

# UNEHEALTH GUIDEBOOK

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# KEY TERMS AND DEFINITIONS

## ACADEMIC DEPARTMENT INFORMATION SYSTEM (ADIS)

ADIS is a web-based UNMC system that has campus-wide functionality, but UNeHealth uses ADIS to complete Internal Forms. Each study requires a set of ADIS Internal Forms to be completed.

<https://edge.unmc.edu/adis/>

## BUNDLE

Each bundle is generated in the Research Admin database and is emailed to the PI, the Department Administrator, and SPA Accounting to notify them that the WBS is active. The bundle may be accessed in ADIS, and includes: Internal Budget, Award Document, Routing Form, and Checklist, which lists the account number (WBS), personnel, effort, budget, regulatory requirements, and budget and award period.

## CHARGE MASTER

A list detailing the official rate charged by a hospital for individual procedures, services, and goods.

## CHESAPEAKE IRB

Currently the only approved external IRB for Industry Sponsored Clinical Trials.

## CLINICAL RESEARCH CENTER (CRC)

Outpatient clinical research facility, which serves as a central resource to investigators and departments. The unit includes five general examinations rooms, two procedure rooms, a dedicated exercise/stress testing room, a room for dental or other chair specialty examinations, and a specimen processing laboratory.

Clinical Trials Analysts assist departments with development and negotiation of the study budget and Regulatory Personnel assist departments with the entire IRB process.

<http://www.unmc.edu/cctr/resources/crc>

## CLINICAL TRIAL AGREEMENT (CTA)

Legal document governing the conduct of the Study in accordance with Protocol.

## CONFIDENTIAL DISCLOSURE AGREEMENT (CDA)

A contract for the protection of proprietary information. CDAs require one or both parties to keep specific information confidential (normally the Protocol and Investigator's Brochure). Without a CDA, the individual or company receiving information is prohibited from using and transmitting this information to others. CDAs help preserve the value of any proprietary information that might be exchanged when parties are determining interest/feasibility in pursuing a particular study.

## CONFLICT OF INTEREST (COI SMART)

Program used to monitor any conflicts of interest. Active researchers and study personnel disclose annually. All personnel involved in the conduct of a study must complete a disclosure in COI Smart.

## CONTRACT

Legal document negotiated by UNeHealth. Can include Industry Sponsored Clinical Trial Agreements, Master Industry Sponsored Clinical Trial Agreements, Compassionate Use Agreements, Emergency Use Agreements, PI-Initiated Trials, and Device Studies.

## CONTRACT RESEARCH ORGANIZATION (CRO)

Many Sponsors utilize CRO's to manage various aspects of the Study. These can include contract negotiations, monitoring, and finances (payments).

### **COVERAGE ANALYSIS**

Using the matrix, the coverage analysis verifies conventional “standard” care vs. research only costs to identify what can or cannot be billed to a third party payer (either private insurance or Medicare). The process also compares the matrix, Informed Consent Document (ICD), and preliminary budget to ensure that all costs are covered, thereby assuring that the study budgets reflect the true cost of research.

### **DEPARTMENT ADMINISTRATOR**

Department personnel responsible for completion of ADIS Internal Forms and department specific account reconciliation, among various other duties.

### **DEPARTMENT COORDINATOR**

Department personnel responsible for negotiating the budget and/or managing budget negotiations with the CRC and keeping the Department Administrator updated as necessary, i.e., when sponsor budget is completed, when patients have been seen, and when invoices are required, among various other duties.

### **FACILITIES & ADMINISTRATIVE RATE (F&A)**

Also known as Indirect Costs or Overhead costs. These are provided to the institution proportional to the project total to cover research administrative costs such as research compliance and building upkeep.

Current rate for UNeHealth projects = 26%

### **INSTITUTIONAL BASE SALARY (IBS)**

Annual compensation paid by an institution of higher education for an individual’s appointment, whether that individual’s time is spent on research, instruction, administration, or other activities. IBS excludes any income that an individual earns outside of duties performed for the institution.

### **INSTITUTIONAL REVIEW BOARD (IRB)**

Composed of members from a variety of scientific disciplines and individuals from the community, assuring the protection of all human subjects in research projects conducted by anyone on the premises of UNMC, Nebraska Medicine, Nebraska Medicine - Bellevue, Children’s Hospital & Medical Center (CH&MC), and the University of Nebraska at Omaha (UNO)

### **MATRIX**

An Excel spreadsheet workbook that records basic information about the clinical trial along with Protocol specific scheduling of research related procedures/treatments and details how these procedures/treatments will be billed. The matrix was designed to function as a “stand alone” document that serves as a resource for authorized personnel who do not have immediate access to the Contract, budget, and/or Protocol.

### **ONECHART (EPIC)**

UNMC and Nebraska Medicine’s combined electronic medical records system.

### **PRINCIPAL INVESTIGATOR (PI)**

A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a study/contract in compliance with the laws and regulations and institutional policy governing the conduct of study.

### **SPA ACCOUNTING**

Accounting department responsible for managing UNeHealth’s WBS accounts.

### **WORK BREAKDOWN STRUCTURE (WBS)**

Corresponds to the financial account where transactions related to the Study and other Study-related expenses are tracked.

