

# WAYNE STATE UNIVERSITY

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SPONSORED PROGRAM ADMINISTRATION

## SPA's Guide to Clinical Trial Agreements

A Step-by-Step Guide to Processing Clinical Trial Agreements with SPA: from receipt of agreement to award close out

Please visit <https://research.wayne.edu/spa/contracts/clinical-trials> for additional information

## STEP 1 – BUDGET NEGOTIATION

After a Principal Investigator (PI) decides to move forward with a clinical trial based on their review of the protocol, the study team should conduct a thorough analysis to determine if the funding is on par with the cost to perform the study. In most cases, the initial offer provided by the sponsor is NOT final. Negotiating the budget is unlikely to affect selection as a site.

### START THE BUDGET NEGOTIATION PROCESS EARLY TO AVOID RUSHING THROUGH THE ENTIRE CONTRACT PROCESS

#### Major budget categories to keep in mind:

- Start-up charges (should be non-refundable as they will be charged whether or not any subjects are recruited)
  - Institutional Review Board (IRB) fees - initial, amendments, and renewals
  - OnCore/ Clinical Research Service Center (CRSC) fees
  - Detroit Medical Center (DMC) fees
- Ancillary departments such as Pharmacy fees (study setup, maintenance, and close out), Lab fees; obtain cost-analysis if possible
- PI's time for things like protocol review, Site Initiation Visit (SIV), meetings
- Personnel time for responsibilities such as budget development and negotiation, completing the IRB application, Informed Consent Form (ICF) negotiation, chart and/or database review, SIV, protocol-specific training, reviewing study subject bills etc.
- Contingent charges (invoiced only if they occur) like Serious Adverse Events (SAEs), screen failures, unplanned visits, advertising
- 32% Indirect Cost (IDC or F&A) Rate on ALL direct study costs for clinical trials with industry sponsors; any exceptions to this rate would require an approved waiver before the contract can be finalized
- Close-out charges for study close-out visits, administrative close-out, IRB close-out, record retention

EVALUATE THE PROTOCOL TO MAKE SURE ALL COSTS ARE COVERED! IT IS THE DEPARTMENT'S RESPONSIBILITY TO ENSURE THE BUDGET WILL ADEQUATELY COVER ALL COSTS ASSOCIATED WITH CONDUCTING A CLINICAL TRIAL

## STEP 2 – SUBMISSION OF STUDY DOCUMENTS

After the budget has been finalized with the sponsor, the PI and study team should proceed with required startup activities including submission to Sponsored Program Administration (SPA), the IRB, and, if the study will be taking place within the Detroit Medical Center or Karmanos Cancer Institute, submission to their respective clinical trial offices.

### CONCURRENT SUBMISSION OF STUDY DOCUMENTS GREATLY REDUCES OVERALL STUDY START UP TIME!

For SPA submission, enter a complete proposal into Cayuse including the following attachments:

1. Clinical trial checklist\*
2. Clinical Trial Agreement (CTA)
3. Affirmation memo for Research Agreements completed and signed by the PI\*
4. Final sponsor budget
5. Study protocol
6. Sponsor contact information

### THE PI SHOULD USE THE AFFIRMATION MEMO TO CONVEY ANY CONTRACT TERMS THEY DO NOT AGREE WITH OR THINK SHOULD BE UPDATED

*Please ensure the PI certifies the Cayuse proposal.* The Contract Team cannot move forward until all of the above documents are attached, the proposal has received departmental approval and the PI has certified the proposal.

\*These documents can be found on the SPA website at <https://research.wayne.edu/spa/forms/contracts>

## STEP 3 – CONTRACT NEGOTIATION

After the proposal has been approved by SPA, the Contract Team will work directly with the Office of General Counsel (OGC) and the sponsor to negotiate the terms of the agreement.

SPA is responsible for reviewing, negotiating, and legally executing contracts from external funding sources for all Wayne State University faculty. No one should sign a sponsored agreement unless it has been requested by SPA following negotiations with the sponsor. To do so can negatively impact negotiations and our ability to finalize an agreement.

**SPA IS COMMITTED TO PROVIDING TRANSPARENCY REGARDING THE STATUS OF CONTRACTS IN REVIEW; PIS AND ADMINISTRATORS CAN ACCESS THE STATUS OF ALL AGREEMENTS THROUGH THE RESEARCHER'S DASHBOARD**

While the agreement is being negotiated, continue to move forward with all other study start up processes. Be sure to provide the IRB approval and approved ICF to SPA as soon as you receive them so the Contract Team can proceed with award establishment upon receipt of the fully executed agreement.

The clinical trial may commence once the IRB approves the protocol, the contract has been fully executed, and DMC (or KCI) approval, for any study being performed on their premises, has been received.

