Departments and OSR
Partnering for Subagreements

Amy Mabry
Subaward Specialist, Office of Sponsored Research

Brie Teer
Subaward Team Manager, Office of Sponsored Research

8th Annual Symposium
for Research Administrators

November 10, 2020
What is the best way to ensure subagreements can be issued as quickly as possible?

Required Documents and Importance

Compliance Information and Requirements

Tips for Review and SIP Submission

Tips for document review and SIP submission
UNC Subaward Process

**OVERVIEW OF SUBAWARD PROCESS**

**Proposal Stage**
- Letter of Intent
- Scope of Work
- Budget & Justification

**Award Stage**
- Revised SOW
- Revised Budget
- Revised Budget Justification

**Risk Assessment**
- Subrecipient Commitment Form
- Post-Audit Team Review
- Subaward Team Review

**Monitoring Plan**
- Analysis of Risk
- Plan incorporated into agreement (if necessary)

**Draft and Execute**
- Annual Audit Review
- Desk Reviews
- Monitoring

**OSR**
- Sponsored Projects Specialist (SPS) and Campus Partner (CP)

**OSR**
- Subaward Team Audit and Subrecipient Monitoring Team
Initializing a Subagreement- SIP Submissions

• RAM Trackers are auto-generated for new Outgoing Subaward Project ID’s

• The “New Project ID Notification” email includes a link to initiate a SIP request

• Departments must review SIP questions carefully and confirm responses with the Project team
  ➢ Ensure all Subrecipient documentation is up to date including Human and Animal Subjects and Data Use responses

• For Modifications, the Department will need to initiate a SIP upon receipt of a Fully Executed Prime Award

• If you have SIP questions, please watch the SIP presentation or reach out to Brie at bteer@email.unc.edu with your questions!
What are the required subaward documents and why are they important?

- LETTER OF INTENT/PHS 398 FACE PAGE
- STATEMENT OF WORK
- BUDGET
- BUDGET CHECKLIST (IF APPLICABLE)
- BUDGET JUSTIFICATION
### OVERVIEW OF SUBAWARD PROCESS

#### Award Stage

**Required Documents**

<table>
<thead>
<tr>
<th>Transaction Type</th>
<th>Detailed Budget</th>
<th>Budget Justification</th>
<th>Scope of Work</th>
<th>Prime Award</th>
<th>Sponsor Final Approval</th>
<th>LOE / Forecasts</th>
<th>Internal/UNC HR Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Funding</td>
<td>X</td>
<td>(x)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Terms &amp; Conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carryover and Additional Funds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(x)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Carryover Only</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(x)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Change in Budget</td>
<td></td>
<td></td>
<td></td>
<td>(x)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in Subrecipient PI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(x)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in UNC PI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(x)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Change in SOW</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deobligation of Funds &amp; Early Termination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deobligation of Funds without Early Termination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early Termination without Deobligation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Subagreement Break in Peace of Performance</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

X = Requirement to issue draft agreement.

(x) = Required only if required by Sponsor that they are included in the amendment or Sponsor Approval is needed for action. Check with your SPS if you are unsure.

*Additional requirements for the budget or amendment, additional documentation needs to be provided acknowledging sponsor’s confirmation of forthcoming deobligation. Deobligation amendments may require a revised budget and budget justification dependent upon sponsoring entity requirements.*
WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?

Letter of Intent/PHS 398 Face Page

Provides key information for research project such as:
- Key Collaborators
- Project dates
- Indirect rate for project
- Human or animal subjects

Provides key information for subrecipient such as:
- Certifications and assurances
- Conflict of Interest Policy information
- DUNS number (please encourage Subsites to provide – very helpful)
WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?

Letter of Intent/PHS 398 Face Page

• Outgoing Subrecipient Letters of Intent are to be filled out and signed by authorized official of the subrecipient organization.

• If available, please provide PHS 398 Face Page.