# **AGREEMENT TYPES NEGOTIATED BY UNeHEALTH**

**CDAs (NON-DISCLOSURE AGREEMENTS) FOR INDUSTRY SPONSORED CLINICAL TRIALS**

**INDUSTRY SPONSORED CLINICAL TRIALS, PHASE I-IV**

**MASTER INDUSTRY SPONSORED CLINICAL TRIAL AGREEMENTS**

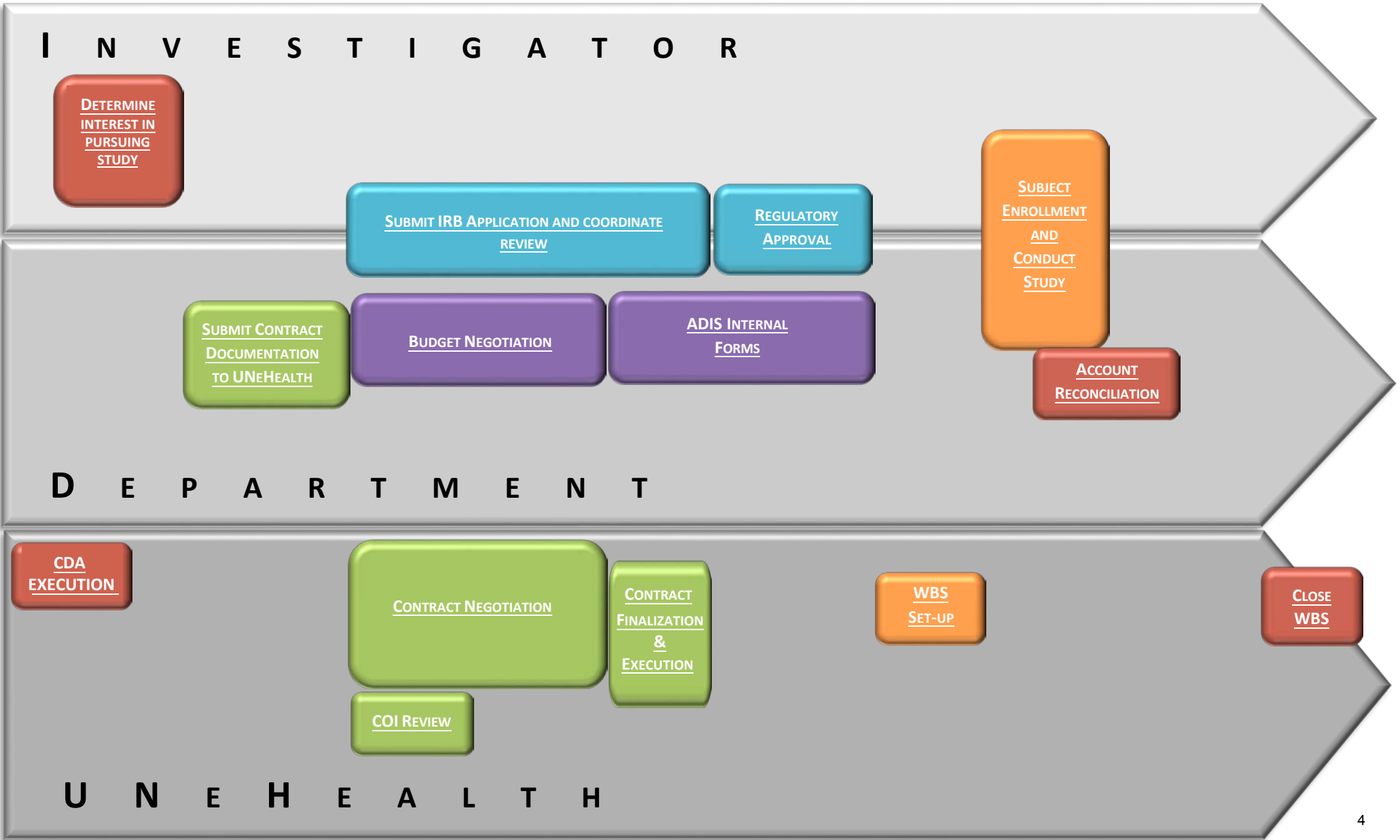
**COMPASSIONATE USE AGREEMENTS**

**EMERGENCY USE AGREEMENTS**

**PI-INITIATED TRIALS**

**DEVICE STUDIES**

# CONTRACT PROCESS WORKFLOW



## ASSESS FEASIBILITY/CDA EXECUTION (INVESTIGATOR)

PI/Department Coordinator receives a CDA from Sponsor for a particular Study. The PI determines if they are interested in receiving confidential information related to the potential Study (ie. Protocol and investigator's brochure) in order to further determine interest in participating in the Study. If interested, the Department Coordinator sends the CDA to UNeHealth for negotiation. Once the CDA is executed, the PI will receive confidential information related to the potential Study. At this point, PI, Department Administrator and Department Coordinator will then determine if they are interested in proceeding with the Study and/or if it is feasible for the department to participate.

### ACTIONS REQUIRED

- Upon confirmation of PI interest in potential Study, Department Coordinator forwards CDA with Sponsor contact information to UNeHealth for review and execution
- Following CDA execution, PI reviews Protocol, involving others as desired, to assess feasibility
- Department Chair vets protocol for feasibility (if required by department)
- PI, Department Coordinator and/or Department Administrator confirms interest in participation

### ACTIONS REQUIRED

- UNeHealth negotiates and executes the CDA to allow the PI to review confidential information related to the Study

### WHO

- Principal Investigator
- Department Administrator
- Department Coordinator
- UNeHealth

### WHAT

A CDA allows Sponsor to share confidential information for a limited time (normally one (1) year), and obligates PI to keep all information disclosed under the CDA confidential. PI is required to maintain confidentiality of information received for 3-15 years after the termination of the CDA.

Protocol review and feasibility assessment helps PI determine if Sponsor and Study are a good match for UNMC by reviewing the following variables:

- Is Protocol viable?
- Do we have the patient population?
- Do we have the necessary personnel?
- Does PI have effort available?
- Are costs prohibitive or is Sponsor flexible on budget?

### WHEN

Department Coordinator should send CDA to UNeHealth for negotiation as soon as possible to ensure negotiations are completed quickly, allowing PI to obtain the Study Protocol. The department determines the timeframe but with Sponsor deadlines in mind.

Next: [Contract Documentation](#)

## SUBMIT CONTRACT DOCUMENTATION (*DEPARTMENT*)

Contract documentation is submitted to UNeHealth to allow Contract negotiations to begin.

Documents to be submitted by department to UNeHealth:

- Protocol
- UNeHealth contract questionnaire (that should contain Sponsor/CRO contact information)
- Fully editable Word version of the Contract

### WHO

- Department Coordinator, or
- Department Administrator

### WHAT

After the Protocol has been reviewed by the PI and the PI and department have decided to move forward with the Study, the Department Coordinator will compile the necessary Study documents (Protocol, UNeHealth questionnaire, Word version of Contract) and send to Amanda Leingang. The Study documents are uploaded to the UNeHealth Contract queue and assigned to a Contract Negotiator so that negotiations can begin.

### ACTIONS REQUIRED

Send required Study documents to UNeHealth

- Protocol
- UNeHealth Questionnaire
- Word version of Contract

Send to: Amanda Leingang ([amanda.leingang@unmc.edu](mailto:amanda.leingang@unmc.edu))

### WHEN

Once the Protocol has been received from the Sponsor, the PI has confirmed interest, and the Department Coordinator has completed the UNeHealth questionnaire, all documents should be promptly sent to UNeHealth to ensure timely negotiations.

OCCUR IN PARALLEL

Next: [IRB Application & Review](#)

Next: [Budget Negotiation](#)

Next: [Contract Negotiation](#)



## CONTRACT NEGOTIATION (UNeHEALTH)

Contract negotiation begins when UNeHealth has received all necessary Study documents:

- Protocol
- UNeHealth Questionnaire
- Editable contract

Contract must be fully executed before the IRB will be fully approved. The IRB must be fully approved and ADIS Internal Forms must be completed before the WBS can be set up and enrollment can begin.

If any questions specific to the department arise, during the Contract negotiation, the UNeHealth negotiator will contact the Department Coordinator or the PI for input.

### WHO

- UNeHealth

### WHAT

Contract negotiations protect UNMC and the PI and primarily focus on legal/policy issues such as:

- Federal Regulations
- State law and constitution
- Board of Regent/UNMC policies
- Sponsor terms and conditions
- Confidential Information
- Insurance requirements
- Indemnification
- Subject Injury
- Intellectual property
- Protected Health Information (PHI)
- Publication
- Use of biological samples, data, etc.

### ACTIONS REQUIRED

- UNeHealth Negotiates contract with Sponsor/CRO
- If any questions specific to the department arise, UNeHealth will contact the Department Coordinator or PI for input

### WHEN

Contract is negotiated by UNeHealth in a prompt manner, as WBS set-up and Study enrollment cannot begin until a finalized IRB and fully executed Contract are in place.

Next: [Contract Finalization](#)

UNeHealth is responsible for reviewing conflict of interest disclosures for the PI and all personnel directly involved in the conduct of each Study. PI's and other Study personnel are required to disclose any conflicts on an annual basis via COI Smart.

If a conflict is identified during the COI review, UNeHealth notifies the Compliance Office. The Compliance Office then conducts a review of the conflict and establishes a management plan, if it is deemed necessary. As soon as the conflict has been appropriately managed, the Compliance Office notifies UNeHealth.

The final Contract cannot be executed until all identified conflicts have been reviewed and managed.

### ACTIONS REQUIRED

- UNeHealth conducts COI review in [COI Smart](#)

### WHO

- UNeHealth
- Compliance Office
- Conflict of Interest Committee
- IRB

### WHAT

Per UNMC's Conflict of Interest Policy (Policy No. 8010), UNeHealth shall:

- Review conflict of interest disclosures for the PI and all Study personnel directly involved in the conduct of the Study
- Coordinate with the Compliance Office when any such personnel disclose financial interest related to an industry sponsored research study to determine if a conflict of interest management plan is required

The Conflict of Interest Committee meets once a month. At least one week's notice must be provided to the COI Committee to allow preparation of the documentation for the COI Committee's review.

### WHEN

UNeHealth conducts the COI review as soon as ADIS Internal budget is created, preferably at the beginning of the Contract negotiation process. Conflicts are reviewed and managed once the ADIS Internal budget identifies personnel for the study

Next: [Contract Finalization](#)

A fully executed Contract requires a finalized Contract budget. The budget negotiation process includes the completion of the Matrix and Coverage Analysis. The Coverage Analysis is used to determine costs that will be inserted into the Contract budget. The Matrix is a tool to help staff understand who the payer is for the various terms/procedures within the Protocol.

Department may choose to use the CRC to handle the budget negotiations.

## ACTIONS REQUIRED

### Department Coordinator:

- Contacts Clinical Trials Analyst at the CRC for completion of Coverage Analysis
- Completes Matrix
- Compares budget template to Matrix and Study Protocol to identify costs Sponsor has omitted from the budget template
- Negotiates total payment amount directly with Sponsor

### Send finalized budget immediately upon completion to:

- Department Administrator or whomever will generate the electronic ADIS Internal Forms\*\*
- UNeHealth negotiator\*\*\*

### Why it matters

\*\*ADIS Internal Forms have to be fully approved before the WBS can be set up. The WBS must be set up before the study build can be completed in OneChart and Patient enrollment can begin

\*\*\*ADIS Internal Forms drive review of Conflict of Interest; Conflicts of Interest must be managed prior to obtaining Contract signatures; Management plans can take up to two months to put in place which may create delays in executing the Contract and setting up the WBS

## WHO

- Department Coordinator, and/or
- CRC

## WHAT

The Coverage Analysis evaluates costs that are standard of care that will be billed to private insurance or Medicare vs. costs that are research-specific and need to be reimbursed by the Sponsor. The Matrix coordinates information from the Coverage Analysis with research costs in the Protocol to determine research costs for the Study as aligned with the charge master. The budget negotiation ultimately ensures the coverage of all Protocol-specified procedures, including F&A of 26%.

