UCI Health

Research Compliance SOP: Scientific Clinical Research Internship Program

Purpose

To provide a consistent framework for University of California, Irvine (**UCI**) and non-UCI undergraduates (UCI undergraduates limited to Summer term only) and graduates, non-professional or other affiliate program participants, and high school students over the age of 16 who participate in clinical research. The Scientific Clinical Research Internship Program (**SCRIP**) offers direction to participants engaged in research projects under the supervision of eligible faculty members within UCI Health. Additionally, it ensures compliance with Federal, State, and University regulations governing the protection of human and animal subjects in clinical trials and research projects. SCRIP also emphasizes the importance of delivering high-quality patient care while supporting the educational and research objectives of UCI Health. It serves as a comprehensive resource, containing guidelines, rules, and procedural standards for faculty sponsors, department administrators, and participants.

Background

SCRIP is a non-credit and non-compensatory course administered by departments within UCI Health. Departments participating in SCRIP designate SCRIP Coordinators to serve as the primary point of contact for participants, faculty, and departmental staff.

The program is designed to provide participants with the opportunity to experience research as an intern under the direct supervision of an eligible faculty member in the School of Medicine. It offers experience in biomedical research settings. Assignment periods may range from a minimum of one (1) month to twelve (12) months.

Procedure

A. Faculty Sponsor Responsibilities

1. Ensure participants adhere to the standards of SCRIP, UCI Health policies and procedures, UCI Campus policies and procedures, and University of California, Office of the President (**UCOP**) policies surrounding the specific intern duties (including but not limited to: Personal Protective Equipment, Minors in Laboratories, etc.), IRB and IACUC policies, and any regulatory requirements attached to grants or financial sponsorship.
2. Add participants to approved IRB, IACUC, and IBC protocols before they begin working on them (See **Appendix B**).

3. Provide training and documentation related to any duties before participants begin performing them.
4. Ensure participants obtain special permission to restricted areas, such as operating rooms and the emergency department (See **Appendix A**).
5. Uphold the physical and regulatory safety of the participants, patients, and faculty by prohibiting participants enrolled in SCRIP from:
    i. Performing duties for industry-supported clinical trials where prohibited by contract.
    ii. Performing clinical practice or answering/discussing clinical or medical questions.
    iii. Performing high-level/high-risk duties (e.g., operating certain equipment,
    iv. exposure to radiation, exposure to CDC high-risk agents, etc.).
    v. Accessing UCI Health Electronic Medical Records (**EMR**)
6. Prohibit minors (under 18 years old) enrolled in SCRIP from performing duties involving:
    i. Highly hazardous materials.
    ii. International Agency for Research on Cancer (**IARC**) Group 1 or 2A carcinogens or Cal/OSHA-regulated carcinogens.
    iii. Controlled substances.
    iv. Anesthetization, euthanization, or surgical procedures performed on animals.
    v. Human blood, body fluids or tissues, unless prior special approval is granted by the department (The faculty sponsor must submit request for exception prior to an internship).
7. Uphold patient confidentiality during research assignments by having participants adhere to the **Confidentiality of Medical Information Act** (See **Appendix A**).
8. Avoid sharing faculty login credentials with participants as an assurance to the integrity of the program and University policies, as this grants access to information that participants are not authorized to view or have not been properly trained to handle.
9. Maintain full regulatory and safety compliance in the lab and/or clinical setting.
10. Communicate to the SCRIP coordinator if the participants work on subsequent approved Institutional Review Board (**IRB**), Institutional Animal Care and Use Committee (**IACUC**), or Institutional Biosafety Committee (**IBC**) protocols outside of what is described in the faculty screening questionnaire.
11. Inform the SCRIP Coordinator in writing if the participants' duties and responsibilities expand during the internship.
12. Require participants to reapply approximately one month before the approved end date if a faculty sponsor requests an extension beyond the 12-month maximum.

B. SCRIP Coordinator Responsibilities

1. Act as a primary point of contact regarding information about SCRIP for participants, faculty, and departmental staff.
2. Assist the faculty sponsor, their staff, and participants in navigating the application process.
3. Request a sponsored UCInetID for participant access to complete required online training (See **Appendix C**).
4. Review all mandatory training with the participant prior to starting an internship (See **Appendix C**).
5. Review application paperwork/materials and inform interested parties regarding approval or incomplete requirements in a timely manner. Details regarding the review of application paperwork/materials are addressed in **Appendix C**.
6. Conduct a check to confirm if any necessary updates are needed for continuing health clearance for participants who continue past the 12-month maximum window.

C. Participant Responsibilities

1. Complete all forms and provide all documents required by the SCRIP application.
2. Complete all required trainings as instructed by the faculty sponsor and SCRIP coordinator.
3. Obtain written approval from a SCRIP Coordinator prior to beginning an internship.
4. Follow appropriate policies when shadowing as part of a SCRIP internship.