• Example provided on OSR website under OSR Forms and Tools and in Ramses Proposal Module. Refer to OSR Operating Standards and Procedures 300.08 and 500.11.
WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?

Statement of Work

• Should answer “Who is doing what, when, where and how much?”
  • Detailed, yet concise, description of research work specific to the subrecipient
  • Description should be clear for non-technical reviewers
  • List of deliverables or planned milestones including dates or timeframes
  • Mirrors budget and justification
  • May need updating each year, depending on work being completed or any changes at the sub site (SOW changes require sponsor prior approval)

• If the SOW is too generic and there are concerns of performance at the sub site, it may be difficult to terminate the subagreement!
**WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?**

**Budget- Direct Costs**

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE ON PROJECT</th>
<th>GRI</th>
<th>Total</th>
<th>FTE</th>
<th>STMT</th>
<th>SALL</th>
<th>INSTR</th>
<th>CONTRACT</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Detailed Budget for Initial Budget Period**

**Direct Costs Only**

- From 06/01/20
- Through 09/30/21

**Budgeted Personnel**

- Should include first and last names (middle initials are helpful and can prevent delay upon award issuance) for compliance.

**Line-item portrayal of costs relating to the science of the project, should clearly reflect the costs to complete the Scope of Work.**

**If personnel has changed at subrecipient site, we must have a revised budget that matches the personnel who will be performing the work.**

**Budget expenses should be allowable, necessary, allocable, reasonable, and consistent.**

**Budget and justification must match in terms of dollars and use of funds.**
WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?

Budget - Indirect Costs

- Checklist should be provided for projects when the budget is submitted on a SF424 form.
- Regardless of budget format, indirect cost rate should be listed on budget as well as amount of base and indirect cost total.
- Indirect rate should be verifiable based upon published rate for subrecipient or sponsor guidelines.
WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?

**Budget Justification**

- Required for all subaward initial agreements; for amendments only if required by sponsor
- Should clearly identify all cost categories
- Detailed text version of budgeted line items
- Personnel names should be complete, full names for compliance purposes
- Percent effort/calendar months should be listed for each person on budget
- Expenses for each category must match budget and be for correct budgeted period
- Indirect costs should state rate and any exclusions from calculation

---

**UCLA Budget Justification**

UCLA employer-based fringe benefits include costs such as retirement, taxes, health and welfare, and are assessed as a percentage of employee salary using Current Benefit Rates (CBR) based on employee title code and payroll classifications. Current Benefit Rates (CBR) are approved by the US Department of Health and Human Services (DHHS) as part of UCLA's federally negotiated rate agreement dated Oct 12, 2018. These negotiated rates are established through June 30, 2019 and are provisional as of July 1, 2019 and beyond.

For additional information see: https://www.finance.ucla.edu/composite-benefit-rate-assessment.

**Key Personnel**

- **PhD, Subaward Lead** (1.2 cal months in Year 4)

**Travel**

- **Domestic Travel** ($1,745 per year in Year 4)
- **International Travel** ($5,105 per year in Year 4)

**Other Expenses**

- **TIF Fee** ($53 in Year 4)
- **Indirect Costs**

---

2020 SYMPOSIUM FOR RESEARCH ADMINISTRATORS
Research Subjects and Data Transfer

DID YOU KNOW?!

- DEPARTMENTS CAN DOWNLOAD THE RESEARCH SUBJECTS AND DATA TRANSFER FORM AND SEND TO A MEMBER OF THE RESEARCH TEAM SO THEY CAN ANSWER THE QUESTIONS AROUND SCIENCE!
IRB Questions – Why the change?

• FDP subaward templates are updated nearly every year. The contracts capture the never-ending changes to human subject research compliance which adds a new level of complexity to subagreement drafting.
• The updated SIP questions allow for clarity when drafting subagreements and reviewing compliance documentation.
WHAT ARE REQUIRED DOCUMENTS AND WHY ARE THEY IMPORTANT?