Each contract will have a different budget template. Some will be very specific and be detailed in an Excel spreadsheet providing verbiage on specific budget terms, while others will provide limited information in the form of a total dollar amount that covers the total cost sponsor will pay for each subject.

## WHEN

The Matrix and Coverage Analysis are completed prior to budget negotiations. Once completed, the Department Coordinator or CRC should work with the Sponsor to negotiate the Contract budget in a timely manner. As soon as negotiations of the final Contract budget are finalized, the Contract budget should be sent to the Department Administrator so ADIS Internal Forms can be started, and to UNeHealth to be attached to the finalized Contract.

Next: Contract Finalization

Next: ADIS Internal Forms

IRB application and review is necessary for IRB approval, which is required before subjects can be enrolled in the Study.

There are currently two IRB options:

- UNMC's internal IRB
- Chesapeake IRB

Department may choose to use the CRC to coordinate the IRB submission and review.

## ACTIONS REQUIRED – IRB APPLICATION AND REVIEW

- IRB application submitted via RSS portal
- IRB application is reviewed
- Application and consent are revised as needed and interface with Sponsor until approved by both the Sponsor and the IRB

IRB releases the Study *after* Contract is fully executed, AND:

- Application and consent receive final IRB approval
- P&T Approval
- Pathology Approval
- COI Management Plan (if applicable)
- Coverage Analysis
- Matrix
- Miscellaneous others (as applicable)

## ACTIONS REQUIRED – REGULATORY APPROVAL

- Any identified conflicts of interest specific to the Study must be managed.
- IRB notifies UNeHealth when the IRB has been fully approved.
- \* UNeHealth cannot assign a WBS number until the IRB is fully approved

## WHO

- Department Coordinator, and/or
- CRC

## WHAT

All UNeHealth studies must have IRB approval prior to enrolling subjects. UNMC has an IRB and will allow Central IRB review under certain circumstances

The role of the IRB is to ensure that Study subjects are properly protected and ensure that subjects have been accurately informed of the details of the procedures required by the Protocol of the Study.

## WHEN

The IRB application and review should begin as early in the process as possible. Ideally, the Contract negotiation, budget negotiation and IRB application, submission and review occur in parallel and are all finalized in a similar timeframe.

Next: [WBS Set-up](#)

## CONTRACT FINALIZATION AND EXECUTION (UNeHEALTH)

UNeHealth is in contact with the Department Coordinator and/or the CRC over the course of the Contract and budget negotiation. Once both the Contract and the Contract budget have been agreed upon, UNeHealth works with the Sponsor to finalize the Contract and routes for signatures. When the fully executed Contract is received from the Sponsor, UNeHealth notifies the IRB. The IRB cannot be fully released until the Contract has been fully executed.

### ACTIONS REQUIRED

- UNeHealth works with the Sponsor to obtain a final Contract
- Once received, UNeHealth routes the Contract for PI signature to acknowledge the terms of the Contract
- After PI has signed, UNeHealth routes the Contract for Authorized Official signature
- Partially executed Contract is then returned to the Sponsor
- Upon receipt of the fully executed Contract, UNeHealth immediately notifies the IRB which allows the IRB to grant full approval
- \*If ADIS Internal Forms are completed and IRB is fully approved, UNeHealth will set-up the WBS

### WHO

- UNeHealth

### WHAT

Upon agreement of final Contract language (UNeHealth) and a final Contract budget (Department Coordinator/CRC), UNeHealth works with the Sponsor to finalize the Contract. Once the final Contract is received, and the final Contract budget is verified by Department Coordinator/CRC, UNeHealth will route the Contract to designated department personnel for PI signature.

After PI signature has been obtained, UNeHealth will route the Contract for Authorized Official Signature. Once the signature is obtained, the partially executed Contract is returned to the Sponsor for their signature.

Upon receipt of the fully executed Contract from Sponsor, UNeHealth immediately notifies the IRB which allows the IRB to grant full approval (assuming all other IRB requirements have been satisfied).

If the ADIS Internal Forms and the IRB are fully approved, UNeHealth will set-up the WBS.

### WHEN

Contract can be finalized after the Contract language and Contract budget have been agreed upon.

Next: WBS Set-up

Next: ADIS Internal Forms

## ADIS INTERNAL FORMS (DEPARTMENT)

Department Administrator translates Contract budget into ADIS Internal Forms so that a WBS number can be generated.

### ACTIONS REQUIRED

Department Administrator (or designee):

- Receives final Contract budget from Department Coordinator
- Logs into ADIS and selects appropriate Study
- Enters budget:
  - Assigns effort for each person on the budget
  - Direct costs
    - IBS for all personnel (If unknown, designee obtains IBS from Department Administrator or UNeHealth)
  - Other Study-related costs (generally fall into the “Operating” category)
  - Include IRB cost in “Exempt” category
- Indirect costs
  - F&A at 26%
- Once completed, submits to PI for electronic signature

#### \*Additional ADIS Internal Forms Tips

PI reviews/approves electronic budget and sends to UNeHealth

UNeHealth reviews/approves ADIS Internal Forms electronically and sends to Chair/Dean and Authorized Official

Chair/Dean and Authorized Official reviews/approves ADIS Internal Forms electronically

UNeHealth is notified by ADIS that ADIS Internal Forms have been completed. If IRB has been fully approved, the WBS will be set-up

### WHO

- Department Administrator

### WHAT

ADIS Internal Forms allow tracking of PI effort as well as assigning costs to the project. ADIS Internal Forms:

- Translate the total dollar amount agreed to by the Sponsor into direct and indirect costs, i.e. salaries, operating, exempt (IRB fees)
  - Indirect costs (F&A) = 26%
  - Approval is required by the PI, Department Chair/Dean, UNeHealth, and Authorized Official

### WHEN

ADIS Internal forms can be completed as soon as the Contract budget has been agreed upon with Sponsor. The earlier, the better.

Next: WBS Set-up

## WBS SET-UP (UNeHEALTH)

A WBS number is required to be established prior to subject enrollment to ensure proper billing. A Study will not be activated in OneChart until a WBS number has been created for that Study.

### ACTIONS REQUIRED

UNeHealth assigns WBS as soon as:

- IRB is released AND
- ADIS Internal Forms are fully approved

UNeHealth notifies OneChart team of WBS number so the Study build can be completed

Department Administrator and PI are notified via email when the WBS is active and can access the bundle in ADIS

### WHO

- UNeHealth

### WHAT

Only after the IRB is released *AND* ADIS Internal Forms are fully approved, UNeHealth will generate a WBS number based on the four digit department code provided on the ADIS Internal Forms.

After WBS has been generated, UNeHealth sends a bundle of Study-related information to SPA Accounting who will set up the WBS number in SAP.

Once this is completed, the Department Administrator and PI are notified via email that the WBS number is active. The WBS number is included on the Checklist, which is a part of the Award Bundle received by the Department Administrator. The Award Bundle also includes the final Contract and the approved ADIS Internal Forms. This Bundle can be accessed in ADIS by Department Administrator or approved personnel.

### WHEN

The WBS is set up as soon as the IRB is released and ADIS Internal Forms are completed to ensure there are no unnecessary delays in Study enrollment.

Next: [Account Reconciliation](#)

Next: [Subject Enrollment/Conduct Study](#)

## SUBJECT ENROLLMENT/CONDUCT STUDY (INVESTIGATOR & DEPARTMENT)

After the WBS has been set-up, UNeHealth notifies the OneChart team so that the OneChart study build can be completed.

The OneChart build will need to be completed prior to Study subject enrollment to ensure that all Study charges are correctly billed.

### ACTIONS REQUIRED

- Enroll Subjects
- Conduct Study as required by the Protocol

### WHO

- Principal Investigator
- Department Administrator
- Department Coordinator

### WHAT

#### Subject Enrollment

- PI and staff work to find patients who meet the criteria to participate in the Study

#### Conduct Study

- Study subjects complete all activities required by the Protocol
- Study team completes all responsibilities required by the Protocol

### WHEN

Subject enrollment can begin once the WBS has been created and the OneChart build has been completed.

