

UCI School of Medicine

INTERVENTIONAL CLINICAL TRIALS POLICY

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I. PURPOSE

The purpose of this policy is to facilitate efficient, compliant, and ethical clinical research study conduct and management. Specifically, to ensure adherence to University of California, Irvine (UCI) institutional policies and procedures that are designed to (i) ensure the safe and appropriate use of investigational devices, drugs, and biologics and the safety of human participants who have consented to participation in clinical research studies, and (ii) ensure that clinical services associated with clinical research studies are billed appropriately and in compliance with relevant laws, regulations, and contractual obligations.

All clinical research studies covered by the scope of this policy are *required to be coordinated and facilitated through one of the central research coordinating units.* Oversight by the coordinating units does not in any way reduce or eliminate the Investigator's responsibility for the conduct, billing, and reporting of clinical studies or data obtained through clinical trial investigations.

II. SCOPE

This policy applies to all faculty, employees, contractors, consultants, students, and volunteers engaged in the conduct of clinical research who reside within the School of Medicine (SOM) that meets one or more of the following criteria:

1. Involves an FDA-regulated drug, biologic, or device;
2. Involves an interventional clinical trial (unless intervention and outcomes are strictly behavioral and do not meet other criteria listed herein); or
3. Involves healthcare items or services that may be billed to the participants or their insurers.

III. DEFINITIONS

- A. **Clinical Research** refers to the study of health and illness in people.
- B. **Interventional Clinical Trial** refers to studies involving human participants in which the investigator assigns study participants (randomly or not randomly) to receive a specific intervention based on the applicable protocol. Such participants may receive diagnostic, therapeutic, and/or another type of intervention. These interventions may, but need

not, be investigational or involve an investigational agent (e.g., clinical trials involving surgery, radiation, or screening tests). The participants are then followed, and biomedical and/or health-related outcomes are assessed. Interventional clinical trials meet all of the following criteria:

- i. Studies involve human participants.
 - ii. Participants are prospectively assigned to an intervention.
 - iii. The study is designed to evaluate the effect of an intervention on participants.
 - iv. The effect being evaluated is a health-related biomedical or behavioral outcome.
- C. **Investigator** means an individual who actually conducts a clinical investigation. Where an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team.
- D. **Investigator-Initiated Trials (IIT)** are clinical investigations initiated and managed by UCI investigators. This means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug or test article is administered or dispensed. The investigation may or may not include external funding. These studies may include already approved drugs or devices involved in a research protocol.
- E. **Central Research Coordinating Units** provide support for the administration of clinical trials during all phases of the lifecycle of a protocol from start-up and execution, to reporting, audit support, and study closeout.

IV. POLICY

All clinical research studies covered by the scope of this policy are *required* to be coordinated and facilitated through one of the central research coordinating units:

- Stern Center for Cancer Clinical Trials and Research: oncology clinical trials
- Alpha Clinic (AC): cell and gene therapy clinical trials
- Center for Clinical Research (CCR): non-oncology and non-cell/gene therapy clinical trials
- Memory Impairments and Neurological Disorders (MIND): NIH-funded memory and neurological disorders clinical trials

Researchers performing research activities that do not fall into the categories above may also choose to work with one of the coordinating units.

UCI SOM will rely on this oversight to ensure that clinical research is:

- Scientifically aligned with the interests of the faculty and our academic mission.
- Is compliant with applicable regulatory requirements and institutional standards for

clinical research.

- Financially transparent and accountable.
- Conducted by individuals with the appropriate qualifications, training, and/or certifications in clinical research and UCI Health requirements.

Each clinical research coordinating unit will engage in a feasibility review for the interventional protocols relevant to their unit. As part of this process, a waiver may be employed that delineates oversight to ensure the responsibilities listed above are met by the study investigator, which will be documented in OnCore.

V. PROCEDURE

The central research coordinating units will provide central management and oversight functions for activating, facilitating, and reporting on interventional clinical trials and/or clinical research studies that require items or services that may be charged or billed (including billing to a third-party insurance, study sponsor, or patient) in the electronic health record (EHR) billing system of UCI Health and SOM.

Oversight functions ensure:

- The study is feasible.
- Contract negotiations are coordinated through the appropriate contracting unit.
- Internal and external regulatory submissions are complete and timely.
- Study-specific training for faculty and staff.
- Adequate planning for participant identification, screening, consent, enrollment, retention, and other accrual goals.
- Adherence to the policies of the Investigational Drug Services (IDS) pharmacy.
- Adherence to clinical research billing requirements (e.g., coverage analysis preparation, participant registration in the clinical trials management system, study record reconciliation for consistency, etc.).
- Study teams are prepared and have tools to participate in internal or external (directed and routine) audits and monitoring visits and give feedback on appropriate corrective action, as needed.
- A plan for data collection, integrity, privacy, security, transfer, receipt, and short- and long-term storage of study records and data.
- Overall support for development, implementation, and quality control of clinical research.

VI. QUESTIONS

Questions regarding this policy can be directed to Daniela Bota, MD, PhD, Vice Dean for Clinical Research (dbota@hs.uci.edu) or Shauna Stark, MS, Director of Research Operations (starks@hs.uci.edu).

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VII. REFERENCES

- [False Claims Act, 31 U.S.C. 3729](#)
- [Centers for Medicare and Medicaid Services \(CMS\) Medicare Claims Processing Manual, Pub 100-4; Chapter 32, § 69.6 \(Billing for Clinical Trials\)](#)
- [Centers for Medicare and Medicaid Services \(CMS\) Medicare National Coverage Determination for Clinical Trials 310.1](#)
- [Office of Inspector General; Office of Management and Budget Circular A-100, A-21](#)
- [Code of Federal Regulations Title 21 Part 312 Investigational New Drug Application](#)
- [Code of Federal Regulations Title 21 Part 361 Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used in Research](#)
- [Section 351 of the Public Health Service Act](#)
- [Code of Federal Regulations Title 21 Part 600 Biological Products General](#)
- [Code of Federal Regulations Title 21 Part 612 General Biological Products Standards](#)
- [Code of Federal Regulations Title 21 Part 812 Investigational Device Exemptions](#)
- [Code of Federal Regulations Title 21 Part 11 Electronic Records; Electronic Signatures](#)
- [Code of Federal Regulations Title 45 Section 164 Privacy and Security Rule](#)
- [California Medical Information Act §56 et sequelae](#)