Planning & managing budgets across multiple sites: Avoiding subaward Hades

CTSI Research Career Development Seminar
Multisite Trial Development and Implementation Miniseries

Hosted by the Clinical Research Support Center (CRSC) and
CTSI's Research Education, Training, and Career Development core (CTSI-Ed)

CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

UNIVERSITY OF MINNESOTA

Driven to Discover℠

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Stacy Valenzuela, RAC, Director of Clinical Research Grants Development, Department of Pediatrics, UMN

Slides 25-31: Roles and responsibilities of sponsored projects for multisite projects; tips on getting multisite subawards smoothly through the system
Pamela Webb, Associate Vice President for Research Administration, Sponsored Projects Administration, UMN

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Clinical Trial Site Budget Development

And the Importance of Clinical Research Billing Compliance

Where to start?

Create a cost analysis (cost budget)

- How much will it cost for the site to complete all protocol required tasks?
- What expenses will post to the project and how?
- The funding source is non-negotiable (ex. government agencies) or non-existent (ex. intramural funding), do I still need to create a cost analysis?
  - Yes!
- The sponsor is stating all procedures are performed as routine care/standard of care, do I still need to create a cost analysis?
  - Yes! A CMS coverage analysis is also required.

Intro: Clinical Research Billing Compliance

Center for Medicare & Medicaid Services (CMS) Coverage Analysis

Coverage analysis (CA) is performed for protocols that require any billable items/services, regardless of payer (e.g. CPT/HCPCS items/services).

**Trigger Question(s):*

- *"Will all protocol-required items and services that produce data for the study be funded by intramural or extramural funding/support?"*
- *"Will one or more services required by the protocol be billed to participants or their insurers?*

Why is Medicare coverage often considered the basis for coverage analysis?

- Medicare is driver of reimbursement in the U.S.
  - CMS beneficiaries represent significant population of patients
  - Most private payers adhere to Medicare rules
- Medicare is considered "most favored nation (payer)"
  - Requires sites to provide Medicare best contractual terms (pricing implications)

CA used as a financial budgeting and billing blueprint for research studies.

- Effective budgeting tool, ordering tool, billing tool, auditing & monitoring tool, invoicing and financial reconciliation tool

Intro: Clinical Research Billing Compliance

Center for Medicare & Medicaid Services (CMS) Coverage Analysis

Potential points of failure

- CA not performed
- CA not performed properly
- Timing of performing CA (too early or too late)
- Relying on investigator statements or site-specific practices when documenting Routine Costs

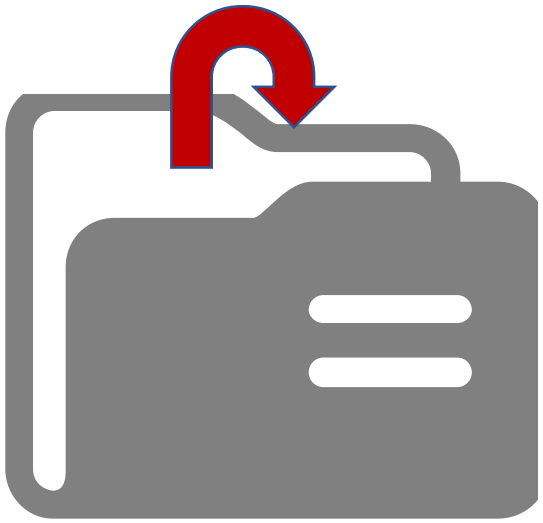
Risk Mitigation

- Budgeting shortfalls and/or potential “kick-backs”
- False Claims, including but not limited to “double-billing” and associated fines
  - “Double-billing” billing for services already paid by a study sponsor
  - Billing for services performed for research-purposes only
- Litigation and settlements that may result due to inconsistencies between the budget, contract teams, and informed consent (s)
- Billing for services promised free in the informed consent

