

Symposium for Research Administrators



Reengineering Research Administration

Connecting the Dots for Industry Sponsored Projects

By: Barbara Hall

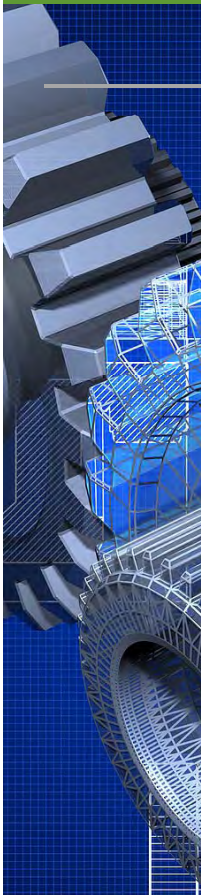
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This session will be informative for those research administrators new to the industry sponsored research arena, and remediation for those research administrators with advanced experience.

It is imperative for a research administrator to understand who, what, why and when regarding industry sponsored contracts.

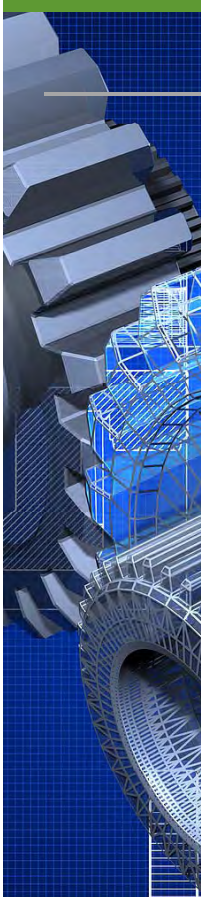
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Objectives

- 1) In this workshop, we hope to provide facts regarding the industry sponsored contract approval process that will enable the research administrator to better understand the process and equip them to connect the dots.
- 2) We also will share best practices for preparing a successful SPS entry for industry sponsored projects that when implemented, will reduce the number of incorrect proposals returned by ORA, and therefore allowing the research or clinical practice of the PI to proceed in a timely manner.

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Topics of Discussion

- What are the mechanisms of an Industry Sponsored Project?
- How do I prepare a SPS entry for an Industry Sponsored Project?
- Why is the signed DPAF important?
- WBSE Request Form – When and Why
- The Routing Process

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Topics of Discussion, cont.

- The contract review process
- Partially and Fully executed contracts
- Awarding the SPS record
- Project extensions

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What are the Mechanisms of an Industry Sponsored Project?

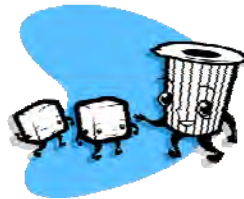
INDUSTRY SPONSOR: The industry sponsor is an entity that provides funds to test a product they have commercially manufactured.

In this presentation, the sponsor is **CAKES GALORE.**



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Cakes Galore is seeking FDA approval for their artificial sweetener, RAGUS.



PRINCIPAL INVESTIGATOR: The Principal Investigator (PI) is the person that leads and directs the project. The PI for this presentation is an Endocrinologist, Larry Luvit, MD/PhD. Dr. Luvit is a Research Scientist.



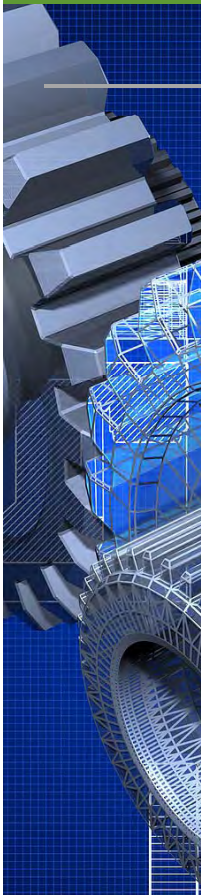
He is also a Clinician that treats patients that are Hyperglycemic.



Dr. Luvit has a history with the sponsor, Cakes Galore, as he also received research funding from them to test RAGUS on mice in his laboratory.



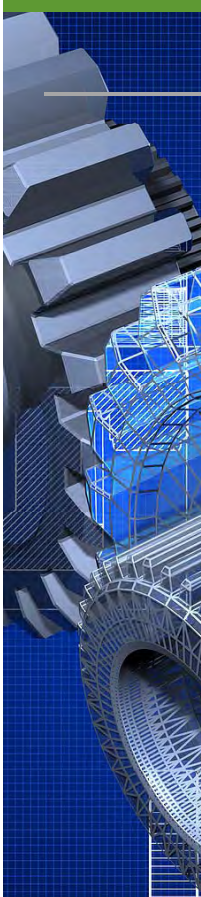
After years of performing different research experiments, his hypothesis was proven true. RAGUS could be used in Hyperglycemic mice with minimal adverse effects.



Dr. Luvit has now agreed to host a Phase I Clinical Trial, using RAGUS in Red Velvet Cupcakes.



The sponsor will provide one dozen RAGUS sweetened red velvet cupcakes monthly to the 25 subjects that meet the criteria for admission onto the study. The clinical trial is planned for a six month project period.



