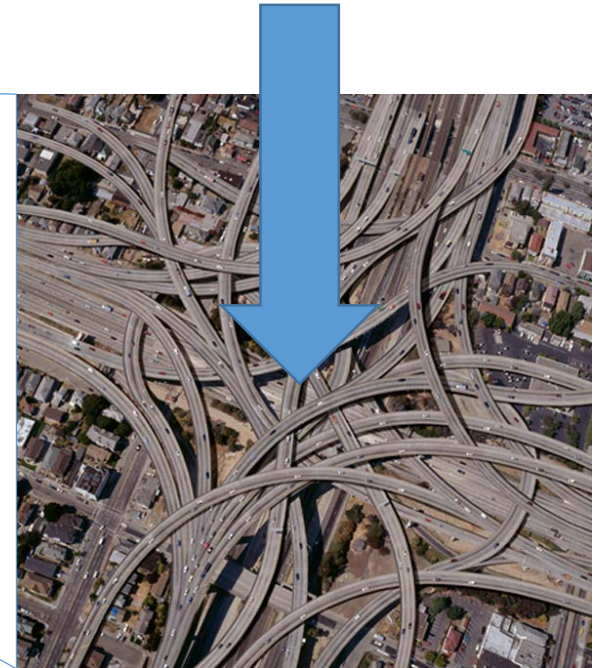


Your Study



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# Emory Pediatrics Clinical Research Pre-Award Process

PEARLS  
August 9<sup>th</sup>, 2019

Bridget Wynn  
Clinical Trials Pre-Award Specialist III  
E: [bridget.wynn@emory.edu](mailto:bridget.wynn@emory.edu)  
P: 404-712-6693



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# Who are we, anyway?

- The Clinical Trials Team is in the School of Medicine, Department of Pediatrics, Research Administration Services (RAS)
- We support the Study Teams and PI's with Clinical Research:
  - Proposal preparation
  - Budget development and negotiations
  - Enter proposal into EPEX (Emory's Proposal Routing System)
  - Monitor and facilitate contract negotiations
  - Request subcontract if needed



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# Meet the RAS CT Team



**Jyotsna Saxena**

Clinical Trials Pre-award Specialist I

RAS Pediatrics

404-727-4520

[jsaxen2@emory.edu](mailto:jsaxen2@emory.edu)



**Alexandria "Alex" Wilkerson**

Clinical Trials Assistant Project Coordinator

RAS Pediatrics

Emory University

404-727-0851

[awilke3@emory.edu](mailto:awilke3@emory.edu)



**Bridget Wynn**

Clinical Trials Pre-award Specialist III

RAS Pediatrics

404-712-6693

[bridget.wynn@emory.edu](mailto:bridget.wynn@emory.edu)



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# Types of Studies

Clinical trials are clinical research studies.

- [Clinical research](#) includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.
- [Clinical trials](#) are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome

(source: grants.nih.gov)



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# Types of Studies

## **Clinical Research:**

- Observational
- Studies that measure, not intervene
- Registry
- Comparing diagnostic performance
- Studies only utilizing standard or routine clinical care

## **Clinical Trials:**

- Interventions
- Drug study
- Device study
- Behavioral modifications
- Procedures
- Delivery systems



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# Why does this matter?

- Routing!



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# PRISM: Please use!

Good morning,

I will be the Emory University Clinical Trials Administrator working on with you.

Best,

Bridget Wynn

Bridget A. Wynn, MPH  
Clinical Trials Pre-award Specialist III  
RAS Pediatrics  
Emory University  
404-712-6693

[bwynn@emory.edu](mailto:bwynn@emory.edu)

Please send Pediatric Clinical Research agreements and contracts to [pediatric.ras@emory.edu](mailto:pediatric.ras@emory.edu)



<http://ras.emory.edu/>

[Pre-Award Satisfaction Survey](#)

**Link to Intent To Submit form: [PRISM \(Pediatric Research Initiation System\)](#)**

Click  
Here!

www.pedsresearch.org/research/support-services/research-administration

QUICK LINKS

EMORY Children's Pediatric Research Alliance

RESEARCH PEOPLE NEWS & EVENTS ABOUT US

Research Administration

RESEARCH ADMINISTRATION

- Getting Started
- CHOA IRB
- Emory IRB
- Emory OCR
- CHOA ORA
- Emory RAS
- CHOA OSP
- Emory IACUC
- Emory EHSO
- Emory OSP/OTT

RESEARCH

- Centers
- Cores
- Research Resources

Research Administration provides the infrastructure for pre- and post-award management of sponsored research projects. This includes proposal submission, budget preparation, routing documents for appropriate internal approvals, and ongoing fiscal management over the duration of the award.

