

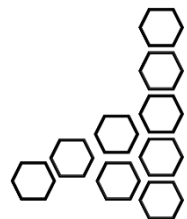


Sponsored Projects Contacts / Agreements

Valerie Bomben, PhD
Supervisor, Specialized & Collaborative Research Agreements

Take-away

- *Institutional policy on contract negotiations*
- *Why is a contract needed?*
- *What types of contracts might SPA assist with?*
- *What's the process for a SPA contract?*
- *Where can you find assistance?*



Institutional Policy on Contract Negotiation

Inside UTHHealth

Search: UTHHealth Web
 Looking for something? GO

Office of Legal Affairs

Office of Legal Affairs

- General Legal & Ethics Counsel
- Healthcare Risk Management
- Institutional Contract Information**
- International Affairs
- Privacy Office
- Public Information Requests
- Notary

Institutional Contract Information

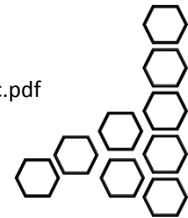
Links:

HOOP Policy 124 - Authority to Execute Contracts and Make Purchases
 (entering into contracts or making purchases on behalf of the university)

Delegation of Authority Matrix for The University of Texas Health Science Center at Houston
 (matrix of signature authority to execute and deliver contracts, agreements, instruments and other documents)

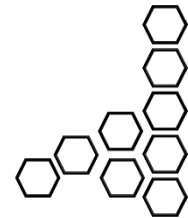
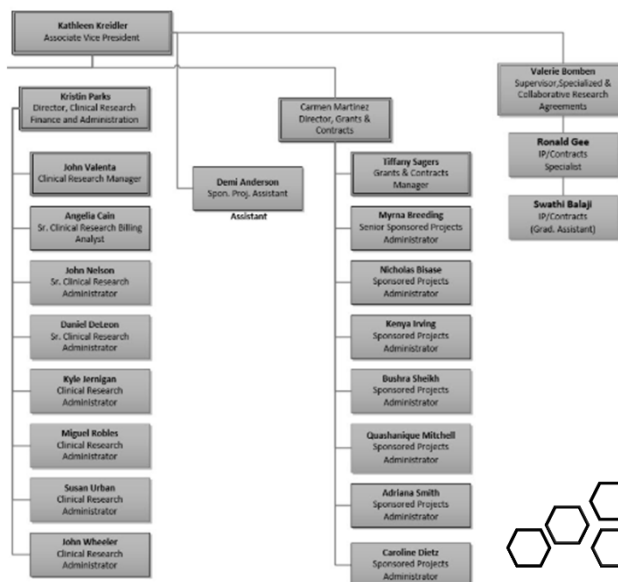
<https://inside.uth.edu/dotAsset/e0543079-ff92-4eeb-8722-d37f8266a3ac.pdf>

- Depends on needs of the contract
- Technology Management, Legal Affairs, Procurement, SPA

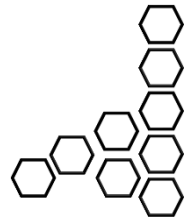


Sponsored Projects Administration Contracts Assistance

- *3 Preaward Teams that negotiate SPA contracts*
 - *Clinical Research Finance Administration*
 - *Grants & Contracts Administration*
 - *Specialized & Collaborative Research Agreements*



Why have a Sponsored Projects Contract?



Contracts provide:

- *Clarity in a business relationship between entities*
 - *Setting expectations*
 - *For example, American Heart provides money in exchange for:*
 - *Progress Reports on the science progression*
 - *Financial reports on the award spending*
 - *Expectations regarding publication, intellectual property rights*

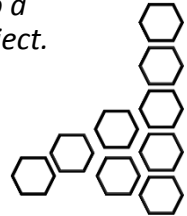


By Aaron
Johnson –
<http://whatttheduck.net>



Why do central offices negotiate contracts?