Dr. Luvit begins to work with his staff to produce an Institutional Review Board (IRB) approved protocol, which is another important element of this clinical trial.

The sponsor, Cakes Galore sends him the agreement which is forwarded to the Office of Corporate Research Collaborations (OCRC) for their review and approval. If there are legal issues with the agreement, OCRC will work with the sponsor to clear them.

Dr. Luvit also projects the costs he will incur and provides this information to his Grants Manager, or Financial Practice Manager who starts the SPS entry.

How Do I Prepare a SPS Entry for an Industry Sponsored Project?

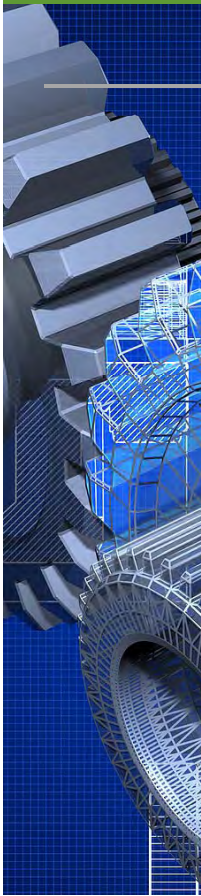
The screenshot shows a software window titled "Main Notebook - Terry Milch - Your Name (First Last) Sample Proposal". The window contains several input fields and buttons. The "Proposal ID" is 4219, and the "Date Initialized" is 8/31/2001. The "Short Title" is "Your Name (First Last) Sample Proposal". The "Principal Investigator" section includes "Last Name (CL)" as Milch, "First Name" as Terry, "Title" as Professor, and "Appt. Duke Dept." as Genetics (Primary). There are also fields for "Fellow, Resident, Graduate Assistant (for Fellowships Only)" with "Last Name (CL)" and "First Name" fields. At the bottom, there are tabs for "Main", "Expense", "Admin", "Activity", "Spans. Matl.", "NSF", and "Summary of Work".

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The SPS entry requires:

- 1. Proposal Title:** For industry sponsored projects, the entries can be the same for the Short and Proposal Full Title. The Short Title versus the Proposal Full Title is mainly relevant for those research applications wherein sponsors have a defined number of allowable character spaces.
- 2. Principal Investigator's Name:** Larry Luvit, MD/PhD
- 3. Project Period:** The date referenced in the contract as the effective date should be used as the start date. The end date is derived from the contract's stated term duration. If not stated, department should use the PI's projected term.

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Main Notebook - Terri Milich - Your Name (First Last) Sample Proposal

File Actions Help

Proposal Full Title:
Your Name (First Last) Sample Proposal

Co-PI Information:

Last Name (C)	First Name	Duke Org
Hurka Owen	Keith P.	Genetics

Insert Row Delete Row Person Details

Project Period: Start Date: 9/1/2004 End Date: 8/31/2009 Proposed Duration: 60 month(s)

Current Budget Period: 9/1/2004 8/31/2005

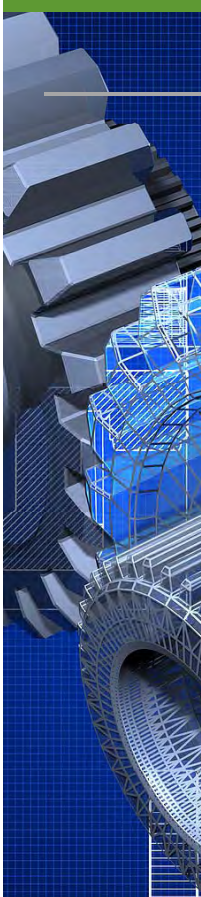
Owning Duke Org (C): Comprehensive Cancer Ctr

PHS 398/2590 Face Page Organization (Box 3e/Box 2c): Genetics

Main Sponsor Admin Activity Spons. Matl NSF Summary of Work

Save INIT New Regular Main Admin Close

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4) Activity Selection:

Main Notebook - Terri Milich - Your Name (First Last) Sample Proposal

File Actions Help

Proposal Activity

Research Inst. Training Prgm Public Service Construction/Renovation

Fellowship Clinical Trial Inst. Support Equipment Conference

Clinical Trial Phase(s): Phase I Phase II Phase III Phase IV

Does the study involve the use of a CR0? Yes No

If yes, please specify the CR0 (C):

This research predominantly involves the use of:

Wet Lab (Bench Research) Dry Lab (Computer, Data Analysis, Clinical Research)

Will space, services, and/or procedures (e.g., MRIs) from other departments be used? If yes, please specify: Yes No

Will a new degree program or curriculum be developed? Yes No

Will Summer University Housing be required? Yes No

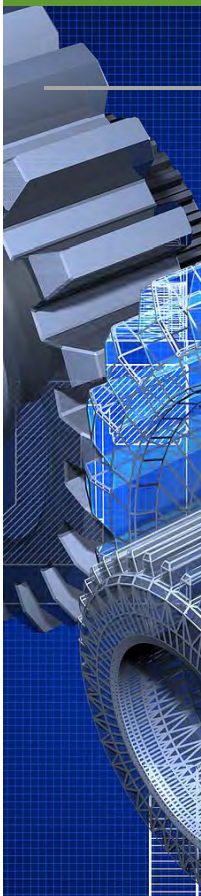
Will any part of the project work take place in the Duke Forest? Yes No

