

REQUEST FOR HLVI REGULATORY CORE SERVICES

INSTRUCTIONS:

1. Please fill out this intake form and send to HLVIRegCore@uc.edu.
2. All associated supporting documents should be complete and attached to the initial email request.
3. Upon receipt of your email, you will receive an automatic email response acknowledging our receipt.
4. Your project will be reviewed and placed in our queue.
5. Within 5 business days or less, you will receive a personal response to your request from the regulatory team. It will include information regarding any fees for our services and this form notifying you of any additional information or documentation that is required. Please submit any outstanding information to the regulatory team as soon as possible.
6. Once this form is returned to you signed and finalized, the regulatory team will follow-up with you to communicate a start date for work on your project.

QUESTIONS:

General questions about the form or process can be directed to Jennifer Daniels, HLVI Regulatory Core Manager at 513-558-3864 or Jennifer.Daniels@uc.edu.

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

Person Completing Form:	
Name	
Email	
Phone	
Principal Investigator (PI):	
Name	
Email	
Phone	
Sponsor or CRO Regulatory Contact (if applicable):	
Name	
Email	
Phone	
I acknowledge that there may be a non-refundable fee associated with the regulatory work that begins on this project (<i>please note: all fees will be negotiated & agreed upon prior to start of work</i>):	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
I acknowledge that feasibility assessments (i.e. budget, operational, etc.) and site selection are complete and the project is ready to move forward with IRB Submission:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	

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SERVICES REQUESTED

Please indicate. This list is NOT all-inclusive; please let us know if you need a regulatory service not listed here.

**If you are requesting comprehensive regulatory services for the life of your project, please select Yes for each of the services you would like us to provide. If the scope of work changes, revised intake form(s) may be submitted in the future.*

Services/General Documents	Please Indicate	Comments
Regulatory Consultation	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Initial IRB Submission	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Consent Form Development	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Request for ICF/HIPAA Waiver	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Partial HIPAA Waiver for Epic Screening	<input type="checkbox"/> Yes <input type="checkbox"/> No	
DSMB Charter Development	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Monitoring Plan Development	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Misc Documents (i.e. Data Collection Tools, Questionnaires, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Recruitment Materials and/or request for UC Health branding	<input type="checkbox"/> Yes <input type="checkbox"/> No	
IND Submission Maintenance, and Correspondence with FDA	<input type="checkbox"/> Yes <input type="checkbox"/> No	
IDE Submission, Maintenance, and Correspondence with FDA	<input type="checkbox"/> Yes <input type="checkbox"/> No	
CMS Submission & Maintenance	<input type="checkbox"/> Yes <input type="checkbox"/> No	
ClinicalTrials.gov	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Monitoring and/or Audit Visit Prep	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Internal Audit Review Services	<input type="checkbox"/> Yes <input type="checkbox"/> No	
eREG Development/Support	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Protocol Amendments	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Revised Consent Form	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Services/General Documents	Please Indicate	Comments
Changes in Staff	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Annual Continuing Reviews	<input type="checkbox"/> Yes <input type="checkbox"/> No	
SAEs/ Prompt Reportable Events	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Manage IND Safety Reports	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Revisions to Misc Documents and/or Recruitment Materials	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Closure Report	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Other	<input type="checkbox"/> Yes <input type="checkbox"/> No	<i>[list here]</i>

PROJECT SCOPE (please complete, if applicable to your request)

If there is additional information you would like to provide, please use the comments column and/or please provide additional details in your initial email request.

General	Please Indicate	Comments	
Project Name			
Sponsor Name	<input type="checkbox"/> Industry Pharma company, please indicate <input type="checkbox"/> Investigator-Initiated <input type="checkbox"/> other, please indicate		
24hr# for ICF	<input type="checkbox"/> if known, please indicate <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"/> Quorum <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"/> UCMC local lab <input type="checkbox"/> West Chester Hospital <input type="checkbox"/> IDS Pharmacy <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 Physician Office- West Chester <input type="checkbox"/> other, please indicate		
Project Team	Name	Role	Comments
# of enrollments			
Subject Payment	<input type="checkbox"/> Yes <input type="checkbox"/> No *if yes, please provide us with specifics when your budget is available		

STOP HERE

This page is for HLVI Regulatory use only.

HLVI REGULATORY TEAM REVIEW OF INTAKE FORM

HLVI USE ONLY	Please Indicate
Is the Intake Form Complete? Are all documents final and included?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Comment(s), Questions, and/or Request(s) for Additional Information:	

I certify that this form is final and the above-mentioned items have been reviewed and addressed. The HLVI Regulatory Team will follow-up with you to communicate a start date for work on your project.

 HLVI Regulatory Team Member Signature

 Date