UC Riverside, School of Medicine Policies and Procedures
Policy Title: Student External Research Policy (SERP)
Policy Number: 950-10-001

Responsible Officer:	Senior Associate Dean for Research
Responsible Office:	SOM Research
Origination Date:	September 20, 2022
Date of Revision:	October 19, 2022
Scope:	Applies to all UCR SOM Medical Students

I. Policy Summary

a. The goal of this policy is to provide an outline for an efficient, uniform, and compliant process for enabling students' to develop research opportunities with external partners (within limits related to safety, liability, and ethics).
b. As members of the UC Riverside School of Medicine (SOM) community, medical students are owed opportunities to engage in healthcare research opportunities, are encouraged to engage in research activities with broader research and scientific communities, but must also abide by the processes outlined in this policy. Failure to comply may lead to academic and/or other consequences for the student.
    i. UCR SOM Responsibilities: UCR SOM's goal is to provide students with access to high quality research opportunities with internal and external partners while also adhering to internal guidelines and requirements. To ensure that we meet these obligations, the school will:
        1. Actively develop and build new research affiliate partnerships within the UC's and beyond
        2. Support students in developing these relationships through the SOM's grants and contracts processes
        3. Create a student-facing list of available sites with whom the school has established research affiliate status
    ii. Student Responsibilities: UCR SOM's goal is to enable students to partner with scholars, researchers, and clinical experts at a range of partner institutions. Students must follow all defined processes in order to engage these outside partners, including:
        1. Following the process outlined in this policy
        2. Identifying the necessary contacts at external institutions with authority to enter into student research affiliate agreements with UCR
        3. Clearly communicating with relevant administrators as defined by the process
        4. Operating in a transparent, ethical, and proactive way during the entire process

5. Immediately alerting administrators to any incidents related to ethics or safety

II. Definitions

a. "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research:
   i. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

b. "Research" is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. This may include any activity that involves the collection, analysis, and/or dissemination of data intended to be applicable to populations or situations beyond that studied.

c. "Human subjects research" is research that involves human subjects as defined above.
   i. This includes projects such as participating in the conduct of clinical trials, performing patient interviews, administering surveys, or reviewing privately-held datasets
   ii. Any instance when new data is collected from more than three human subjects, or is identified as generalizable beyond a single site
   iii. The Institutional Review Board (IRB) and IRB staff will be the final arbiter of whether any project constitutes "human subjects research"
   iv. Any activity may require an IRB submission of some type (General IRB application or Determination Of Activities (DOA's))

d. "Not-human subjects research activities" are defined as activities that are of interest to the broader academic or healthcare community but do not meet the "human subjects research" definition above. These activities may include projects that:
   i. Are not generalizable (e.g. a sample of less than three participants, CQI projects),
   ii. Rely on publicly available secondary datasets, or
   iii. Involve the analysis of existing published literature (e.g. meta analyses, systematic reviews, literature reviews in support of future publications)
   iv. Attendance or participation in conferences (e.g.

e. "UCR Clinical Faculty" include individuals directly employed by UC Riverside. These faculty may serve as signatories, mentors, co-mentors and Principal Investigators for the purposes of filling out IRB forms in accordance with UCR Policy #527-3..

f. “UC Faculty" include individuals directly employed by a University of California academic site, such as UC San Diego, UC Irvine or UC Los Angeles. These faculty may serve as a mentor or co-mentor for your research project. In the event that your primary mentor is a UC Faculty member, a UCR Faculty must be identified for oversight of your research project at UC Riverside.
g. “Affiliate Faculty” are defined as clinical faculty members who are granted certain academic and access rights to UC resources, but are not directly employed by a UC site. Affiliate faculty may not serve as signatories, Principal Investigators, or other legal roles for the purposes of IRB approval. Affiliate faculty include:
    i. Community-based physicians at partner sites who are not directly employed by the University of California system
    ii. Non-physician clinical partners at partner sites who are not directly employed by the University of California
h. “External Partners” are defined as any educational institution, clinical site, healthcare facility, or other group that is not judged to be within the UC Riverside network of subsidiaries.
    i. The Office of Research and Economic Development will be the final arbiter of whether any group constitutes an ‘external partner’

