provide briefly where the material is from.
 - As a note, plasmid is defined as: A plasmid is a small, circular, double-stranded DNA molecule that is distinct from a cell's chromosomal DNA. Plasmids naturally exist in bacterial cells, and they also occur in some eukaryotes. plasmid plasmids | Learn Science at Scitable (nature.com)
- 3. What is the material type?
 - For this question, you can check all that apply or if nothing applies or "other" applies, you may check that.
 - If you click other, please provide briefly what the material type is.
- 4. *Are you requesting or providing live animals?
 - This question is somewhat repetitive as #1 and #2 above. However, as there are special compliance concerns with the transfer of live animals, this question is separated out.
- 5. *Identify any hazardous biological agents involved:
 - This question could be somewhat repetitive as #1 and #2 above. However, as there are special compliance concerns with hazardous agents within materials, this question is separated out.
 - Please review these two links to help determine what might be a hazardous biological agent that should be added to the list.
 - To answer this question, you may start typing an agent or you may click the three dots (...) to see a list of agents.
 - If there are no hazardous agents involved, please write "None" and click "None None No" when it appears as you type.

MTA Material Source - Questions for <u>SENDING</u> materials:

- 1. *Identify the institution that developed the material:
 - To answer this question, you may start typing an institution or organization or you may click the three dots (...) to see a list of institutions or organizations.
 - If the correct institution or organization is not listed, please put in your department or school and then also add the correct institution or organization name in #6 on this page.
 Please note there is a glitch in the system that is preventing you from putting in another "Institution name" only. Therefore, the above steps are a way forward until this can be fixed.

MTA Material Source - Questions for <u>SENDING</u> materials:

- 2. *Name of investigator who developed the material:
 - Please provide a person's name who developed the material
 - If this is unknown because we purchased or otherwise received the material that we are now transferring, please write "Unknown" as this question is required to be answered.
- 3. *How was the material obtained?
 - This question is asking how we obtained the material that we are now sending/transferring.
 - This question is important because it helps us ensure we properly check any restrictions/other legal terms affecting this material. This also ensures that this MTA does not conflict with any other previous MTA or agreement.
 - Please answer and provide additional information as needed to help us locate any related documents, agreements, or other legal terms, if applicable.
- 4. *For material developed at your institution, does it incorporate research material received from others?
 - For this question, please specifically answer whether or not this material might be a combination or incorporation of material developed at GW *and* material received from other places
- 5. What is the function of the material?
 - Please describe how the material will be used by you.
- 6. Describe additional material
 - If you filled in #s 1, 3, 5, 6, or 7 from #3 above on this page 6, please provide a brief description of the where the material was obtained.
 - This information helps us ensure that we have reviewed and gathered all the right related agreements, documents, and legal terms to inform the drafting and negotiation of this MTA.

MTA Material Development – Questions for <u>SENDING</u> Materials:

- 1. *Was development of this material funded by a sponsored research agreement or other extramural funding?
 - This question is aimed at determining if an agreement or other funded source funded the development of the Material. This is important because it will help ensure that all the right terms and conditions are checked to ensure this MTA does not conflict another agreement related to the Material.
 - If you click "Yes" additional information will appear to help gather this information.
 - a. Please type in the Funding source or click the three dots (...) to pick a funding source. If your funding source does not appear, in the space below, please list it or provide additional relevant details regarding the funding source.
 - b. Please type in the proposal or project number. If you do not have one, please write N/A.
- 2. Has the researcher published about the material or a related methodology?
 - This question is asking whether the PI or researcher (that this MTA is for) has ever published on this material or published on methodology related to this material.

MTA Material Use – Questions for <u>SENDING</u> Materials:

- 1. * Provide a concise scientific description of the recipient's use of this material:
 - Please provide a description of what the recipient will do with the material
- 2. *List the quantity of the material to be transferred (specific units)
 - How much material will be transferred?
 - Please list the number and type of unit of measurement.
- 3. * What is the approximate value of the materials?
 - Please provide an estimated monetary value of the material (even if the receiver of the material is not paying a cost or fees for the material)
- 4. *Will the material be used with material owned by an industrial or non-profit agency?
 - If this material is combined with or will be used with material owned by a for-profit industry sponsor or a non-profit sponsor (including foundations), please click yes.
- 5. Comments: Please use this section to explain your answer to any of the above questions on this page.

MTA Additional Information – Questions for <u>SENDING</u> Materials:

- 1. Add any comments that will be helpful to the MTA staff:
 - Please use this section to add any information that you feel is needed and/or helpful that has not been captured by the questions.
- 2. * Do you anticipate that an invention or a modified research material will result from your use of the Material?
 - Could any intellectual property or invention be created from use of the material? If so, click yes.
 - Could any derivatives or modified material be created from use of the material? If so, click yes.
- 3. *Do you have any existing patents, pending patent applications, or license agreements related to the Material?
 - Does any IP already exist that is related to the material? This could be in the form of invention disclosures, patents, patent application, or license agreement.