Next: [Account Reconciliation](#)



## ACCOUNT RECONCILIATION (DEPARTMENT)

Once the WBS and corresponding bundle have been released, SPA Accounting submits an invoice for start-up costs and IRB fees. The Department Coordinator is responsible for communicating new subject enrollment to the Department Administrator to ensure that the Department Administrator is invoicing appropriately.

Over the course of the Study, expenses are incurred, invoiced and reimbursed. At the conclusion of the Study, the account must be reconciled accordingly.

### ACTIONS REQUIRED

- SPA Accounting sends initial invoices for start-up costs and IRB fees only
- Department Administrator is responsible for all other invoiceables associated with Protocol procedures. All invoices are required to be submitted through Management Resources to allow accurate tracking and as required per UNMC Policy 6084
- Department Administrator and Department Coordinator work together to determine when invoicing is required
- Department Administrator monitors internal budget end date for appropriate extension request notice to UNeHealth, if necessary

### WHO

- Department Administrator
- Department Coordinator
- SPA Accounting

### WHAT

Account reconciliation (invoicing as procedures are performed and ensuring receipt of payment) should happen as soon as the WBS is set up and continue on as appropriate throughout the duration of the Study.

At the conclusion of the Study at UNMC, it is imperative that all accounts are reconciled in a timely manner to ensure all expenses have been invoiced and all payments have been received from the Sponsor. We must also ensure that we have not received excess payments that would need to be returned to Sponsor. There is often language in the Contract that dictates a timeline by which we are allowed to request money owed to UNMC.

### WHEN

Begin upon WBS setup and continue until Study is closed and all funds are received from Sponsor.

Next: [Close WBS](#)

## CLOSE WBS (UNeHEALTH)

At the conclusion of the Study or if the Study is earlier terminated, the WBS will need to fully reconciled and closed. The WBS cannot be fully closed until the final payment has been received from the Sponsor.

### WHO

- UNeHealth
- SPA Accounting

### ACTIONS REQUIRED

Department Administrator ensures costs are allocated appropriately (including salary) and payments are received, e.g. 10% hold back per contract terms

*\*See SPA Accounting/UNeHealth Closeout flow chart*

### WHAT

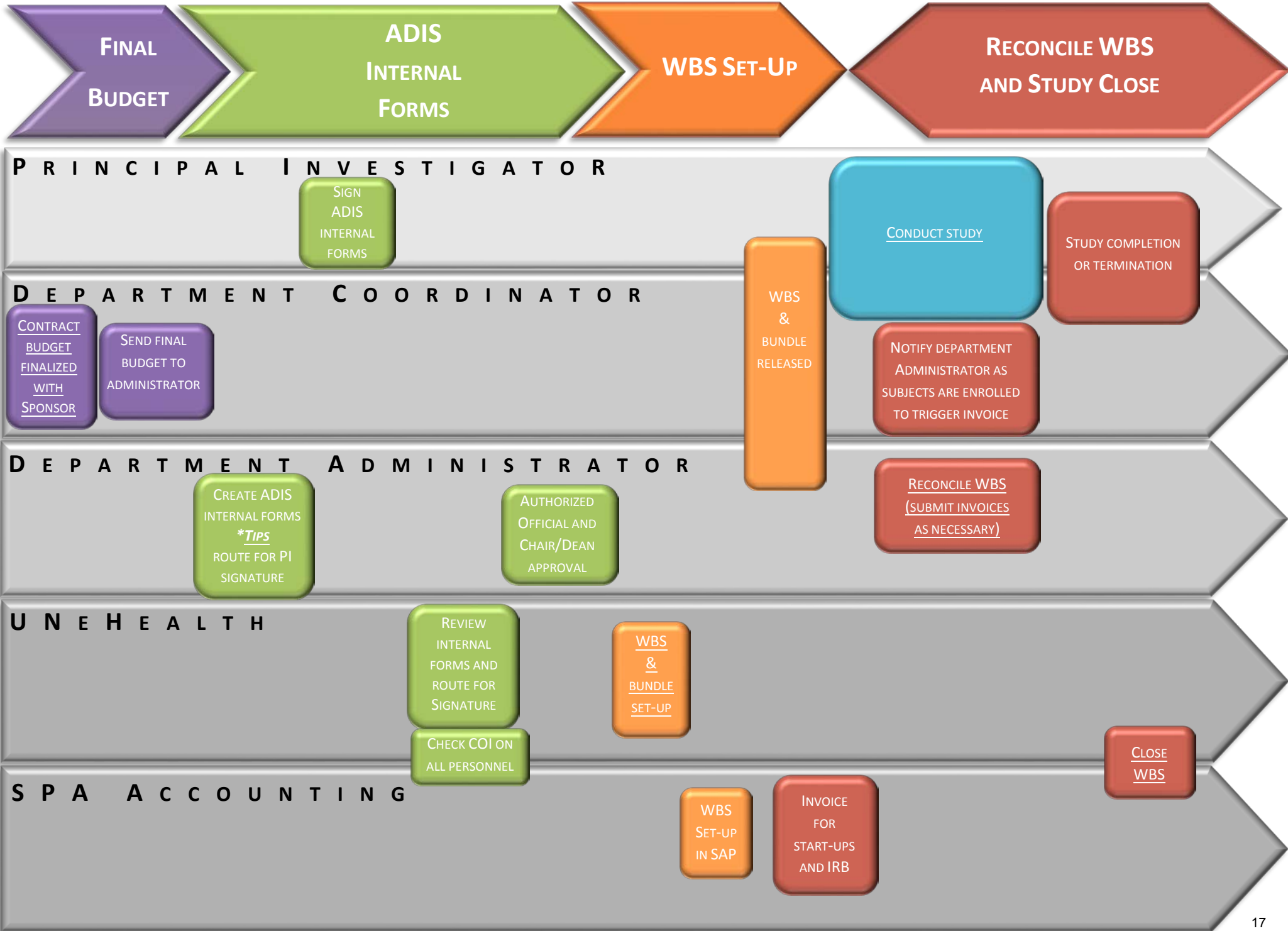
- Close WBS after work is complete and all payments have been received
- UNeHealth works closely with SPA Accounting to close the WBS.

### WHEN

Timely, once final payment has been received and account has been fully reconciled by SPA Accounting.

STUDY  
COMPLETION

# BUDGET PROCESS WORKFLOW



# BUDGET WORKFLOW DETAIL

FINAL BUDGET		
WHO	WHAT	WHEN
Department Coordinator, or CRC	A Contract budget provides documentation for how the Sponsor will pay for the costs of the Study. Budget negotiations occur in parallel to the Contract language negotiations and IRB application process. In order for a Contract to be finalized, the Contract budget must be final and appended to the Contract.	The Contract budget should be sent to the Department Administrator by the Department Coordinator as soon as it has been finalized with the Sponsor. A copy of the Contract budget should also be sent to the UNeHealth Contract Negotiator.
ACTION REQUIRED	<p><b>Contract Finalized with Sponsor</b></p> <ul style="list-style-type: none"> <li>Department Coordinator or CRC is responsible for negotiating the Contract budget, as they have access to the true costs associated with all start-up responsibilities and activities required by each Protocol. Department is best equipped to balance what the Sponsor is willing to provide and what the Department finances will allow</li> </ul> <p><b>Send Final Budget to Administrator</b></p> <ul style="list-style-type: none"> <li>Department Coordinator sends finalized Contract budget to Department Administrator to allow the ADIS Internal Forms to be completed. A copy should also be sent to the UNeHealth Contract Negotiator to be appended to the final Contract</li> </ul>	
ADIS INTERNAL FORMS		
WHO	WHAT	WHEN
PI Department Administrator UNeHealth	ADIS Internal Forms are completed by the Department Administrator, who translates the Contract budget into the ADIS Internal Forms for the generation of a WBS number. The ADIS Internal Forms are comprised of the effort of the PI and Department Coordinator (and any other study personnel), costs associated with procedures required by the Protocol, and initial IRB fees and Study start-up costs, as well as any miscellaneous costs that will be incurred during the Study. Tips for creating ADIS Internal Forms can be found <a href="#">here</a> .	ADIS Internal Forms may be started as soon as the Contract budget has been finalized and the Department Coordinator has sent the final Contract budget to the Department Administrator. The generation of a WBS number is possible only after ADIS Internal Forms have been approved, so it is imperative that the Department Administrator is provided the final Contract budget as soon as it has been completed. This also allows UNeHealth to complete the COI review on all Study personnel.
ACTION REQUIRED	<p><b>Create ADIS Internal Forms, Route for PI Signature</b></p> <ul style="list-style-type: none"> <li>Department Administrator generates ADIS Internal Forms, and routes for PI signature within ADIS</li> </ul> <p><b>Sign ADIS Internal Forms</b></p> <ul style="list-style-type: none"> <li>PI reviews ADIS Internal Forms and approves, which will route to UNeHealth for review</li> </ul> <p><b>Review ADIS Internal Forms and Route for Signature, Check COI on all Personnel</b></p> <ul style="list-style-type: none"> <li>UNeHealth reviews ADIS Internal Forms, completing a final COI check on all personnel listed</li> <li>If approved, UNeHealth routes for Authorized Official and Chair/Dean approval</li> </ul> <p><b>Authorized Official and Chair/Dean Approval</b></p> <ul style="list-style-type: none"> <li>Authorized Official and Chair/Dean review and approve ADIS Internal Forms electronically. At this time, UNeHealth is notified that ADIS Internal Forms have been completed.</li> </ul>	

