**GETTING STARTED: REQUESTING A SUBCONTRACT AMENDMENT**

1. **Create a Change Request**
   - Upon logging into the InfoEd portal, create a change request by clicking Change Requests and then clicking Subcontract - Subcontract Amendment from the Create New menu.
   
   *(Note: If you do not see the option to create a Change Request, you may need to submit a security form)*

Learn more: [osr.northwestern.edu/resources/infoed](osr.northwestern.edu/resources/infoed)
2. Complete the New Change Request Questionnaire

- **Step 1**: Link the Change Request to a Sponsored Project by clicking Linked Proposal and selecting Add New.

- **Step 2**: After linking a proposal (i.e. the SP#) to your change request, the relevant questions will appear below.

- **Step 3**: Complete options below:
  - Subaward Number
  - NUFinancials Project ID: enter project chartstring
  - Subaward Organization Name
  - Subaward PI Name
  - Period of Performance, SOW, and PI Information
  - Budget & Carry Forward
  - Other Information & Uploads

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**TIP SHEET**

**SUBCONTRACT MODIFICATION: SUBCONTRACT AMENDMENT**

<table>
<thead>
<tr>
<th>Tracking #</th>
<th>CR00000773</th>
</tr>
</thead>
</table>

**Proposal**

- **Principal Investigator**: Dinner, Shira Naomi
- **Title**: Prot#MV15-655: A Randomized, Double-Blind, Placebo Controlled Phase 3 Study of Venetoclax in Combination with Azacitidine Versus Azacitidine in Treatment Naive Subjects with Acute Myeloid Leukemia Who Are Ineligible for Standard Induction Therapy
- **Original Sponsor**: AbbVie Inc.
- **Sponsor**: AbVie Inc.
- **Award**: Hematology-Oncology

**Subaward Number:**

**NUFinancials Chartstring (Fund-Department-Project-Activity):**

**Subaward Organization Name:**

**Subaward PI Name:**

- **Period of Performance, SOW, and PI Information**
- **Budget & Carry Forward**
- **Other Information & Uploads**

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Period of Performance, SOW, and PI Information:
- Change Subaward PI:
  Upon selecting Yes to the question regarding whether to change the Subaward PI an additional prompt for more information about the PI change will appear

(Note: Unless required by the sponsor, providing a biosketch and other support is optional, but it is a best practice to include these documents in all cases)

Subcontract Conflict of Interest (COI) Policy:
- If the subawardee has a PHS or other sponsor-compliant policy, then select "Subawardee has their own policy"
- If the subawardee does NOT, then select "Following NU COI Policy"
- N/A should be used in very rare instances when the sponsor does NOT have a COI requirement. Reference your Notice of Award in these cases.

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Modify period of performance:
If selecting Yes to the question regarding whether to Modify period of performance, an additional prompt to enter the new budget period dates will appear
GETTING STARTED:
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• Modify statement of work:
  If selecting Yes to the question regarding whether to Modify statement of work, an additional prompt to upload the revised statement of work will appear.

  □ Modify statement of work?  
  □ Upload modified statement of work:

Budget & Carry Forward
• Change in funding amount:
  The options include Decrease, Increase, or No Change.

  (Note: If Decrease or Increase, you will be prompted to enter the amount of change, the cumulative amount to date and upload the subaward budget, and provide input whether we need to authorize carry forward for the subcontract with the amendment)

Decrease
Follow the prompts for more information.

  □ Is there a change in funding amount? (Not including carryforward changes)  
  □ Amount of change:  
  □ Cumulative amount to date (including this request):  
  □ Upload subaward budget:

Learn more:  
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Upon selecting Increase, a prompt to provide whether there are sufficient funds appears.

If selecting Yes, a prompt to upload the verification document appears. (e.g., department tracking sheet). A verification document that you can use for this purpose can be found on the OSR website Tools page.

### TIP SHEET

**GETTING STARTED:**
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### Increase

Upon selecting Increase, a prompt to provide whether there are sufficient funds appears.

- **Is there a change in funding amount?** (Not including carryforward changes)
  - **Amount of change:** $0
  - **Cumulative amount to date (including this request):** $0
  - **Upload subaward budget:**
    - **Are sufficient funds allocated to the subcontract budget line(s) in NU Financials for this action and all previous subaward obligations?**
      - Yes
      - No
  - **Upload verification documentation:**

### If selecting No, a prompt to provide budget revisions appears

- **Is there a change in funding amount?** (Not including carryforward changes)
  - **Amount of change:** $0
  - **Cumulative amount to date (including this request):** $0
  - **Upload subaward budget:**
  - **Are sufficient funds allocated to the subcontract budget line(s) in NU Financials for this action and all previous subaward obligations?**
    - No
  - **List budget revisions:** Calculate F&A as applicable. [e.g., if budget category 78651 78643 (which do not incur F&A) is increased, then also include a line item for the corresponding decrease in F&A.]