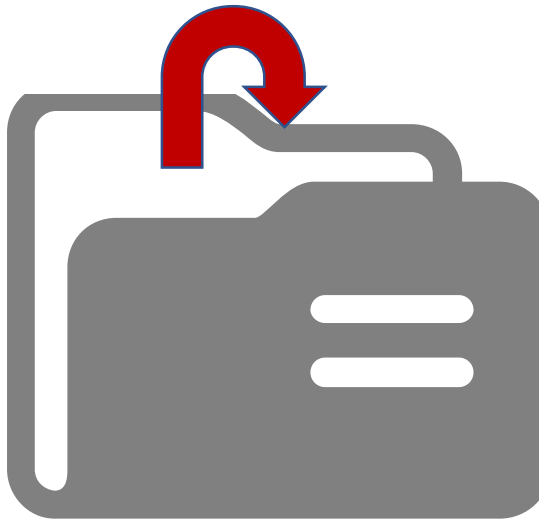
Coverage Analysis Process

Required Documents

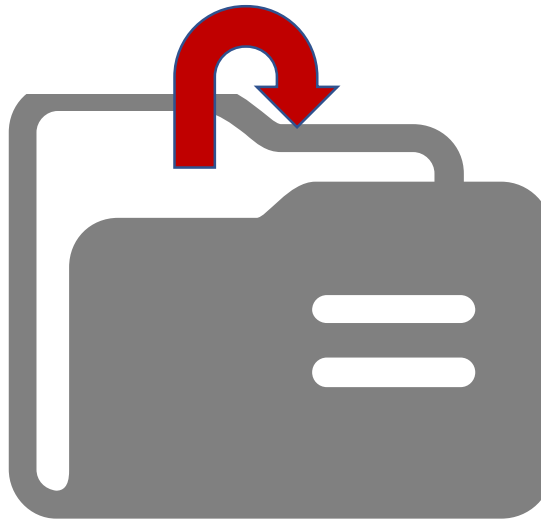
Current Protocol



Draft Contract



Draft Informed Consent



**Coverage analysis should be completed before site budgeting begins.*

Coverage Analysis Process

STEP 1 – Determining Qualifying Clinical Trials (QCT)

Must meet ALL of the following criteria:

1. The subject or purpose of the trial is the evaluation of an item or service that falls within a Medicare benefit category; and
2. The trial must have therapeutic intent; and
3. Interventional studies must enroll patients with diagnosed disease

QCTs must also meet at least one of the following criteria:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA; or
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA; or
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; or
4. Drug trials that are exempt from having an IND under 21 CFR 312.2 (b) (1)

Coverage Analysis Process

STEP 2 – Identifying "Routine Costs" for Qualifying Trials

"Routine Costs" under the Federal Clinical Trials Policy:

1. "Items or services that are typically provided absent a clinical trial (e.g. conventional care);
2. "Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. "Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications."

Conventional Care (CC)

1. CMS refer to "conventional care" and not "standard of care" – concepts are similar but not identical. Conventional care defined as items/services typically provided absent clinical trial participation.
2. CC services should be documented by citing specialty guideline, or in lieu of guidelines, nationally recognized peer-reviewed publications.

- Professional association specialty guidelines and treatment (Ex. NCCN)
- Specialty disease textbooks
- Nationally recognized peer-reviewed publications
- NIH recommendations
- Drug compendia
- Guidelines.gov

Coverage Analysis Process

STEP 3 – Do CMS Rules Allow for Coverage/Reimbursement?

National Coverage Determinations (NCDs)

1. Issued by CMS (federal)

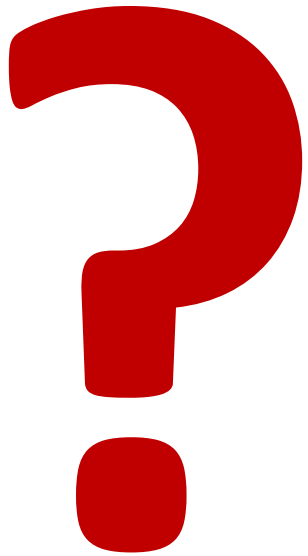
Local Coverage Determinations (LCDs)

1. Issued by Medicare Administrative Contractors (state)
2. May take precedence over NCDs

Coverage analysis documentation/rationale should address:

1. What does the service do? (diagnostic vs. therapeutic)
    - Therapeutic – service designed to impact human condition
    - Diagnostic – service performed for symptomatic patient
    - Screening – service performed for asymptomatic patient
2. Why is it clinically relevant for this disease and study? (e.g. which category of Routine Costs)
    - CC (site specialty guidelines and/or publications)
    - Monitoring the effects of the investigational treatment
    - Detection or prevention of complications (safety monitoring)
    - Administration of investigational item/service
3. Applicable specialty guidelines/publications & NCDs/LCDs supporting coverage.

Quiz Questions



True/False: The lead PI for a trial states that a laboratory test required for a study visit is routinely performed for the patient population. Since it is institutional practice to perform the test, it is okay to bill the test to a third-party payer without documenting coverage.