The process varies and depends on many different factors: your institution affiliation, type of research conducted and location where research activities will occur.

Click below to see Your Research Pre-award Pathway:

- CHOA PI: All Research Types
- Emory PI: Human Subject Research
- Emory PI: Animal Research
- Emory PI: Wet/Bench Laboratory Research
- Emory PI: Human Subject + Wet/Bench Laboratory Research
- Emory PI: Human Subject + Animal Research

Ready to get started?

For Emory Department of Pediatrics Faculty, complete the [Intent to Submit Form](#).

For CHOAs PIs and Emory Faculty\* outside of Department of Pediatrics, complete [this form](#).

\*please also contact your department's RAS



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# Volume

- Emory Pediatrics Clinical Trials RAS receives 150+ new studies and amendments per year
- PRISM is the database where we track all these studies



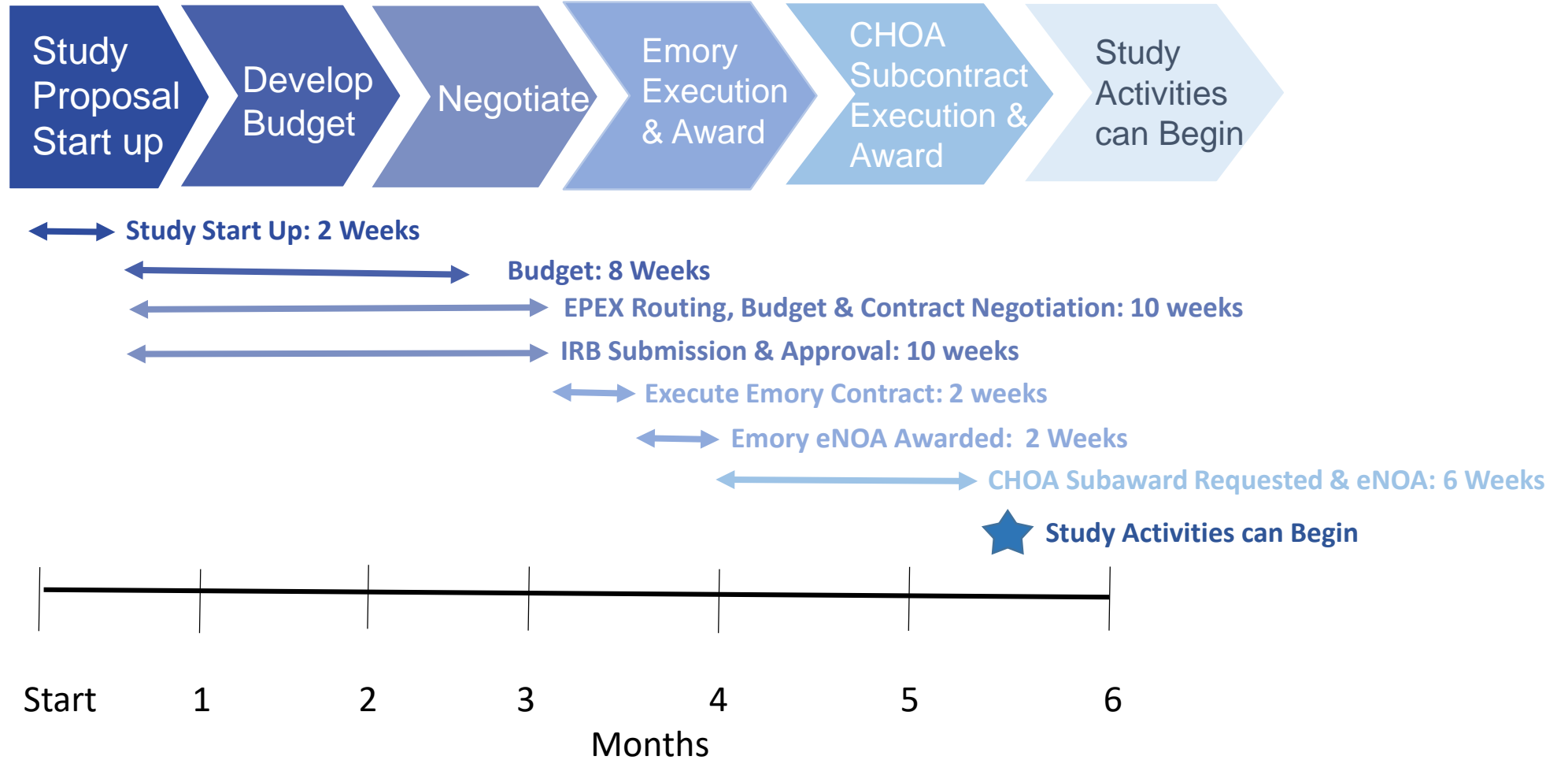
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# Timeline



