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 **Reliance on External IRB Supplement**

NUMBER DATE PAGE

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**INSTRUCTIONS:**

* This template is required for studies that have marked that an external IRB will act as the IRB of record for this study on the RAP Basic Information smartform page.
* Attach this template along with the protocol to the RAP Basic Information smartform page.
* For commercial IRBs, attach the Cover Page on the RAP Local Site Documents smartform page.
* Depending on the nature of your study, some sections may not be applicable to your research. If so, enter “NA”.

**PROTOCOL TITLE:**

*Include the Full Protocol Title*

**LOCAL PRINCIPAL INVESTIGATOR INFORMATION**

*Name*

*Department*

*Enter the PI’s Telephone Number*

*Enter the PI’s Email Address*

**LOCAL CONTACT PERSON**

*Name*

*Department*

*Enter the Local Contact’s Telephone Number*

*Enter the Local Contact’s Email Address*

**LEAD PRINCIPAL INVESTIGATOR**

*Name*

*Enter the PI’s Telephone Number*

*Enter the PI’s Email Address*

**LEAD CONTACT PERSON**

*Name*

*Enter the Lead Contact’s Telephone Number*

*Enter the Lead Contact’s Email Address*

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# IRB Reliance Information

* 1. Which institution/commercial IRB will be the IRB of record?

*Enter the IRB that will be reviewing the study. UC will only rely on institutions that are registered with OHRP. Please contact your IRB Coordinator if you have any questions or concerns.*

1.2 What type of reliance agreement will be utilized? (For more information regarding UC’s current agreements, please visit the [UC Human Research Protection Program website](https://research.uc.edu/support/offices/hrpp/irb).

[ ]  Individual Authorization Agreement (IAA)

*Complete the IAA and upload on the RAP Local Site Documents smartform page for Institutional Official signature. The IAA can be found in the RAP Library under Templates.*

[ ]  Contract with commercial IRB

*Complete the Cover Page and upload on the RAP Local Site Documents smartform page for HRPP signature. UC currently has contracts with WIRB-Copernicus Group, Advarra IRB, and Quorum Review IRB*

[ ]  Central IRB for the National Cancer Institute (NCI CIRB)

[ ]  Consortium of Greater Cincinnati IRBs (CGCI)

*Complete the CGCI Signature Page and upload on the RAP Local Site Documents smartform page for Chair signature. The CGCI Signature Page can be found in the RAP Library under Templates.*

[ ]  IRB Reliance Exchange (IREx)

[ ]  Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT)

[ ]  Ohio Clinical and Translational Science Award (CTSA)

[ ]  Prevention and Early Treatment of Acute Lung Injury (PETAL) Network

[ ]  SMART IRB

*Complete the SMART IRB Acknowledgement Letter and upload on the RAP Local Site Documents smartform page for HRPP signature. The SMART IRB Acknowledgement Letter can be found in the RAP Library under Templates.*

1.3Why is the researcher seeking reliance on another IRB?

[ ]  To comply with the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research

[ ]  The research study is industry-sponsored and industry-initiated and qualifies for commercial IRB review

[ ]  To comply with a non-NIH sponsor’s requirement

[ ]  To comply with another institution’s requirement, where the other institution is conducting the majority of the research activities

[ ]  To comply with the requirements set by the Trial Innovation Network (TIN)

[ ]  Other

*Provide the reason for seeking reliance on an external IRB.*

#

# Study Information

2.1 Which of following activities will be conducted by the local study team?

*Select all that apply:*

[ ]  Obtain a signed consent and/or assent/parent permission.

*Forward the UC Local Context Reference Sheet to the Lead PI to incorporate required language into the informed consent document. The informed consent document must then be reviewed and approved by the IRB of record. The reference sheet can be found in the RAP Library under Templates.*

[ ]  Perform research procedures

[ ]  Administer investigational products/interventions

[ ]  Obtain, use, or analyze identifiable data/specimens

[ ]  Review of UCHealth medical records without obtaining consent/HIPAA authorization

If marked, will the IRB of record serve as the privacy board (approve the HIPAA waiver)? *Please note that the NCI CIRB will not serve as the privacy board.*

[ ] Yes [ ] No

*If no, complete the HIPAA Waiver of Authorization Form and upload on the RAP Local Site Documents smartform page for UC IRB review and approval. The HIPAA Waiver of Authorization Form can be found in the RAP Library under Templates.*

[ ]  Other activities: *Explain the scope of the local study team.*

2.2If the study is considered a clinical trial, what is the phase?

