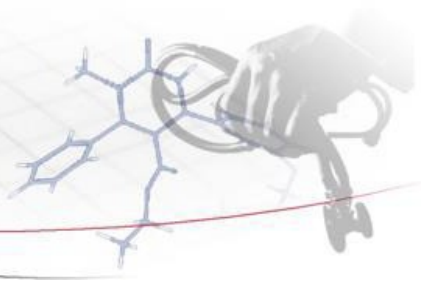
FROM THE DEPARTMENT OF
Internal Medicine
Academic Research Services (ARS)
Medical Sciences Building (MSB) Room 6111
Email: imresearch@ucmail.uc.edu



UNIVERSITY OF Cincinnati

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.

It is imperative that you complete this form thoroughly and completely. All regulatory documents are created utilizing the information provided. Please take time to correctly answer the facilities and study team information.

QUESTIONS:

General questions about the form or process: (Helen) Gina Shelton, 513-558-7183 or sheltoHn@ucmail.uc.edu

We look forward to providing you with our services and collaborating with you on this project. Thank you!

Principal Investigator:	***Name:***	
Sponsor or CRO Regulatory Contact - if applicable *****Mandatory for Sponsored Studies*****	***Name:***	
	Email:	***Phone:***
Individual Completing this Intake Form:	***Name:***	
	Email:	***Phone:***

☐ Yes ☐ No	I acknowledge that there may be a non-refundable fee associated with the work for this project. This intake form serves as the PI's approval of the IM Regulatory Service fees. Please review the fees prior to submitting this intake form. ARS IM Regulatory Fee Schedule
☐ Yes ☐ No	I acknowledge that site selection **under this PI** is complete (as applicable) OR I am submitting approval from the sponsor to open under a different PI. I confirm that this project is ready to move forward with IRB Submission. I acknowledge that my regulatory documents will be created utilizing the information in this form and I am ready to proceed with the regulatory process. I also acknowledge that if the information provided is incomplete or inaccurate and all regulatory startup documents need to be revised due to incomplete information, there may be additional fees charged by IMRegulatory services for those revisions up to an additional startup fee.

SERVICES PROVIDED

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

Study renewals will be billed at the time the Continuing Review is submitted to the IRB of record and will continue to be renewed until the IMRegulatory CRP is notified to close the study. If this study will not require continuing reviews, additional fees may be charged for staff modifications.

I, the PI of this study, have reviewed the intake form being submitted and agree that:

The facilities listed are inclusive of all needs in the protocol, they are correct, and should be listed on the 1572.

I have had conversations with those listed as SubIs on this form, and they have agreed to participate on this study in this capacity.

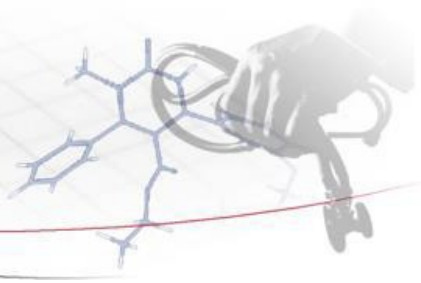
If subsequent changes are made to study staff requiring updated regulatory documentation, there may be additional fees incurred. (Addition of SubIs not listed on this form)

PI Signature _____ **Date** _____

Do you, the PI, have any financial conflicts of interest with this study sponsor/funding source?

☐ **YES**, please follow up with me on the details to be submitted to the IRBs and a disclosure may need to be listed in the Informed Consent.

☐ **NO**, at this time, I do not have anything that will need disclosed.



PROJECT DETAILS

General	Please Indicate	
Protocol Number		
Study Title		
Sponsor	☐ Industry Pharma company, please indicate ☐ Investigator-Initiated ☐ Grant/Federal funding ☐ Other	Sponsor Name: Site # Assigned by Sponsor:

PROJECT DETAILS- continued

Use the comments column and/or page 6 to provide additional details

General	Please Indicate	Comments/Details
**Mandatory if your study has an ICF IRB mandated: Phone number to be listed on ICF that participants can call 24hr		
IRB of Record	☐ UCIRB ☐ Advarra ☐ WCG UCIRB# if already assiged: ☐ Other IRB Reliance *	ICF Translation required? If so, indicate language:
Source of Funding	☐ Federally Funded (NIH/FDA/NIAID etc.)* ☐ Department Funded - (ex: DOIM awards)* *Primarily used for Investigator Initiated Studies* ☐ Industry Funded (Pharmaceutical Companies) ☐ Foundation Funded * ☐ No Funding * Provide Detail In Comments	**If using a Sponsor's Central IRB, please provide details regarding IRB payments (see CTA/ Budget for this information - who should invoices go to:**