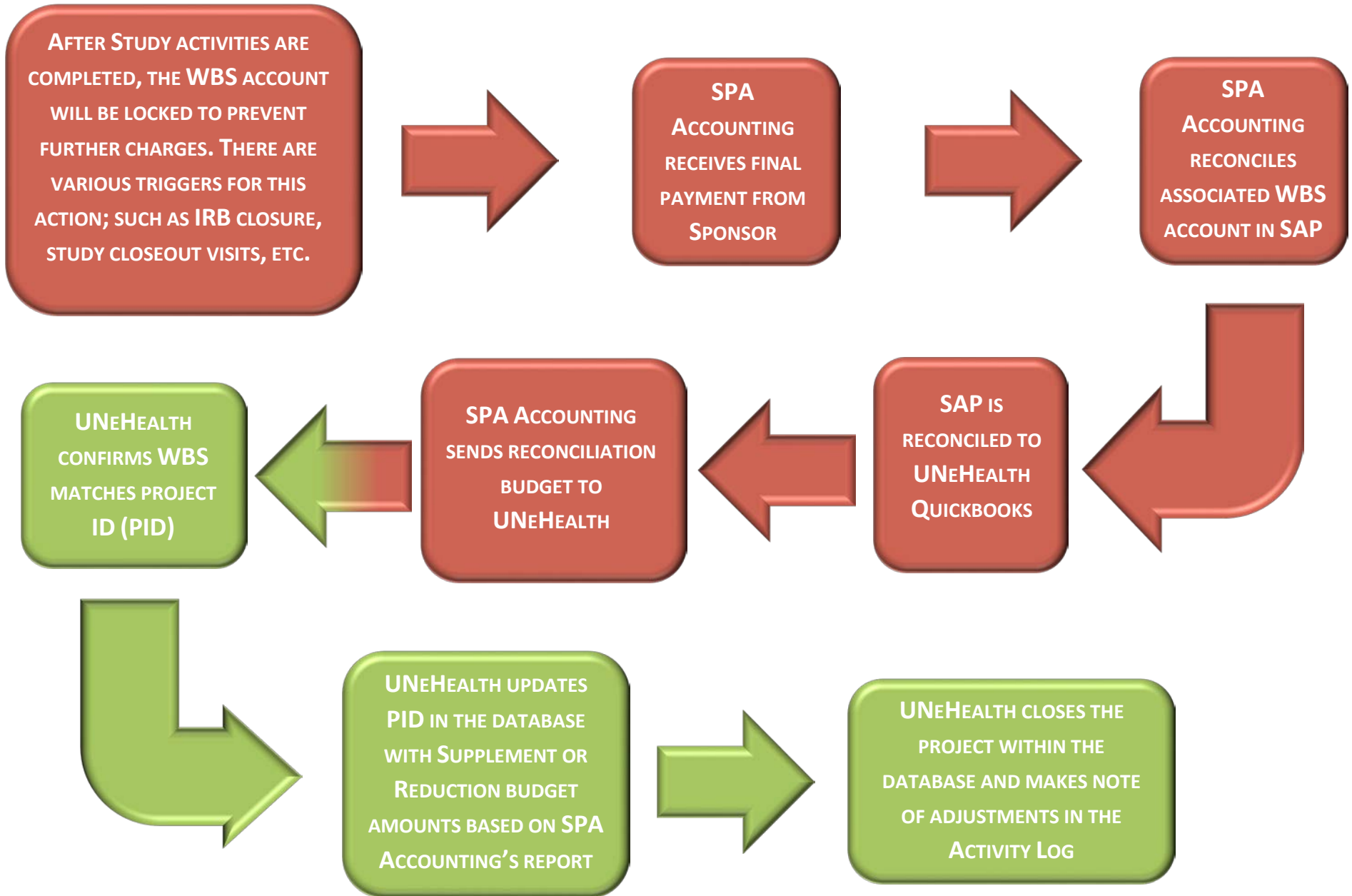
## WBS SET-UP

WHO	WHAT	WHEN
PI Department Coordinator Department Administrator UNeHealth SPA Accounting	UNeHealth generates a WBS number based on the department code provided on the ADIS Internal Forms, and sends an Award Bundle of Study-related information to the PI, Department Administrator, and SPA Accounting who will set up the WBS number in SAP. An example of the Bundle Checklist, which includes the WBS number, can be found <i>here</i> . The Award Bundle also includes the final Contract and ADIS Internal Forms. After the WBS has been generated and the Award Bundle has been sent out, UNeHealth notifies the OneChart team who will complete the OneChart study build, allowing for subject enrollment.	The WBS can only be generated after the Contract has been finalized and fully executed and the IRB and ADIS Internal Forms are fully approved. Subject enrollment is dependent on the Study build in OneChart, which is dependent on the creation of a WBS, so it is essential to complete the ADIS Internal Forms and IRB application as soon as possible.
ACTION REQUIRED	<p><b>WBS &amp; Bundle Set-Up</b></p> <ul style="list-style-type: none"> <li>– UNeHealth generates a unique WBS number for the Study, and sends an Award Bundle notifying SPA Accounting of this number</li> </ul> <p><b>WBS Set Up in SAP</b></p> <ul style="list-style-type: none"> <li>– SPA Accounting receives the Award Bundle and sets up the newly generated WBS number in SAP</li> </ul> <p><b>WBS &amp; Bundle Released</b></p> <ul style="list-style-type: none"> <li>– SPA Accounting releases the Award Bundle, generating an email to the PI and Department Administrator, allowing them to view the newly generated WBS number</li> <li>– UNeHealth notifies OneChart team of WBS number</li> </ul>	

## RECONCILE WBS AND STUDY CLOSE

WHO	WHAT	WHEN
PI Department Coordinator Department Administrator UNeHealth SPA Accounting	At the start of a Study, SPA Accounting invoices for start-up costs and IRB fees. All other invoices are submitted by the Department Administrator who ensures the Study WBS is reconciled regularly (i.e., invoices submitted, payments received). The Department Coordinator is responsible for notifying the Department Administrator as subjects are enrolled in order for invoices to be generated and to ensure Department Administrator is aware of expected receivables where payments do not require invoicing. Usually either the PI or the Department Coordinator will be notified by the Sponsor of Study closure or termination, and are responsible for coordinating WBS closeout with SPA Accounting.	Study start-up costs and IRB fees are invoiced shortly after the WBS has been created. The Department Coordinator is responsible for notifying the Department Administrator of any new subject enrollment to ensure that the Department Administrator is submitting new invoices appropriately. At such time that the Study is completed or terminated, the Department Administrator will work with SPA Accounting to complete necessary closeout details. Upon receipt of final payment, SPA Accounting will complete a final reconciliation of the WBS in SAP and send any necessary budget adjustments to UNeHealth to complete the final closeout process.
ACTION REQUIRED	<p><b>Invoice for Start-Ups and IRB</b></p> <ul style="list-style-type: none"> <li>– SPA Accounting submits initial invoice for start-up costs and IRB fees</li> </ul> <p><b>Reconcile WBS (Submit Invoices as Necessary)/Notify Department Administrator as Subjects are Enrolled to Trigger Invoice</b></p> <ul style="list-style-type: none"> <li>– Department Administrator submits new invoices for additional subject enrollment as necessary and ensures WBS is reconciled and submits new invoices for additional subject enrollment as necessary</li> </ul> <p><b>Study Completion or Termination</b></p> <ul style="list-style-type: none"> <li>– PI and Department Coordinator will work with Department Administrator to allow Department Administrator to know what, if any, additional costs need to be collected and/or advise when monitoring process is completed</li> </ul> <p><b>Close WBS</b></p> <ul style="list-style-type: none"> <li>– UNeHealth will adjust budget in the ITS database based on SPA Accounting’s final reconciliation; the WBS will be closed in SAP</li> </ul>	