- *UTHealth is a state institution*
 - *We have to conform to state law requirement; University of Texas System requirements; UTHealth policy (RCOI, compliance, finance requirements)*
- *Parties to the agreement are NOT the PI and the sponsor. The institution takes on the risk and governance of an award.*
 - *Insurance,*
 - *Even NIH awards are conditional. By accepting the award, we agree to a number of federal laws and regulations in the maintenance of the project.*
 - *<https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf> (405 pages)*



Protecting the patients; Protecting UTHealth; Protecting the PI



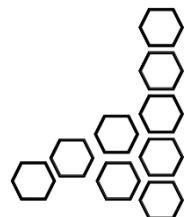
Jesse Gelsinger, 19 years old

1999 - First person known to have died from experimental gene therapy

Lawsuit against Univ. of Pennsylvania

- PI was heavily invested in the company, Genova, Inc.
- University failed to disclose death of monkeys in the informed consent
- University failed to disclose SAE of two other enrolled patients.

Settled for an undisclosed amount



What else can go wrong?

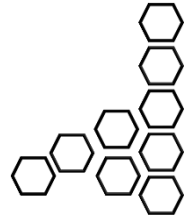


- When expectations in a contract aren't met, the contract typically has language on what the other party can do.

Return funds?

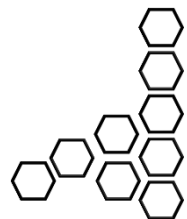
Hurt relationships?

Impede research progress?



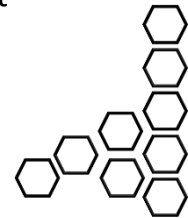
Types of contracts SPA assists with:

- *Subcontracts (in or out) – off awards from a primary funding source*
- *Confidentiality agreements (receiving CI)*
- *Data use/transfer agreements*
- *Material transfer agreements*
- *Sponsored/Collaborative Research Agreements*
- *Clinical Trial/Study Agreements*
- *Service Agreements (Sponsored)*
- *Salary Reimbursement Agreements*
- *“Other” Sponsored Projects Agreements*



Contract Categories:

- Contracts to receive money (sponsored project)
 - Process very similar to grants proposal process
- Contracts off of existing sponsored projects
 - Subcontracts off of existing projects; SPA already has the information
- Contracts to exchange information, material, or data for project purposes
 - No budget to review



Internal Forms

UTHealth | Sponsored Projects Administration
The University of Texas Health Science Center at Houston

REVIEW & APPROVAL FORM

PROJECT INFORMATION:

PROJECT TYPE	PROPOSAL TYPE	AWARD TYPE	RESEARCH	FUNDING SOURCE	PROTOCOL/RESEARCH PLAN
<input type="checkbox"/> Instruction <input type="checkbox"/> Research <input type="checkbox"/> Scholarship/Fellowship <input type="checkbox"/> Service <input type="checkbox"/> Construction/Equipment <input type="checkbox"/> Other	<input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Renewal <input type="checkbox"/> Resubmission <input type="checkbox"/> Supplement <input type="checkbox"/> Transfer	<input type="checkbox"/> Contract/CTA <input type="checkbox"/> Coop Agreement <input type="checkbox"/> grant <input type="checkbox"/> subcontract	<input type="checkbox"/> Basic <input type="checkbox"/> Clinical Research <input type="checkbox"/> Clinical Trial <input type="checkbox"/> N/A	<input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local <input type="checkbox"/> Foundation/Not For Profit <input type="checkbox"/> Industry/For Profit <input type="checkbox"/> Other	<input type="checkbox"/> UTHealth <input type="checkbox"/> Sponsor <input type="checkbox"/> Joint <input type="checkbox"/> N/A

Project Title: _____ Short Title: _____
(20 Characters Max)

Existing Grant/Award # _____ Existing FMS Project # _____

UTHEALTH INFORMATION:

PI Name: _____ % Effort on this Project: _____
(Minimum 2% required on all Sponsored Projects)

If PI is a new faculty member then provide a copy of offer letter.

Other Covered Individuals *List all covered individuals (as defined above) responsible for the design, conduct or reporting of the research.

Name	Role	% Effort	Department	Faculty
_____	_____	_____	_____	<input type="checkbox"/>

UTHealth | Sponsored Projects Administration
The University of Texas Health Science Center at Houston

TRANSFER FORM

Materials/Data will be sent: to UTHealth from UTHealth **Transferring:** Material Data Both

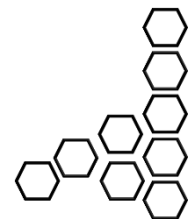
UTHealth Information

PI Name: _____ Department: _____

Outside Organization Information

PI Name: _____ Phone: _____ Email: _____

Organization Name: _____



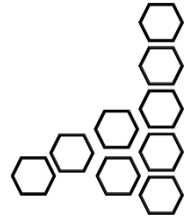
Why does SPA need to know?