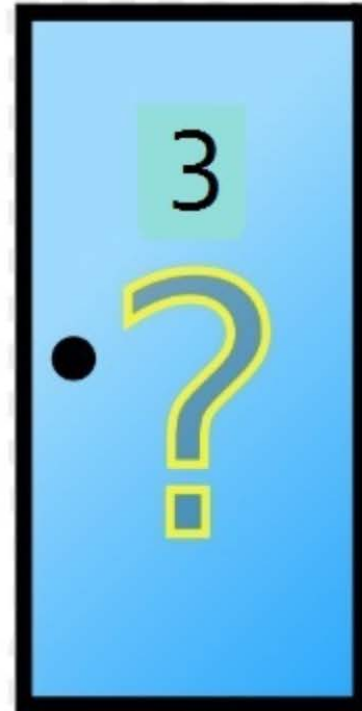
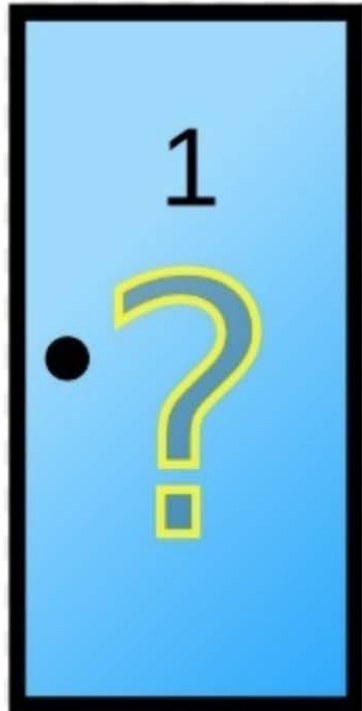
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# Emory or CHOA



# Where does my research route?

\*We are working to create guidelines which make the most sense for the study. Please be patient.\*

Type of Study:	Submit to Emory	Submit to Children's	Emory IRB	CHOA IRB
Clinical Research: -Observational -Registry	X		Emory Patients: X	CHOA Patients only: X
Investigator initiated funded Clinical Trials	X		Emory Patients: X	CHOA Patients only: X
Children's Oncology Group (COG) funded studies		X		X
Federally sponsored research (i.e., NIH, FDA, CDC)	X		Emory Patients: X	CHOA Patients only: X
Research sponsored by Foundations and other supporting agencies	X		Emory Patients: X	CHOA Patients only: X
Industry studies with Pediatric (CHOA) population		X		X
Industry studies conducted at CHOA		X		CHOA Patients only: X
Industry studies that are a subaward from prime institution	X		Emory Patients: X	CHOA Patients only: X
Studies not involving CHOA	X		X	
Studies with most, or all adult populations	X		X	
Population up to 21, but all at CHOA		X		X
<b>Anything not clear? Contact Children's/Emory</b>				

# Process Flow



Action: Emory, CHOA, PI, Study Team study start up meeting

Must have:

1. Draft budget template
2. Draft agreement
3. Final proposal
4. Draft consents

Action:  
CHOA:

- Coverage Analysis
- DAF
- Budget Development

Emory:

- Submit to OCR
- Submit to Investigational Drug Service
- Emory Internal and Sponsor Budget Development

Action: PI/Study Team works with RAS to build and approve budgets

- Action: RAS sends draft budget to Sponsor  
Negotiates budget as needed

- Action: Sponsor and PI final approval

- Action: RAS submits draft contract to Sponsored Programs via EPEX.  
Analyst reviews and negotiates contract

- Action: RAS requests PI eCOI

- Action: Study Team submits IRB and receives approval

- When you have IRB approval and budget is final, study is ready for execution aka signatures

- Action: Signatures needed: PI, Emory, Sponsor

- Action: Award is submitted to RGC for review, award set up, eNOA

- Action: Once we have Emory eNOA, RAS requests CHOA subaward. Documents submitted: CHOA LOI, budget, statement of work.

- Action: Emory Sponsored Programs prepares subaward, sends to CHOA Sponsored Programs.

- Action: CHOA review, signature. Emory signature.