# UNeHEALTH WBS CLOSEOUT PROCESS WORKFLOW



## **ADIS Internal Budget How-to**

### ***What you need:***

1. Sponsor Budget - obtained from Department Coordinator once agreed upon with Sponsor (Exhibit A = Sample Sponsor Budget that correlates to example below)
2. Optional: CRC Internal Budget (if applicable)

### ***Steps:***

1. Log into ADIS (<https://edge.unmc.edu/adis/index.php>). Enter the PI's last name in the designated field to search for the project for which you are completing internal forms.
2. Once the project is located, click on the green plus sign and select "Routing/Budget." The Routing Form will appear and has been pre-populated with project-specific information. Complete additional fields as required and progress through forms until you get to the Budget Staffing Information page.
3. Insert full Institutional Base Salary (IBS) for PI (UNeHealth can provide if needed)
4. Determine PI effort
  - a. Review final Sponsor Budget (Exhibit A) and determine how much time PI will need to spend at each scheduled visit per year, i.e.; PI (on average) needs 60 minutes for each patient visit for a Study with 24 cycles (one cycle per month)
    - $60 \text{ (minutes per visit)} \times 12 \text{ (visits per year)} = 720 \text{ (minutes per year)}$
    - $720 \text{ (minutes per year)} / 60 \text{ (minutes per hour)} = 12 \text{ (hours per year)}$

\*as a general rule, 20.8 hours per year = 1% effort
  - b. So, if you plan on enrolling 1 patient per year, PI effort should be 1%; 2 patients per year, PI effort should be 1-2%, etc.
    - i. Generally, we recommend rounding up to 1% effort for anything under 20.8 hours.
  - c. Optional: if using the CRC internal budget, PI time in minutes per cycle is a line item which can be quickly calculated into effort per year.
5. Add personnel as needed using full IBS for each
6. Determine Coordinator effort
  - a. Review final Sponsor Budget (Exhibit A) and determine how much time Coordinator will need to spend at each scheduled visit per year, i.e.; Coordinator (on average) needs 300 minutes for each patient for a Study with 24 cycles (one cycle per month)
    - $300 \text{ (minutes per visit)} \times 12 \text{ (visits per year)} = 3600 \text{ (minutes per year)}$
    - $3600 \text{ (minutes per year)} / 60 \text{ (minutes per hour)} = 60 \text{ (hours per year)}$
    - $60 \text{ (hours per year)} / 20.8 \text{ (hours per 1% effort)} = 3\% \text{ (effort per patient per year)}$
  - b. So, if you plan on enrolling 1 patient per year, Coordinator(s) effort should be 3%; 2 patients per year, Coordinator(s) effort should be 6%.
  - c. Optional: if using CRC internal budget, use Coordinator effort line item to calculate.
7. After all personnel has been entered, proceed to Budget Other Expenses Information page.
  - a. Determine your Grand Total using the final Sponsor Budget
    - i. Grand Total should be: Start-up costs + IRB costs + Per patient costs x number of patients enrolled.

- b. Insert IRB costs into the “Exempt” category
    - i. Should be either \$3000 if using UNMC IRB, or \$1000 if using Chesapeake IRB
      1. IRB rate in Sponsor Budget should match the actual cost (ie. \$3,000 or \$1,000), IRB related expenses (ie. personnel time for submission), should be captured in a different category on the budget.
  - c. Remaining costs generally are captured in the “Operating” category and sometimes in the “Supplies” category. The other remaining categories are rarely used in UNeHealth studies.
    - i. The Grand Total will adjust in real-time, so you can easily change your Operating number as necessary to match your projected total.
8. After all projected expenses have been entered, proceed to the Budget Summary page (Exhibit B). Review the numbers to ensure they match as anticipated.
  9. Proceed to the Requirements Summary page and click the “Send to PI” button. An email will be generated and sent to the PI. This will start the signature routing process.

***ADIS Internal Forms Tips:***

- Department Coordinator should notify the Department Administrator as soon as the Sponsor Budget has been finalized, so that ADIS internal forms can be started
- Department Administrator should consult with PI and Department Coordinator to determine actual anticipated enrollment
- We recommend setting-up the initial budget period for two years. ADIS defaults to one year, but this can be modified
  - This reduces administrative effort in requesting no cost extensions if study is not completed in one year
- Use IBS salaries, not the NIH cap. If you do not have access to this number, UNeHealth can obtain
  - Upon UNeHealth review of internal forms we verify this number with Business and Finance
- Current F&A rate is 26%. This percentage will be taken off the top by SPA Accounting regardless of what was negotiated
- The start date may be slightly modified during set-up depending on IRB release date, as WBS cannot be set up until IRB is fully released



# Exhibit A: Sample Sponsor Budget

Sponsor A Project: ABC15 P.I.: Jones Jane  
 Sponsor Address Study: D123 Center#: 345

## Schedule A - Amendment 1 Visit Cost

The total amount of this Amendment equals:

With this Amendment, the total dollar value of this contract has changed from:

\$2,670.98	to:	\$513,005.22
\$510,334.24		

Cost Per Patient: **\$45,489.85** \*

Overhead included

	Scr_35-1	Scr_28-1	Scr_14-1	c1d1	c1d8	c1d15	c2d1	c2d15	c3	c4	c5	c6	c7	c8
Cost per visit	\$682.44	\$2,388.95	\$726.49	\$1,349.14	\$815.28	\$1,441.56	\$987.94	\$1,192.69	\$1,495.09	\$1,095.04	\$1,761.86	\$1,095.04	\$1,495.09	\$1,095.04

	c9	c10	c11	c12	c13	c14	c15	c16	c17	c18	c19	c20	c21	c22
Cost per visit	\$1,761.86	\$1,095.04	\$1,495.09	\$1,095.04	\$1,761.86	\$1,095.04	\$1,495.09	\$1,095.04	\$1,761.86	\$1,095.04	\$1,309.24	\$1,280.89	\$1,576.01	\$1,095.04

	c23	c24					Effic FU	Survival
Cost per visit	\$1,495.09	\$1,095.04					\$724.35	\$369.33

Total cost	2	allocated patients	\$90,979.71
Total Cost	1	additional patients with written approval from Sponsor.	\$45,489.85

Additional visits will be paid at the C25D1 and C26D1 rates respectively

Additional Survival Follow Ups will be paid at the Survival rate

Additional Efficacy Follow ups will be paid at the Effic FU rate

### Patient-Related Invoice Items (includes overhead if applicable) - Institution to Invoice

Procedure	Freq.	Max. Unit Cost	# Patients	Total
Radiological Assessment <sup>1</sup>				Up to: \$48,459.42
Local Lab Assessments (If not SOC and protocol required) <sup>1</sup>				Up to: \$3,000.00
Fulvestrant (500mg, if not SOC as first line treatment)	26	\$10,000.00	1	Up to: \$260,000.00
Archival Tumor Tissue	1	\$315.00	2	Up to: \$630.00
Optional Skin Biopsy (Includes professional fees, local anesthesia, shipping and lab handling)	3	\$1,000.00	2	Up to: \$6,000.00
Fresh Tumor Biopsy (due to insufficient or absent archival tumor tissue)	1	\$3,780.00	2	Up to: \$7,560.00
Optional Tumor Biopsy (at progression)	1	\$3,780.00	2	Up to: \$7,560.00
Collection, Processing, and Shipping of Tumor Tissue and Blood for germ-line DNA (at Progression)	1	\$98.99	2	Up to: \$197.98
PI, Coordinator, and Data Manager Fees (at Progression)	1	\$488.25	2	Up to: \$976.50
Sparse PK, C1D8	1	\$72.00	2	Up to: \$144.00
Sparse PK, C1D15	6	\$72.00	2	Up to: \$864.00
Blood sample for Alpelisib/Placebo & Fulvestrant trough PK sampling (C2,4,6,8 D1)	4	\$85.00	1	Up to: \$340.00
Blood sample for Alpelisib/Placebo & Fulvestrant sparse PK sampling (C2, 4, 6, 8 D1)	4	\$85.00	1	Up to: \$340.00
Additional Fasting Plasma Glucose	1	\$34.67	2	Up to: \$69.34
Additional Cardiac Enzymes - Troponin I c (as clinically indicated, if not SOC)	1	\$109.29	2	Up to: \$218.58
Additional Cardiac Enzymes - Troponin T c (as clinically indicated, if not SOC)	1	\$109.29	2	Up to: \$218.58
Additional Urinalysis testing (if not SOC)	3	\$70.42	2	Up to: \$422.52
Diagnostic photography	14	\$47.00	2	Up to: \$1,316.00
Screen Failures (All) (minus the cost of procedures not performed)	1	\$3,797.88	2	Up to: \$7,595.76
Hotel Fee	1	\$228.00	2	Up to: \$456.00
<b>Subtotal patient related invoiced costs</b>				<b>\$345,439.66</b>