*Enter the phase 1, 2, 3, or 4, or NA*.

2.3Does the proposed research involve embryonic stem cells or xenotransplantation?

[ ] Yes [ ] No

2.4Does the proposed research require review by the Institutional Biosafety Committee (IBC)?

IBC review is required for research that will utilize infectious agents, select agents, recombinant DNA or viral gene transfer vectors, toxins for human gene transfer or a genetically modified agent.

[ ] Yes [ ] No

2.5Does the proposed research require Radiation Safety Committee (RSC) review?

RSC review is required if the research involves participants being exposed to radiation for research purposes or an increase in frequency or duration of radiological imaging procedures.

[ ] Yes [ ]  No

2.6 Does the study deliberately recruit any vulnerable populations?

*Select all that apply:*

[ ]  Children

[ ]  Cognitively impaired adults

[ ]  Native Americans/Alaskan Natives

[ ]  Neonates of nonviable or uncertain viability

[ ]  Pregnant women/fetuses

[ ]  Prisoners

[ ]  Other unique populations that may require additional protections:

*Describe the targeted population.*

# Funding Information

* 1. Where will the funding be held?

*If the study is funded, complete the RAP Funding Sources smartform pages and execute the Manage COI Forms activity to upload Conflict of Interest Forms for all study team members, including the PI.*

[ ]  Funds held in Sponsored Research Services for a Grant or Contract \*\*funds are held internally at UC

[ ]  Funds are from a UC department account (held internally at UC)

[ ]  Funds held in a Corporate account from a Contract (funds held externally at UC)

[ ]  No Funding

# Research Locations

4.1Where will research activities take place and data be stored/accessed?

*Select all applicable UC /UC Health Affiliated Research Sites:*

[ ]  Barrett Cancer Center (Including IV Therapies & Pancreatic Disease Clinic)

[ ]  Infectious Disease Clinical Trial Unit (Holmes-UC)

[ ]  Blue Ash Campus

 [ ]  Kettering Laboratory

[ ]  Cincinnati State Technical and Community College

 [ ]  Linder Center of Hope

[ ]  Clermont College

[ ]  Liver Transplant Clinic (Medical Arts Building)

[ ]  College of Allied Health Sciences

 [ ]  Medical Sciences Building

[ ]  College of Business

 [ ]  Shriners Hospital

[ ]  College Conservatory of Music

[ ]  Talbert House

[ ]  College of Design, Art, Architecture & Planning Institute

[ ]  UC Gardner Neuroscience

[ ]  College of Education

[ ]  UCMC (Emergency Department, Inpatient, and Outpatient Units)

[ ]  College of Engineering [ ]  UCMC (Emergency Department, Inpatient, and Outpatient Units)

[ ]  College of Nursing

 [ ]  UCMC NICU

[ ]  Crossroads Center [ ]  University of Cincinnati Physicians (UCP)

[ ]  Drake Center

 [ ]  Genome Research Institute (Reading Campus)

 [ ]  University Pointe Surgical Hospital

[ ]  VA-Cincinnati Medical Center  **\*The VAMC does NOT accept commercial IRB review**

[ ]  Hoxworth: Inpatient Unit

 [ ]  West Chester Hospital

 [ ]  Hoxworth: Outpatient Clinics

 [x]  Other UC/UCHealth Affiliated Clinic:

*Enter the other UC or UCHealth locations that are not listed above*

[ ]  Infectious Disease Clinic (Holmes-UC Health)

 [ ]  External locations to UC or its affiliates.

*List locations on the RAP Research Locations smartform page.*

# Other Ancillary Reviews

5.1Will any activities occur that require ancillary reviews?

*Select other elements that apply to this study:*

[ ]  UC Student is serving as Principal Investigator.

*Add the Faculty Advisor to the RAP Study Team Members smartform page.*

[ ]  UC study team members conducting research activities at international location(s).

[ ]  Collection of information that may include incriminating activities.

[ ]  Review of UC student records without obtaining signed consent.

[ ]  Sharing of genomic information generated from NIH-funded research.

[ ]  UCHealth Services will be utilized.

[ ]  IDS [ ]  Imaging [ ]  Lab

[ ]  CCHMC Services will be utilized.

[ ]  CICRL [ ]  IRC [ ]  SRC

[ ]  Acute Care Research (Research that occurs within 24 hours of a visit to an emergency department or unscheduled admission, or within 24 hours of identification of a new or worsening condition – characterized by sudden onset requiring immediate care)