Completion Instructions – Questions for <u>SENDING</u> Materials:

- 1. Please validate that all relevant questions are adequately answered.
- One the left side of the screen, you can click back to a certain page to check your answers.
- 2. Correct any errors or omissions.
- 3. When this has been done, please Click "Finish" to exit the form.
- 4. Once back on the workspace page, please click "Submit."
 - These two steps are covered by page 2 and 3 of this guide.

MTA Material Provider Information -Questions for <u>RECEIVING</u> materials:

- Do you, or any immediate or close family member, have any conflicts of interest as described in GW's Policy on Conflicts of Interest for Faculty and Investigators <u>https://compliance.gwu.edu/conflicts-interest-and-commitment-faculty-and-investigators-policy</u> with the provider or recipient of the material, as applicable?
 - While this question may seem slightly repetitive (see General Questions for all unfunded agreements), it is important to double ensure that there are no conflicts when we are receiving Material and to specifically consider potential conflicts from the perspective of transferring and receiving Material

MTA Material Description- Questions for <u>RECEIVING</u> materials:

- 1. *Identity the material:
 - Please provide a brief description of the material
 - Examples of property identifications are: "unmodified proteins or "DNA molecule" or "chromosomal DNA" or "pharmaceutical compound or drug"
- 2. *What is the origin of the material?
 - This question asks where did the material come from?
 - Please review the list and choose the right origin. The origin may be "Other" when it is not from an animal, plant, human, or plasmid. When you click "Other" please provide briefly where the material is from.
 - As a note, plasmid is defined as: A plasmid is a small, circular, double-stranded DNA molecule that is distinct from a cell's chromosomal DNA. Plasmids naturally exist in bacterial cells, and they also occur in some eukaryotes. plasmid (plasmids | Learn Science at Scitable (nature.com)
- 3. What is the material type?
 - For this question, you can check all that apply or if nothing applies or "other" applies, you may check that.
 - If you click other, please provide briefly what the material type is.
- 4. *Are you requesting or providing live animals?
 - This question is somewhat repetitive as #1 and #2 above. However, as there are special compliance concerns with the transfer of live animals, this question is separated out.
- 5. *Identify any hazardous biological agents involved:
 - This question could be somewhat repetitive as #1 and #2 above. However, as there are special compliance concerns with hazardous agents within materials, this question is separated out.
 - Please review these two links to help determine what might be a hazardous biological agent that should be added to the list.
 - To answer this question, you may start typing an agent or you may click the three dots (...) to see a list of agents.
 - If there are no hazardous agents involved, please write "None" and click "None None No" when it appears as you type.

MTA Material Use – Questions for <u>RECEIVING</u> Materials:

- 1. * Provide a concise scientific description of the recipient's use of this material:
 - Please provide a description of what the recipient will do with the material
- 2. *List the quantity of the material to be transferred (specific units)
 - How much material will be transferred?
 - Please list the number and type of unit of measurement.
- 3. * What is the approximate value of the materials?
 - Please provide an estimated monetary value of the material (even if the receiver of the material is not paying a cost or fees for the material)
- 4. *Will the material be used with material owned by an industrial or non-profit agency?
 - If this material is combined with or will be used with material owned by a for-profit industry sponsor or a non-profit sponsor (including foundations), please click yes.
- 5. Comments: Please use this section to explain your answer to any of the above questions on this page.

MTA Additional Information – Questions for <u>RECEIVING</u> Materials:

- 1. Add any comments that will be helpful to the MTA staff:
 - Please use this section to add any information that you feel is needed and/or helpful that has not been captured by the questions.
- 2. * Do you anticipate that an invention or a modified research material will result from your use of the Material?
 - Could any intellectual property or invention be created from use of the material? If so, click yes.
 - Could any derivatives or modified material be created from use of the material? If so, click yes.
- 3. *Do you have any existing patents, pending patent applications, or license agreements related to the Material?
 - Does any IP already exist that is related to the material? This could be in the form of invention disclosures, patents, patent application, or license agreement.

Completion Instructions – Questions for <u>RECEIVING</u> Materials:

- 1. Please validate that all relevant questions are adequately answered.
 - One the left side of the screen, you can click back to a certain page to check your answers.
- 2. Correct any errors or omissions.
- 3. When this has been done, please Click "Finish" to exit the form.
- 4. Once back on the workspace page, please click "Submit."
 - These two steps are covered by page 2 and 3 of this guide.

Please first review Appendix 1 for answering the general questions related to the DUA (Pages 1 & 2)

Nature of the Data & Data Request (Data and Files)

- 1. *Is GW the provider or recipient of the data to be transferred under the proposed DUA?
 - Is GW the one receiving Data? If so, GW is the recipient.
 - Is GW the one sending Data? If so, GW is the provider.
- 2. *Is the data any of the following (check all that apply)?
 - The Data could be Animal Data or Human Subjects Data or both
 - The Data could also be a different type of Data. If so, please put "Other"
- 3. *Nature of data for this Agreement:
 - To answer this question, please click on the box for a drop down.
 - This question is asking whether the data is de-identified, limited data set (LDS), protected health information (PHI), other (classified or falls under FERPA).
 - If you do not know, please choose "Unknown/Needs Guidance"
 - In the box provided under this question #3,

*Please enter as much information about the data and/or data elements as possible, including whether the data is: De-identified; identifiable data; human subjects data or animal research data; survey data; export controlled data, controlled unclassified information, HIPAA, FERPA, etc.:

• The more information you can provide here on the data and what you know about the data the smoother the internal review will proceed, as this information helps to determine how to draft and negotiate the DUA.