Research Subjects and Data Transfer Form

Please indicate how data is being transferred.
☐ From UNC to the Subrecipient
☐ From the Subrecipient to UNC

What Human Subject data will be collected? Select all that apply.
☐ Names (Includes names/signatures/initials on consent forms)
☐ Telephone Numbers
☐ Fax Numbers
☐ Email addresses
☐ Social Security Numbers
☐ Medical Record Numbers
☐ Health Plan Numbers
☒ Date Elements for Individual
☐ Date of Service
☐ Discharge Date
☐ Admission Date
☐ Age in Years, Months, Days or Hours
☐ Date of Birth
☐ Date of Death
☐ Account Numbers
☐ Certificate/License Numbers
☒ Address Elements
☐ Street Address
☐ City
☐ County
☐ State
☐ Zip code
☐ First 3 digits of zip code

☐ Vehicle Identifier, including license plate numbers
☐ Web URLs
☐ Internet Protocol (IP) Addresses Numbers
☐ Photographic Image; Photographic Images are NOT limited to images of the face
☐ Any other characteristic that could uniquely identify the individual
☐ Device Identifiers/Serial Number
☐ Biometric Identifiers, including fingerprint and voice prints
☐ None of the above

Does it really matter if the correct data elements are selected?
YES, it matters!

The identifiers selected determine whether the data is Full PHI, Limited Data Set or De-identified.
Research Subjects and Data Transfer

ATTACHMENT 7

FDP TEMPLATE

Limited Data Set Additional Terms and Conditions:

Data transferred under this Agreement contains identifiable data elements derived from human subjects and constitutes a Limited Data Set ("LDS Data"), defined in the Health Insurance and Portability Act of 1996 at 45 C.F.R. § 164.514(a)(2) ("HIPAA").

Recipient certifies that it will only use LDS Data as permitted by this Agreement, the IRB, Inform consent form or Waiver Authorization, and the Protocol. Nothing herein shall authorize the Recipient use or further disclose the Data in a manner that would violate the requirements of Provider under 45 C.F.R. 164.514.

In accessing LDS Data, Recipient must use appropriate technical and physical safeguards to prevent use or disclosure of LDS Data other than as allowed by this Agreement.

Recipient shall report to the Provider any use or disclosure of the LDS Data not provided for by this Agreement within five (5) business days of when it becomes aware of such use or disclosure.

Recipient will not use LDS Data to identify or contact any individuals who are or may be the sources ("DS Data without specific written approval from Provider and appropriate Institutional Review Board approval. Should Recipient inadvertently receive identifiable information or otherwise identify a subject Recipient shall promptly notify Provider and follow Provider’s reasonable written instructions, which may include return or destruction of the identifiable information.

Additional Terms and Conditions:

Not include personally identifiable information as defined in INIST Special Data being provided is coded, the Provider will not release, and the Recipient to the code.

Covered Entity, the Data will be de-identified data, as defined by the HIPAA Accountability Act of 1996 ("HIPAA").

Recipient use the Data to identify or contact individuals who are or may be the sources if inadvertently receive identifiable information or otherwise identify a subject. I promptly notify Provider and follow Provider’s reasonable written instructions or destruction of the identifiable information.

I promptly report to the Provider any use or disclosure of the Data not permitted by which it becomes aware.
Research Subjects and Data Transfer

The Data Transfer and Use Agreement (DUA) is a component of the FDP template that can outline when data is being transferred and an independent or Master DUA has not been established. This provides the opportunity to incorporate appropriate terms that may prevent a separate DUA from being needed reducing administrative burden for both parties.

A Department may choose to establish a DUA and our team would need a copy of document or ALICE number, as subsite will often request for review. Information required on Research Subjects and Data Use Form and is uploaded as part of SIP request.
What are the requirements? Why do they take so long? Why are they required?
As the recipient of the sponsor’s funds, we are responsible for ensuring appropriate terms and conditions are flowed to the subrecipient and to have a process for subrecipient monitoring to ensure compliance! We are also responsible to ensure that appropriate approvals are in place for research subjects.
Human and Animal Subjects Research

**Human Subjects**

UNC-CH requires current approved IRB documentation from subsite for human subjects research if using their own IRB.