- Action: Award is submitted to CHOA Grants and Contracts for review, award set up, eNOA

Once you have the CHOA eNOA, Study activities can begin

# How to find out information:

Contact Name	Email	Contact Name	Email
<p>PEDS RAS (Emory Budget Development, Sponsor Budget Negotiations, Sponsor Contract Negotiations, and Emory NOA Status)</p>	<p>Bridget Wynn Clin Trials Pre-Awd Spc III (RAS) E: <a href="mailto:bridget.wynn@emory.edu">bridget.wynn@emory.edu</a> P: 404-712-6693</p>	CHOA Coverage Analysis	<a href="mailto:coverageanalysis@choa.org">coverageanalysis@choa.org</a>
	<p><a href="mailto:pediatric.ras@emory.edu">pediatric.ras@emory.edu</a></p>	CHOA Budget Development (non-Aflac studies)	<a href="mailto:grantsadmin@choa.org">grantsadmin@choa.org</a>
	<p>Sarah Marie Huban Director, Research Administration E: <a href="mailto:sarahmarie.huban@choa.org">sarahmarie.huban@choa.org</a> P: 404-785-7477</p>	CHOA Budget Development (Aflac studies)	<a href="mailto:aflacga@choa.org">aflacga@choa.org</a>
<p>Children's Research Administration</p>	<p>Stephanie Meisner Director, Clinical Research E: <a href="mailto:stephanie.meisner@choa.org">stephanie.meisner@choa.org</a> P: 404-785-6453</p>	IRB Status, non-Aflac studies	Your Study Team
	<p>Nadine Spring Director, Clinical Research Services E: <a href="mailto:nadine.spring@emory.edu">nadine.spring@emory.edu</a> P: 404-727-5234</p>	IRB Status, Aflac studies	<a href="mailto:aflacpi@choa.org">aflacpi@choa.org</a>
<p>Emory Pediatrics Research Administration</p>	<p>Liz McCarty Executive Admin &amp; Vice Chair for Administration E: <a href="mailto:mmccar2@emory.edu">mmccar2@emory.edu</a> P: 404-712-8226</p>	CHOA Subcontract Status	<a href="mailto:osp@choa.org">osp@choa.org</a>



# CLINICAL TRIALS PRE-AWARD TRACKING REPORT

PI Last Name	PI First Name	Division	Proposal Type	Study Title	Proposal Status
Adams-Chapman	Ira	SOM: Peds: Neonatology (736504)	Contract Only	TOP5	Awaiting CTA Execution
Anderson	Evan	SOM: Peds: Infectious Diseases (736520)	Original Submission	RSV PED-011)	Awaiting CTA Execution
Anderson	Evan	SOM: Peds: Infectious Diseases (736520)	Original Submission	Pfizer RSV Vaccine in Pregnant Women	Emory Budget Development
Anderson	Evan	SOM: Peds: Infectious Diseases (736520)	Original Submission	Medi MELODY -AZ D5290C00004	Emory Budget Development
Anderson	Evan	SOM: Peds: Infectious Diseases (736520)	Original Submission	MEDI8897 MEDLEY	Emory Budget Development
Arnold	Staci	SOM: Peds: Hematology (736548)	Continuation/Progress Report	Home or Away from Home Study	Awaiting CTA Execution
Bennett	Carolyn	SOM: Peds: Hemostasis/Thrombosis (736546)	Original Submission	ICON3 ETB115JUS33T	CHOA Coverage Analysis
Brown	Clark	SOM: Peds: Sickle Cell (736547)		IMR-SCD-102	CHOA Coverage Analysis
Camacho-Gonzalez	Andres	SOM: Peds: Infectious Diseases (736520)	Original Submission	TMC114FD2HTX1006; Phase 1	Need to Start
Chonat	Satheesh	SOM: Peds: Hematology (736548)	Original Submission	AG348-C-008	HOLD
Chonat	Satheesh	SOM: Peds: Hematology (736548)	Amendment	ALXN-PNH-304	Emory Budget Development
Chonat	Satheesh	SOM: Peds: Hematology (736548)		Hem AMGABP959 Dahlia	CHOA Coverage Analysis
Cossen	Kristina	SOM: Peds: Endocrinology (736508)	Original Submission	Oral Modeling	Emory Budget Development
Dampier	Carlton	SOM: Peds: Sickle Cell (736547)		OMEG-411-02	CHOA Coverage Analysis
Dawson	Paul	SOM: Peds: Gastroenterology (736510)	Original Submission	Protective Effects of Dual ASBT/NTCP Inhibition	Awaiting CTA Execution
Fangusaro	Jason	SOM: Peds: Neuro-Oncology (736542)	Original Submission	PBTC-053	CHOA Budget Development
Felner	Eric	SOM: Peds: Endocrinology (736508)	Original Submission	Tolerion DAWN	Awaiting IDS Budget

