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INTERVENTIONAL CLINICAL TRIALS POLICY

Michael J. Stamos, Dean

PURPOSE

This policy sets standards for the conduct and oversight of interventional clinical trials at the University of California, Irvine School of Medicine (UCI SOM) and establishes that all interventional clinical trials, as defined herein, must be serviced, fully conducted, and overseen by an approved UCI Clinical Trial Unit (CTU) as specified in this policy to ensure appropriate compliance with applicable regulations.

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.

SCOPE

This policy applies to all research studies that meet the definition of an interventional clinical trial. This policy applies to all faculty, employees, contractors, consultants, students, and volunteers engaged in the conduct of clinical research within the UCI School of Medicine.

An interventional clinical trial is a study in which participants are assigned to receive a specific treatment, activity, or change in care so that researchers can evaluate its effect on health outcomes, or in which a drug, biologic, or device is used on participants for research purposes so that researchers can evaluate its safety, effectiveness, or performance In practical terms, if a study is actively changing how the participant's care is managed for research purposes, it is considered interventional.

This includes but is not limited to:

- Studies involving drugs, biologics, or medical devices, whether investigational or approved
- Surgical, procedural, or diagnostic interventions conducted for research purposes
- Assigned treatment plans, clinical pathways, or changes to standard of care
- Behavioral, dietary, or lifestyle interventions

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- Any additional tests, visits, or procedures required by the study that go beyond standard care, and/or include research-specific billing requirements.

Interventional clinical trials are distinct from non-interventional studies, such as observational studies, registries, or retrospective analyses, where patient care is not assigned or altered by the research protocol.

This policy is grounded in federal standards used by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) and aligns with human subject research requirements overseen by the Office for Human Research Protections (OHRP).

Final determination of whether a study meets the definition of an interventional clinical trial, and therefore requires centralized clinical trial unit oversight, will be made through consultation with the centralized unit of consideration: UCI's Stern Center, Alpha Clinic, Center for Clinical Research, or Institute for Memory Impairments and Neurological Disorders (MIND) Institute.

DEFINITIONS

A. **Clinical Research** refers to the study of health and illness in people.

B. **Interventional Clinical Trial** refers to a study in which participants are assigned to receive a specific treatment, activity, or change in care so that researchers can evaluate its effect on health outcomes or in which a drug, biologic, or device is used on participants for research purposes so that researchers can evaluate its safety, effectiveness, or performance. In practical terms, if a study is actively changing how the participant's care is managed for research purposes, it is considered interventional. This includes but is not limited to:
   - Studies involving drugs, biologics, or medical devices, whether investigational or approved
   - Surgical, procedural, or diagnostic interventions conducted for research purposes
   - Assigned treatment plans, clinical pathways, or changes to standard of care
   - Behavioral, dietary, or lifestyle interventions

- Any additional tests, visits, or procedures required by the study that go beyond standard care and/or include research-specific billing requirements

C. **Intervention** means both (1) physical procedures by which information or biospecimens are gathered and (2) manipulations of the participant or the participant's environment that are performed for research purposes, consistent with the Common Rule and NIH definition. The presence of a research intervention alone does not necessarily cause a study to be considered an Interventional Clinical Trial under this policy. Basic Experimental Studies Involving Humans (BESH) that do not evaluate an outcome with the potential for direct advancement of health or research involving a simple biospecimen sample collection are not considered Interventional Clinical Trials solely on that basis, unless another criterion of this policy applies.

D. **Investigator** means an individual who conducts a clinical investigation. Where an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team.

E. **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.

F. Clinical Trial Units (CTUs) 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.

POLICY

All clinical research studies covered by the scope of this policy are *required* to have monitoring oversight provided through one of the Clinical Trial Units:

- Stern Center for Cancer Clinical Trials and Research: oncology clinical trials
- Alpha Clinic (AC): cell and gene therapy clinical trials and CIRM funded clinical trials
- Center for Clinical Research (CCR): non-oncology and non-cell/gene therapy clinical trials
- Institute for Memory Impairments and Neurological Disorders (MIND): Alzheimer's Disease and Related Disorders (ADRD) trials across the spectrum of disease

Researchers performing research activities that do not fall into the categories above may also contact the appropriate CTU to request services.

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.
- 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.

PROCEDURE

The Clinical Trial 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 for conduct.
- The study is conducted in compliance with governing institutional standard operating procedures and governing regulatory requirements.
- 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.

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- 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.

QUESTIONS

Questions regarding this policy can be directed to Eric Vilain, Vice Dean for Clinical Research (evilain@hs.uci.edu), Carey Berkowick, Director of Research Operations (cberkow1@hs.uci.edu) or Shauna Stark, Assistant Dean of Research Operations (starks@hs.uci.edu).

REFERENCES

- 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 610 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

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- Code of Federal Regulations Title 42 Part 11 Clinical Trial Registration and Results Information Submissions
- Code of Federal Regulations Title 45 Section 164 Privacy and Security Rule
- California Medical Information Act §56 et sequelae
- OHRP (45 CFR 46.102 e2)
- NIH Definition of clinical trial
- Harmonizing the NIH Definition of “intervention” with the Common Rule
- FDA (21 CFR 312 & 812)
- E6(R3) Good Clinical Practice (GCP