Research Development Office (RDO)

UNM HSC OFFICE OF RESEARCH

What is Research Development?

Research development includes activities that help faculty, research teams, and administrators obtain research funding, build connections, and improve their institution's competitiveness.

RDO Vision

Our vision is to expand UNM's capabilities to discover and share new knowledge and promote transformative growth in research, education, clinical care, and health equity in New Mexico.

- Promote research career training, planning, and mentorship
- Facilitate interprofessional and interdisciplinary collaborations
- Help with identifying funding opportunities
- Provide navigation for facilities and resources
- Support grant writing

https://hsc.unm.edu/research/research-development/

Dr. Larissa Myaskovsky
Director of Faculty Research Development

Funding Resources

- Funding resources list on website – internal & external
- Office of Research funding support links on website – Equipment and Institutional Commitment Requests forms
- Weekly funding memos – Federal & Foundation
- Management of limited competitions
- Individual consultation

Image created by AI (Pilot) – prompt: image for “research development office,” RDO, rodeo; add some cactus

Partnerships

- HSC Campus – School of Medicine, College of Nursing, College of Pharmacy, College of Population Health, and Health Science Library and Informatics Center
- HSC & Main Campus collaborations
- National Laboratories – Sandia and LANL
- Industry / Biotech
- Health Systems, including VA
- Government

Research & Innovation Webinars

- 1st Wednesdays of the month from 1-2 pm – Next session is **Wednesday, November 6**!
- Partnership between UNM HSC & Main Campus, NMSU, NMTech, Sandia, & LANL
- Please join us!

Zoom Link: **https://hsc-unm.zoom.us/j/93116182996**
Passcode: **Innovation**

Proposal Development

- RFA review and submission planning
- Project consultation
- Guidance on finding resources
- Proposal editing and internal/external review
- Grant writing resource repository

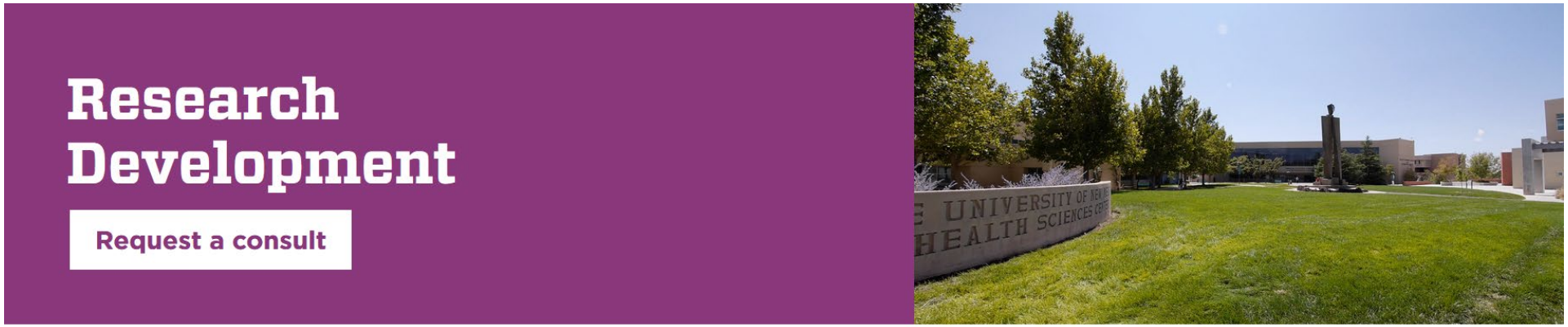
Proposal Example Library

- 18 proposals and counting! R01s, R21s, R24
- Printed copies available to view by appointment in HSSB
- Digital copies are not shared

Image created by AI (Adobe Firefly) – prompt: photo of a simple warm and inviting library with tea

Questions & Requests

- Kara McKinney
  Strategic Support Manager
  kmckinney@salud.unm.edu
- Request Form:



Thank you!

Inpatient and Outpatient Billing for Clinical Trials

UNM HSC Office of Research Memorandum
dated April 19 2021

- Beginning January 1, 2014, Medicare is requiring clinical trials numbers to be listed on all medical invoices that involve clinical trials.

- Change Request (CR) 8401 informs that, effective January 1, 2014, it is mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.

    - For example, when an encounter includes elements for clinical trials in addition to elements for normal clinical care, the clinical trials number must be on the bill that covers normal care.

- The clinical trial number to be reported is the same number that has been reported voluntarily since the implementation of CR 5790, dated January 18, 2008, and is the *same number* assigned by the National Library of Medicine (NLM) website (http://clinicaltrials.gov/) and clinical trials database.

- To accomplish this, the process for informing the billing office has been worked out for each of the following areas:

I. Inpatient

- Patient on clinical trial prior to admission:
  - Identify the NCT# for the patient (on the order for admit, in comments) and
  - Inform the clerk/RN/Tech/MA who is inputting the authorization request for admission.
- Inpatient signed up for clinical trial during/after admission:
  - Call Admitting at 272-2418 with NCT# and have them notate the admission encounter.

II. Outpatient

- A referral account needs to be set up for any encounter regardless of facility/professional fee.

- UH/SRMC Outpatient and ED on clinical trial at time of check-in:
  - Ensure clinic staff knows the patient is in a clinical trial at time of appointment scheduling or during check-in process.
  - Use separate billing sheet (with the appropriate referral account) to track all clinical trials services.

- UH/SRMC Outpatient and ED signs up for clinical trial during regular visit:
  - Ask front desk to create additional registration for the patient (for the clinical trial) if care will start during that visit.
  - Use separate (new) billing sheet (with appropriate referral accounts) to track all clinical trials services.

- UNM Cancer Center Outpatient on clinical trial at time of check-in:
  - Research RN notates NCT# in Mosaiq when ordering future visits.

- Clinical trials FDA 21CFR 50.25 (c) policy: All informed consent documents for applicable trials of drugs and devices (interventional studies, not phase I or small feasibility devices) initiated on or after March 7, 2012 must include a specific statement informing subjects of information available on CT.gov.