<sup>1</sup> Sponsor agrees to reimburse Institution for Subject radiological assessment scans that are not standard of care and are required by the Protocol

Reimbursement for radiological assessments will be made upon receipt of itemized invoices at the following rates:

Chest CT = \$2,082	Skeletal X-Ray = \$640
Abdomen/Pelvic C* = \$2,081	ECHO = \$1,564
Neck CT = \$2,175	MUGA = \$1,831
Brain CT = \$2,284	
Chest MRI = \$2,555	
Abdomen MRI = \$3,038	
Pelvic MRI = \$2,858	
Neck MRI = \$2,355	
Brain MRI = \$2,323	
Full Body MRI = \$2,581	
Osseous X-Ray = \$640	
Bone Scan = \$1,523	

<sup>2</sup> Sponsor agrees to reimburse Institution for Subject laboratory assessments that are not standard of care and are required by the Protocol.

Reimbursement for laboratory assessments will be made upon receipt of itemized invoices at the following rates:

Glucose = \$34.67	LDH = \$59.72
Troponin I c = \$109.29	Creatinine = \$58.81
Troponin T c = \$109.29	ALT = \$43.46
Urinalysis = \$70.42	AST = \$43.46
CBC = \$82.22	Total Bilirubin = \$43.46
CMP = \$133.74	Lipid Panel = \$80.17
Magnesium = \$99.92	PT/INR = \$78.26
C-peptide = \$148.09	PTT = \$75.64
Direct Bilirubin = \$43.46	Amylase = \$88.49
GGT = \$91.80	Lipase = \$60.62
Creatine Kinase = \$38.00	HbA1c = \$57.95
Uric Acid = \$45.61	

### Non-Patient-Related Invoice Items (includes overhead if applicable) - Institution to Invoice

Description	Freq.	Unit Cost	Total	
IRB Initial Review	1	\$3000.00	Up to: \$3000.00	
IRB Annual Review Submission	4	\$945.00	Up to: \$3,780.00	
ICF Translation Fee	1	\$3,000.00	Up to: \$3,000.00	
Protocol Amendment Submission Fee	3	\$945.00	Up to: \$2,835.00	
Study Start-up Fee (includes regulatory, pharmacy and pathology startup)	1	\$11,000.00	Up to: \$11,000.00	
Study Document Storage	1	\$2,500.00	Up to: \$2,500.00	
Pathology Review (if required per protocol amendment)	3	\$252.00	Up to: \$756.00	
Research Pharmacy Annual Fee (beginning the end of Year 2)	4	\$945.00	Up to: \$3,780.00	
Study Closeout	1	\$945.00	Up to: \$945.00	
<b>Subtotal NON-patient related invoiced costs</b>				<b>\$31,096.00</b>

**GRAND TOTAL ALL COSTS \$513,005.22**

AMENDMENT 1 - SUMMARY	
	Total
Original Budget	\$510,334.24
Revised Budget	\$513,005.22
<b>Amendment 1 Amount</b>	<b>\$2,670.98</b>

All changes per Amendment #1 are indicated as highlighted above

\* Total per patient cost

\*\* IRB Initial Review fee. This number should match what is actually charged (ie. \$3,000 for UNMC IRB and \$1,000 for Chesapeake). IRB related expenses (ie. personnel time for submission), should be captured in a different budget category.

\*\*\* Study start-up fees

### Notes:

- IRB Initial Review and Study Start-up's will be invoiced by SPA Accounting (currently: Craig Poole) once the WBS number has been set-up  
 - All additional invoices will need to be by the Department Administrator through the Management Resources system in accordance with the Sponsor Budget

- To create a budget for one (1) subject:  
 \$45,489.85 (total per patient cost) + \$3000 (IRB Initial Review) + \$11,000 (Study Start-up Fee) = **\$59,489.85**

**Exhibit B: Sample ADIS Internal Form**

**SPAdministration Budget Form - Grant ID: 11111 Internal Form ID: 2222**

**Period 1**

Principal Investigator/Director: Jones, Jane  
 Title of Project: ABC 15

From: 06/01/2017  
 To: 05/31/2019

PERSONNEL (begin list with senior personnel)						# Months			Inflation Factor for 2nd Year			0.00%	COST SHARING			
Personnel Name - Personnel ID	POSITION	DEPT #	UNMC Salary	% Benefits	% Effort	This Yr	Next Yr	2nd Yr Out	Annualized Salary	Salary Requested	Benefits	TOTAL	% Effort	UNMC Salary	Benefits	Source
Jones, Jane-	Principal Investigator		\$300,000.00	23.00	1.00 *	1.00	23.00	0.00	\$300,000.00	\$6,000.00	\$1,380.00	\$7,380.00	0.00	\$0.00	\$0.00	
Coordinator	Research Coordinator		\$60,000.00	29.60	3.00 *	1.00	23.00	0.00	\$60,000.00	\$3,600.00	\$1,066.00	\$4,666.00	0.00	\$0.00	\$0.00	
						Totals				\$9,600.00	\$2,446.00	\$12,046.00		\$0.00	\$0.00	

TDC	Budget	Cost Share
517000 Salaries	\$9,600.00	\$0.00
519000 Benefits	\$2,446.00	\$0.00
520000 Operating	\$32,787.00	\$0.00
526000 Consultants	\$0.00	\$0.00
526004 Subcontracts	\$0.00	\$0.00
52XXX Exempt	\$3000.00 **	\$0.00
530000 Supplies	\$0.00	\$0.00
540000 Travel	\$0.00	\$0.00
550000 Equipment	\$0.00	\$0.00
560000 Gov't Aid	\$0.00	\$0.00
Total Direct Costs	\$47,833.00	\$0.00
Less: F&A Exempt		
Subcontracts > \$25k	\$0.00	
Exempt	\$3,000.00	
Capital Equipment	\$0.00	
Gov't Aid	\$0.00	
F&A Basis	\$44,833.00	
F&A Rate	26.00 ***	0.00
F&A Costs	\$11,657.00	\$0.00
Grand Total	\$59,490.00 ****	\$0.00

Revenue	
Project Income:	\$59,490.00
Program Income:	\$0.00
Total:	\$59,490.00

This project IS NOT Federally Funded.  
 This project IS NOT a Major Project.