PROJECT DETAILS- continued

Use the comments column and/or page 6 to provide additional details

General	Please Indicate	Comments/Details
Type of Study	☐ Drug Study ☐ Trainee ☐ Chart Review ☐ Other ☐ Device Study ☐ Humanitarian Use Device (HUD) ☐ Non-Human Subject Research (NHSR)	
HIPAA Waiver	☐ Chart Review (Full) ☐ Screening/eligibility (partial)	
Facilities Utilized NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED ** Please review protocol and make sure you check all that apply	☐ University of Cincinnati Medical Center ☐ West Chester Hospital -7700 University Drive ☐ UC Health Physician's Office – West Chester ☐ Hoxworth- 3130 Highland Ave. UC Health ☐ Holmes- 200 Albert Sabin Way ☐ UC Health Physician's Office- 222 Piedmont Ave. ☐ University Endoscopy Center – 9275 Montgomery Rd. ☐ UCMC Imaging Bldg. – 222 Piedmont Avenue Ste. 1400 ☐ UC Gardner Neuroscience Institute – 3113 Bellevue Dr.	** Other, please indicate

PROJECT DETAILS- continued

Use the comments column and/or page 6 to provide additional details

General	Please Indicate	Comments/Details
Local Lab Information NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY	☐ UCMC Local Lab - *Safety Labs* ☐ IM Division Processing Lab – (UCPC Retrovirology Lab): *Shipping/processing lab* **Submitter will need to reach out to **divisionlabservices@ucmail.uc.edu** to complete their intake process if you have not done so already. Before checking this box, please make sure you have secured approval to utilize their services. ☐ ED Lab - **before checking this box, please make sure you have secured approval from the ED lab to utilize their services.	** Other, please indicate
ANCILLARY SERVICES	☐ UC Health Research Imaging Services *(Any radiology – including DXAs/CT Scan/X-Ray)* **Submitter will need to complete IIS REDCap form if you have not done so already: https://redcap.research.cchmc.org/surveys/?s=N84PR3WTF8 ☐ IDS PHARMACY – Submitter should contact **ids-pharmacy@uchealth.com** ☐ Infectious Diseases Research Pharmacy HOLMES (**for ID use only**)	** Other, please indicate
Supplemental Reviews	**Is Institutional BioSafety Committee Review required for your study?** ☐ YES ☐ NO **IBC review is required if:* • *Human derived materials are handled within a UC Research Lab (does not apply to clinical diagnostic lab)* • *Introduction of recombinant nucleic acids, infectious agents and/or genetically modified cells into human patients* **Does this study involve ANY ionizing radiation? (Xrays, DEXAs, etc. - even if SOC)** ☐ **YES** ☐ **NO** ****NOTE for Reg Team: If YES is checked, send RSC form to submitter. Once back, send study to RSC (Rich Anderson) for review of consent risk language and possible RSC committee review.**	** Other, please indicate

PROJECT DETAILS- continued

Use the comments column and/or page 6 to provide additional details

	Name	**Role**
Project Team INCLUDE ALL SUB-INVESTIGATORS, STUDY COORDINATORS, RESEARCH ASSISTANTS – ANYONE THAT NEEDS TO BE ON YOUR DELEGATION LOG **If IDS Pharmacy or the IM Division lab is checked above, you do NOT need to include individual names for those teams here.		
# of Participants you plan to enroll		**Name of EDC being used:**
	If this is grant funded with an Industry sponsor component, is there a separate contract with the Industry in addition to the grant? ☐ YES ☐ NO ☐ N/A	

Additional Information: *if sponsor is an industry Pharma Co., include template CTA injury text below*

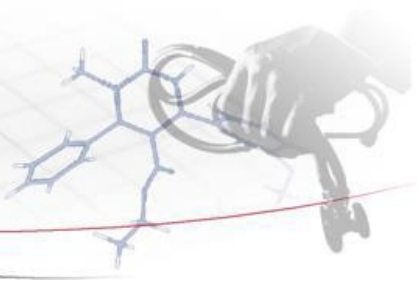
Participant Payment ☐ YES* ☐ NO

** If yes please include the exact language you want in your consent (must match CTA/Budget)*

CTA Injury language for consent form:
(Must match CTA)

Comments and Questions:

** See Page 8 for additional notes



UC HEALTH APPROVAL INFORMATION

NOTE: UC HEALTH approval submission is not part of IMREG services.
As a courtesy, upon IRB approval, IMREG will start the UC Health approval process and load the appropriate documents available to us. We will then send the link to the submitter of this form to finish the remaining items on the REDCap form and to officially SUBMIT the form to UC Health.

Enrollment cannot begin without UC HEALTH APPROVAL.

This is required for **all studies including chart reviews and all investigator initiated studies.

RESEARCH FINANCIAL SERVICES (RFS) INFORMATION

REMINDER: Be sure to send the following to Research Financial Services (RFS) to help with your contracting and budgeting:

- Site Selection Letter
- Informed Consent – (draft template is fine)
- Contract
- Protocol
- Budget
- Lab/Pharmacy Manuals

For more information please contact:
Leah Bischoff - bischolh@ucmail.uc.edu
Kirk Keyser - keyserkd@ucmail.uc.edu

Please also remember to work on your ClinCard set up if applicable.
For more information, contact OCR.

https://researchhow2.uc.edu/search?indexCatalogue=researchhow2%2Ddev&searchQuery=Greenphire&wordsMode=0