- If you have questions of how to register a clinical trial or use Clinicaltrials.gov please contact OfficeOfResearch-ClinicalTrials.gov@salud.unm.edu

Compliance Units and Required Training

Hadya Khawaja, MS, CIP

Associate Director

Office of Research

Conflict of Interest & Commitment (COIC) Office

Compliance Unit	Training	Applicability	Frequency	Source	Link
COIC	Financial Conflicts of Interest (FCOI)	Principal Investigator & all other study team members	Required every 4 years	Learning Central for Health Sciences, Main Campus, UNMH, UNMMG (HSC 104-002) Moodle for non-UNM disclosers (HSC 104-002)	https://learningcentral.unm.edu/ https://hscmoodle.health.unm.edu/

Human Research Protections Office (HRPO)

Compliance Unit	Training	Applicability	Frequency	Source	Link
HRPO	Financial Conflicts of Interest (FCOI)	Principal Investigator & all other study team members	Required every 4 years	Learning Central for Health Sciences, Main Campus, UNMH, UNMMG (HSC 104-002) Moodle for non-COI disclosers (HSC 104-002)	https://learningcentral.unm.edu/ https://hscmoodle.health.unm.edu/
	Group 1 Biomedical Research Investigator **or** Group 2 Social & Behavioral Research Investigators	Principal Investigator & all other study team members	Required every 3 years	Collaborative Institutional Training Initiative (CITI)	https://about.citiprogram.org/

Office of Animal Care Compliance (OACC)

Compliance Unit	Training	Applicability	Frequency	Source	Link
OACC	Working with the IACUC	Principal Investigator & all other study team members	Required every 5 years	American Association for Laboratory Animal Science (AALAS) Library	https://www.aalaslearninglibrary.org/
	Occupational Health and Safety in the Care and Use of Research Animals (if working with lab animals)	Principal Investigator & all other study team members	Required every 5 years	American Association for Laboratory Animal Science (AALAS) Library	https://www.aalaslearninglibrary.org/
	Introduction to Wildlife (if working with field animals)	Principal Investigator & all other study team members	Required every 5 years	American Association for Laboratory Animal Science (AALAS) Library	https://www.aalaslearninglibrary.org/

Radiation Safety Office

Compliance Unit	Training	Applicability	Frequency	Source	Link
Radiation Safety Office	Varies and complete "Statement of Training & Experience" then courses are assigned	All faculty and other users using Radioactive materials and/or equipment in their research/work	Varies and complete "Statement of Training & Experience" then courses are assigned	Varies and complete "Statement of Training & Experience" then courses are assigned	https://hsc.unm.edu/research/compliance/radiation-safety/training/

Course Name:
Introduction to Radiation Safety
Custodial Training in Radiation Safety
General Radiation Awareness Training
Radionuclides in Research Refresher Training
Fluoroscopy Training Program
Nuclear Medicine Radiation Safety Training Programs

Biosafety Office

Compliance Unit	Training	Applicability	Frequency	Source	Link
Biosafety Office	Effective use of Class II Biological Safety Cabinets	Faculty & all other supporting staff w/ Biosafety cabinets	Required every 3 years	Learning Central	https://learningcentral.unm.edu/
	Biosafety Training for BSL-1 & BSL-2 Laboratories	Faculty & all other supporting staff w/ Labs	Required every 3 years	Learning Central	https://learningcentral.unm.edu/
	BSL-3 Laboratory Concepts	Faculty & all other supporting staff w/ BSL-3 labs	Annual	Learning Central	https://learningcentral.unm.edu/
	ABSL-2 Working Safely with Laboratory Animals (ABSA)	Faculty & all other supporting staff in ABSL-2 labs	Required every 3 years	Learning Central	https://learningcentral.unm.edu/
	ABSL-3 Working Safely with Laboratory Animals (ABSA)	Faculty & all other supporting staff in ABSL-3 labs	Annual	Learning Central	https://learningcentral.unm.edu/
	Bloodborne Pathogen Training For HSC	Faculty & all other supporting staff w/ bloodborne pathogen materials	Annual	Learning Central	https://learningcentral.unm.edu/

Biosafety Office

Compliance Unit	Training	Applicability	Frequency	Source	Link
Biosafety Office	A/BSL-3 Hazardous Agent Training	Faculty & all other supporting members working in A/BSL-3 labs	Annual	Learning Central & in-person	https://learningcentral.unm.edu/
	Incident Management Training / Drills in A/BSL-3	Faculty & all other support staff working in A/BSL-3 labs	Annual	Learning Central & in-person	https://learningcentral.unm.edu/
	Biological Agent Shipping Training	Faculty & all other supporting staff shipping biological agents	Required every 2 years	Web based	Biosafety Provides Link after purchase
	US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)	Users of 6.2.1 Agents and Toxins within this policy. Note: Policy will be replaced in May 2025	3-5 years	Learning Central	https://learningcentral.unm.edu

Export Control

Compliance Unit	Training	Applicability	Frequency	Source	Link
Export Control	Compliance with U.S. Export Controls as a Life Science Researcher	HSC Faculty as needed	As needed	HSC Export Control Website	https://hsc.unm.edu/research/compliance/exportcontrol.html
	Bureau of Industry and Security, Licensing for Biological Commodities and Technologies	HSC Faculty as needed	As needed	HSC Export Control Website	https://hsc.unm.edu/research/compliance/exportcontrol.html
	Commerce Department Training	HSC Faculty as needed	As needed	HSC Export Control Website	https://hsc.unm.edu/research/compliance/exportcontrol.html
	General Export Control Training Topics	HSC Faculty as needed	As needed	HSC Export Control Website	https://hsc.unm.edu/research/compliance/exportcontrol.html
	U.S. National Science Foundation, Research Security Training	HSC Faculty as needed	Annually or TBD	HSC Export Control Website	https://hsc.unm.edu/research/compliance/exportcontrol.html

Thank you!

Questions

UNM HEALTH SCIENCES | UNM HEALTH

Contract & Grant Accounting Subaward Invoice Process

October 18, 2024

Changes to Subaward Invoice Approval Process

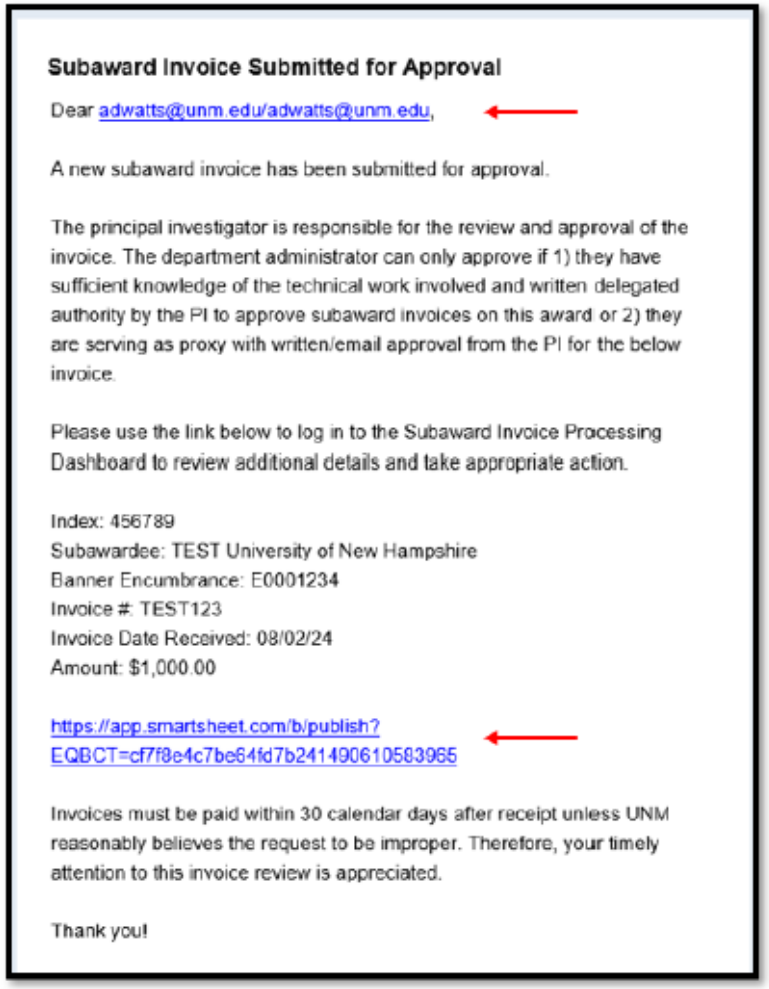
- Subaward Invoice Process Changed 09/01/2024
- New Process routes thru a Smartsheet no longer thru Workflow

