



CALIFORNIA STATE UNIVERSITY  
**BAKERSFIELD**

STANDARD OPERATING PROCEDURE

# Human Subjects Protection and Good Clinical Practice

Defines the ethical, regulatory and operational standards that protect the rights, safety, dignity and wellbeing of human subjects participating in clinical research at California State University, Bakersfield.

DOCUMENT CONTROL

|                |                                                                                         |
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| DOCUMENT NO.   | SOP-001                                                                                 |
| VERSION        | 1.0                                                                                     |
| EFFECTIVE DATE | 9/28/2026                                                                               |
| APPLIES TO     | All personnel involved in clinical research at California State University Bakersfield. |

APPROVAL

| ROLE | NAME AND TITLE | SIGNATURE | DATE |
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Approved by

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## 1 Purpose

SOP-001 defines the ethical, regulatory, and operational standards necessary to protect the rights, safety, dignity, and wellbeing of human subjects participating in clinical research at California State University, Bakersfield (“the Site”). It outlines the required responsibilities and procedures for all research personnel and ensures adherence to Good Clinical Practice (GCP) and all applicable regulatory requirements.

By implementing this SOP, the Site affirms its commitment to scientific integrity, ethical conduct, regulatory compliance, and a culture in which the protection of human subjects is the primary responsibility of every member of the research team.

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## 2 Scope

This Standard Operating Procedure applies universally and without exception to all individuals at California State University, Bakersfield, who are involved in any aspect of the planning, conduct, oversight, documentation, reporting, or management of clinical research involving human subjects. This includes all research activities performed on site, at satellite or affiliated locations, or remotely on behalf of the Site.

Non-compliance may result in corrective action, including any measures required under CSUB HSIRB policies and procedures governing non-compliance.

## 3 Responsibilities

| ROLE                               | RESPONSIBILITY                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Principal Investigator (PI)</b> | Holds overall responsibility for the conduct of the trial at the site. Ensures IRB approval is in place before any research activity begins (5.1.1), submits protocol and amendment packages (5.1.2), reports SAEs to the sponsor within 24 hours of awareness (5.5.3), is notified immediately of every protocol deviation (5.4.2), contacts the sponsor's regulatory affairs team in the event of an unannounced inspection (5.8.4), and completes financial disclosure (5.12.1). |
| <b>Sub-Investigator</b>            | Performs critical trial-related procedures as designated and supervised by the PI, within the limits of the delegation of authority log. Completes GCP and protocol-specific training before performing any trial procedure (5.11.1, 5.11.2) and completes financial disclosure (5.12.1).                                                                                                                                                                                           |

| ROLE                                                    | RESPONSIBILITY                                                                                                                                                                                                                                                   |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Delegated study staff (e.g. study coordinator)</b>   | Conducts the informed consent discussion where qualified and delegated (5.2.1), records data contemporaneously in source documents (5.7.1), and maintains the subject enrollment log, deviation log, IP accountability log and ISF (5.3.4, 5.4.3, 5.6.3, 5.9.1). |
| <b>Personnel authorized for investigational product</b> | Receives, stores, dispenses, and returns or destroys IP strictly as specified in the delegation log and the protocol, and maintains temperature monitoring and accountability records (5.6).                                                                     |
| <b>All research personnel</b>                           | Comply with this SOP and the IRB-approved protocol without exception, maintain current GCP and human subjects protection training (5.11), and protect subject confidentiality (5.10).                                                                            |

## 4 Definitions and acronyms

| TERM                                        | DEFINITION                                                                                                                                                                                                                                                                                                     |
|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Adverse Event (AE)</b>                   | Any untoward medical occurrence in a participant administered an investigational product, which does not necessarily have a causal relationship with the treatment.                                                                                                                                            |
| <b>Assent</b>                               | Agreement by a minor or cognitively impaired individual to participate in research when a legally authorized representative provides consent.                                                                                                                                                                  |
| <b>Case Report Form</b>                     | A CRF is defined by ICH E6 as a printed, optical, or electronic document designed to record all protocol-required information to be reported to the sponsor for each trial subject.                                                                                                                            |
| <b>GCP (Good Clinical Practice)</b>         | An international quality standard for designing, conducting, recording, and reporting clinical trials.                                                                                                                                                                                                         |
| <b>Clinical Research Organization (CRO)</b> | Is a company that provides outsourced research and clinical trial services to pharmaceutical, biotechnology, and medical device sponsors. CROs support drug and device development by supplying the people, processes, and infrastructure needed to run studies efficiently and in compliance with regulations |