Will this proposal have any international aspect requiring large scale or multi-unit efforts? Yes No

Main Sponsor Admin Activity Spons. Matl NSF Summary of Work

Save INIT New Regular Main Admin Close

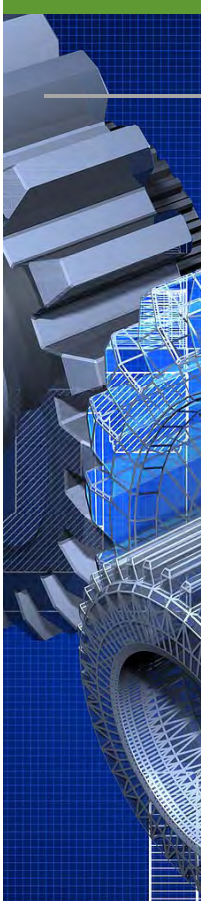
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4-a) Activity Definitions

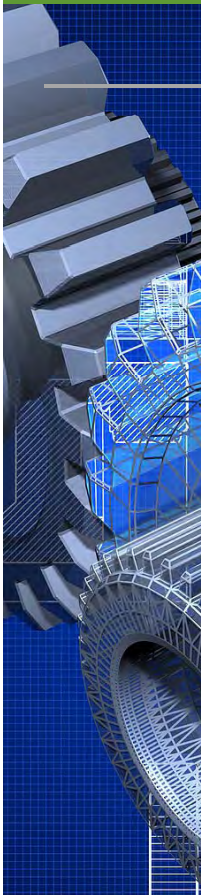
Research – Funding used to support specific PI research projects that are investigator initiated with a hypothesis for the betterment of mankind for a suspected but unknown end result.

Research funding can also be sponsor solicited, wherein a sponsor is looking to obtain proposals for a clearly defined research subject or purpose.



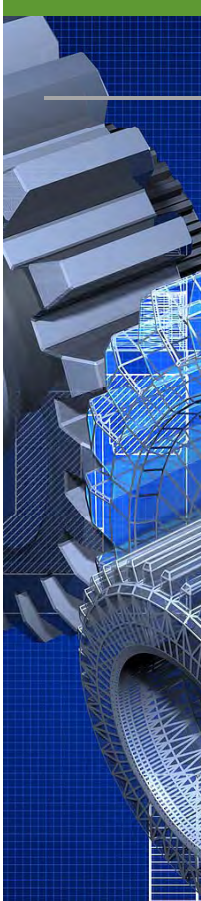
Clinical Trials - Clinical trials are prospective biomedical and behavioral research studies of human subjects that are designed to answer specific questions about biomedical or behavioral interventions (such as drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are also used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subject's research involving an intervention to modify behavior (such as diet, physical activity, cognitive therapy, etc.) fits the definition



Clinical Trials cont. - Research with human subjects to develop or evaluate clinical laboratory tests (imaging or molecular diagnostic tests) might be considered as a clinical trial if the test will be used for medical decision making, or if the test imposes more than minimal risk for subjects. *(This definition was provided by Billy Newton, Vice Dean Finance & Resource Planning)*

Public Service – Public service activities are those that allow the PI to facilitate intervention, health service, education, and opportunities for citizens in the community for their well-being.

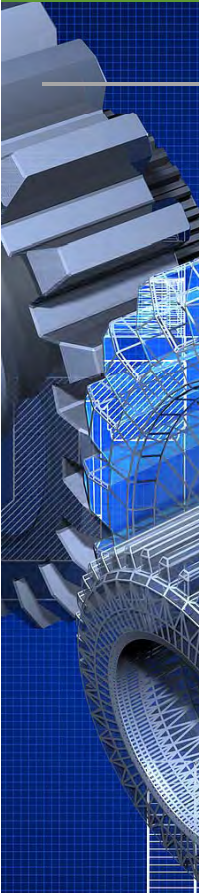


Fellowship – Funding provided to an institution in support of a sponsor selected individual for advance training/study in a specific research area.

Inst. Training Program – Funding provided for an institution to develop or enhance research training opportunities for individuals, selected by the institution in specific scientific areas or research fields.

Inst. Support – Funding for institutional comprehensive scholastic curriculums.

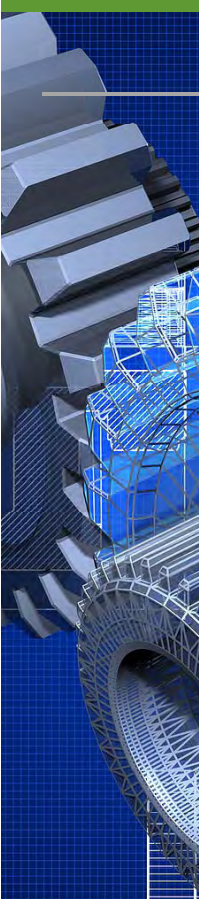
Equipment – Opportunities/funding to support the purchase of equipment only.



Construction/Renovation – Grant opportunities that provide funding to support new building projects and structure or the renovation of existing buildings.

Equipment – Opportunities/funding to support the purchase of equipment only.