Subaward Invoice Smartsheet

- The invoice is uploaded into the Smartsheet by the Fiscal Monitor

- Once the invoice is uploaded into Smartsheet:
  - The Account Administrator and PI will receive an email

Subaward Invoice



Subaward Invoice Submitted for Approval

Dear adwatts@unm.edu/adwatts@unm.edu,

A new subaward invoice has been submitted for approval.

The principal investigator is responsible for the review and approval of the invoice. The department administrator can only approve if 1) they have sufficient knowledge of the technical work involved and written delegated authority by the PI to approve subaward invoices on this award or 2) they are serving as proxy with written/email approval from the PI for the below invoice.

Please use the link below to log in to the Subaward Invoice Processing Dashboard to review additional details and take appropriate action.

Index: 456789
Subawardee: TEST University of New Hampshire
Banner Encumbrance: E0001234
Invoice #: TEST123
Invoice Date Received: 08/02/24
Amount: $1,000.00

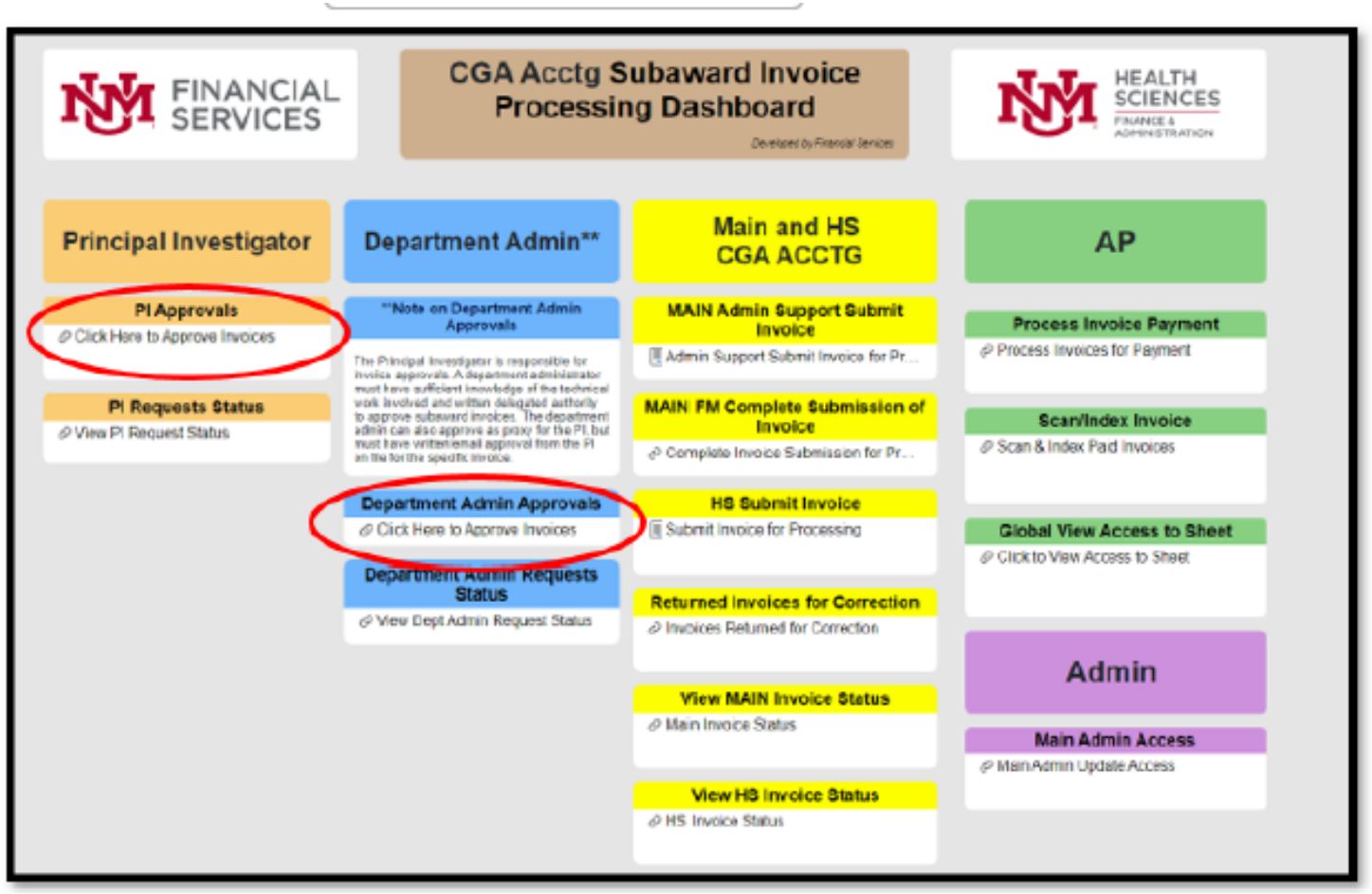
https://app.smartsheet.com/b/publish?EQBCT=cf7f8e4c7be64fd7b241490610583965

Invoices must be paid within 30 calendar days after receipt unless UNM reasonably believes the request to be improper. Therefore, your timely attention to this invoice review is appreciated.

Thank you!