| TERM                                    | DEFINITION                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ICH</b>                              | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.                                                                                                                                                                                                                                                                                             |
| <b>IND</b>                              | Investigational New Drug application filed with the FDA to authorize use of an investigational drug.                                                                                                                                                                                                                                                                                             |
| <b>Informed Consent</b>                 | A process by which a subject voluntarily confirms willingness to participate in a trial after being informed of all relevant aspects of the trial.                                                                                                                                                                                                                                               |
| <b>Institutional Review Board (IRB)</b> | An independent body constituted of medical, scientific, and non-scientific members whose responsibility is to ensure the protection of rights, safety, and well-being of human subjects.                                                                                                                                                                                                         |
| <b>Investigator's Brochure (IB)</b>     | A compilation of clinical and nonclinical data on the investigational product(s) relevant to the study.                                                                                                                                                                                                                                                                                          |
| <b>Investigational Product (IP)</b>     | The drug, biologic, device, vaccine, diagnostic, or placebo being tested or used as a reference in a clinical trial.                                                                                                                                                                                                                                                                             |
| <b>Investigator Site File</b>           | Investigator Site File (ISF) is the complete collection of essential documents that a clinical trial site must maintain to demonstrate proper study conduct, regulatory compliance, and Good Clinical Practice (GCP). It is the site-level counterpart to the sponsor's Trial Master File (TMF) and is created, organized, and retained by the investigator and site staff throughout the study. |
| <b>Protocol</b>                         | A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.                                                                                                                                                                                                                                                                        |
| <b>Serious Adverse Event (SAE)</b>      | Any adverse event that results in death, is life-threatening, requires inpatient hospitalization, results in persistent or significant disability, or is associated with a congenital anomaly or birth defect.                                                                                                                                                                                   |
| <b>Source Documents</b>                 | Original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, subjects' diaries) from which data are captured.                                                                                                                                                                                                                                     |

## 5 Procedure

### 5.1 IRB review and approval

- 5.1.1 No human subjects research shall begin at this site without prior written IRB approval.
- 5.1.2 The PI or designee shall submit the complete protocol (including any amendments), the informed consent form(s) and recruitment materials, the Investigator's Brochure or current package insert, CVs and training records for all key personnel, and any additional materials requested by the IRB prior to study initiation.
- 5.1.3 Continuing review submissions shall be prepared and submitted prior to the IRB approval expiration date. If approval lapses, the study must be suspended immediately.
- 5.1.4 All protocol amendments, including changes to consent forms, must receive IRB approval before implementation unless the change is necessary to eliminate an immediate hazard to subjects.
- 5.1.5 All unanticipated problems involving risks to participants or others must be reported to the IRB within 10 business days or per sponsor instructions, whichever is sooner.

### 5.2 Informed consent process

- 5.2.1 The PI or a qualified delegated individual shall conduct the informed consent discussion in a private setting, in language the potential participant can understand, free of coercion or undue influence.
- 5.2.2 The verbal explanation and written consent document must clearly describe the study purpose; all procedures and any experimental components; foreseeable risks and discomforts; expected benefits; available alternatives; the extent of confidentiality protections; compensation and treatment for research-related injury (if applicable); contact information for questions about the study, participant rights, or injury; and a statement confirming that participation is voluntary and may be withdrawn at any time without penalty.
- 5.2.3 The subject (or legally authorized representative) shall be given adequate time to review the consent form, ask questions, and consult with family or advisors before signing.
- 5.2.4 The signed and dated consent form must be obtained before any study procedures are performed or screening assessments are initiated.
- 5.2.5 A copy of the signed consent form must be provided to the participant.
- 5.2.6 Re-consent is required whenever new information arises that may affect the participant's willingness to continue (e.g. protocol amendment, new safety findings). Re-consent must be documented.
- 5.2.7 For minors or cognitively impaired individuals, the legally authorized representative must provide consent, and assent should be obtained from the subject where appropriate.
- 5.2.8 The consent process and document must be IRB-approved. No unapproved consent forms shall be used.