EPEX#	Emory IRB Status	CHOA Coverage Analysis	CHOA Budget Development	Emory Budget Development	Sponsor Budget Negotiations	Sponsor Contract Negotiations	Emory NOA	Award Set-Up	CHOA/Other Sub-Contract
NA	N/A			N/A	N/A	N/A	N/A	N/A	
51678				In Process	In Process	Complete	Not Started	Not Started	
52090				In Process	Not Started	In Process	Not Started	Not Started	
53225	Pre-Submission			Not Started					
53371									
52704	Approved	N/A	Complete	Complete	Complete	Not Started	Not Started	Not Started	Not Started
53130		Complete	Not Started	Not Started	Not Started	Not Started	Not Started	Not Started	Not Started
53229									
53384				In Process					
51163		Complete	Complete	Complete	Pending Revisions	In Process	Not Started	Not Started	Not Started
53372	Approved			Not Started	Not Started	Not Started	Not Started	Not Started	Not Started
53483									
53316				N/A	N/A	In Process			
51911		Complete	Requested	Not Started	Not Started	Not Started	Not Started	Not Started	Not Started
51161				Complete	Complete	In Process	Not Started	Not Started	

Contact Nadine Spring if you would like to be sent this weekly

# Industry vs grant

**Office of Technology Transfer (OTT):** As a single point of contact for industry OTT is responsible for:

- Negotiating industry clinical trial agreements
- Industry research agreements
- Confidentiality agreements

**Office of Sponsored Programs (OSP) Team** handles proposals, non-industry contracts, and awards for:

- Federal Grants
- Foundation Grants
- Corporate Grants (to formal grant programs)
- Government Contracts (Federal, State, and Local)
- Incoming Subcontracts under above Grants and/or Contracts
- Outgoing subcontracts on above awards



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# OK. I have a new study, who do I send what to? Contracts, budgets, CDAs, DTAs etc.

- **RAS:**
  - Contracts
  - Budgets
  - CDA's (Emory)
  - Incoming Subcontract (Emory)
  - Service/Lab Agreements
  - Industry Clinical Study Start-Up Agreements
  - Clinical Material Transfer Agreements with no funding and an industry provider
- **[OTT-MTA@emory.edu](mailto:OTT-MTA@emory.edu)**; See <http://www.ott.emory.edu/forms/index.html> for further instructions.
  - Data Transfer Agreements, Incoming (Emory)
  - Non-clinical Material Transfer Agreements
  - NDA with industry party for other research-related matters
- **[osp-contracts@listserv.cc.emory.edu](mailto:osp-contracts@listserv.cc.emory.edu)**
  - NDA with non-industry party
  - NDA with industry party for clinical trial



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# What does RAS need from you?

- All the necessary documents: Final protocol, draft agreements, draft budgets
- Sponsor contact information
- Number of patients
- IRB approval letter and approved consents
- Study logistics
- Locating your PI to answer questions, approve budgets, and sign agreements
- Suggestions for improvements



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# What does study team need from RAS?

- Status of budget development
- Status of contract development
- EPEX number
- Assurance study is moving forward and did not end up in black hole
- Cost option
- Post-Award RAS: eNOA



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# I need something, like, right now.

- Send me an email with “urgent” in title
- Come find me! Emory Children’s Center, 2<sup>nd</sup> floor, room 208H
- Call me! 404-712-6693



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# My study is taking too long.

- I am sorry it is taking too long. Let's sit down and determine where it is held up, and work out a plan to expedite it. We want studies to be as successful as possible. We ask that you be patient with us as we work to find the best process moving forward.