Subaward Invoice

Click on either PI or Department approval



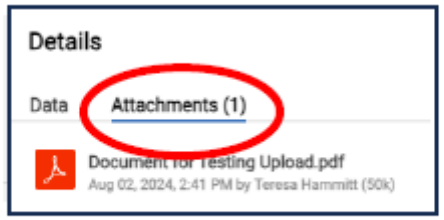
Subaward Invoice

- Click On Document Line

Status	Department Admin Action	Department Comments	Banner Encumbrance Number	Subaward Name	Subaward Invoice Number
Submitted for Department Approval	Submitted		E0000000	TEST University of Alaba	TEST456

Subaward Invoice

- **Step 1**
- Click on Attachment tab



  - Download the document
- **Step 2**
  - Review Invoice
  - Click Data tab
  - Make changes and take action

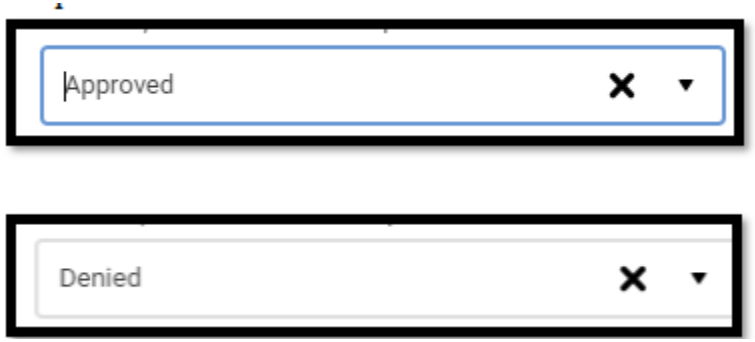
Approval Acknowledgement *

1. All expenditures on the subaward invoice (through the date of this invoice) align with the approved budget.
2. All work for the invoice attached has been completed satisfactorily and in compliance with applicable Federal or non-federal statutes, regulations, and subaward terms and conditions.
3. All required progress reports, technical reports and/or deliverables due through the date of the invoice have been received, reviewed and accepted.
4. If this is the FINAL Invoice, I certify that I have received all work required, all required reports and all deliverables as required by the contract.

CHECK BOX

Department PI or Admin Action

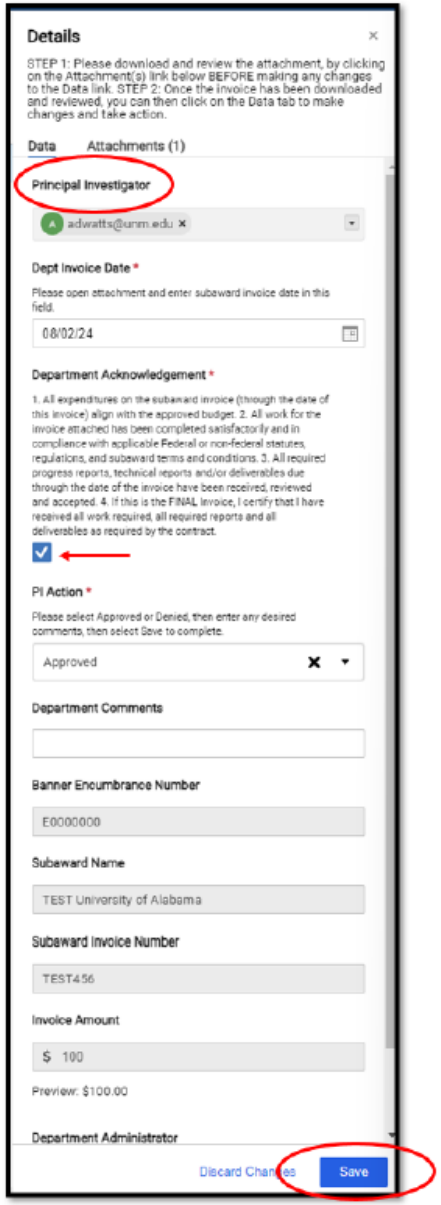
- Select Approved or Denied

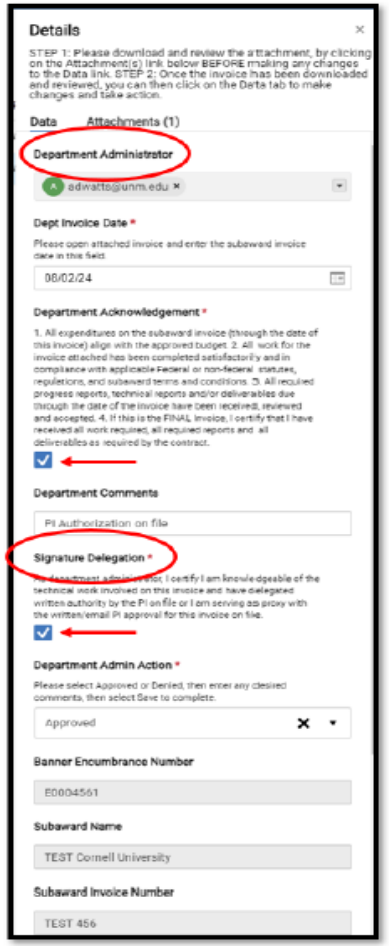


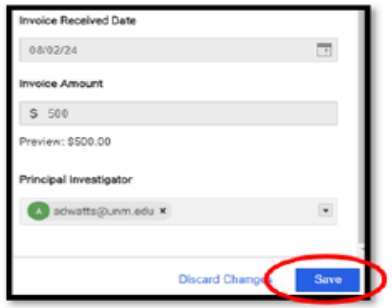
Subaward Invoice

- As Uniform Guidance requires us to pay invoices within 30 days upon receipt, it is important that we "restart" the invoice upon receipt of an updated invoice or documentation.

- Once the PI or Department Admin are satisfied with the received documentation, please let the fiscal monitor know to resubmit.