If subsite is following UNC-CH’s IRB, a Reliance Agreement is required to be signed between UNC-CH and subrecipient indicating subsite is ceding to UNC-CH for IRB oversight.

If there is a Single IRB (sIRB) in place, we require the approved sIRB.

Additional information on IRB Reliance Agreements can be found at: https://research.unc.edu/human-research-ethics/reliance/

**Animal Subjects**

UNC-CH requires current approved IACUC documentation from subsite for animal subjects research.

UNC-CH IACUC office reviews subrecipient’s SOW, IACUC approval and application for congruency and issues required MOU (Memorandum of Understanding) between UNC-CH and subrecipient.
Conflict of interest represents circumstances in which professional judgments or actions regarding a primary interest, such as the responsibilities of a medical researcher, may be at risk of being unduly influenced by a secondary interest, such as financial gain or career advancement.

Reference:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4596167/#:~:text=Abstract,financial%20gain%20or%20career%20advancement.
Conflict of Interest

Per 42 CRF Part 50, any grant or contract administered through a PHS agency

National Science Foundation AAG Chapter IV, Section A

Any Sponsor who requires that Institution follows PHS/NSF regulations in execution of the contract
COMPLIANCE REQUIREMENTS

Conflict of Interest

Internal Processing Form (IPF)

- Additional screen appears when PHS or NSF is sponsor and sub-awards are indicated. Other known agencies being added.
- Must enter each entity name separately
- Must answer YES or NO if the entity has a compliant COI policy. Directions provided to End User on how to confirm if policy is acceptable.
- If Sub does not have a compliant policy, then MUST fall under UNC’s.
Conflict of Interest

Subagreement template requires designation as to which entity’s Financial Conflict of Interest policy (COI) will apply.

If Subrecipient is designating their own policy, then it must comply with the requirements of the awarding agency. For PHS/ NSF funded research, we must be sure that a policy is compliant. If the subrecipient is not a member of the FDP or is not listed in the FDP FCOI Clearinghouse and they have certified to have a compliant policy, we will request a copy of the policy which must be reviewed by the UNC COI office.

If found non-compliant or subrecipient self discloses the lack of a compliant policy, subsite will need to complete UNC COI training by providing all staff involved in research and emails will be sent to complete required training for each subaward project as well as disclosures completed by PI, Investigators, and other key personnel.
A Subrecipient Commitment Form is required annually of each subrecipient for each project and for each budget period of funding.

- Allows UNC to capture important information on human and animal subject use, and details of approved documentation of IRB and IACUC policies for period of research.
- Provides UNC with information on cost sharing, indirect rates of subsite, and financial audit information for non-FDP members.
- Form required to be completed and signed, along with agreement or amendment, from subsite – UNC will not fully execute subaward without a completed subrecipient form.
Risk Assessment

Model simplified to four primary attributes:
- Foreign or Domestic?
- Single Audit finding(s) or not subject to Single Audit
- Subaward greater than $1,000,000
- Subaward is greater than 50% of the prime award

Selected risk attributes for baseline to ensure compliance
Weigh perfect absolute assurance vs. our accepted level of commitment
Determine UNC’s risk appetite
Must determine if a particular risk is applicable to the project
Compare risk to the Statement of Work, Budget, etc. to determine if it is high risk for the particular project
Risk Attributes are both financial and programmatic
Must protect sponsor funds on both fronts

Uniform Guidance §200.331 outlines the requirements for pass-through entities!
TIPS FOR DOCUMENT REVIEW AND SIP SUBMISSION