Export Controls and Intellectual Property

- 1. Do you think the data may be subject to export control considerations?
 - Please review this link to answer this question: <u>https://research.gwu.edu/export-</u> <u>controls-gw-policy</u>
 - While this question may seem repetitive of the general questions, it is important to consider the importance of export concerns for data transfers, as this changes the risk analysis of the agreement.
- 2. Do you have any existing patent(s) pending that are related to the subject matter of the data or the work to be performed under the proposed DUA?
 - This question is aimed at gaging the Intellectual Property concerns, if any for this DUA.
 - If an invention disclosure, patent application, patent, or license is related to the information being disclosed under the DUA, please check yes.
- 3. Is there a reasonable possibility of commercial utility or an invention from use of the data?
 - If you think, IP may be created from using the data, please check yes.
- 4. Are the terms of the proposed DUA acceptable to you?
 - Please review the terms and determine if they are acceptable.
 - If they are not, a new box will appear that will allow you to answer this question.
 - As DUAs are negotiated, now is the time to inform us of any issues you have with the terms.

Outgoing Data and Data Retention

- 1. If GW is the data provider, are there any (check all that apply):
 - Restrictions placed on the data by the prime award which sponsored the data generation?
 - GW collaborators who may have an interest in the data disclosure?
 - External collaborators or third parties who may have an interest in the data disclosure?
 - The aim of this question is to determine if the DUA needs to contain any special terms relating to the data such a restrictions and publication/disclosure of data.
 - If we are receiving data, there is no need to answer this question.
- 2. If the data will be collected or generated, will the data be shared, published or archived?
 - If GW is collecting, generating, or receiving data, what will be done with it?

Completion Instructions

- 1. Please validate that all relevant questions are adequately answered.
 - One the left side of the screen, you can click back to a certain page to check your answers.
- 2. Correct any errors or omissions.
- 3. When this has been done, please Click "Finish" to exit the form.
- 4. Once back on the workspace page, please click "Submit."
 - These two steps are covered by page 2 and 3 of this guide

Please first review Appendix 1 for answering the general questions related to the CDA/NDA (Pages 1 & 2)

Agreement Information

- 1. Describe the purpose of the exchange
 - It is customary for the negotiator to include a purpose for the CDA/NDA.
 - This helps ensure that the CDA/NDA is narrowly tailored to your work/project and it does not affect the rest of the university or other faculty.
 - The more specific you can be the better.
- 2. Who will be disclosing information
 - To answer this question, please click on the box. A drop down menu will appear.
 - If GW is disclosing information, choose institution
 - If the sponsor, company, contracting, or collaborating party disclosing information, choose contracting party
 - If information is flowing both ways, choose both
- 3. Provide a brief description of the confidential technology or information being disclosed:
 - It is customary for the negotiator to include a description of the information in the CDA/NDA.
 - Like with the purpose, this helps ensure that the CDA/NDA is narrowly tailored to your work/project and it does not affect the rest of the university or other faculty.
 - The more specific you can be the better.
- 4. Is it mandatory to receive or disclose information to accomplish the purpose stated above?
 - Receiving confidential information is risky for the university.
 - There needs to be a clear link between needing confidential information and accomplishing the purpose.
 - i. Please choose the correct answer yes or no.
 - ii. If there is no link, we may need to rethink the purpose or the need for Confidential Information.
- 5. Is there a deadline to have the agreement signed?
 - If there is a deadline, a new box will appear where you can input the deadline.
 - As NDAs may need to be done quickly, we appreciate having this information up front.

Additional Information

- 1. *Is there any possibility that the company's confidential information may co-mingle with similar work or information in your possession?
 - This question helps us determine the level of risk of this CDA/NDA
- 2. *Will you be sharing any confidential information with non-employees, including students?
 - This is usually a term on the CDA/NDA. Thus, we need to know the answer to properly negotiate the agreement.

- 3. *Has an invention disclosure been submitted by you related to this information that will be received or disclosed?
 - This question is aimed at gaging the Intellectual Property concerns, if any for this NDA.
 - If an invention disclosure, patent application, patent, or license is related to the information being disclosed under the NDA, please check yes.
- 4. *Do you plan to submit an invention disclosure prior to receipt or disclosure of confidential information?
 - This question is also aimed at gaging the Intellectual Property concerns, if any for this NDA.
 - If an invention disclosure is planned to be submitted that is related to the information being disclosed under the NDA, please check yes.

Completion Instructions

- 1. Please validate that all relevant questions are adequately answered.
 - One the left side of the screen, you can click back to a certain page to check your answers.
- 2. Correct any errors or omissions.
- 3. When this has been done, please Click "Finish" to exit the form.
- 4. Once back on the workspace page, please click "Submit."
 - These two steps are covered by page 2 and 3 of this guide