Multiple Choice: Properly performing a coverage analysis protects the University from which of the following:

A) Submitting false claims

B) Budgeting shortfalls

C) Penalties

D) All of the above

True/False: The trial is funded by the NIH, so our site does not have to complete a coverage analysis in order to bill third-party payers for protocol required procedures.

Budget Development: Categories

Startup Fees: one-time, upfront, unconditional & non-refundable

Administrative startup
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

IRB/IEC review
- Charge or Effort?
  - Industry – Charge & Effort
  - Non-industry – Effort

Investigational pharmacy setup
- Charge or Effort?
  - Industry – Charge & Effort
  - Non-industry – Effort

Radiology startup
- Charge or Effort?
  - Industry – Charge
  - Non-industry - Effort

Laboratory setup
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

CMS coverage analysis
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

Other institution-specific fees

Budget Development: Categories

Capitated Reimbursement (per subject/per visit): Protocol-driven, based on milestones & typically non-invoiceable

Study procedures per protocol

* Use coverage analysis to determine procedures that are non-billable/study paid

- Charge or Effort?
  - Industry – Charge
  - Non-industry – Charge

Research Space

- Charge or Effort?
  - Industry – Charge
  - Non-industry – Charge

Subject reimbursement

- Charge or Effort?
  - Industry – Charge
  - Non-industry – Charge

Study Team Effort

- Investigator oversight
- Study coordinator
- Research nurse
- Data entry
- Administrative

Effort Estimates

- Per protocol:
  - Informed Consent
  - Inclusion/Exclusion
  - Medical History
  - Study Medical Procedures
  - Questionnaires & Surveys
  - Randomization
  - Adverse Event Reporting
  - Concurrent Medications

- **Hidden costs**
  - Pre-screening
  - Scheduling visits
  - Travel to/from clinics
  - Waiting for subject/nurse/pharmacy
  - Data entry (eCRFs)
  - Query resolutions
  - Communication with:
    Sponsor/monitor, PI, manager, compliance, Subject, pharmacy, lab, billing, IRB, clinic staff, etc.
  - Special populations

Budget Development: Example

Items and Services	Unit Cost	Screening Visit	Example						Total
			Example						
			Visit 1	Visit2	Visit 3	Visit 4	Visit 5	Visit 6	
Time/Effort									
Informed Consent	175.00	1.00							175.00
Adverse Events	175.00	0.25	0.25	0.25	0.25	0.25	0.25	0.25	306.25
Concomitant Medications	175.00	0.25	0.25	0.25	0.25	0.25	0.25	0.25	306.25
Demographics/Medical History	175.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1225.00
Inclusion/Exclusion Criteria	175.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1225.00
Tanner Staging Assessment - reporting only	175.00	0.50	0.50	0.50	0.50	0.50	0.50	0.50	612.50
Vital, height, weight - reporting only	175.00	0.50	0.50	0.50	0.50	0.50	0.50	0.50	612.50
Questionnaires	175.00	1.50						1.50	525.00
PI Oversight	175.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1400.00
Data entry (eCRF's – Screening Visit)	54.00	2.00							108.00
Data entry (eCRF's – other visits)	54.00		1.50	1.50	1.50	1.50	1.50	2.00	513.00
Scheduling study visit (PCH, CCTS, etc.)	54.00	0.50	0.50	0.50	0.50	0.50	0.50	0.50	189.00
Travel time (PCH, U of U, CCTS, etc.)	54.00	0.50	0.50	0.50	0.50	0.50	0.50	0.50	189.00
Administrative Effort	54.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	378.00
Coordinator Effort	54.00	5.00	4.00	4.00	4.00	4.00	4.00	5.00	1620.00
Evaluation & Management Services									
Physical Exam	248.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1736.00
Labs									
Venipuncture	27.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	189.00
Specimen Handling	69.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	483.00
CMP	90.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	630.00
CBC	55.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	385.00
Urinalysis	47.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	329.00
Procedures/Scans									
Chest x-ray	200.00	1.00						1.00	400.00
DXA scan and interpretation	150.00	1.00						1.00	300.00
Study Medications/Administration									
Investigational Pharmacy Dispensing	60.00		1.00	1.00	1.00	1.00	1.00		300.00
IV Drug administration	350.00		1.00	1.00	1.00	1.00	1.00		1750.00
Research Space/Participant Reimbursement									
CCTS Space	36.00	3.00	1.00	1.00	1.00	1.00	1.00	1.00	324.00
CCTS Nurse	111.00	1.00	0.50	0.50	0.50	0.50	0.50	0.50	444.00
Visit Sub Total - Total Coordinator Effort		9.00	7.50	7.50	7.50	7.50	7.50	9.00	55.50
Visit Sub Total - Amount		2991.00	2230.00	2230.00	2230.00	2230.00	2230.00	2513.50	16654.50
Overhead (36.5%)		1091.72	813.95	813.95	813.95	813.95	813.95	917.43	6078.89
Total		4082.72	3043.95	3043.95	3043.95	3043.95	3043.95	3430.93	**22733.39**