Review Tips

- Take time to review all documents from subsite and ensure all information is present.
- Verify budget and justification to ensure that calculations are accurate and the documents are in agreement.
- Ensure scope of work matches science and answers the key question.
- Provide all necessary documents/attachments requested during SIP process for initial agreement or amendment; don’t skip questions or attachments, we will have to come back to the submitter, which delays the process.
- Provide compliance documents and/or work with research staff or subsite to obtain necessary requirements.
- *Being proactive will save department and subaward time in preparing submitted awards!"
Potential Delays: Initializing a Subagreement

Delay in SIP Submission

Conflicting information in SIP, documentation and/or notes

Obtaining documents from Subrecipient
- Subrecipient Commitment Form
- FDP Attachment 3B (Subrecipient Contacts)
- Correct SOW and Budget (including full name, no initials)
- Subrecipient Rate Agreement
- Subrecipient Audit Report

Completing Risk Assessment

Conflict of Interest requirements

Subrecipient or department responses

Human/Animal Subjects Research or Data discrepancies

Budget issues (calculations, names, not matching justification, etc.)

TBN (To Be Named) Subrecipients
Opportunities for Efficiency

• Open Lines of Communication
  • with your OSR Sponsored Projects Specialist and members of the OSR Subaward Team- we are all one team. Promptly communicate revised award amounts to Subrecipients and request revised documents.
  • Build a partnership and here to help!
  • Confirm appropriate contacts in the UNC Department and at the subrecipient institution including a central office email.

• Provide DUNS Number
  • This almost always helps to move the issuance along a bit faster; we are able to verify key pieces of information and ensure we are issuing to the correct legal entity.

• Review Compliance Information Early!
  • Compliance can be a hard stop, by reviewing early we can work together to get a head start on the requirements.

• RAM Tracker Transparency
  • Subaward team will type clear, concise notes in RT and encourage departments to check Notes section prior to contacting subaward team, as information being sought may already be available. This will allow the departments to obtain the information quicker and will allow the Subaward Specialist to continue drafting.

• Ensure Subrecipient is listed in the ConnectCarolina Vendor Table
RESOURCES

Helpful Links:

Office of Sponsored Research Subagreement Initiation Portal:
https://research.unc.edu/sponsored-research/subagreements/subagreement-initiation-portal-guidance/

Subagreement Matrix of Required Documents:

Subrecipient Letter of Intent (Outgoing Award):

Research Subjects and Data Transfer Form:
https://research.unc.edu/files/2019/09/osr-Subagreement-Data-Form.pdf

FDP Tool for Classifying Human Subjects Data:
RESOURCES

Helpful Links:
FDP Expanded Clearinghouse:
https://thefdp.org/default/expanded-clearinghouse/
*to find entities that have certified to a PHS compliant COI policy (FDP FCOI Clearinghouse), select the list of compliant institutions and entities

FDP Subaward Frequently Asked Questions (FAQ’s):
https://thefdp.org/default/subaward-forms/
*under “Guidance” you will find the most current version of the FAQ’s

RAM Tracker Transparency Information:
https://research.unc.edu/2019/06/13/ram-tracker-transparency-update/

ConnectCarolina Vendor Table:
*Found by the following breadcrumbs in ConnectCarolina
Finance Menu > Suppliers > Supplier Information > Add/ Update > Review Suppliers
RESOURCES

Helpful Links:

UNC Vendor Information:
https://finance.unc.edu/services/becoming-a-vendor-with-unc/

UNC Office of Sponsored Research Policy 500.11 - Outgoing Subrecipient Agreements:
https://unc.policystat.com/policy/6590565/latest/

UNC Office of Sponsored Research Helpful Resources Links:
https://research.unc.edu/sponsored-research/resources/#rscLinks

UNC Office of Sponsored Research Helpful Regulatory Compliance Links:
https://research.unc.edu/sponsored-research/resources/#rscCompliance
CONTACT US

Brie Teer
bteer@email.unc.edu | (919) 962-4678 | www.research.unc.edu/sponsored-research

Amy Mabry
amy.mabry@unc.edu | 919-962-4691 | www.research.unc.edu/sponsored-research

www.symposium.web.unc.edu | OSR_Symposium@unc.edu