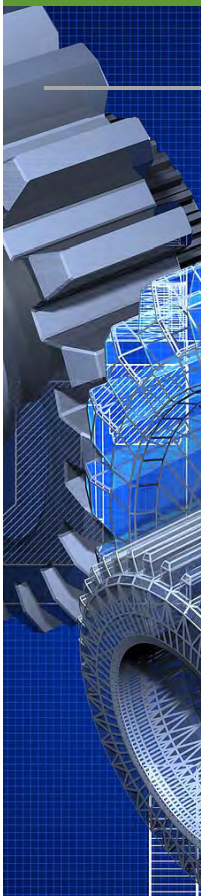
Conference – Used when funds are provided to support the attendance to or organization of scientific meetings/conferences.



5) **Personnel Roster** – Unless there will be sub-

Last Name [C]	First Name	Duke Org	Key	VA	Project Role
Milich	Terri	Genetics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	PI
Harka-Dwen	Keith P.	Genetics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Investigator

Last Name	First Name	Subcontract Org [C]	Key	Project Role
Rhine	Cynthia	University of North Caro	<input checked="" type="checkbox"/>	Subcontractor PI

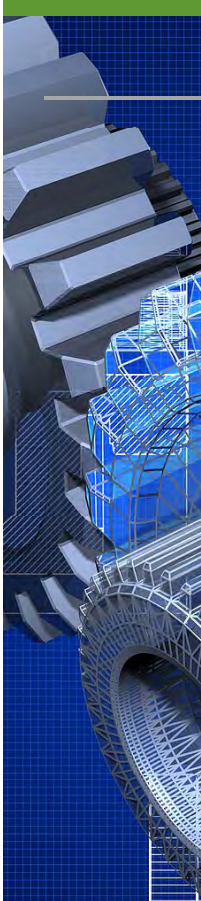


6) Abstract or Statement of Work – This is a summary of the project’s proposed work that should be obtained from the PI and provided in SPS.

7) Rules Tab — *Per Duke’s Department of Health & Human Services Negotiated Rate Agreement*

- An indirect cost rate of 28% should be used for industry sponsored clinical trials.
- For on-campus industry sponsored research, an IDC rate of 57% should be used. For off-campus, < 50 miles 28.5% is the appropriate rate; 26% for > 50 miles.
- If the clinical trial is federally sponsored, 57% would be the appropriate indirect cost rate.
- Except in cases where the industry sponsor has a different published rate, an IDC rate of 0% should be used for Conference projects, Fellowships, Institution Training, and Institution Support programs.

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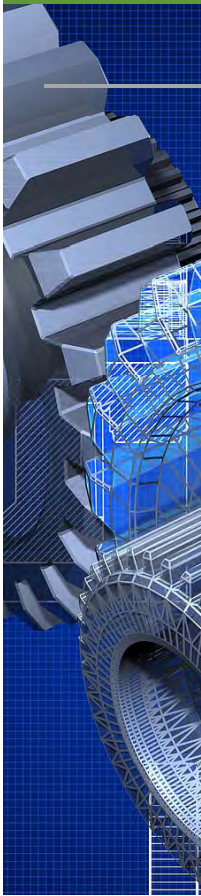


8) Salary Worksheet – A minimum of 1% effort is required for the PI. Anything greater, is left to the discretion of the PI.

If there is a question to whether or not the PI will remain compliant with the greater than 98% rule for effort reporting, the following aggregated statement may be used for their clinical trial projects when preparing other support documents:

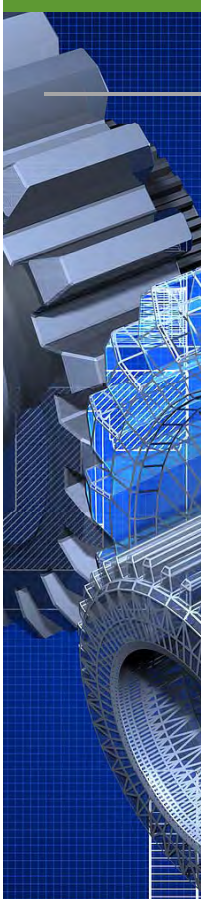
- Duke University lists aggregated effort assigned to the following eligible industry-sponsored clinical trial projects. Each of these individual projects has a varying need of effort depending on the type of activity currently in progress such as protocol development, start-up, patient recruitment, enrollment, follow-up, monitoring, data analysis, publication, and closeout. Faculty determines each project's need and adjust their effort between projects within the total aggregated effort assigned to the clinical projects.

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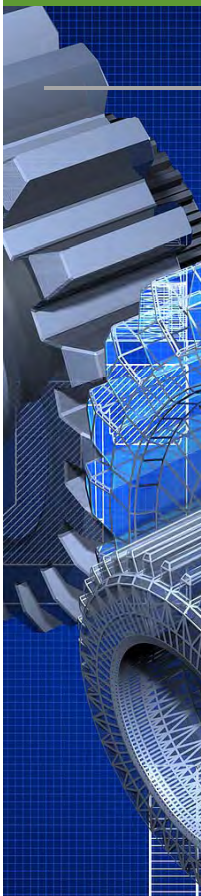
- 9) **Budget Entry** – ORA’s main two points of review for the industry sponsored clinical trials are the F&A rate, and 1% effort for the PI. Therefore, it is strongly suggested that the Excluded and Included direct cost categories be used when preparing the SPS budgets.