Work Scope!

- The more information we have, the better we can match the agreement terms
- Any materials/data being exchanged?
- What do YOU want the project to look like
- What does the Sponsor want the project to look like
- Any material/data being exchanged?
- Who wrote the work scope?

Internal forms help us gather information

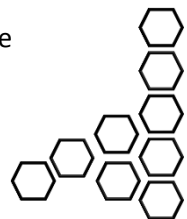
- Review & Approval Form/Transfer Form



Monetary Agreements Process

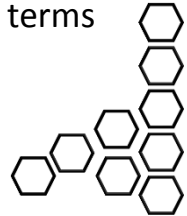
Route Application to SPA (in coordination with department admin)

- Route Agreement and Administrative and Financial (A&F) Packet to SPA when you've received an agreement (**or alert SPA previous submitted proposal funded**)
- Contracts specialist will review (as applicable):
 - Agency guidelines, RCOI forms, Budget, Budget Justification, Administrative and science pages, terms of the agreement.
 - Once award is reviewed and contract agreed upon, we communicate with the post-award team for award set-up



Contracts off existing Sponsored Projects

- Communicate with your department administrator and SPA regarding what other contracts may be needed
- Subcontracts that are written into grant proposals are already part of SPA processing of an award set-up
- Clearly answering the questions on the forms helps SPA get the terms right the first time



Contracts transferring information, data, or materials

- If you have a CDA and you are not sharing UTHHealth Confidential Information
 - Send agreement to crf@uth.tmc.edu or preaward@uth.tmc.edu
- If ONLY transferring material and/or data, fill out a transfer form
 - Send agreement (if you have it) to preaward@uth.tmc.edu



Sponsored Projects Administration

TRANSFER FORM

Materials/Data will be sent: to UTHHealth from UTHHealth **Transferring:** Material Data Both

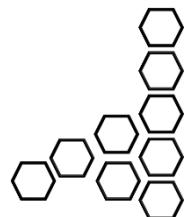
UTHealth Information

PI Name: Department:

Outside Organization Information

PI Name: Phone: Email:

Organization Name:



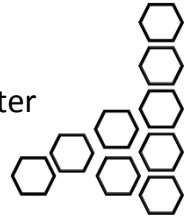
What's taking so long?

Contracts also depend on who the other entity is that we're negotiating with
 -our mission aligns with other academic institutions, NIH, etc. does it always align well with industry?

Some sections of a contract are not easy to come to agreement on:

- Confidentiality
- Indemnification
- Subject Injury
- Data Rights and Intellectual Property
- Publication
- Budget and Payment Terms

InfoEd Grants & Contracts Management System will be providing greater transparency into the contracting process (Summer 2019 training)



Contracts Assistance

- Contact SPA with any questions during the contract process:

preaward@uth.tmc.edu

(713) 500-3999

- Visit SPA Website for Additional Resources:

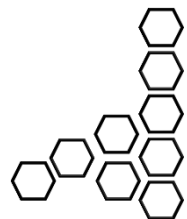
<https://www.uth.edu/sponsored-projects-administration/index.htm>

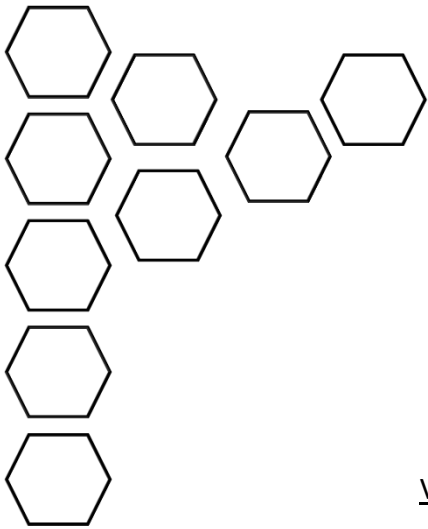
- Join the SPA List Serve – “AURA” for research administration updates and information, Contact: SystemsReporting@uth.tmc.edu

- My contact information:

Valerie.C.Bomben@uth.tmc.edu

713-500-3174





Questions?

Thank you!

Valerie.C.Bomben@uth.tmc.edu

713-500-3174