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# Questions

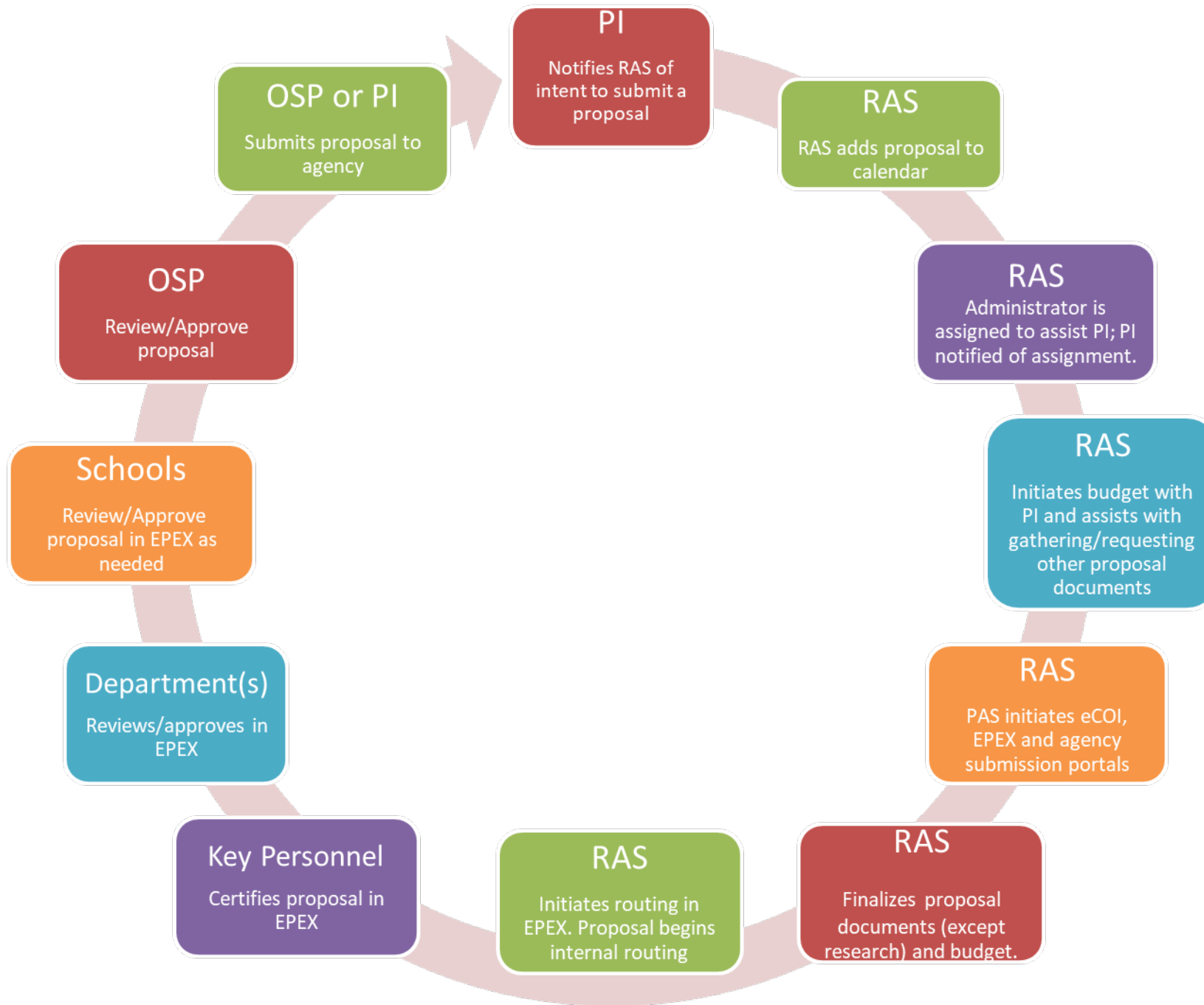


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# Office of Sponsored Programs (OSP)

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**Manager: Tanya Blackwell, 404-785-7275**