Please note that industry sponsored **research** projects receive the same thorough review as all other research grant applications.



After the department completes the SPS entry, they should print out the Duke Proposal Approval Form (DPAF) and obtain the PI’s signature.

(Please see Handout #1)

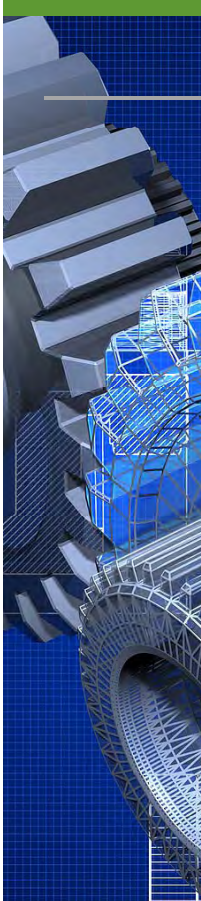


WHY IS THE SIGNED DPAF IMPORTANT?

The DPAF provides:

- The demographic information of the PI
- The title of the project
- The name of the sponsor
- The number of years projected for the proposal
- Projected direct and indirect cost; total cost for project
- Applicable protocol information
- PI's signature that assures that he/she has agreed to do the work proposed by the sponsor
- The PI's answer to the Conflict of interest question which helps to keep Duke University's and the PI's integrity in check.

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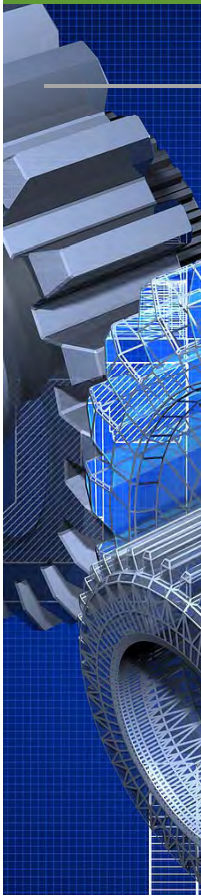
WBSE Request Form – When and Why

Prior to routing the SPS record, the department should complete the WBSE request form, obtain the applicable signatures and attach this document in the internal documentation section.

(Please see Handout #2)

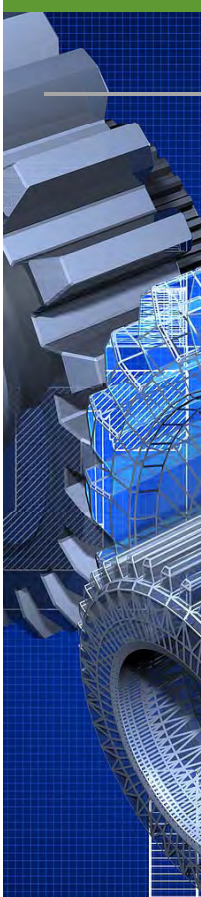
It is not necessary for the department to send ORA a separate email notifying them of the WBSE request. When the SPS record becomes PCA, it goes into the inbox of the department's assigned ORA Research Administrator.

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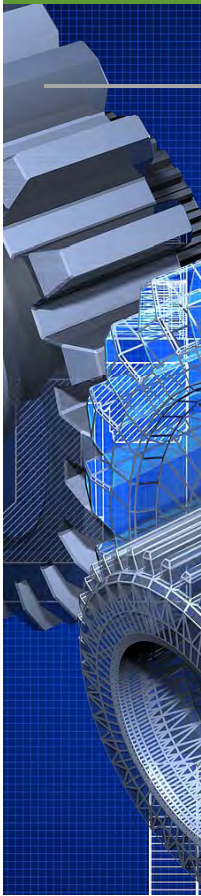
The department's ORA assigned RA approves the record so that it is routed to the inbox of the Contract's Specialist. The SPS record remains PCA until OCRC forwards the agreement to ORA.

ORA **will not approve** contracts prior to OCRC's review and approval. Therefore, documents attached in SPS's Internal Documentation section (WBSE request form, DPAF, etc.) are processed when the contracts are received in ORA with OCRC's stamp of approval; this lessens the duplicity of effort.



The WBSE form is forwarded to the Office of Sponsored Programs (OSP) for them to generate a code. This signifies ORA's approval for the creation of a WBSE.

If the department does not include a WBSE request form upfront when they route the SPS proposal to PCA, a WBSE is requested at the backend of the process when the record is awarded with the fully executed agreement.

