

Internal Medicine

Academic Research Services (ARS)
 Medical Sciences Building (MSB) Room 6111
 Email: imresearch@ucmail.uc.edu



REQUEST FOR REGULATORY SERVICES- NEW PROJECT

INSTRUCTIONS:

1. Please complete and send to IMRegulatory@uc.edu.
2. Attach the final protocol and supporting documents with your initial email request.
3. Your project will be reviewed and placed in our queue.
4. Within 5 business days or less, the regulatory team will communicate a start date for work on your project.

QUESTIONS:

General questions about the form or process: (Helen) Gina Shelton, 513-558-7183 or sheltoHn@uc.edu.
 We look forward to providing you with our services and collaborating with you on this project. Thank you!

Principal Investigator:	<i>Name:</i>	
Sponsor or CRO Regulatory Contact - if applicable **Mandatory for Sponsored Studies**	<i>Name:</i>	
	<i>Email:</i>	<i>Phone:</i>
Individual Completing this Intake Form:	<i>Name:</i>	
	<i>Email:</i>	<i>Phone:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	I acknowledge that there may be a non-refundable fee associated with the work for this project per MOU (please note: all fees will be negotiated & agreed upon prior to start of work).	
<input type="checkbox"/> Yes <input type="checkbox"/> No	I acknowledge that site selection and ARS review are complete (as applicable) and the project is ready to move forward with IRB Submission.	

SERVICES PROVIDED

Regulatory services will be provided for this initial request and covered under the initial fees for this project per MOU.

PROJECT DETAILS

Use the comments column and/or page 3 to provide additional details.

General	Please Indicate	Comments/Details
Project Short Title		
Sponsor Name	<input type="checkbox"/> Industry Pharma company, please indicate <input type="checkbox"/> Investigator-Initiated <input type="checkbox"/> other, please indicate	

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PROJECT DETAILS- continued

Use the comments column and/or page 3 to provide additional details

General	Please Indicate	Comments/Details
24hr# for ICF	<input type="checkbox"/> if known, please indicate <input type="checkbox"/> NA <input type="checkbox"/> request for us to ask the PI	
IRB of Record	<input type="checkbox"/> UCIRB <input type="checkbox"/> Advarra <input type="checkbox"/> WIRB <input type="checkbox"/> Copernicus Group (CGIRB) via WIRB <input type="checkbox"/> other IRB Reliance, please indicate	
Source of Funding	<input type="checkbox"/> funds held in SRS for Grant or Contract (held internally at UC), if NIH Grant, provide a copy <input type="checkbox"/> funds from UC departmental account (held internally at UC) <input type="checkbox"/> funds held in Corporate account from a Contract (held externally to UC) <input type="checkbox"/> no funding	
Facilities Utilized	<input type="checkbox"/> University of Cincinnati Medical Center <input type="checkbox"/> West Chester Hospital <input type="checkbox"/> UC Health Hoxworth- 3130 Highland Ave. <input type="checkbox"/> UC Health Holmes- 200 Albert Sabin Way <input type="checkbox"/> UC Health Physicians Office- 222 Piedmont Ave.	<input type="checkbox"/> UC Health Physicians Office- West Chester <input type="checkbox"/> UCMC local lab <input type="checkbox"/> IDS Pharmacy <input type="checkbox"/> other, please indicate
Project Team **Use Additional sheet if necessary.	Name	Role
# of enrollments planned		
Subject Payment	<input type="checkbox"/> Yes ** please provide exact wording to be used in the consent. Use comment section if needed. <input type="checkbox"/> No	

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Comment(s), Questions, & Additional Information: *if sponsor is an industry Pharma Co., include template CTA injury text below*

STOP HERE *below is for DOIM Regulatory use only* _____

DOIM REG USE ONLY	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the Intake Form Complete? Are all documents that are necessary for the submission included? Is there any additional information needed or to be communicated?

Comment(s), Questions, and/or Request(s) for Additional Information:

I certify that this form is final; any changes needed/items requested have been reviewed and addressed. The DOIM Regulatory Team will follow-up to communicate timelines for work and anticipated approval.

DOIM Regulatory Team Member Signature

Date