Budget Development: Categories

Contingent Reimbursement: Per occurrence/unit, conditional & typically invoiceable

IRB/IEC amendments & continuing reviews

- Charge or Effort?
  - Industry – Charge
  - Non-industry – No Charge

IRB/IEC submission prep fee

- Charge or Effort?
  - Industry – Effort
  - Non-industry - Effort

Maintenance (pharmacy, lab, radiology)

- Charge or Effort?
  - Industry – Charge
  - Non-industry – Charge

Subject travel reimbursement

- Charge or Effort?
  - Industry – Charge
  - Non-industry - Charge

SAE reporting and follow-up

- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

Sponsor monitoring visits

- Charge or Effort?
  - Industry – Effort
  - Non-industry - Effort

External agency audit, not-for-cause (FDA, sponsor)

- Charge or Effort?
  - Industry – Charge
  - Non-industry - Charge

Screen failures

- Charge or Effort?
  - Industry – Charge & Effort
  - Non-industry – Charge & Effort

Conditional medical procedures

- Charge or Effort?
  - Industry – Charge
  - Non-industry - Charge

Pre-screening/chart review

- Charge or Effort?
  - Industry – Effort
  - Non-industry - Effort

Budget Development: Categories

Closeout Fees: One-time at end of study

Site closeout
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

IRB/IEC closeout
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

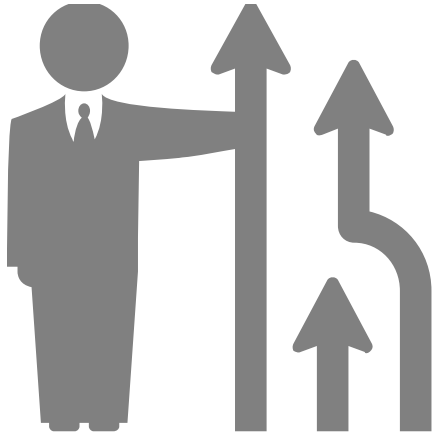
Investigational pharmacy closeout
- Charge or Effort?
  - Industry – Charge
  - Non-industry – Charge

Investigational product disposal
- Charge or Effort?
  - Industry – Charge
  - Non-industry – Charge

Document archival & storage
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

Post closure queries
- Charge or Effort?
  - Industry – Effort
  - Non-industry – Effort

Budget Development



Resource allocation at sites depends on available budget. Inadequate resources jeopardize:

- Trial success
- Site reputation with sponsor
- PI and research staff employment
- PI's ability to do research

Introduction

- Roles and responsibilities of key preaward team for budget planning
- Costs for prime site, participating sites, and single IRB
- What makes a multisite budget solid, and why it matters for effective contract management

Preaward Team Roles and Responsibilities

Principal Investigator

- PI key decisions to make (payment schedule, vendors for central services)
- Decisions should be made EARLY

Project Manager

- Assist with determining overall study logistics
- Generally coordinate all the activities of the planning process

Grant Coordinator

- Assist with proposal preparation
- Develop budget in partnership with study team

Information Needed to Start Budget Planning

Protocol or synopsis

Schedule of events

Sample size per site - may be the same or may differ by site

Enrollment rate per year of grant

Key decisions on central services

Prime Site Budgeting - Key Decisions

Central services

(laboratory, central readers, pharmacy, data management, recruitment, etc.)

Single IRB - for multisite protocol and cooperative research

- Review fees
- Coordinator time to manage correspondence for all sites

Participating Site Costs

Recognize site costs that are often used in industry sponsored budgets

- Screen fails
- Unscheduled visits
- Supplies - if you are not sending supply kits
- Ongoing effort - for non-enrollment-based activities
  - Regulatory activities
  - Team meetings

Prime Site Budgeting Tips

Provide guidance to subs, do not make them develop their entire budget on their own

Provide a sample site budget of anticipated costs (allow negotiation if possible)

Know when to use “capitation budget”

Definition: The site agrees to accomplish project objectives within a specific timeframe for a set dollar amount. The total amount of the award may be unknown when the agreement is created. Applies to per-participant cost in a clinical trial or in an observational human subjects study.