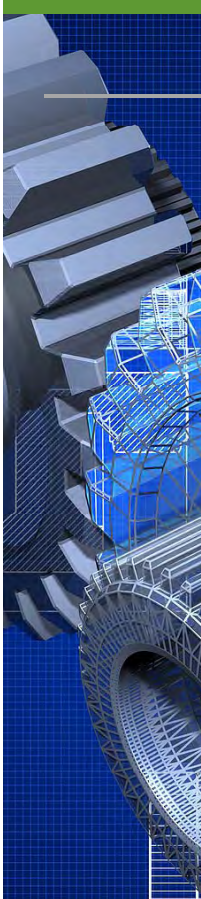


The Contract Review Process

Office of Corporate Research Collaborations -

- review and negotiate agreement terms for industry-sponsored or industry-funded research
- review the research's related injury language in the IRB consent form and recommend any revisions needed to be consistent with the agreement terms and Duke policies
- provide agreement information to the Duke Office of Clinical Research (DOCR) for grid review
- obtain confirmation from the Clinical Research Unit (CRU) that budget and payment terms are consistent with School of Medicine policies

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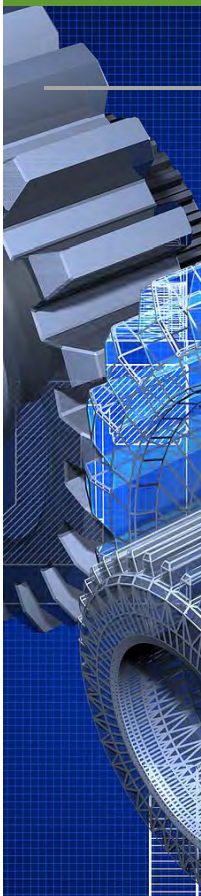


The Contract Review Process, cont.

OCRC also:

- obtain insurance information from industry consistent with Risk Management requirements
- determine status of research project in SPS
- approve the finalized contract and send to ORA for the institutional signature

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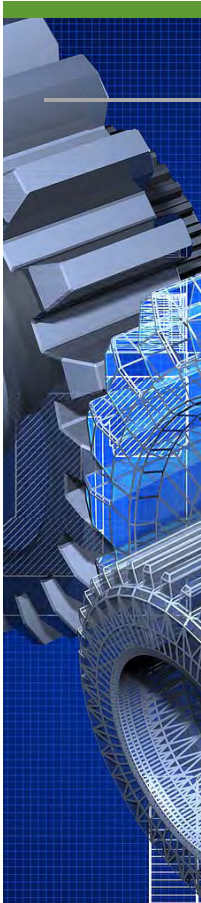


The Contract Review Process, cont.

Office of Research Administration –

- Log the date contract is received in ORA into applicable SPS record, ensuring OCRC has provided their stamp of approval
- Ensure SPS record is routed to PCA
- Check SPS for internal documentation:
 - ensuring DPAF is signed; if the Conflict of Interest question is answered yes, the DPAF and Statement of Work are forwarded to the Research Integrity Office (RIO) for approval.
 - Detach WBSE request form; ensure it is signed appropriately; forward it to Office of Sponsored Programs (OSP) for them to generate a code.

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Office of Research Administration also –

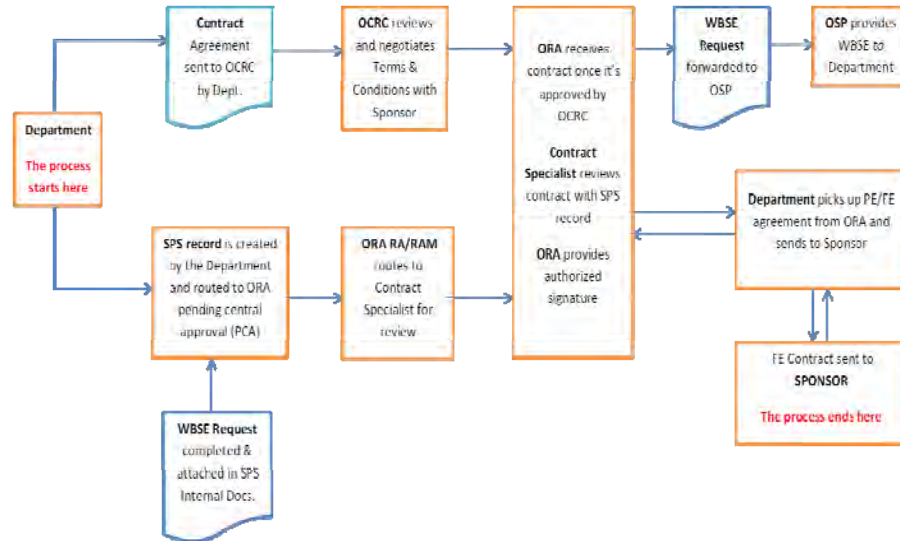
- Ensure PI has at least 1% effort listed in the budget
- Review contract for period of performance
- Peruse listed costs
- Provide authorized signature
- Notify department partially or fully executed contract is ready for pick-up.

ORA updates the SPS record in the Proposal Memo tab when actions are taken. Therefore, this would be the appropriate place for departments to check first for a contract's status.