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Appendix A. References

- Confidentiality of Medical Information Act
- Observers and Vendors in Clinical Areas
- Observers in the Procedural Setting

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Appendix B. When to Add a Participant to your IRB or IACUC Protocol

A. IRB

1. To determine if the participant needs to be listed on the study team, follow the IRB's guidance on the IRB FAQs webpage.
2. The participant is responsible for completing required IRB training, including CITI training, prior to engaging in any research related activities. See the Human Research Protections (**HRP**) Training and Education webpage for IRB training requirements.

B. IACUC

1. Participants who are engaged in research involving the following must be listed on an IACUC-approved protocol:
    i. Accessing a vivarium unattended.
    ii. Handling or caring for live animals.
    iii. **Please note**: If a participant is strictly working with animal cells, blood, and/or tissues but NOT live animals, they do not have to be listed on the protocol.

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Appendix C. Application Submission Instructions and Checklist

A. Required Participant Documents

1. The required participant documents must be provided to the SCRIP Coordinator along with the required program forms to process the application:
    i. Resume or curriculum vitae (**CV**)
    ii. Proof of current health insurance
    iii. Copy of driver's license or student ID.

B. Required Program Forms

1. The following forms are to be completed by participants:
    i. Intern Application Form
    ii. UCI Health Confidentiality Statement Form
    iii. UC Waiver of Liability, Assumption of Risk & Indemnity Agreement Form
    iv. UCI Parental Authorization for Minors Form
    v. SCRIP Medical Clearance Form (***required for participants on any UCI Health premises***).
2. The following forms are to be completed by faculty sponsors:
    i. Faculty Screening Questionnaire Form
3. The following forms are to be completed by both participants and faculty sponsors:
    i. SCRIP Workplace-Lab Safety Orientation Form
4. The following form is not required to be completed but serves as a resource for both faculty and the participant:
    i. Intern Competency Form

C. UCInetID and ID Badge

1. The SCRIP Coordinator can request a sponsored UCInetID at the following link: https://activate.uci.edu/sponsored/request.php
    i. It will take 24-48 hours to receive a sponsored UCInetID.
    ii. A sponsored UCInetID must be forwarded to the participant to complete the required online training.
    iii. Participants must activate their sponsored UCInetID (**instructions provided with ID**).
    iv. A photo ID badge must be obtained from the Parking and Transportation Services office and worn while on duty (**contact 714-456-5636 for assistance**).

D. Required Online Training

1. **University of California Learning Center (UCLC)**
    i. Please access the "Student and Affiliate Access Request" at the following link: http://uclc.uci.edu/. Complete required training and print certificates of completion.
    ii. For participants at UCI Medical Center, affiliated clinics, or any location where patient contact is anticipated:

1. UCI Health Privacy and Security HIPAA Healthcare Privacy Laws
2. Annual Training Students Only
3. UCI Responsible Conduct of Research (**RCR**)
4. Healthcare Vendor Relationship Policy
5. UCI Health Compliance Program

iii. For participants at the UCI Medical Center or on-campus in basic science laboratories with no patient care areas or contact with patients:

1. UCI RCR
2. Privacy and Security Training HIPAA – Campus
3. UC Laboratory Safety Fundamentals
4. Hazardous Waste eCourse
5. Bloodborne Pathogens eCourse (**8 modules to complete**)
6. Fire Safety Training (**as applicable/consult with faculty sponsor**)
7. Radiation-Producing Machine Safety or Radioactive Material Safety (**as applicable/consult with faculty sponsor**)
8. Laser Safety (**as applicable/consult with faculty sponsor; 7 modules to complete**)

iv. For UCI Health employees involved with minors, the Child Abuse and Neglect Reporting Act (CANRA) training must be completed.

2. **CITI Human Research protections and Animal Research Training**
   i. For participants working on an approved IRB or IACUC protocol, the Office of Research will require additional training through CITI at www.citiprogram.org.
3. **HIPAA Research Tutorial**
   i. For participants working on an approved IRB protocol involving protected health information (**PHI**), the Office of Research will require additional training through UCLC. See the HRP Training and Education webpage for IRB Training requirements.
4. **Laboratory Animal Occupational Health Program Questionnaire**
   i. The Laboratory Animal Occupation Health Program (**LAOHP**) Questionnaire must be completed if you will have contact with animals. You will receive an email confirmation once you have registered; please submit a copy of this information in your application packet.
   ii. All participants that will have direct contact with live animals in the lab must:
      1. Have a sponsored or guest UCInetID
      2. Complete all training and orientation requirements for working with live animals in labs
      3. Complete the Participant Registration Form
      4. Enroll in the LAOHP

5. Be listed as authorized personnel on all approved IACUC protocols
6. Contact IACUC@uci.edu for questions

E. Remote Participant Activities

1. The department is responsible for facilitating access to UCI-Health-owned and operated devices when participants need remote access for research purposes.
    i. For additional information, please reach out to UCI Health IT at 714-456-3333.
2. The department is responsible for establishing procedures to ensure supervisory oversight, training, and accountability, along with any other applicable University and Health system requirements.
3. As SCRIP is a voluntary program, participants are not eligible for Epic access.