Interchangeable with “fixed rate,” “fixed fee”, “payment schedule”

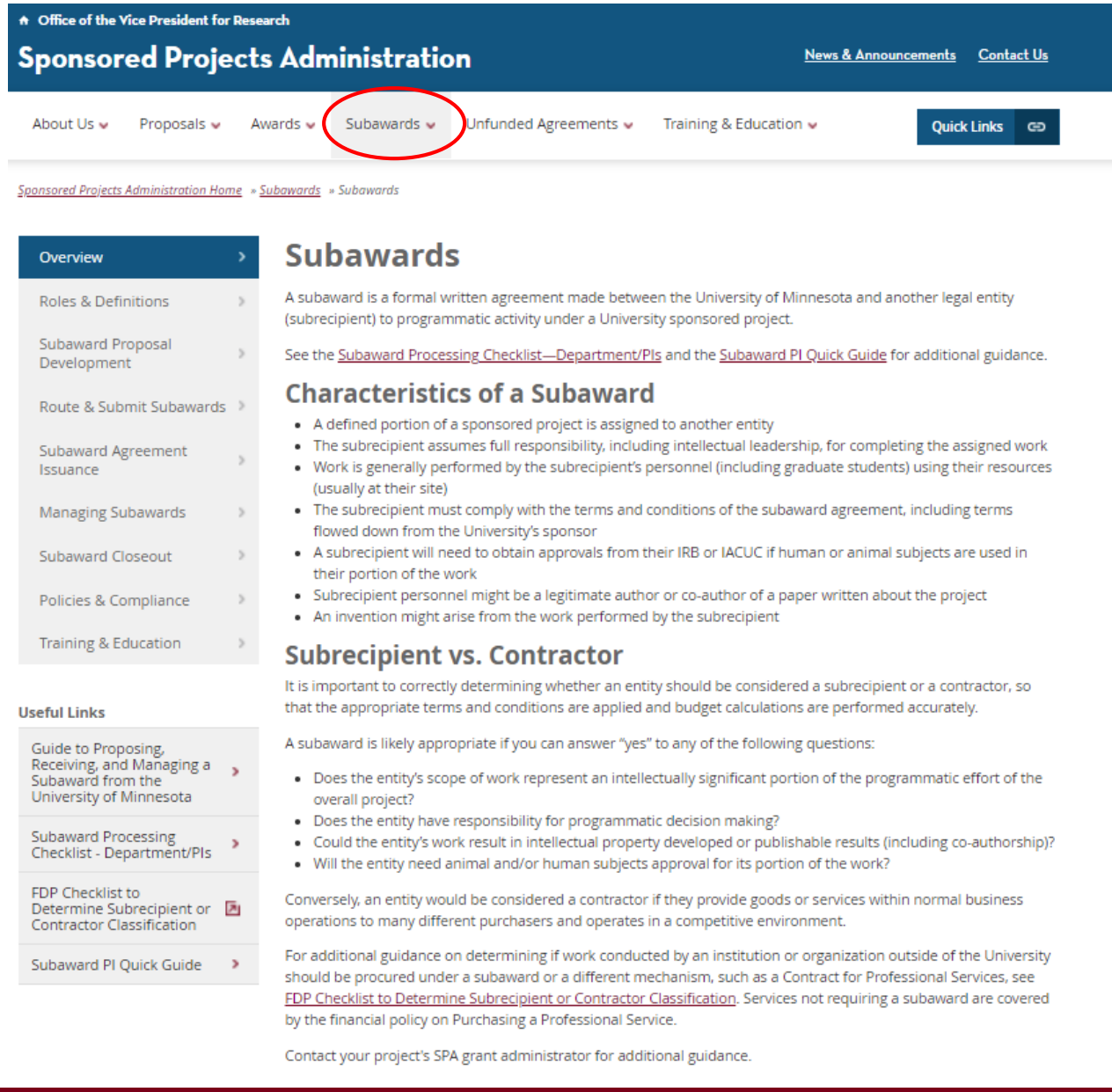
Best Practices for Subaward Agreements

- Be familiar with cost reimbursable and fixed rate agreement structures.
- Think about these subaward payment types early in proposal planning process so that your proposal budget will be aligned with subaward agreements if awarded.
- Be as clear as possible in the terms and conditions of the payment schedule that you offer to the subaward site, so they understand exactly what is being offered.