III. Policy Text

A. When Does This Policy Apply?

1. This policy applies to occasions with the following parameters:
    a. Students are planning to engage in research activities with faculty (clinical or non-clinical) who hold primary appointments at non-UCR affiliated sites, with faculty who hold volunteer/community faculty or without salary appointments at a UCR-affiliated site, or another U.C. location,
    b. Students are planning to physically visit a clinical site for the purposes of conducting human subjects research (collecting data, interviewing patients, accessing clinical datasets, reviewing clinical data in Electronic Medical Records)
    c. Students are planning to digitally receive or store human subjects data for the purposes of analysis for generalizable research, publication, or other kinds of dissemination
2. This policy ***does not*** apply to occasions with the following parameters:
    a. Students are planning to engage in not human subjects research activities including:
        i. Clinical case reports involving fewer than 3 people
        ii. Analysis of publicly available datasets
        iii. Literature reviews, systematic reviews, or meta analyses

b. DOA's may still be due to the IRB before engaging in these projects

B. Pathways 1 – Extra-Curricular Research

1. For students who are engaging with a research project at an institution with which UCR already has a research affiliate agreement, they must:
    a. Begin this process 30 days before they intend to start their research project
    b. Identify a local UCR Clinical Faculty member to serve as a mentor
    c. Discuss with the Director of Scholarly Activities and review the project information
    d. Submit a copy of the study's approved IRB protocol to the UCR IRB office
        i. Students should consult with the PI of the IRB protocol on the steps needed to be added as project personnel on the protocol
        ii. Some institutions/sites may require that the UCR IRB execute a reliance agreement with the institution/site for the addition of the student's involvement. Students should contact the UCR IRB office with this information if this request is made.
    e. Receive a letter of Good Standing from Student Affairs
    f. Submit a copy of your research project to Sponsored Research & Programs within the SOM, as well as all relevant information and contacts for the collaborating institution
    g. Students may not start their research project, receive data, or begin data analysis research until they receive confirmation that the addendum to the research affiliate agreement has been finalized and their IRB protocol, if necessary, has been approved

2. For students who are engaging with a research project at an institution with which UCR *does not* have a research affiliate agreement:
    a. Begin this process *at least* 90 days before they intend to start their research project
    b. Identify a local UCR Clinical Faculty member to serve as an advisor
    c. Submit a copy of the study's approved IRB protocol to the UCR IRB office

i. Students should consult with the PI of the IRB protocol on the steps needed to be added as project personnel on the protocol
ii. Some institutions/sites may require that the UCR IRB execute a reliance agreement with the institution/site for the addition of the student's involvement. Students should contact the UCR IRB office with this information if this request is made.

d. Provide the required information to Sponsored Research & Programs within the SOM (including site coordinator contact, emergency services information, etc.)
e. Students may not start their research project, receive data, or begin data analysis research until they receive confirmation that the research affiliate agreement has been finalized and their IRB protocol, if necessary, has been approved

C. Pathways 2 – Research Selectives/Electives

1. For students who are engaging with a research project at an institution with which UCR already has a research affiliate agreement, they must:
    a. Begin this process 30 days before they intend to start their research project
    b. Verify that UCR SOM has an active research affiliation agreement with the external institution
    c. Identify a local UCR Clinical Faculty member to serve as an advisor
    d. Discuss with the Director of Scholarly Activities and review the project information
    e. Submit a copy of the study's approved IRB protocol to the UCR IRB office
        i. Students should consult with the PI of the IRB protocol on the steps needed to be added as project personnel on the protocol
        ii. Some institutions/sites may require that the UCR IRB execute a reliance agreement with the institution/site for the addition of the student's involvement. Students should contact the UCR IRB office with this information if this request is made.
    f. Receive a letter of Good Standing from Student Affairs

g. Submit a copy of your research project to Sponsored Research & Programs within the SOM, as well as all relevant information and contacts for the collaborating institution
h. Students may not start their research project, receive data, or begin data analysis research until they receive confirmation that the addendum to the research affiliate agreement has been finalized and their IRB protocol, if necessary, has been approved