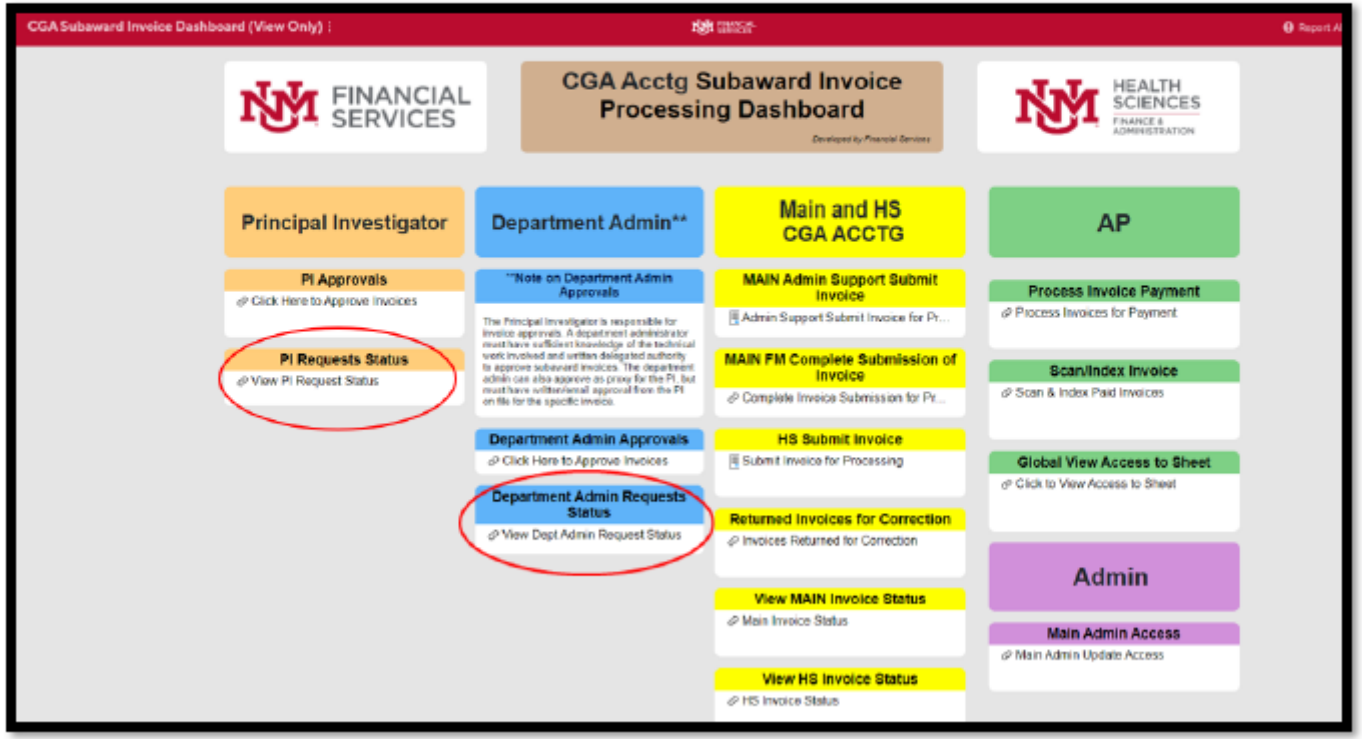

Details
STEP 1: Please download and review the attachment, by clicking on the Attachment(s) link below BEFORE making any changes to the Data link. STEP 2: Once the invoice has been downloaded and reviewed, you can then click on the Data tab to make changes and take action.
Data
Attachments (1)
Principal Investigator
adwatts@unm.edu
Dept Invoice Date *
Please open attachment and enter subaward invoice date in this field.
08/02/24
Department Acknowledgement *
1. All expenditures on the subaward invoice (through the date of this invoice) align with the approved budget. 2. All work for the invoice attached has been completed satisfactorily and in compliance with applicable Federal or non-federal statutes, regulations, and subaward terms and conditions. 3. All required progress reports, technical reports and/or deliverables due through the date of the invoice have been received, reviewed and accepted. 4. If this is the FINAL invoice, I certify that I have received all work required, all required reports and all deliverables as required by the contract.
PI Action *
Please select Approved or Denied, then enter any desired comments, then select Save to complete.
Approved
Department Comments
Banner Encumbrance Number
E0000000
Subaward Name
TEST University of Alabama
Subaward Invoice Number
TEST456
Invoice Amount
$ 100
Preview: $100.00
Department Administrator
Discard Changes
Save


Details
STEP 1: Please download and review the attachment, by clicking on the Attachment(s) link below BEFORE making any changes to the Data link. STEP 2: Once the invoice has been downloaded and reviewed, you can then click on the Data tab to make changes and take action.
Data
Attachments (1)
Department Administrator
adwatts@unm.edu
Dept Invoice Date *
Please open attached invoice and enter the subaward invoice date in this field.
08/02/24
Department Acknowledgement *
1. All expenditures on the subaward invoice (through the date of this invoice) align with the approved budget. 2. All work for the invoice attached has been completed satisfactorily and in compliance with applicable Federal or non-federal statutes, regulations, and subaward terms and conditions. 3. All required progress reports, technical reports and/or deliverables due through the date of the invoice have been received, reviewed and accepted. 4. If this is the FINAL invoice, I certify that I have received all work required, all required reports and all deliverables as required by the contract.
Department Comments
PI Authorization on file
Signature Delegation *
Banner Encumbrance Number
E0004561
Subaward Name
TEST Cornell University
Subaward Invoice Number
TEST 456
Department Admin Action *
Please select Approved or Denied, then enter any desired comments, then select Save to complete.
Approved


Invoice Received Date
08/02/24
Invoice Amount
$ 500
Preview: $500.00
Principal Investigator
adwatts@unm.edu
Discard Changes
Save

Subaward Invoice

Review Status of Subaward Submissions



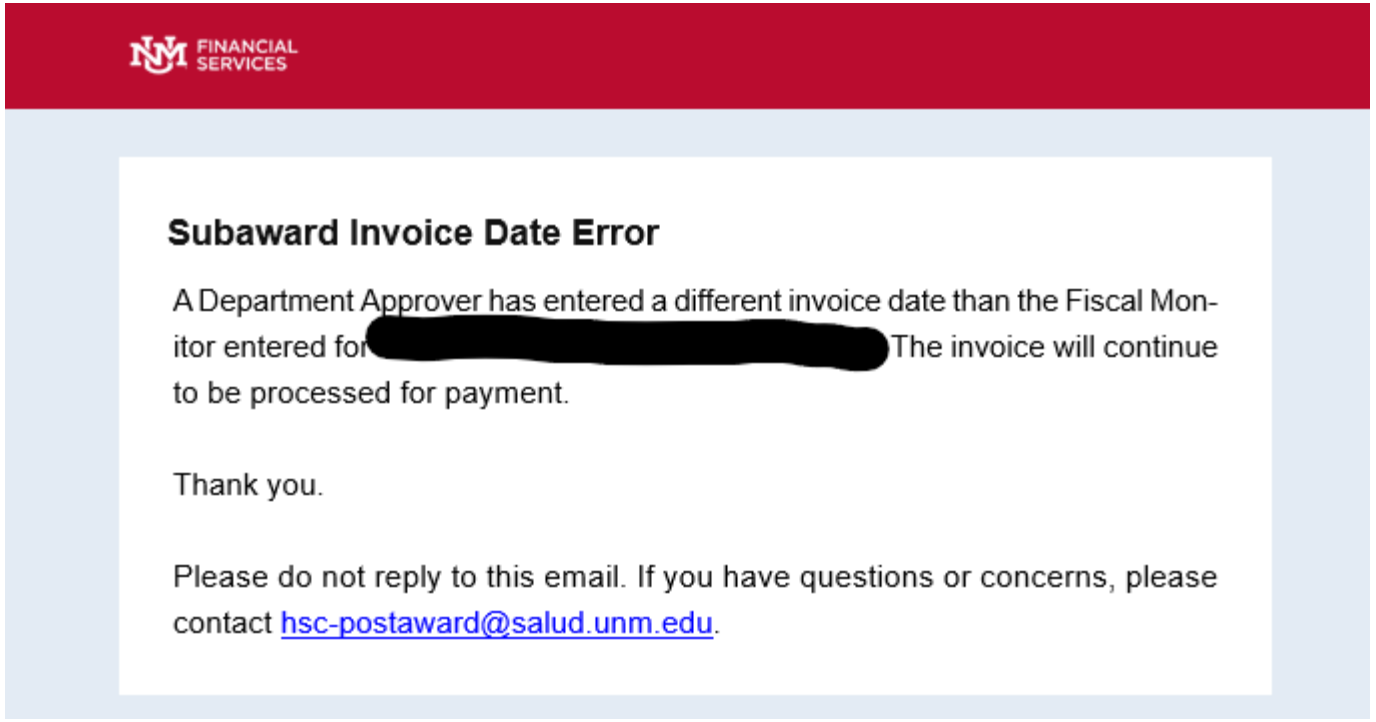
Subaward Invoice

Subaward Invoice

- The Principal Investigator is responsible for invoice approvals
- The Department Administrator must have sufficient knowledge of the technical work involved and written delegated authority to approve invoices.
- The DA can also approve as a proxy for the PI but must have written/email approval from the PI on file for the specific invoice.