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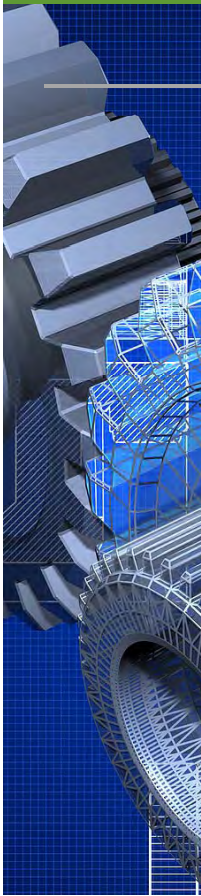
The Routing and Review Process

Please see Handout #3



Partially Executed (PE) Contracts

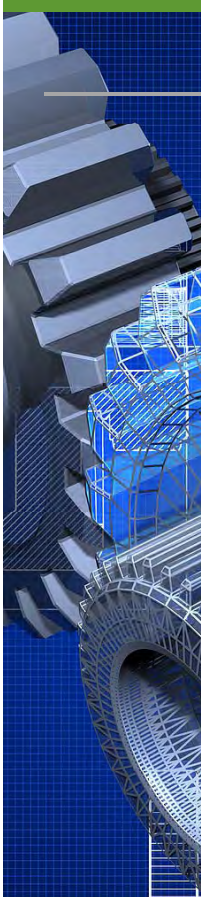
- If there are other signatures required after ORA has provided authorized signature, the PE original contract is returned to the department or OCRC for the missing signatures to be obtained. ORA marks the record as “Award in Progress” and maintains a copy of the contract in its pending files.
- After obtaining the applicable signatures, the department or OCRC will provide ORA with a fully executed PDF for further processing.



Fully Executed (FE) Contracts

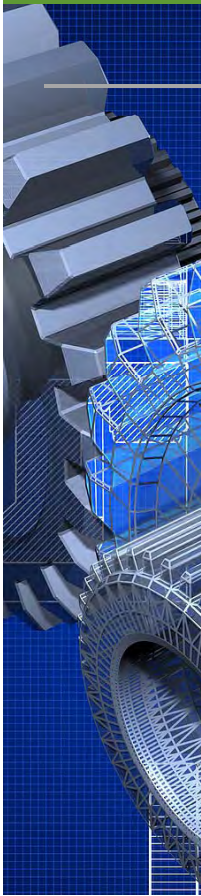
- When the department returns the FE contract to ORA, the SPS record is awarded, and the IRB protocol is released in eIRB. The SPS record printout and contract are forwarded to OSP. These documents are also scanned to ORA's electronic files.
- If all signatures except ORA's have been applied to the contract when it arrives in ORA, once ORA signs the contract it is considered fully executed.

ORA updates the SPS record in the Proposal Memo tab when actions are taken. Therefore, this would be the appropriate place for departments to check first for a contract's status.



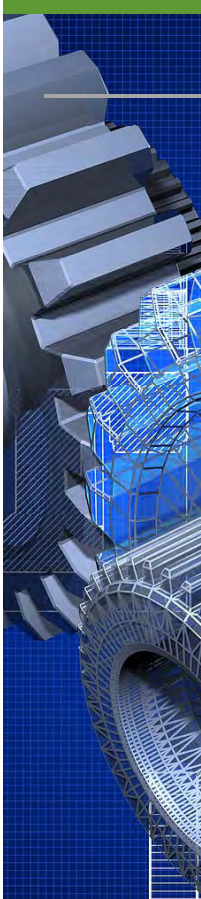
Awarding the SPS Record

- When the agreement has a stated value or its budget is created in a way that reflects the total amount of the project, the contract value should match the SPS budget total. A 5% variance between the contract value and the SPS budget total is acceptable. ORA will "Award" the SPS proposal with the stated contract value.
- If the variance between the contract value and the SPS budget total exceeds 5% or if for other reasons ORA cannot reconcile the SPS budget total with the contract value, the SPS proposal will be returned to the department for them to adjust the SPS budget as needed.



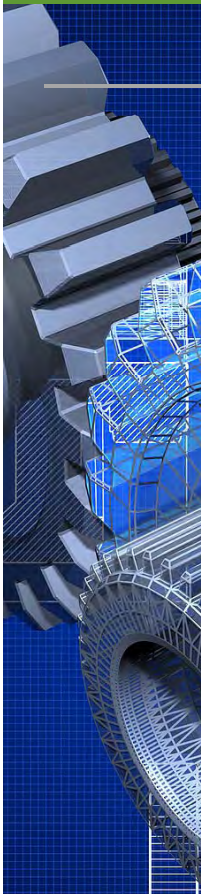
- When the contract value is not stated in the agreement, the department will determine the estimated contract value based on projected subject enrollment and incurrences of fees or other such milestones. They will summarize their approach in the SPS budget justification section.
- ORA will review the SPS budget and budget justification and will award the proposal per the SPS budget total. The SPS proposal will be returned to the department for budget adjustment or clarification if the SPS budget total and budget justification do not reconcile.

This approach is also taken whenever the contract references a “shall not exceed” amount.



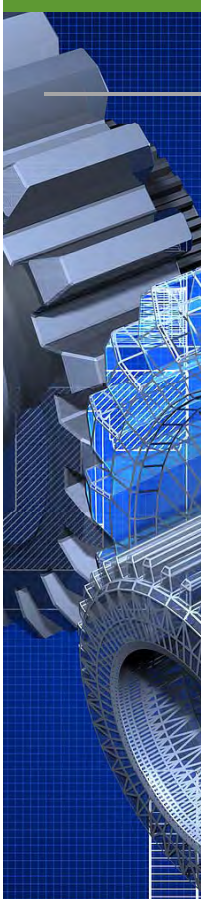
- Whenever the sponsor provides drugs or devices for a project and zero dollars are involved, ORA will award the record for \$1, which is the minimum amount allowed to be awarded in SPS.