2. For students who are engaging with a research project at an institution with which UCR does not have a research affiliate agreement:
    a. Begin this process *at least* 90 days before they intend to start their research project
    b. Identify a local UCR Clinical Faculty member to serve as an advisor
    c. Verify that UCR SOM has an active research affiliation agreement with the external institution
    d. Submit a copy of the study's approved IRB protocol to the UCR IRB office
        i. Students should consult with the PI of the IRB protocol on the steps needed to be added as project personnel on the protocol
        ii. Some institutions/sites may require that the UCR IRB execute a reliance agreement with the institution/site for the addition of the student's involvement. Students should contact the UCR IRB office with this information if this request is made.
    e. Provide a copy of your research project to Sponsored Research & Programs within the SOM, as well as all relevant information and contacts for the collaborating institution (including site coordinator contact, emergency services information, etc.)
    f. Students may not start their research project, receive data, or begin data analysis research until they receive confirmation that the addendum to the research affiliate agreement has been finalized and their IRB protocol, if necessary, has been approved

D. Consequences for Violation of the Policy

1. Students who 1) conduct research at institutions that do not have current research affiliate status with UCRSOM, or 2) actively avoid reporting activities or prevent SOM staff from learning about external research activities may face the following penalties:

a. First infraction: Referral to Director of Scholarly Activities for clarification of policy
b. Second infraction: Referral to professionalism committee for conduct evaluation
c. Third infraction: Referral to Professionalism committee plus negative note on MSPE reports

2. Researchers (this includes the UCR Faculty mentor and student) who conduct human subjects research without IRB approval are subject to the sanctions as outlined in the UCR IRB Policies and Procedures.

IV. Responsibilities

A. Students
   a. Students must provide the following information to the Sponsored Research & Programs in *Form 1*:
      i. The name of the external site with whom they will be working during the project
      ii. The physical address of the external site
      iii. Contact information (including email and phone number) for the contracts and business process department at the external site, along with any additional information that can be provided
      iv. Contact information for their research mentor at the external site, including email address and emergency contact number
      v. A declaration of the potential risks to the health and safety of patients, students, and the community posed by the research
      vi. A description of available emergency care
      vii. The possibility of natural disasters, political instability, and exposure to disease
B. Senior Associate Dean of Research
C. Director of Scholarly Activities
   a. Reviews student proposal to determine whether the student is engaged in an appropriate role in the research project, that the student
      i. has the necessary skills and resources to engage in the research project,
      ii. has a plan for publication and dissemination of the project,
      iii. and to advise the student on how to secure approval from the ORI.
D. Student Affairs
   a. Reviews student academic record to provide Letter of Good Standing
E. Professionalism Committee

a. Will review student behavior if found to be in non-compliance with this policy

F. Office of Sponsored Programs Administration
   a. Review the research proposal for institutional compliance
   b. Review, negotiate, and sign the research agreement

G. IRB Office
   a. Reviews the IRB protocol
   b. Reviews and signs Institutional Authorization Agreement (IAA) for IRB reliance agreements, if needed

V. Procedures

A. Workflow and Procedures

a. Refer to Exhibit A

VI. Forms/Instructions

In compliance with LCME and University Policy, the following forms will be collected when students conduct extramural research:

Form 1 – Submitted by the UCR SOM student to the Sponsored Research & Programs:

- Institution
- Location
- Point-of-Contact (PoC) for research affiliation agreements
- Potential risks to the health and safety of patients, students, and the community.
- The availability of emergency care.
- The possibility of natural disasters, political instability, and exposure to disease.
- The need for additional preparation prior to, support during, and follow-up after the elective.
- The level and quality of supervision.
- Any potential challenges to the code of medical ethics adopted by the home school.

Form 2: Summary of Research Project Proposal: Filled out by the student in conjunction with the Director of Scholarly Activities to ensure that:

- Student is engaged in appropriate role in the research project
- Student has negotiated authorship/credit for their work on the project
- Student has a plan for publication or dissemination of research project
- Project does/does not have IRB approval

VII. Related Information

a. **See Exhibit A for flow-chart diagram of**

VIII. Revision History

a. **Draft created 9/20/2022**
b. **Reviewed by Compliance (Paul Hackman) on 9/28/2022**
c. **Reviewed by RED (Ursula Prins and Lorraine Castro) on 10/19/2022**

Approvals:

COMPLIANCE COMMITTEE (01/23/2023)

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PAUL HACKMAN, J.D., L.LM.
CHIEF COMPLIANCE AND PRIVACY OFFICER,
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UCR SOM Student External Research Policy (SERP) Workflow (Version 1.1, 9/29/22)