Subaward Invoice

- Error Message received from Smartsheet



UNM FINANCIAL SERVICES

Subaward Invoice Date Error

A Department Approver has entered a different invoice date than the Fiscal Monitor entered for [redacted] The invoice will continue to be processed for payment.

Thank you.

Please do not reply to this email. If you have questions or concerns, please contact hsc-postaward@salud.unm.edu.

Combined IBW/ABS

- **IBW/ABS form did not work as expected**

- **Effective 01/01/2025**
  - Reverting to the Old process
  - Forms will be updated
  - SPO and CGA will have Training and Q&A Sessions

Questions

UNM HEALTH SCIENCES | UNM HEALTH

Sponsored Projects Office General Updates

RESEARCH ADMINISTRATION FORUM AND TRAINING (RAFT) – OCTOBER 18, 2024

Marisa Sanchez

ORCID ID's

ORCID, which stands for Open Researcher and Contributor ID, is a name-independent person-identifier founded specifically to help solve the problem of name ambiguity in research and to enable transparent and trustworthy connections between researchers, their contributions, and their affiliations.

- **NIH's** adoption of Common Forms for Biographical Sketch and Current and Pending (Other) Support to be used with all applications and Research Performance Progress Report(s) (RPPRs**) by May 25, 2025.** NOT-OD-24-163
- All PIs and Key Personnel will need an ORCID ID to create their Biosketches and Other Support in the Science Experts Network Curriculum Vitae **(SciENcv)** platform.
- **Register Here!** It's fast and easy! https://orcid.org/register

NIH WORKSHOPS

NIH Grants Process Primer: Application to Award, Two-Part Virtual Event

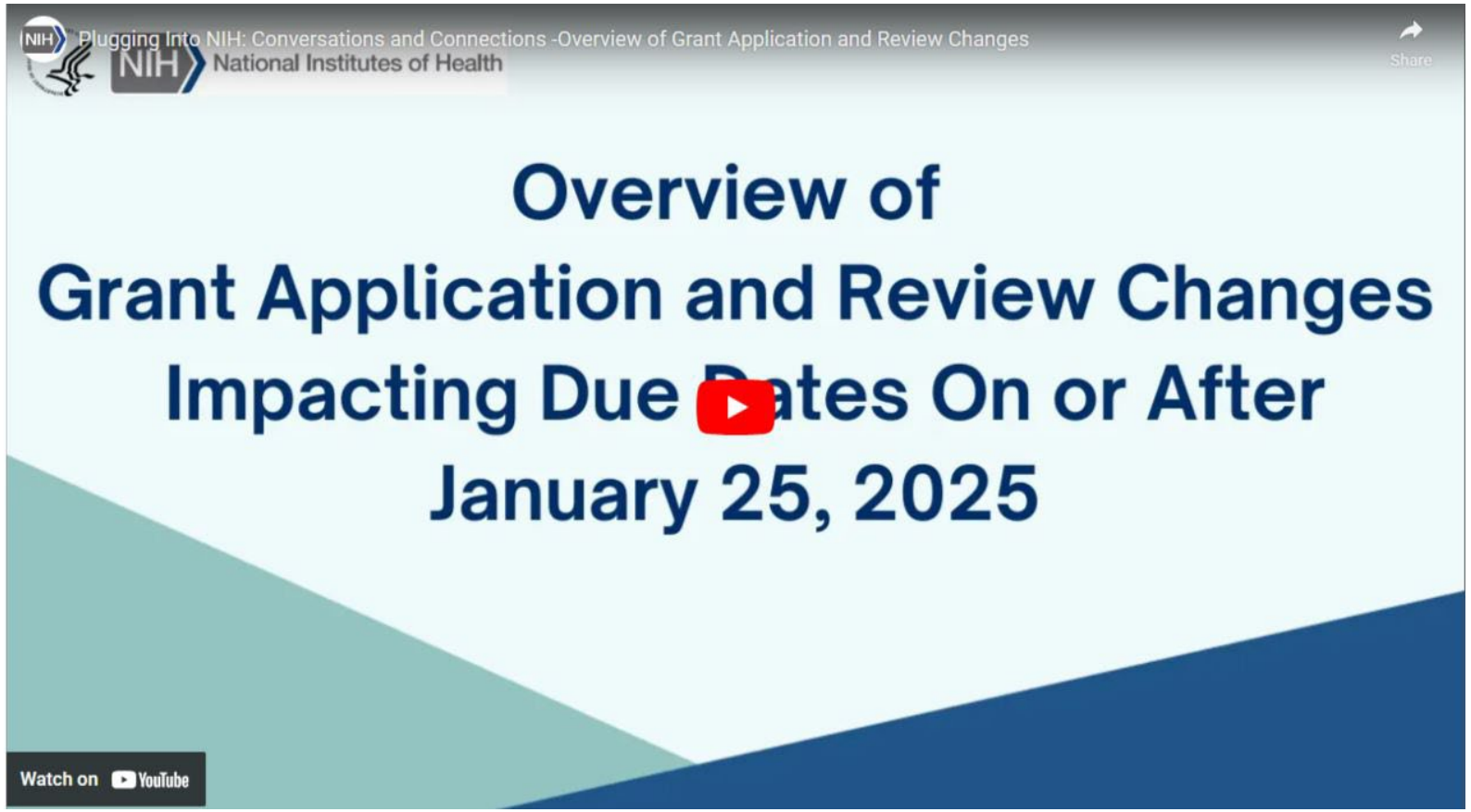
Understanding the structure of NIH, the application process, policies, tools and systems, and knowing where to find valuable resources are key components to create a strong NIH application. The NIH is hosting a two-part event that will provide participants with the basics to help you in your role working with the NIH grants process from application preparation to award.

Part One: An Overview of the Pre-Award Process: NIH experts will introduce participants to the NIH as an organization, key components of finding the right funding opportunity, the NIH team, application, and more.
Part Two: An Interactive Experience: participants will have the opportunity to view demos and engage during this next-level look at tools and systems used during the application process.