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### *SOME WSU STATUTES AND POLICIES\* AFFECTING CONTRACT NEGOTIATIONS:*

- *2.41.01 University Research Policy*
- *2.41.04 Patent and Copyright Policy*
- *2.42.01 Academic Freedom*
- *03-05: Facilities and Administrative Costs Distribution Policy*
- *04-6 Contract Signatories (Third Release)*

*\* <https://policies.wayne.edu/ws-policy-levels-and-manuals>*

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## STEP 4 –DURING THE STUDY

- SPA will send all CTAs to Pharmaseek Financial Services (PFS) for billing purposes.
  - Typically, if a CTA does not have a “per patient” budget, it will be handled by the SPA billing team.
  - Ensure billing information is provided to PFS or the SPA billing team, as applicable, in a timely manner to avoid funding delays.
  - Contact Sheila Dennis ([SDennis@pfsclinical.com](mailto:SDennis@pfsclinical.com)) for PFS-specific inquiries.
- Make sure IRB renewals are submitted in a timely manner
  - Review your agreement prior to requesting an account extension to see if an end date amendment is needed.
  - Send all IRB Renewals to Shatterra Childs ([ax9127@wayne.edu](mailto:ax9127@wayne.edu)) for award extension.
- Send *any* agreement amendments to SPA upon receipt.
  - Budget amendments should be reviewed and approved by the department prior to being sent to SPA.
  - Any amendment with an increase greater than \$10,000 should also have a Cayuse proposal that includes only the additional amount provided by the amendment.
  - Send all CTA amendments to Liane Howey ([lianehowey@wayne.edu](mailto:lianehowey@wayne.edu)) for processing.

## STEP 5 – STUDY CLOSE OUT

Once a study has terminated, there are a number of steps that must be taken to properly close out the study. Keep the following in mind as they relate to SPA:

- Inform the IRB, DMC and any other department(s) that supported the study that the study has ended
  - Obtain IRB termination letter and forward to sponsor and relevant reviewing entities
- Establish record retention for applicable study records based on the requirements in the CTA, protocol and/or by the FDA
  - Also note any end of retention requirements by the sponsor
- Ensure that all revenue has been received, all expenses have been paid and that the index has been reconciled
- Complete a Clinical Trial Closure Checklist\* and submit it to Shattera Childs ([ax9127@wayne.edu](mailto:ax9127@wayne.edu)) for processing
- Post data to Clinicaltrials.gov, if necessary

**MAKE SURE YOU FOLLOW INSTRUCTIONS PROVIDED BY OTHER DEPARTMENTS TO COMPLETELY CLOSE-OUT A CLINICAL TRIAL AND ENSURE PROPER STUDY TERMINATION**

\*This document can be found on the SPA website at <https://research.wayne.edu/spa/forms/contracts>

## HELPFUL LINKS

### Clinical Research Services Center



*The CRSC is a one-stop shop where investigators can access a wide range of support for their research projects. Consider the CRSC your go-to core facility for research activity.*

<https://clinicalresearch.med.wayne.edu/>

### Detroit Medical Center Clinical & Translation Research Office



*Our mission is to support clinical researchers across the DMC hospitals by providing comprehensive legal, regulatory and billing consultation on in-patient and out-patient studies.*

<https://www.dmc.org/for-health-professionals/clinical-translation-research-office>

### Fringe and IDC rates



*These costs should be requested on all proposals unless the policy of the sponsoring agency specifically prohibits them or offers other predetermined rates.*

<https://research.wayne.edu/spa/proposals/fringe-benefits>

### WSU Institutional Review Board Fees



*Wayne State University charges for IRB review of research studies supported by industry and for-profit entities.*

<https://research.wayne.edu/irb/irb-fees>

### Karmanos Cancer Institute Clinical Trials Office



*The mission of the Clinical Trials Office is to provide outstanding support to clinical trials being offered at the Karmanos Cancer Institute with the goal of improving cancer therapy and patient quality of life through research.*

<https://www.karmanos.org/cto>

### School of Medicine Research Administrative Services



*We're here to provide assistance in all phases of the grants and contracts process, from pre to post. In short, our responsibilities are to help make the lives of departments within the School of Medicine easier when it comes to grants and contracts, and how we do that is up to you.*

<https://blogs.wayne.edu/somras/>

## WHO WE ARE

The Sponsored Program Administration office within the Division of Research is responsible for the institutional oversight of Wayne State University's external sponsored programs. In this capacity, SPA provides service to three distinct groups: 1) faculty, 2) the University, and 3) the sponsors. SPA plays a role throughout the lifecycle of the project that includes:

- Proposal preparation and submission
- Award acceptance
- Successful completion of the project objectives

The SPA Contracts Team assists faculty and researchers in negotiating and executing contracts with sponsors (local, state and federal government agencies and private sponsors) by facilitating discussion and negotiation of contractual clauses affecting intellectual property, confidentiality, publications and other contractual concerns. The Contracts Team also handles all aspects of processing of subcontracts to outside entities involved in the substantive and/or programmatic aspects of a specific portion of a sponsored project.

## CONTACT US

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Sponsored Program Administration  
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Detroit, MI 48202  
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Email: [SPA@wayne.edu](mailto:SPA@wayne.edu)  
Web: <https://research.wayne.edu/spa/contracts/clinical-trials>



Contact Liane Howey for all CTA related inquiries directly at:

Phone: (313) 577-7945  
Email: [lianehowey@wayne.edu](mailto:lianehowey@wayne.edu)

Contact Shatterra Childs for all post-award clinical trial matters directly at:

Phone: (313) 577-3275  
Email: [ax9127@wayne.edu](mailto:ax9127@wayne.edu)