### **5.3 Subject eligibility and screening**

- 5.3.1** Eligibility (inclusion and exclusion criteria) must be verified for each subject before enrollment. All screening assessments must be conducted under a signed and dated consent form.
- 5.3.2** Eligibility determinations shall be documented in the source documents and CRF prior to enrollment.
- 5.3.3** Any waiver of eligibility criteria must receive prior written approval from the sponsor's medical monitor.
- 5.3.4** A subject enrollment log shall be maintained to track all screened and enrolled subjects.

### **5.4 Protocol compliance and deviation management**

- 5.4.1** All research activities must be conducted strictly in accordance with the IRB-approved protocol. No deviations from the approved protocol are permitted without prior sponsor and IRB approval, except to eliminate an immediate hazard.
- 5.4.2** When a protocol deviation occurs, it must be documented promptly in the source documents and CRF, the PI must be notified immediately, and the impact on subject safety and data integrity must be assessed. The deviation must be reported to the sponsor per their instructions, submitted to the IRB if required by IRB policy or regulation, and recorded on the Protocol Deviation/Violation Report Form.
- 5.4.3** A log of all deviations shall be maintained in the ISF.
- 5.4.4** Recurring deviations shall trigger a CAPA (Corrective and Preventive Action) process.

### **5.5 Adverse event and serious adverse event reporting**

- 5.5.1** All AEs occurring after consent is obtained through the end of the follow-up period defined in the protocol shall be recorded in the source documents and CRF .
- 5.5.2** AE assessment shall include onset date, description, severity (per protocol criteria or CTCAE grading), relationship to investigational product, outcome, and action taken.
- 5.5.3** SAEs shall be identified and reported by the PI to the sponsor within 24 hours of awareness, or as specified in the protocol, whichever is sooner.
- 5.5.4** SAE reports to the IRB shall be submitted per IRB policy (typically within 5 to 10 business days).
- 5.5.5** SUSAR (Suspected Unexpected Serious Adverse Reaction) reports received from the sponsor shall be forwarded to the IRB per IRB instructions.
- 5.5.6** All AE and SAE documentation must be retained in the ISF and subject source file.

### **5.6 Investigational product management**

- 5.6.1** IP shall be received, stored, dispensed, and returned or destroyed only by authorized personnel as specified in the delegation log.

- 5.6.2** IP shall be stored under conditions specified in the protocol and IB (temperature, light, humidity). Temperature monitoring logs shall be maintained and reviewed daily.
- 5.6.3** An IP accountability log shall be maintained, documenting every unit received, dispensed, returned, and destroyed.
- 5.6.4** IP shall be dispensed only to enrolled, eligible subjects under a valid prescription (if applicable) and per protocol instructions.
- 5.6.5** Unused, expired, or recalled IP shall be returned to the sponsor or destroyed per sponsor instructions and applicable regulations. Documentation of return or destruction shall be retained.
- 5.6.6** IP must never be used for any purpose other than the clinical trial.

## **5.7 Data collection, management, and source documentation**

- 5.7.1** All data must be recorded promptly, accurately, legibly, and contemporaneously in source documents at the time of observation.
- 5.7.2** Corrections to paper source documents must be made by drawing a single line through the error, writing the correct entry, and initialing and dating the correction. White-out and obliteration are prohibited.
- 5.7.3** Electronic source data must be captured in validated systems with audit trail functionality.
- 5.7.4** CRFs (paper or electronic) must be completed in accordance with the sponsor's completion guidelines and submitted per agreed timelines.
- 5.7.5** All source documents supporting CRF data must be available for review by sponsor monitors, auditors, and regulatory inspectors.
- 5.7.6** Subject identifiers (e.g. subject number, initials) must be used in lieu of full names in data submissions to protect confidentiality.

## **5.8 Monitoring and audits**

- 5.8.1** The site shall cooperate fully with sponsor-initiated monitoring visits. Monitors shall be provided access to all relevant source documents, CRFs, IP records, and regulatory files.
- 5.8.2** All monitoring findings (queries, action items) shall be addressed promptly, documented, and resolved in the CRF or ISF as directed.
- 5.8.3** The site shall cooperate fully with sponsor audits and regulatory inspections (FDA, EMA, and others). Site staff must not obstruct, mislead, or limit access to any study documentation.
- 5.8.4** In the event of an unannounced FDA inspection, the PI or designee shall immediately contact the sponsor's regulatory affairs team.