In this case, the PI is not required to reflect the 1% effort, but the department will need to provide in the budget justification where the PI’s effort is covered elsewhere.



Project Extensions

Please see Handout #4

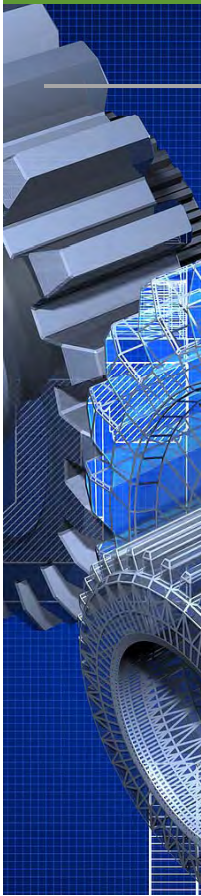


Project Extensions

Scenario One:

Cakes Galore realizes that they need for Dr. Luvit to recruit 10 more patients, which will require an additional 6 months for the studies completion. Therefore, they send an amendment specifying that they are providing additional products and funds for the extended period.

The PI agrees to extend the trial and the amendment is forwarded to OCRC for their review and approval. Once the amendment is approved by OCRC, it is forwarded to ORA for Institutional signoff. The SPS record is updated once the amendment is fully executed and the document is forwarded to OSP for them to update R3. In this case, it is not necessary to generate a No Cost Extension (NCE) form for ORA's approval.



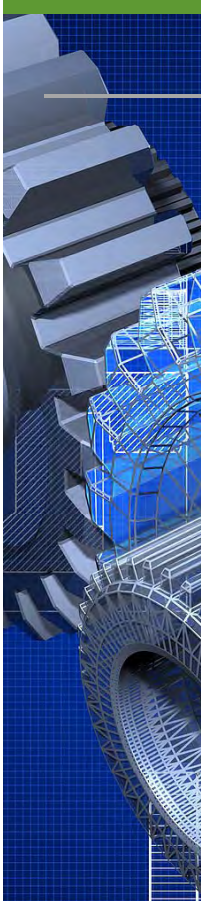
Project Extensions, cont.

Scenario Two:

Dr. Luvit has been unsuccessful in recruiting the total number of subjects needed for the study and he still has funds remaining from the original budget. His research administrator will complete and forward a No Cost Extension form after obtaining the applicable signatures. Because the original agreement does not have a definite end date, it is not necessary for Dr. Luvit to obtain the sponsor's approval for this extension.

If the original agreement listed a definite end date, Dr. Luvit would need to obtain the sponsor's approval of the extended period and the department will need to include this documentation with the NCE. Contingent upon how the original contract is written, this scenario may require an amendment from the sponsor.

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Resourceful Websites

Office of Research Administration

<http://research.som.duke.edu/>

Office of Sponsored Programs

<http://finance.duke.edu/research/departments/osp.php>

Office of Corporate Research Collaborations

(database access by permission only)

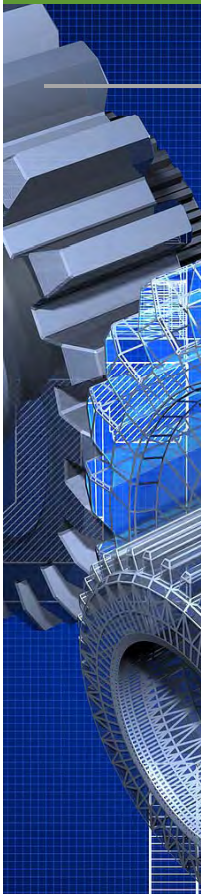
http://10.136.4.183/Reports_REPORTSERVER_1/Pages/Folder.aspx?ItemPath=%2fSBR+Reports

Institutional Review Board for Clinical Investigators (eIRB)

(database access by permission only)

[https://eirb.mc.duke.edu/eirb/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity\[OID\[AC482809EC03C442A46F2C8EEC4D75D3](https://eirb.mc.duke.edu/eirb/Rooms/DisplayPages/LayoutInitial?Container=com.webbridge.entity.Entity[OID[AC482809EC03C442A46F2C8EEC4D75D3)

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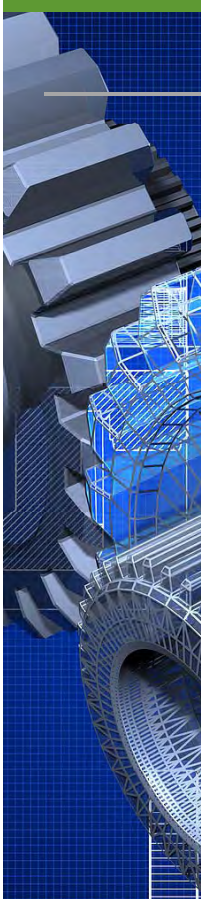


Contacts

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Research Administrator
Effort Specialist
Office of Research Administration
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Questions?