Subawards – Making it all Go Smoothly

Pamela A. Webb
Associate Vice President for Research
October 29, 2021

Plentiful subaward info on SPA website



Two subaward training classes in SPECTRUM

https://research.umn.edu/units/spa/training-education/spectrum-courses

SP10 Planning & Issuing Subawards

Instructor-led (core, 4-hours) - register for this course

This instructor-led course provides learners with an in-depth look at the various policies and procedures associated with planning and issuing a subaward. Upon completion of this course, participants will be able to:

- Determine if a given activity should be classified as a subaward or a contract for professional services, what paperwork is needed to include a subaward in a proposal, how sub-recipients are "vetted" by the University, and the special obligations associated with subawards under federal contracts
- Explain how subawards are issued and how to start the subrecipient monitoring process during the life of the subaward

SP15 Managing Subawards

Instructor-led (core, 4-hours) - register for this course

This instructor-led course focuses on issues key to successful management of a subaward once it has been issued. It includes a brief review of the subaward planning and issuance phases.

Upon completion of this course, participants will be able to:

- Identify the major responsibilities of PIs and departments to effectively manage a subaward, including compliance oversight, review and approval (or disapproval) of invoices, technical progress reviews, providing additional funding or deobligating support, and the steps involved in closing out a subaward
- Understand how to manage special circumstances, including disputes between subrecipients and the University, managing equipment title, PI transfers, handling foreign subawards, and managing export controls

Departmental/PI Roles and Responsibilities

Subaward Processing Checklist– Departments/PIs

University of Minnesota – Office of Sponsored Projects Administration

PROPOSAL PROCESSING

PI requests proposal package from proposed subrecipient, to include:

- ☐ Statement of Work
- ☐ Budget and Justification
- ☐ Any other documents required by UMN or Sponsor (example: NSF Nondiscrimination cert.)
- ☐ W8 or W9 if subrecipient is new to UMN
- ☐ Signed Subrecipient Commitment Form - if not participating in FDP Expanded Clearinghouse
- ☐ Signed Letter of Intent – optional sample that can be used for institutions participating in the FDP Expanded Clearinghouse

PI evaluates subrecipient

- ☐ Assess technical expertise and financial viability of subrecipient organization and key personnel
- ☐ Fair and Reasonable Cost Analysis (Form I or II)
- ☐ Verify FCOI policy and/or obtain FCOI Forms 1 & 2 if sponsor uses PHS FCOI regulations

PI prepares proposal

- ☐ Integrate the subrecipient's statement of work and budget into UMN's proposal
- ☐ Include other forms (budget, biosketches, other support) as required by sponsor
- ☐ Forward completed UMN proposal to SPA for review, including subrecipient proposal package

SUBAWARD ISSUANCE:

PI/Dept. provide information requested by SPA for subaward issuance

- ☐ Collaborator and contact information
- ☐ Statement of work
- ☐ Budget (including cost share if applicable)
- ☐ Technical/financial reporting requirements
- ☐ Payment terms and schedule
- ☐ Subaward performance period
- ☐ Verification that subrecipient is compliant with IRB, IACUC approvals (if applicable)
- ☐ Fair and Reasonable Cost Analysis (Form I or II)
- ☐ Other information as needed

SUBAWARD PROBLEMS?

Subrecipient not submitting timely or accurate invoices?

Subrecipient not complying with the terms of the agreement or its budget?

Subrecipient isn't performing?

Contact your SPA Grant Administrator early!

We'll work with you and subrecipient to resolve.

SUBAWARD MONITORING:

PI monitors subrecipient technical progress and adherence to terms of award and cost sharing requirements

- ☐ Communicate regularly with subrecipient PI to monitor progress on the project
- ☐ Monitor receipt of technical reports for timeliness and content
- ☐ Communicate with SPA if changes need to be made to statement of work, reporting requirements, budgeting

PI/Dept. monitor subrecipient's adherence to financial reporting terms

- ☐ Are invoices and financial reports arriving on schedule?
- ☐ Do they contain the right level of detail to allow adequate review?

