

Miami Children's Hospital Application for Research

To Facilitate Processing of Research Contracts, Clinical Trial Agreements, Grant And Foundation Applications
Please Include the MCH Application for Research With All Study-Related Documents.

Project **Lawson Activity #**

CHECK EACH BOX THAT APPLIES

<input type="checkbox"/> Industry Sponsored Clinical Trial	<input type="checkbox"/> Sponsored- Investigator Initiated Study	<input type="checkbox"/> Chart Review/Database Project (Retrospective)	<input type="checkbox"/> Other:
<input type="checkbox"/> Private or Governmental Research Grant	<input type="checkbox"/> Un-sponsored- Investigator Initiated Study	<input type="checkbox"/> Research Subcontract with another institution	Please specify:

Phase: (if appropriate) I II III IV

Clinical Trial: Single Site Multi-Site Coordinating Center

Protocol Title: _____

Protocol # (if applicable): _____ IND/IDE #: _____

<p>Does the research involve investigational drugs? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, will the MCH Pharmacy be responsible for storage, control, and dispensing of the investigational drug? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If the MCH Pharmacy will not be responsible for the investigational drug, attach a description of the procedures for storage, control, and dispensing of the investigational drug.</p>	<p>Does the research involve investigational devices? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, will the MCH Clinical Supply Department be responsible for storage, control, and dispensing of the investigational device? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If the MCH Clinical Supply Department will not be responsible for the investigational device, attach a description of the procedures for storage, control, and dispensing of the investigational device.</p>
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For a Medical Device without an IDE, check one: Significant Risk Non-Significant Risk

IRB (MCH utilizes Western IRB)

New Project Amendment Continuing Review

Check here if you believe this project may be deemed Exempt

Site Information

Principal Investigator (First, Last, Degree) _____ MCH Employee Non-employee, Contracted Non-contracted

Department: _____ Phone: _____
 Fax: _____ Email: _____

Alternate Study Site Contact (First, Last, Degree) _____ Title: _____

Phone: _____ Fax: _____ Email: _____

Co-Investigator(s) (First, Last, Degree)

1. _____
2. _____
3. _____
4. _____
5. _____

Study Coordinator(s)

1. _____ Phone: _____
 _____ Fax: _____
 _____ Email: _____

2. _____

 Phone: _____
 Fax: _____
 Email: _____

Sponsor Information (if applicable)

Sponsor Name: _____	Key Contact: _____
CRO Name (if applicable): _____	Address: _____
Medical Monitor Name: _____	_____
Phone: _____	Phone: _____
Fax: _____	Fax: _____
Email: _____	Email: _____

Signatures

Principal Investigator Attestation

I certify that to the best of my knowledge, this proposal is scientifically sound, ethical, and respects and protects the rights and welfare of human participants in research.

I certify the information contained in this application is complete and true, to the best of my knowledge.

I agree to adhere to all MCH's Research Institute Policies & Procedures regarding compliance and all billing practices and , not to bill any third party payer for items specifically reimbursed by the sponsor, and to conduct the study within guidelines of good clinical practice.

The total direct cost of this research project is estimated at \$ _____

SIGNATURE _____ DATE: _____
 NAME (printed): _____

Department Head (If PI is Department Head, Chief Medical Staff signature is required) (check all that apply)

- This research project is supported entirely by extramural funding. Sponsor information is above.
- I have secured partial extramural support in the amount of \$ _____ . Sponsor information is above.
- I have secured support from the Office of Research Administration (ORA) in the amount of \$ _____
- I have allocated funds - in the amount of \$ _____ out of Cost Center _____ - to support this research project

Dept. Head Signature		Print Name & Date	
CMO Signature		Print Name & Date	
CRO Signature		Print Name & Date	

Checklist

- WIRB Submission Packet
- Financial Conflict of Interest Disclosure
- Draft Contract or Grant
- Budget
- CitiTraining Certificates

FOR RESEARCH ADMINISTRATION USE ONLY

Contract or Grant

Date Contract/Grant Received: _____	Contract/Grant Contact: _____	Phone: _____
Date Contract/Grant Sent to Sponsor: _____	Address: _____	Fax: _____
Date Contract/Grant Approved: _____		Email: _____

Budget

Date Budget Received: _____	Budget Contact: _____	Phone: _____
Date Budget Sent to Sponsor: _____	Address: _____	Fax: _____
Date Budget Approved: _____		Email: _____

Administrative Review

PI's FDA/OIG Sanction Check _____	Comments: _____
Verification of Human Subjects Protection Training _____	Comments: _____