**Cost Sharing:**

Signatures Needed/Received				
Position	Department	Signee	Approved	Date Signed
Principal Investigator	Department	Jones, Jane		
Dean	Department Chair	Smith, James		
Dean	College of Medicine	Kathol, Galen L		
Chairperson	Internal Medicine	Romberger, Debra J		
SPA Staff	Sponsored Programs Administration	Carson, Amy		
SPA Signature Authority	Sponsored Programs Administration	Kratochvil, Christopher		

\* PI and Coordinator effort is determined using anticipated actual time required for each visit for each patient per year

\*\*IRB Fee's

\*\*\*UNMC Industry Sponsored F&A Rate

\*\*\*\*Grand Total for one patient (Start-ups + IRB + 1 total cost per patient amount). Should match Sample Sponsor Budget (Exhibit A)

**UNMC GRANT/CONTRACT CHECKLIST**

**Investigator:** Jones, Jane  
**Department:** Department

**Sponsor:** Sponsor Name  
 **CRO:**  
**Payer:** Payer Name

**Project Title**  
 ABC 15

**Date of Award Notice:** 06/01/2017  
**Date Award Received:** 06/01/2017  
**ID Number.....:** 11111

**Project Type:** Grant \_\_\_\_\_ **Contract** Research  
**Award Type:** New \_\_\_\_\_ **CFDA** \_\_\_\_\_

**ARRA Funded:**  **Federal Pass Thru:**  **Extension:**   
**Closeout:**  **Subcontract Out:**  **Clinical Trial:**

**Mandatory Cost Share:** \$0.00  
**Voluntary Committed Cost Share:** \$0.00

Staff Name	Role	Proj	CS	Staff Name	Role	Proj	CS
J. Jones	PI	1.00	0.00				
Coordinator	CO	3.00	0.00				

**Project Compliance**      IACUC:     IRB:     IBC:

Type	No.	Released	Approved	Type	No.	Released	Approved
IRB	123-12-FB	06/01/17	05/28/17				

**Future Years Support**

**WBS: 36-XXXX-XXXX-888**

**Grantor Number:**

**Document:**

**Budget Award (tdc+idc)**  
 \$47,833.00 + \$11,657.00 = \$59,490.00

**Budget Period**      **Project Period (Cycle)**  
 From: 06/01/2017 Through: 05/31/2019      From: 06/01/2017 Through: 05/31/2019

**CC:** Alvin Poole - 5100  
 Linda Vondras - 5100  
 Department Administrator

**Remarks:**  
 Invoicing instructions as well as invoicing contact information should be included here.

ITEM	DATE	INITIALS
WBS Notice	06/01/2017	ALEINGANG
WBS Process		
DAS Update		
SAP Upload		
Budget Entry		
Income Entry		
Personnel Budget Review		

Date: June 05, 2017

**UNIVERSITY OF NEBRASKA MEDICAL CENTER  
SPONSORED PROGRAMS ADMINISTRATION  
SAP / WBS NOTICE**

Action: Amendment No. 1

Investigator: Dr. Jane Jones

SPA Project ID: 11111

Department: Department Name will appear here

**WBS: 36-XXXX-XXXX-888**

Grant/Contract No.:

**REVISED END DATE: 05/31/2019**

Sponsor: Sponsor Name will appear here

Project Title: Project Title will appear here.

**No Cost Extension Effort**

**CC:** Dr. Jane Jones  
Alvin Poole - 5100  
Linda Vondras - 5100  
Department Administrator

**Remarks:**  
No changes to the internal budget at this time.

Prepared by: ALEINGANG

## UNEHEALTH INFORMATION OVERVIEW

Rev. 6.5.2017

Contract		Institutional Information	
<b>Contract types</b>	Industry-sponsored: <ul style="list-style-type: none"> <li>• CDAs</li> <li>• Industry Sponsored Phase 1-IV Clinical Trials</li> <li>• Master clinical trial agreements</li> <li>• Compassionate use agreements</li> <li>• Emergency use agreements</li> <li>• PI-initiated trials</li> <li>• Device studies</li> </ul>	<b>Financial official payment address</b>	Jeffrey D. Miller, CPA Accounting Manager 985090 Nebraska Medical Center Omaha, NE 68198-5090 Phone: 402-559-2704 Email: <a href="mailto:jeffrey.miller@unmc.edu">jeffrey.miller@unmc.edu</a>
<b>Negotiated by</b>	UNeHealth	<b>Payee type</b>	UNeHealth is the fiscal arm of the University of Nebraska Medical Center for the conduct of clinical trials
<b>Submit to</b>	<a href="mailto:amanda.leingang@unmc.edu">amanda.leingang@unmc.edu</a>	<b>Payee</b>	UNeHealth
<b>Parties to agreement</b>	UNeHealth AND UNMC plus Sponsor	<b>EIN and federal tax ID</b>	47-0771713
<b>Budget</b>		<b>W-9</b>	Signed by Chris Kratochvil, M.D.
<b>Negotiated by</b>	Department/CRC	<b>NPI number</b>	1790042786
<b>Compliance</b>		<b>Human subject assurance number</b>	FWA 00002939
<b>IRB submitted via</b>	<a href="#">RSS</a>	<b>Primary signatory</b>	Chris Kratochvil, M.D.
<b>COI disclosures via</b>	COI Smart	<b>Contracting address</b>	UNeHealth Attn: Chris Kratochvil, M.D. 985331 Nebraska Medical Center Omaha, NE 68198-5331 Phone: 402-559-7614 Email: <a href="mailto:unehealth@unmc.edu">unehealth@unmc.edu</a>
<b>Internal Forms</b>		<b>Legal Name</b>	UNeHealth  However, BOR acting by and behalf of UNMC is ALSO a party to the contract
<b>Format</b>	<a href="#">Electronic ONLY through ADIS</a>	<b>Organization type</b>	An non-profit ancillary organization of the University of Nebraska formed by UNMC, authorized by the Board of Regents
<b>Indirect rate</b>	26%		
<b>Fringe benefit rate</b>	Standard UNMC rates		
<b>Approved by</b>	Chris Kratochvil, M.D.		

# MASTERS: CTAs and CDAs

Rev. 6.5.2017

## ACTIVE Master Clinical Trial Agreements

- Abbott Cardiovascular Systems
- Allergan Sales, LLC
- Astellas Pharma Global Development, Inc.
- Bayer Healthcare Pharmaceuticals
- Boehringer Ingelheim Pharmaceuticals
- CareFusion 2200
- Celgene Corp.
- Discovery Laboratories, Inc.
- Genentech
- Genzyme Corp.
- Gilead Sciences, Inc.
- GlaxoSmithKline
- Incyte Corporation
- InterMune, Inc.
- Juno Therapeutics, Inc.
- Lilly USA, L.L.C.
- Millennium Pharmaceuticals
- Myrexix, Inc.
- Novo Nordisk Pharmaceuticals
- Pfizer, IncPharmacyclics, LLC
- Purdue Pharma
- Regeneron Pharmaceuticals, Inc.
- Sanofi Aventis U.S. Inc.
- Seattle Genetics
- TG Therapeutics
- UCB Biosciences, Inc.

## PENDING Master Clinical Trial Agreements

- Biogen Idec, Inc.MA
- EMD Serono, Inc.
- Novartis Pharmaceuticals
- Merck, Sharp, Dohme

## ACTIVE Master Confidential Disclosure Agreements

- Amgen, Inc.
- Biogen Idec, MA
- Boehringer Ingelheim
- Merck, Sharp, Dohme
- Quintiles
- Siemens Medical Solutions

## PENDING Master Confidential Disclosure Agreements

(none)

KEY: UNMC / UNeHealth

# FREQUENTLY ASKED QUESTIONS (FAQ)

Q: Who invoices for UNeHealth studies?

A: SPA Accounting invoices for start-up costs and IRB fees unless other arrangements have been made between the Department and SPA Accounting. All other invoices are submitted by the Department Administrator who ensures the Study WBS is reconciled regularly.

Q: Why is a CDA necessary? Who signs?

A: Confidential Disclosure Agreements (CDAs), are completed at the beginning of the Study review process to allow the PI to receive proprietary information (normally the Protocol and Investigator's Brochure) related to the Study. Without a CDA, the recipients of confidential information are not prohibited from using and disclosing any confidential information received. Sponsor's want to ensure that any such confidential information is appropriately protected.

A UNMC Authorized Signatory should sign CDA's. If the PI is the party to and signs the CDA, they bear the responsibility and obligations of ensuring that all of the agreement terms are followed.

Q: If we choose to use Chesapeake for our IRB, how do they get paid?

A: Ideally, the Sponsor will work directly with Chesapeake and Chesapeake will submit all invoices directly to the Sponsor. However, there have been Sponsors who will not work with Chesapeake directly, so UNMC/the department has to act as the middle man. This is important to consider when deciding which IRB to use as departments must weigh the costs of taking on those invoicing and payment responsibilities.

Q: What if the Study is closed to enrollment, and the IRB is expiring, but all final payments have not been received, does the IRB have to be extended?

A: No, as long as there are no further activities taking place related to patient information. At this time, SPA Accounting will likely lock the account to new expenses, but keep it open to receive new revenue.

Q: How can the PI and Department help with Contract negotiations?

A: When asked, the PI and Department can be of help with communicating with the Sponsor.