## **5.9 Investigator site file (ISF) and regulatory binder maintenance**

- 5.9.1** An ISF shall be established and maintained for each clinical trial conducted at the site.
- 5.9.2** The ISF must contain, at a minimum, IRB approvals and correspondence; the signed protocol and all amendments; signed informed consent form(s); the delegation of authority log; staff training records and CVs; financial disclosure forms; the Investigator's Brochure or current package insert and updates; investigational product accountability records; the subject enrollment log; the protocol deviation log; monitoring visit reports and related correspondence; SAE reports and correspondence; all laboratory certifications and normal ranges (if applicable); and sponsor correspondence and agreements.
- 5.9.3** ISFs shall be maintained in a secure location accessible only to authorized personnel.
- 5.9.4** Records shall be retained for a minimum of 3 years after the last marketing application approval, or 3 years after the investigation is discontinued and FDA notified (per 21 CFR 312.62), unless a longer period is required by the sponsor agreement or applicable law.

## **5.10 Subject confidentiality and privacy**

- 5.10.1** Subject identities shall be kept confidential in all study documentation. Only the sponsor, monitors, auditors, IRB, and regulatory authorities who require access shall be permitted to review identifiable subject records.
- 5.10.2** All research data shall be stored securely. Electronic files shall be protected by password and access controls. Paper records shall be stored in locked cabinets in restricted-access areas.
- 5.10.3** Site staff shall comply with all applicable privacy regulations including HIPAA.
- 5.10.4** Subjects must be informed in the consent form of how their data will be used, stored, and shared.

## **5.11 Training requirements**

- 5.11.1** All personnel conducting or supporting the clinical trial must complete GCP training (ICH E6) prior to performing any study-related activities. Refresher training is required every 4 years or as required by the sponsor or IRB.
- 5.11.2** All personnel must complete protocol-specific training prior to performing any trial procedures and document this training in the delegation and training log.
- 5.11.3** Training records (certificates, sign-in sheets, completion logs) shall be maintained in the ISF and individual personnel files.
- 5.11.4** Human subjects protection training (e.g. CITI Program) shall be completed and kept current per IRB requirements.

## **5.12 Financial disclosure and conflict of interest**

- 5.12.1** The PI and all sub-investigators shall complete FDA financial disclosure forms (Form FDA 3454 or 3455) prior to study initiation and update them as required during the study and at study closeout.
- 5.12.2** Any actual or potential conflicts of interest shall be disclosed to the IRB and sponsor and managed per site policy.

## **5.13 Study closeout**

- 5.13.1** Upon study completion or termination, the site shall conduct a closeout visit with the sponsor or CRO monitor to reconcile all documents, CRFs, and IP.
- 5.13.2** Outstanding queries shall be resolved and all CRF data shall be finalized.
- 5.13.3** Remaining IP shall be returned to the sponsor or destroyed per protocol instructions.
- 5.13.4** The IRB shall be notified of study completion and a final report submitted as required.
- 5.13.5** All study records shall be archived per the retention schedule in section 5.9.4.

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# **6 Related documents**

N/A

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# **7 References**

- ICH E6(R2) Guideline for Good Clinical Practice (2016, with integrated addendum)
- ICH E6(R3) Good Clinical Practice Guideline (2023 Final)
- 21 CFR Part 50 — Protection of Human Subjects (Informed Consent)
- 21 CFR Part 56 — Institutional Review Boards
- 21 CFR Part 312 — Investigational New Drug Application (IND)
- 21 CFR Part 812 — Investigational Device Exemptions (IDE)
- 45 CFR Part 46 — Protection of Human Subjects (Common Rule)
- Declaration of Helsinki (World Medical Association, most recent revision)
- The Belmont Report (1979) — Ethical Principles and Guidelines for the Protection of Human Subjects
- FDA Guidance: Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring
- Applicable sponsor protocol and agreements

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## 8 Appendices

N/A

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## 9 Revision history

| VERSION | EFFECTIVE DATE | DESCRIPTION OF CHANGE |
|---------|----------------|-----------------------|
| 1.0     | 9/28/2026      | Initial release.      |