<table>
<thead>
<tr>
<th>Budget Category</th>
<th>Increase Amount</th>
<th>Decrease Amount</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$0</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td><strong>Totals:</strong></td>
<td>$0</td>
<td>$0</td>
<td></td>
</tr>
<tr>
<td><strong>Grand Total:</strong></td>
<td>$0</td>
<td>$0</td>
<td></td>
</tr>
</tbody>
</table>

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- **Carry Forward:**
  
  If selecting Yes to the question regarding whether to authorize carry forward for the subcontract with the amendment, an additional prompt provide the carry forward budget periods (to/from) and upload the budget (optional) which appear as the full amount or specific amount.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do we need to authorize carryforward for the subcontract with this amendment?</td>
<td>Yes, for full amount</td>
</tr>
</tbody>
</table>

- **Do we need to authorize carryforward for the subcontract with this amendment?**
  
  Carry forward requested:
  
  * FROM budget period: | to: |
  
  * TO budget period: | to: |

- **Do we need to authorize carryforward for the subcontract with this amendment?**

  * Please provide specific amount: |

  Carry forward requested:
  
  * FROM budget period: | to: |
  
  * TO budget period: | to: |

- **Learn more:**
  
  osr.northwestern.edu/resources/infoed
**GETTING STARTED:**
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**Other Information and Uploads:**
Upon selecting **Yes** to the question regarding whether the subaward involves human or animal subjects, additional prompts for more information will appear.

- **Human Subjects Assurance:**
  If you choose to **Upload IRB Approval**, an additional prompt appears to upload the IRB approval letter.

  If you choose to **Provide Assurance Number**, you will be prompted to **Provide subawardee FWA**. If you need to find the subrecipient’s FWA, click on the **NIH Search** link to bring up the NIH’s Office for Human Research Protections search tool.

  - **Human subjects involved on subaward:**
    - **Yes**
    - **No**

  - **Provide subawardee FWA (NIH Search):**

Upon selecting **Yes**, not previously address on an agreement under this project, to the question regarding whether Human subjects data will be exchanged, additional prompts for more information will appear.

  - **Will human subjects data be exchanged?**
    - **Yes, addressed on a previous agreement under this project.**
    - **Yes, not previously addressed on an agreement under this project.**

  - **Human subjects data will be exchanged under the subcontract:**
    - from Northwestern to subrecipient.
    - from subrecipient to Northwestern.
    - in both directions.

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Upon selecting **No** to the question regarding whether human subjects data will be completely de-identified, additional prompts for more information will appear.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Is the human subjects data completely de-identified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Please provide a description of the human subjects data:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Please provide the permitted uses of the human subjects data:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Upon selecting **Yes** to the question regarding whether Personally Identifiable Information (PII) or Protected Health Information (PHI) is included, additional prompts for more information will appear.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there Personally Identifiable Information (PII) or Protected Health Information (PHI) included?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>* Is the data a limited data set (as defined by HIPAA)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>* Does the provider IRB approval, consent, and protocol contemplate or reflect the anticipated disclosure and/or use of the data including subject identifiers?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

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• Animal Subjects Assurance:
  • Is animal work (including development of custom antibodies) being done at the subcontract site?
  • Has the subrecipient IACUC protocol been acknowledged by Northwestern IACUC? Note that Northwestern IACUC acknowledgement must be obtained prior to OSR execution of the subcontract agreement. Please refer to Northwestern IACUC for guidance.
  • Upload Northwestern IACUC acknowledgement letter listing the subrecipient site.
  • Upload subrecipients IACUC approval letter.
• Provide additional information or uploads as applicable.
  (NOTE: For requests involving animal subjects or development of custom antibodies, more information is available on the IACUC website).

• Embryonic Stem Cells:
  If Yes, then stem cells need to be included on the NIH Human Embryonic Stem Cell Registry
  • Are embryonic stem cells involved in the subaward?
  • Is the subcontract following Northwestern’s COI policy (i.e., subrecipient does not have their own policy)?
  • Upload current COI status from eDisclosure:
• Special Additional Terms:
• Upload most recent (within the last year) subrecipient progress report:

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• Provide additional information or uploads as applicable.

Additional information for OSR (optional):

Additional Documents for OSR (optional):

3. Save
• Click Save at any time to save your work and return to it later

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