☐ **PI/Dept. verify compliance approvals remain current for subrecipient's portion of statement of work (human subjects, animal subjects, biosafety)**

☐ **Subrecipient sends invoice to sub-inv@umn.edu**

PI reviews invoices electronically via WorkflowGen (see checklist for PIs)

- ☐ Ensure all costs are allowable, allocable, and reasonable
- ☐ Ensure all costs were incurred within the period of performance of the subaward
- ☐ Confirm that expenses are aligned with technical progress and all required reports are received
- ☐ Cost sharing is appropriately reflected, if required
- ☐ If acceptable, PI approves invoice

SUBAWARD AMENDMENT ISSUANCE:

PI assesses need to modify statement of work, budget, period of performance

- ☐ Notify SPA in a timely manner to request amendment
- ☐ Provide information to SPA (budgets, dates, reporting requirements, etc.)
- ☐ Assist SPA in negotiating changes, if needed

SUBAWARD CLOSE-OUT

PI/Dept. plan for timely closeout

- ☐ Check status with subrecipient 90 days before end date
- ☐ Follows up on late or missing reports or deliverables
- ☐ Ensure subrecipient submits final invoice (marked FINAL) to sub-inv@umn.edu

Rev. 2/19/18

Timing Challenges Abound

- SPA takes time to set up an award (even if we get it on time)
- Departments take time to establish award after SPA does
- PI/dept needs to advise SPA on certain subaward requirements
- SPA takes time to issue a subaward
- Subrecipient takes time to negotiate, accept, and return a subaward
- SPA has a time limit on reporting FFATA (federal subs)
- Subrecipient may need the full period of time to do their work
- Subrecipient needs to submit progress reports in time for UMN to incorporate into our progress reports
- (Small) subrecipients need cash in time to pay their own bills (may not have resources to advance funds)
- Subrecipient has to complete their work in harmony with progress on the parent award or ask us if we will do a no cost time extension
- Subaward has to closeout their subaward and file final invoice in time for their costs to be included in our final invoice or financial report to sponsor

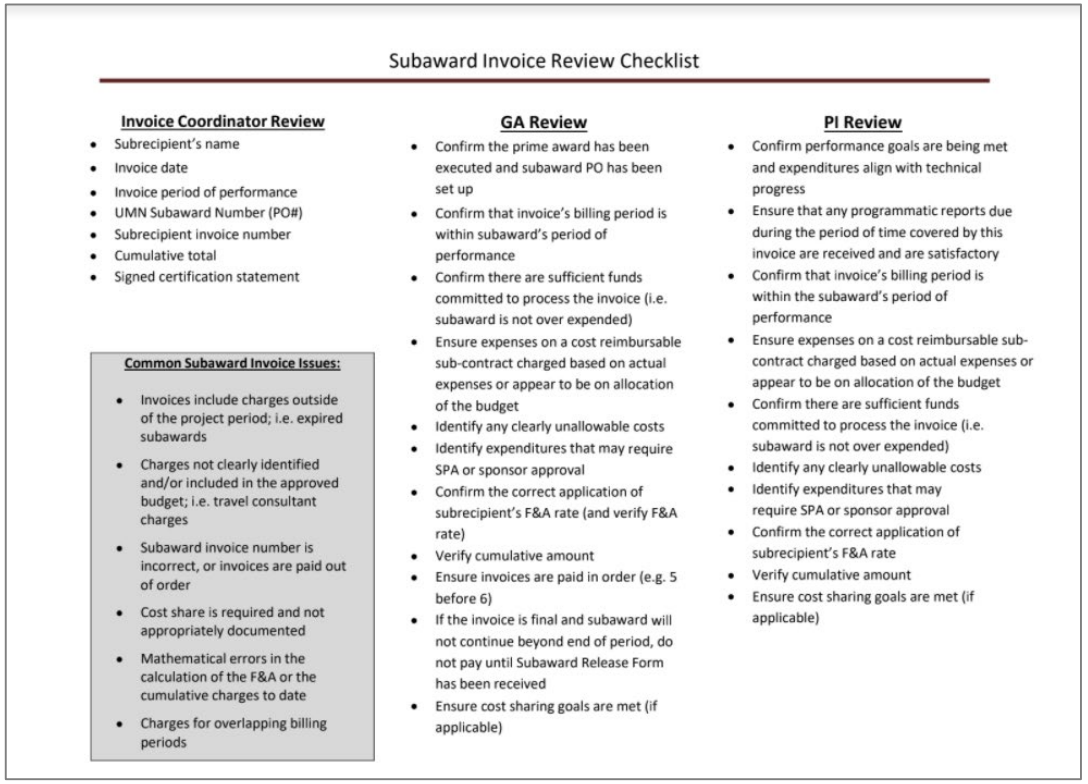
Pitfalls to Avoid

- Paperwork Requirements
  - Standard subaward: SOW, budget, sign-off by subrecipient SPA + agency requirements
  - Multi-Site: Truth in advertising
- Federal versus industry multi-site
  - Federal: Typically cost-reimbursement based on regular agency budget forms
    - sIRB charges – who is paying for what
  - NIH “cooperative groups” may limit F&A recovery or cost recovery – make sure you can do the work
  - NIH and DOD – allow fixed price/ capitation budgets over the simplified acquisition threshold ($250K); other federal agencies typically do not
  - Industry – typically capitation budget
- Can you cover your TRUE costs?

