



UNIVERSITY OF COLORADO
HOSPITAL

HRRC APPROVAL FORM FOR CONDUCTING RESEARCH

CHECK BOX FOR WIRB STUDY

Primary Information

COMIRB #	UCHSC Grants & Contracts #		
Protocol Title:			
Study Sponsor:	UCH Billing Contact:	Fax:	
Principal Investigator:	Phone:	Campus Box:	Rm.#
Principal Investigator's Department:	Phone:	Campus Box:	
Research Coordinator:	Please list any additional non-physician personnel who will be providing direct patient care:		
Name(s):			
Co-Investigator(s):			

Study and Participant Information

When is this study expected to begin?
 When is the renewal/termination date for this protocol?
 Will investigational devices be utilized during the study? No Yes
 If Yes, how is the device categorized by the FDA? A B
 How long will each participant be a part of the study?
 Will monetary compensation be offered to participants? No Yes
 If Yes, specify amount and process:
 Will this study involve use of the Adult General Clinical Research Center (GCRC)? No Yes
 Will this study involve use of the Pediatric General Clinical Research Center (GCRC)? No Yes
 If Yes, please indicate GCRC#

Projected Volume: Anticipated patient volume for duration of study

<u>Inpatient:</u>	Projected total number of inpatient participants? Projected total number of inpatient admissions? Will the study increase the length of stay for inpatient admissions? <input type="checkbox"/> No <input type="checkbox"/> Yes
<u>Outpatient:</u>	Projected total number of outpatient participants? Projected total number of outpatient visits?



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Ancillary Services: This section MUST be completed if the services below will be utilized.

Pharmacy: *For pharmacy questions, please contact the Investigative Drug Service Pharmacist at (303) 372-6625.*
 Will investigational medications be used? No Yes
 Will the UH Pharmacy be required to mix or dispense medications? No Yes
Pharmacy contact's name (Print):
Pharmacy contact's signature of agreement: _____ **Date:** _____

Laboratory: *For laboratory questions, please contact the Client Services Manager at (303) 372-0320.*
 Will the UH Laboratory be required to process lab work? No Yes
 Will special lab procedures be necessary? No Yes
Laboratory contact's name (Print):
Laboratory contact's signature of agreement: _____ **Date:** _____

Radiology: *For imaging/radiology questions, please contact the UH Director of Radiology at (303) 372-0220.*
 Will UH Imaging/Radiology services be required? No Yes
Radiology contact's name (Print):
Radiology contact's signature of agreement: _____ **Date:** _____

Direct Patient Care Services: This section MUST be completed if research involves direct patient care. The UCH Approval Form WILL NOT BE PROCESSED without the appropriate signatures below.

Inpatient Services: *For inpatient service questions, please contact the Director/Manager of the clinical area.*
 Will special nursing services be required beyond standard-of-care and usual staffing patterns? No Yes
 If "yes", please explain:
Please note: All direct care clinical research REQUIRES staff education.
 Is there a plan for staff education? No Yes Not Applicable
 If appropriate, briefly explain the plan for staff education:
Manager/Director's name (Print):
Manager/Director's signature of agreement: _____ **Date:** _____

Outpatient Services: *For ambulatory service questions, please contact the Practice Manager.*
 Will the study impact outpatient scheduling services? No Yes
Please note: All direct care clinical research REQUIRES staff education.
 Is there a plan for staff education? No Yes Not Applicable
 If appropriate, briefly explain the plan for staff education:
 Is the budget amenable to outpatient care provisions? No Yes
Practice Manager's name (Print):
Practice Manger's signature of agreement: _____ **Date:** _____



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Use of Hazardous Material

Will this study use Gene or Recombinant DNA Therapy? No Yes
If "yes", the following is required:
UCH Safety Officer Signature
UCHSC Biohazards Form (Form 86-1)
UCHSC Registration Form for the use of biological materials (Form 101)
UCH Safety Officer's name (Print):

UCH Safety Officer's signature of agreement: _____ **Date:** _____

ATTACHMENTS

Please include the documents noted below. Failure to do so WILL delay HRRC Approval.
Send to: Mary Schumer, Research Administrator
Campus Box F417

(1). *Two collated copies of:*
a. HRRC Approval Form
b. COMIRB Application
c. COMIRB Approval Letter (if available)
d. Protocol Summary
e. Subject Consent
(2). HIPAA Authorization
(3). One copy of the Master Protocol
(4). One copy of the Clinical Trial Agreement & Budget

Signature of Investigator

(Please Note: Applications without the Investigator's signature WILL NOT BE PROCESSED).

I, _____, do hereby certify that all information contained herein this
(Signature of Investigator) HRRC Application for Approval is truthful and accurate.

Signed this day, _____.
(Date)

UCH APPROVAL

HRRC CHAIRPERSON APPROVAL: _____
(Signature) (Date)

Please Note: Page 4 is the "Budget Worksheet"