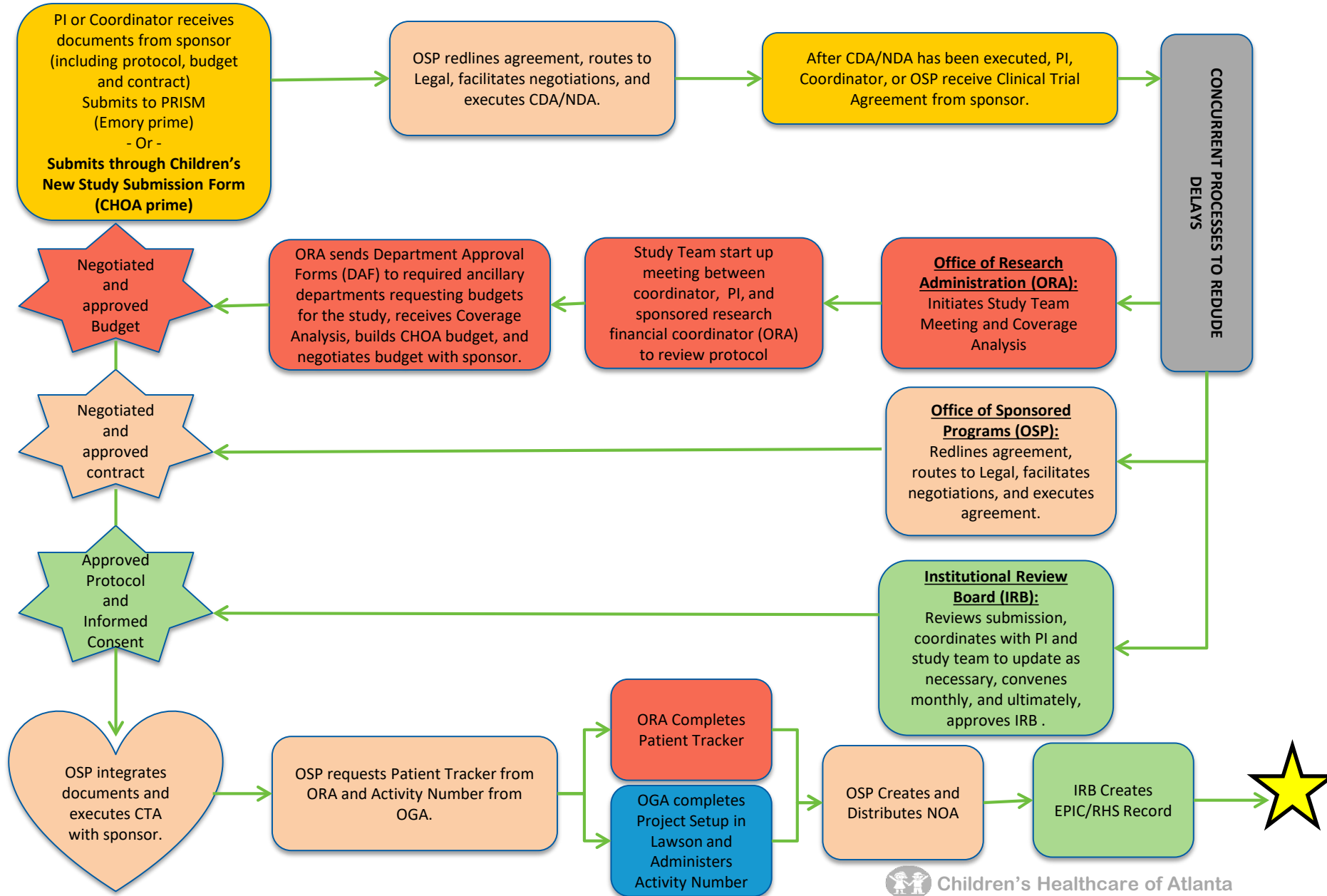
Key Functions of OSP:

- Reviews, edits, and submits proposals and letters of intent for sponsored research
- Negotiates and executes sponsored grants and contracts
- Drafts and routes other research agreements
- Responsible for Intramural Award/Grant Letters
- Provides non-financial management of sponsored projects

Team Members and Assignments:

- Ty Bell – Sponsored Program Analyst, 404-785-5198
  - Supports the AFLAC Cancer Center research team
- Tatiana Marcus – Sponsored Program Analyst, 404-785-7287
  - Supports non-AFLAC research teams (ORA)
- **TBD – Sponsored Program Coordinator**
  - **Pre-Award Applications/LOIs, and Federal Subawards and Amendments**

# Research Process at CHOA – Industry Sponsored Clinical Trials



# The Infamous Question

## Where should I route my research?

Type of Study	Submit to Emory	Submit to Children's
Industry Sponsored Pediatric Clinical Trials		X
Industry Sponsored Adult Clinical Trials	X	
Children's Oncology Group (COG) Funded Studies		X
Investigator Initiated Clinical Trials	X	
Federally Sponsored Research (i.e., NIH, FDA, CDC)	X	
Research Sponsored by Foundations and other Supporting Agencies	X	
Other Types of Studies	Contact Children's/Emory	

**The Pediatric Institute cannot receive a grant, contract, or gift award.**





# Expected Turn-Around Times

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## **Goal: 75 Business Days from Receipt of CTA to Execution \***

### Office of Sponsored Programs

- Preliminary review and redline completed and routed to Legal in DETERMINE - 3 business days of receipt
- Edits from Legal provided to other party - within 2 business days of DETERMINE notification
- Edits/responses from other party provided to Legal - within 1 business day of receipt
- Prepare and print for signatures - within 1 business day of DETERMINE “Ready for Signatures” notification
- Financial activity requested - within 1 business day of fully executed agreement
- NOA distributed - within 2 business days of financial activity completed
- GTMS record updated and completed - within 2 business days of NOA distribution

### Office of General Counsel (Legal)

- Legal: 5 business days from receipt – first reviews back to sponsor

**Current Average (June 2018 – July 2019): 105.57 (based on 24 CTAs)**

**Current Average (June 2018 – July 2019): 71.40 (based on 5 CTAs)**

# Contract Status Inquiry

Survey Distribution Tools  
Record Status Dashboard  
Add / Edit Records

---

**Record ID 2193**  
VICKERY,R668-ALG-16114,630359-0000  
[Select other record](#)

Data Collection Instruments:

- Initial Data Sheet
- ORA-Coverage Analysis
- ORA- Department Approval Form Checklist
- ORA- Budget Process Form
- Patient Tracker
- Document Library Includes Docs
- ORA Sponsored Project Approval Form
- OSP- Spaf Assignment
- Contract Status**
- Contract
- Outgoing Agreements Contract
- OSP Financial Action Form
- OSP-Notice Of Award
- CHANGE FORMS-----
- ORA- Coverage Analysis Change
- ORA- Department Approval Form Checklist Change
- ORA- Budget Process Form Change
- Change Document Library Includes Docs
- ORA Sponsored Project Approval Form Change

Record ID 2193 successfully edited

---

Editing existing Record ID 2193 VICKERY,R668-ALG-16114,630359-0000

**Record ID** 2193

**Date of Current Update** 05-23-2019  Today M-D-Y

**Current Status**

- Pending additional information
- In OSP queue
- Routed in DETERMINE/with Legal
- In negotiation with other party
- Sent for CHOA signatures
- Partially executed - sent to other party
- Fully executed - received
- Financial activity requested
- Ready for NOA

**Notes**

Routed to legal 11/20  
In negotiation with other party 02/13/2019-03/25/2019  
Routed back to legal 03/18/2019  
Sent for CHOA signatures 05/15/2019  
Fully executed - received 05/23/2019  
Financial activity requested 05/23/2019

**Form Status**

# Subawards from Emory

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- Pediatric Institute only impacts industry sponsored pediatric clinical trial agreements. All others will continue to route to Emory and be subcontracted to CHOA.
- **No work should be conducted at Children's until a CHOA NOA has been distributed.**
- If Emory eNOA has been received, but the project involves CHOA patients, services, or otherwise requires a subcontract to CHOA, OSP must first receive an agreement from Emory, route through internal processes, and distribute the NOA before the project can start.
- This is a compliance matter and could result in negative audit findings if we start projects and/or enroll patients before the agreement has been executed or the NOA has been distributed.

# Intramural Award/Grant Letter

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- Defined as a commitment of funding using Children’s philanthropic or operational funding to support an academic program of an outside entity. Can be used to support the following:
  - Programmatic Support
  - Recruitment Support
  - Sustainability/Bridge Support
  - Research Program Support
- \* To the extent possible, support should be provided for programs as opposed to individual projects

# Intramural Award/Grant Letter

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- Should \*NOT\* be used in the following situations
  - Funds that have been awarded/granted to Children's that included contractual obligations that should be flowed down to collaborating organizations
  - Federal or state funds
  - Projects that include specific deliverables, terms and conditions
  - Clinical Support or Medical Director Support

# Intramural Award/Grant Letter

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## Request Form:

- Requesting Leader should be someone who has financial decision making power for the funds being allocated.
- Request date should be at least 1 month prior to the requested start date. Will soon be processed yearly, along with annual department budgets.
- Funding should be for 1 year for programmatic and endowment support. Recruitment support can be for multiple years.
- Activity Number – include documentation for approval of funds in associated activity number for requested purpose.
- Reports and invoices should be someone at Children's.

## Intramural Award Agreement Request Form

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*This form should be utilized when a transferring Children's donor or other internal sources to support research initiatives such as Recruitment or Program/Initiative Support. (This mechanism should not be used to support individual research projects)*

**Requesting Leaders Name:** [Click here to enter text.](#) **Request Date:** [Click here to enter a date.](#)

**Type of Support:**     Recruitment     Program     Endowment     Other

**Funding Total:** [Click here to enter text.](#)    **Funding Period:**  1 year     5 year  
 Other: [Click here to enter text.](#)

**Does your donor have reporting requirements?** Yes     No

**If yes, please attach donor agreement or list reporting requirements:** [Click here to enter text.](#)

**Activity number that will fund this request:** [Click here to enter text.](#)

- **Are funds available to support entire request?**    Yes     No
- **Have funds been encumbered for this use?**    Yes     No

**Start Date:** [Click here to enter a date.](#)    (must be at least 30 days from request date)

**Name/Email address of staff member designated to receive reports:** [Click here to enter text.](#)

**Name/Email address of staff member to review/approve invoices:** [Click here to enter text.](#)

### Additional Information Needed

Recruitment Support: Please attach Offer Letter including the financial terms

Program Support: Please attach Proposal and Detailed Budget

Endowment/Quasi Endowment: Please attach endowment letter or other relevant documents

# Intramural Award/Grant Letter

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- Considerations (for use of the Grant Letter):
  - Source of funds
  - Purpose of the funds
  - Other financial support for intended purposes
  - Effort of personnel
  - If personnel are covered by the Pediatric Institute
  - Role of personnel for the requested purpose
  - Involvement of any of Emory's Core

# Questions?

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