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Agenda

- Contracts Managed by SPA
- Role and Process of Subawards
- Terms & Conditions
- PI & Department Role
- Application of F&A Rate
- Q&A



Deaggregated Contracting Functions

- UNeHealth Industry Sponsored Phase I-IV Clinical Trials, CDAs, Emergency Use
- UNeMed Material Transfer Agreements, CDAs associated with business development, Licensing/Royalty Contracts
- Procurement Purchase of laboratory supplies, equipment, and other materials.
 Consulting/Independent Contractor Agreements
- Business & Finance Business Associate
 Agreements, some Testing/Service Agreements, and
 internal funds expended for Research

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Key information: SPAdmin negotiates

- Data Use/Transfer Agreements
- Confidential Disclosure Agreements
- Federal Contracts direct contractual privity with Federal Agency (FAR-based)
 - Incoming and Outgoing GovCon Subcontracts
- OTA Other Transactional Authority
 - Incoming and Outgoing Subcontracts
- Public Contracts (County, State, City, Municipality)
 - Incoming and Outgoing PublicCon Subcontracts



- Master Clinical Trial Agreements
 - Federally Funded
 - Cooperative/Consortium Group Agreements
 - Post market data collection
- Work Orders, Child Studies, Task Orders off Master Agreements
- Clinical Trial Agreements (stand alone)
 - Federally Funded
 - Cooperative Group Agreements
 - Post market data collection
- Clinical Study Agreements



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- Registry Agreements
- Testing agreements (exceptions)
- Master (non-clinical, non-FAR)
 - > Sponsored Research Agreement (SRA)
 - Collaborative Research Agreement
 - > Technical Research Agreement

(non-clinical, animal, bench, basic)

 Work Orders, Child Studies, Task Orders off Masters (non-clinical, FAR)



Stand Alone Agreements -

- Sponsored Research Agreement (SRA)
- Collaborative Research Agreement
- Technical Research Agreement



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Vocabulary:

Subproposal -

The proposal prepared by an institution (Subrecipient) and signed by its institutional signatory, which provides a letter of intent, scope of work, budget, budget justification and other supporting documentation. The proposed Subrecipient provides the subproposal to the Pass Thru Entity (PTE) to be included in the PTE's formal proposal.

Subaward -

Legally binding agreement by which the PTE provides the funding to the Subrecipient and "flows down" the terms of the prime source of funding.



SUBAWARDS

(FDP Template or Non-FDP Contract)

- Incoming Sub off SBIR/STTR Prime Award (CFDA #)
- Incoming Sub off Grant or Cooperative Agreement (CFDA#)
- Incoming Sub off Grant (foundation or other sponsor)
- Outgoing Sub off Grant or Cooperative Agreement (CFDA #)
- Outgoing Sub off Grant (foundation or other sponsor)



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Key information: Subaward agreement

Federal government

- Considers prime recipient responsible for subrecipient
- · Requires prime recipient to
 - Pass federal terms and conditions to subrecipient
 - Provide certain information to subrecipient (e.g., total federal award amount)
 - Confirm that the subrecipient is registered in Sam.gov and has an active UEI (unique entity identifier)



Key information: Subaward agreement

Federal Demonstration Partnership

- Includes
 - Over 150 academic institutions
 - Ten federal agencies
- Works to streamline federal research administration
 - e.g., Subaward template initiative



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Key information: Subaward agreement SPA Work Flow - **SubOut**:

- Until the Prime Award is set up internally UNMC cannot issue a subaward.
- Grants Analyst forwards request to Contracts Team for the drafting of a subaward out
- Contract Analyst will confirm budget, Scope of Work, and Period of Performance with PI and Dept
- SPA requires PI approval for Subawards.
- Contract Analyst forwards Subaward to the other party for review and execution – possible updates and negotiations may follow.
- Contract Analyst receives final agreement may return for PI approval if any substantive changes have been requested.
- Forwards to SPA Manager for Signature.
- · Returns Fully Executed Agreement to Dept, PI and Other Party



Commences Award Set up – sends to Post-Award

Key information: Subaward agreement SPA Work Flow - **SubIn**:

- Contracts Team receives Subaward from Other Institution or forwarded by Dept/PI
- Contract Analyst will confirm budget, Scope of Work, and Period of Performance with PI and Dept
- SPA requires PI approval for Subawards.
- Contract Analyst possible updates and negotiations may follow.
- Once finalized, may return for PI approval if any substantive changes have been made.
- Forwards to SPA Manager for Signature.
- Returns Partially Executed Agreement to the Other Party
- Once Fully Executed Agreement is received distributes to PI and Department
- Confirms regulatory compliance as applicable and commences Award Set up – sends to Post-Award



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UNMC Signatory Authority

Governed by Executive Memorandum 14 Per Board of Regents Policy 6.3.1

- Signatory authority categorized by type of transaction.
- Grants, gifts and subcontracts limited to a select group of Vice Chancellors, Asst Vice Chancellors, Sr. Vice Chancellors, and the Director and Assistant Directors of Sponsored Programs Administration.
- Faculty and Department Administrators are not able to bind the institution.



Key information: Selected terms and conditions

- Confidentiality
- Publications
- Intellectual Property
- Budget Terms
- Deliverables/Reports
- Subcontracts



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Key information: Confidentiality

- Confidential information may or may not be marked as "confidential"
- UNMC includes time limitation on confidentiality obligations
- Definition of "Confidential Information" has to be carefully evaluated to exclude results of studies impacting ability of investigators and other project personnel to publish



Key information: Publications

- BOR policy: "Central to the University of Nebraska's mission is the creation, preservation, and dissemination of knowledge"
- UNMC retains right to publish
- Sponsor cannot require prior approval, ability to edit
- Sponsor can delay publications (reasonable timeline) to review for confidential information or patent-related information



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Key Information: Intellectual Property

- In compliance with Board of Regent's Policy RP 4.4:
 This Policy is intended to promote and encourage excellence and innovation in scholarly research and teaching by identifying and protecting the rights of the University, its faculty, staff, and students.
- Patent and copyright ownership and their associated rights are concepts that are defined by federal law. This Policy and the University's patent policies are structured within the context of those federal laws.
- The nature of the agreement, development of Scope of Work/Protocol, and Prime Sponsor terms all inform how the IP is protected within the individual Agreements.

Key Information: Budget Terms/Conditions

- · Study budget/feasibility
- · Proposed payment schedule
- Payments tied to deliverables
- If Clinical:
 - ➤ Non-refundable start up payments
 - Screen failure costs
- Ensure correct F&A rate utilized



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Key Information: Deliverables/Reports

- Specify the end result for the Sponsor (e.g. data, study reports, case report forms, publication)
- Timing of deliverables can PI meet deliverable timelines as set forth in the contract?



Key Information: Subaward or Subcontracts

- Scope of Work or Protocol that each subcontractor is expected to follow.
- Budget and payment terms for each subcontractor.
- F&A rate for each subcontractor
- Timing for subcontract.
- · Sponsor's approval of subcontractor.



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PI and Department Roles



Key information: Required documents

- Final Protocol or Scope of Work
- Sponsor's editable contract template
- Budget
- Intake:
 - If Clinical Trial Study Intake Redcap: https://www.unmc.edu/cctr/clinical-trials/ctms-training/intake-process/
 - > Others: Department Admin can submit in Ticker or the PI/Dept Admin via email to: spadmin@unmc.edu
 - Outgoing Subs will be handed off internally by SPA Grants Team to SPA Contracts Team during award set up of Prime funding award.

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Key Information: PI and Department responsibilities to finalize the contract and set up the award

- Finalize project budget with sponsor it will be attached to contract. If Clinical, the CRC may be managing the negotiation.
- Receive PI Review/Approval of Agreement may request "Read & Acknowledge" signature
- Disclosure of Conflicts of Interest managed
- Regulatory IRB, IACUC, IBC, Export Control
- Internal budget and routing forms required for account set-up

F&A Rate

Type of Project/Sponsor	Rate
All Research (aside from exceptions below)	53.5% (MTDC)
DoD Research	54.5% (MTDC)
DoD Off Campus	27.5% (MTDC)
Industry-sponsored Research	53.5%(MTDC)
Instruction	38.5% (MTDC)
Other Activities	40.0% (MTDC)
Off Campus	26.0% (MTDC)
Industry-sponsored Clinical Trials	28.0% (TDC)



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Contracts Team Members

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