(Proper) Subaward Invoices Need to be Paid within 30 days

PI /Dept Review

- **Confirm performance goals are being met and expenditures align with technical progress**
- Ensure that any programmatic reports due within the time period covered by this invoice have been received and are satisfactory
- Confirm that the invoice billing period is within the subaward's period of performance
- Confirm that expenses are consistent with the budget and within the total funds available
- Identify any unallowable costs or costs that need sponsor approval
- Ensure cost sharing goals are met if applicable



Subaward Invoice Review Checklist

Invoice Coordinator Review

- Subrecipient's name
- Invoice date
- Invoice period of performance
- UMN Subaward Number (PO#)
- Subrecipient invoice number
- Cumulative total
- Signed certification statement

Common Subaward Invoice Issues:

- Invoices include charges outside of the project period; i.e. expired subawards
- Charges not clearly identified and/or included in the approved budget; i.e. travel consultant charges
- Subaward invoice number is incorrect, or invoices are paid out of order
- Cost share is required and not appropriately documented
- Mathematical errors in the calculation of the F&A or the cumulative charges to date
- Charges for overlapping billing periods

GA Review

- Confirm the prime award has been executed and subaward PO has been set up
- Confirm that invoice's billing period is within subaward's period of performance
- Confirm there are sufficient funds committed to process the invoice (i.e. subaward is not over expended)
- Ensure expenses on a cost reimbursable sub-contract charged based on actual expenses or appear to be on allocation of the budget
- Identify any clearly unallowable costs
- Identify expenditures that may require SPA or sponsor approval
- Confirm the correct application of subrecipient's F&A rate (and verify F&A rate)
- Verify cumulative amount
- Ensure invoices are paid in order (e.g. 5 before 6)
- If the invoice is final and subaward will not continue beyond end of period, do not pay until Subaward Release Form has been received
- Ensure cost sharing goals are met (if applicable)

PI Review

- Confirm performance goals are being met and expenditures align with technical progress
- Ensure that any programmatic reports due during the period of time covered by this invoice are received and are satisfactory
- Confirm that invoice's billing period is within the subaward's period of performance
- Ensure expenses on a cost reimbursable sub-contract charged based on actual expenses or appear to be on allocation of the budget
- Confirm there are sufficient funds committed to process the invoice (i.e. subaward is not over expended)
- Identify any clearly unallowable costs
- Identify expenditures that may require SPA or sponsor approval
- Confirm the correct application of subrecipient's F&A rate
- Verify cumulative amount
- Ensure cost sharing goals are met (if applicable)

What percentage of invoices to SPA are "improper"?

Multisite Budgeting

Leslie Kennedy

Post-Award Management

- Contract establishment and set-up
- Invoicing
- Close-out

Contract Establishment

- Complete the Subcontract Cover Page and submit to SPA
  - Workscope – what is the subsite supposed to do
  - Terms and Conditions – CRFs? Submitting data? Participating in Zoom calls?
  - Cost reimbursable versus Payment Schedule or both
  - Make sure you don’t over-commit funds – funds are encumbered, can legally be invoiced
  - Risk Analysis needs to be completed by SPA (FCOI and audit) – THIS TAKES TIME so PLEASE BE PATIENT!

Invoicing

- Funds aren’t just transferred. A Purchase Order is generated and the funds are encumbered and the sub needs to invoice.
- Subrecipients need to submit invoices to: sub-inv@umn.edu
- Routes to the PI for approval
- SPA generates the payment

Close-out

- Need final invoice from the subrecipient
- Complete the Sub close-out form
  - SPA will send this form and work with the Sub site to close out
- PO gets closed and any remaining funds are unencumbered

Resources

Process for Working with Subsites Multisite Trials: A high-level step-by-step process for working with subaward sites for a multisite clinical research proposals.

What is Coverage Analysis in Clinical Research? This resource breaks down consequences to non-compliance, as well as offers solutions to avoid non-compliance in the future.

SPA Subcontract Cover Page: This form provides all of the necessary information for SPA to complete their Risk Analysis, write-up the subcontract and send it out.