When: Wednesday and Thursday, November 13 and 14, 11AM - 2PM MST
Register Here:
https://nih.zoomgov.com/webinar/register/WN_S1xz1PVpR2yMP6wQ26HZcQ#/registration

Plugging Into NIH: Conversations and Connections - Overview of Grant Application and Review Changes

This video provides the research community with an overview of application and peer review changes impacting grant applications submitted for due dates on or after **January 25, 2025.**



Video Overview
00:00 Welcome
02:49 Simplified Review Framework for Most Research Project Grant Applications
08:02 Improvements to the Ruth L. Kirschstein National Research Service Award (NRSA) Fellowship Application and Review Process
12:58 Updates to Reference Letter Guidance
15:04 Updates to NRSA Training Grant Applications
17:58 Updated Application Forms (FORMS-I)
20:41 Common Forms for Biographical Sketch and Current and Pending (Other) Support

Follow link for additional information:

Changes Coming to NIH Applications and Peer Review in 2025 | Grants & Funding

Q&A SESSIONS - SPO/C&G ACCOUNTING

We are excited to invite you to a new series of Q&A Sessions jointly hosted by SPO and Contract & Grant Accounting. These sessions will focus on general questions that you may have. This will be a great opportunity to get your questions answered and learn more about our processes and services!

Upcoming : Wednesday, October 23rd 9:30am - 10:30am
Where: https://hsc-unm.zoom.us/j/93087984116?from=addon
Passcode: Q&A

Please pre-register for these sessions with the following Link:
Q&A Sessions with SPO and C&G Accounting

Additional dates are scheduled for:

November 5 - 1:30pm – 2:30pm
November 19-1:30pm – 2:30pm
December 3 - 1:30pm – 2:30pm
December 17-1:30pm – 2:30pm

FSD TOOLS: F&A SPLITS/IBW/ABS

- The HSC SPO has listened to your concerns regarding **F&A Splits** and, after thorough evaluation, we have changed the process.

  F&A splits will no longer be required at the proposal phase of a project.
  Once your SPO Officer receives your award notice, they will contact you to initiate the F&A split process if required. As a reminder, you can find the F&A Split Instructions here: **https://hsc.unm.edu/about/finance/sponsored-projects/training.html**

  Together with Main Campus OSP we are working toward expediting the F&A Split approval process!

- The combined **IBW** and **ABS** which was rolled out last year presented some challenges. As we work toward improving these tools which are essential to managing your sponsored projects, we ask that starting in January you revert to using the two distinct documents which can be found on the 'Forms and Documents' section of our respective sites.
  SPO: https://hsc.unm.edu/about/finance/sponsored-projects/forms-documents/
  C&G: https://hsc.unm.edu/about/finance/contract-grant/forms-documents.html

CAREER OPPORTUNITY!

Come join the HSC SPO Team! We are seeking a detail-oriented and proactive Sponsored Projects Officer to join our team. In this role, you will be responsible for managing the pre-award process for research contracts and incoming subawards. See full announcement here: **https://unm.csod.com/ux/ats/careersite/18/home/requisition/31282?c=unm&sq=req31282**

Sponsored Projects Officer

Requisition ID	req31282
Working Title	Sponsored Projects Officer
Position Grade	13
Position Summary	This is an intermediate staff level position in a sponsored research office and supports one or more functional areas including, but not limited to: funding information; regulatory compliance; proposal review, approval and processing; award negotiation and acceptance (including contracts, subcontracts, material transfer agreements, and data use agreements); and award setup. This is a core function with university wide scope. See the Position Description for additional information.
Conditions of Employment	
Minimum Qualifications	Bachelor's degree; at least 3 years of experience directly related to the duties and responsibilities specified. Completed degree(s) from an accredited institution that are above the minimum education requirement may be substituted for experience on a year for year basis.
Preferred Qualifications	-Experience with grant reviews to include budget development and thorough evaluation against a funding announcement -Experience reviewing, drafting, negotiating, and interpreting contracts -Familiarity with Protected Health Information (PHI) and Personally Identifiable Information (PII) in the use of research contracts -Experience with Huron Click Electronic Research Administration Database -Strong customer service skills and demonstrated ability to interact effectively with faculty and scientific, management, technical and other staff from R&D, academic, public and private sector environments -Attention to detail and keen organizational skills -Knowledge of UNM Business Policies & Procedures related to Health Sciences Center sponsored project administration -Ability to work independently and as a team member in a complex, multi-deadline work environment -Ability to use sound judgement in complex situations -Certification: Certified Research Administrator (CRA) or Certified PreAward Research Administrator (CPRA)

SPO ANNUAL SURVEY

To receive additional information and assistance you can contact our office through various means:

Phone: 272-9383

Email: HSC-PreAward@salud.unm.edu

Smartsheet Contact Link:

Request for Additional SPO Information

Physical Location: 1650 University, UNMHSC Business & Communications Center, 2nd Floor, Suite 2200

Always remember that we are here to help support your research needs!

The Basics of Clinical Trials

By: Caitlin Vinyard

HSC Sponsored Projects Office

What is a Clinical Trial?

Clinical trials or Clinical Study are defined in concurrence with NIH and Office of Human Protections (HRPO) guidelines.

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Source: https://grants.nih.gov/policy/clinical-trials/definition.htm

Phases of a Clinical Trial

Clinical trials are conducted in a series of steps called “phases.” Each phase has a different purpose and helps researchers answer different questions.

Phase I trials: Researchers test a drug, treatment or device in a small group of people (20–80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.

Phase II trials: The new drug treatment, or device is given to a larger group of people (100–300) to determine its effectiveness and to further study its safety.

Phase III trials: The new drug, treatment or device is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.

Phase IV trials: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment’s benefits, and optimal use.

Source: https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

Types of Clinical Trials

Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition.

Natural history studies provide valuable information about how disease and health progress.

Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning.

Quality of life trials (or supportive/compassionate care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness.

Screening trials test the best way to detect certain diseases or health conditions.

Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Definitions

IND: Investigational New Drug (Application)

IDE: Investigational Device Exemption

NDA: New Drug Application (for sale and marketing)

IRB: Institutional Review Board –the “Ethics Board”

FDA: Food and Drug Administration

EMA: European Medicines Agency

MHRA: Medicines and Healthcare products Regulatory Agency (UK)

GCP: Good Clinical Practice

GMP: Good Manufacturing Practice (drug manufacturing)

CDA/NDA- Confidentiality Disclosure Agreement aka Non-Disclosure Agreement

Definitions

Principal Investigator/Investigator: individual who conducts the study

Site: where the study is taking place

Sponsor ($): provides financial support for the study but does not conduct the research. the IND holder; responsible party to the FDA

IIT: Investigator Initiated Trial

CRO: Contract Research Organization –the “middle man” between Sponsors and the Sites/Investigators

Data Safety Monitoring Board: independent group of experts monitoring conduct of trial (patient safety and efficacy)

CTA: Clinical Trial Agreement

AAHRPP: Association for the Accreditation of Human Research Protection Programs, Inc.

Funding of Clinical Trials

Industry-Sponsored

- Industry developed protocol. Investigators/institutions may propose a protocol to industry. This would be an IIT funded by industry.

Unfunded or Internally funded

- Investigator-Initiated Trials (IITs) are often funded internally

Grant-funded

- Government (NIH, for example)
- Foundation
- For-profit

The Elements of (Industry) Clinical Trials

- Clinical Trial Agreement (contract)
- Budget
- Protocol
- Informed Consent Form
- IRB Approval
- Any other documents/approvals that may be required in order to proceed (e.g., conflict of interest documentation, IT Security Review, Privacy Office Review, Legal Department Review)

Submission to SPO

In order for the Sponsored Projects Office to begin negotiations on a Clinical Trial Agreement, the department/ PI will need to initiate the review process by creating a CLICK ERA (http://era.health.unm.edu) record, obtain departmental approval through your designated approver, and submit to SPO for review.

If you do not have access to Click ERA, please email HSCPreAward@salud.unm.edu to request access.

- Be sure to upload the draft CTA, budget (draft or final), protocol and any other documents prudent to the study (i.e. payment terms, Letter of Indemnification, etc.), ICF. This will help negotiations begin quicker.

Clinical Trial Agreement (CTA)

The Clinical Trial Agreement (CTA) is the contractual arrangement between the Sponsor and our Institution. Below are a list of the most important contract provisions we look for in the CTA. Depending on the complexity of the terms, HSC-OUC (legal) may have to review the agreement prior to it being sent to the Sponsor.

- Intellectual Property
- Indemnification
- Subject Injury
- Confidentiality
- Publication
- Data Ownership
- Audits and Inspections
- Record Retention
- Governing Law
- AAHRPP

Budget Negotiations

The Sponsored Projects Office (SPO) **DOES NOT** handle the negotiation of the budget for a Clinical Trial. This is done by the PI or whomever the PI designates to negotiate directly with the Sponsor/CRO. SPO **does not** have the in-depth clinical knowledge to accurately represent what the PI needs or if the associated costs proposed by the Sponsor are adequate to perform the study.

As a note, the budget and CTA can be negotiated in conjunction with each other.

Budget Review

Below describes the main costs associated with clinical trials and what must be included.

- IRB Fees - Should budget for the following:
  - New Study Review: $2,500
  - Continuing Review: $1,000
  - Modification: $500
  - Please refer to: https://hsc.unm.edu/research/compliance/hrpo/investigators.html for additional information on how these fees are invoiced from IRB.
- Non-refundable start up fees (4-5k at least): for time spent by PI and clinical staff on IRB review paperwork, other regulatory document completion, trips to investigator meeting, protocol review time, etc. (paid regardless of whether or not the contract/study goes forward). If sponsor won't accept, try adding in coordinator/PI time for investigator meetings.
- Payment upon execution of the contract – if you can negotiate it, for other start up type costs
- Payment upon completion of study – do not tie this to a site visit (if they don't come, you don't get paid!), only to submission of all case report forms or data or termination of the study
- Per patient costs (tests, supplies, labor, 1% PI effort) (this will translate into the per patient reimbursement or the reimbursement for completed case report forms as determined by the sponsor - see UH charges memo)
- Payment for departments doing testing (e.g. Pathology, Radiology) – both the hospital fee and the professional fee

Budget Review Con't

- Screen failures payments
- Unscheduled visit payments
- 28% F&A on total costs
- Document storage fees
- Pharmacy fees (include a start up fee and then a fee/prescription)
- Postage if needing to send things regularly to sponsor
- Publication preparation costs
- Investigator meeting time – for investigator and support staff ($750/per person, per meeting)
- Regulatory/administration time (adverse event reporting, etc) ($750 per 6 months)

Remember: most time spent on studies is maintaining regulatory documents including review & submission of adverse events to HRPO – this adds up in a long term (1 year or more) clinical trial

Budget Review Con't

Pricing contact info:

- Procedures: Contact Julie Alliman (jalliman@salud.unm.edu) or Bonnie White (bwhite@salud.unm.edu)
- Professional fees & CPT codes: contact the director of the unit/department in which the procedures will be performed to get the correct CPT code and professional fees associated with the procedure

If you need additional assistance with your CTA Budget, contact CTSC as they can help with the budget negotiation.

- As a note, the IRB Fees and 28% F&A (and other fees; i.e. payment upon execution of contract, non-refundable fees, etc.) are applicable to only Industry Clinical Trials. Federally funded Clinical Trials (including flow through) will require our federal negotiated rate (51.5%, 52.5% starting July 1, 2022) and IRB Fees do not apply.

Other Considerations

- DUA's and MTA's are not needed on Pharma sponsored Clinical Trials as the data information is stated in the protocol.
- Non-Pharma funded studies (i.e. PCORI, flow through institution), the ancillary process will be triggered by the department/ PI's submission to IRB. We prefer not to hold up a funded agreement if a DUA/MTA is needed as it could be months before it's executed which holds up the funding.
- If the Sponsor is requesting us to use their database (or a third party) for uploads, please provide us with the website and whether the information being uploaded is de-identified. It will help expedite the review process with IT security and Privacy offices.
- If there is a CRO negotiating the agreement but the sponsor has a foreign address, export control will need to be submitted and cleared before the Click record can be awarded.
- Internal CDA's must also be signed by the PI before a record can be awarded. The SPO office send these via Adobe Sign once an agreement has be finalized.

NEW!!! Clinical Trials Operations (CTO) Unit

What is the CTU?

They are a new unit in the hospital that provides:

- Internal Feasibility review and support for clinical trials
- Education for clinical/non-clinical team members
- Billing compliance training and guidance
- Quality assurance throughout the clinical trial process
- Monitoring services for moderate and high risk IITs

Currently they are only helping with interventional clinical trials that are being conducting in the hospital setting.

For more information, questions or concerns, please reach out to the following contacts:

Pam Powers Moesser: Quality and Operations ppowersmoesser@salud.unm.edu
Cristal Lujan Portillo: Billing and Finance clujanportillo@salud.unm.edu
Leslie Pimentel Byatt: CTO Director lpbyatt@salud.unm.edu

Resources

NIH Clinical Trials Information: https://grants.nih.gov/policy/clinical-trials.htm

FDA:

https://www.fda.gov/patients/learn-about-drug-and-device-approvals

Center for Information & Study on Clinical Research Participation (CISCRP):

https://www.ciscrp.org/education-center/important-information/#faq

HSC SPO website: https://hsc.unm.edu/about/finance/sponsored-projects/grants-contracts-clinical-trials/clinical-trials.html

UNM HRPO

https://hsc.unm.edu/research/compliance/hrpo/