



KORDATA
DYNAMICS

GOOD CLINICAL PRACTICE TRAINING

SOP-001: Human subjects protection & *good clinical practice*

Clinical research staff training

DOCUMENT NO.

SOP-001

DEPARTMENT

Clinical Research

VERSION / STATUS

1.0 — Approved

EFFECTIVE DATE

Sept 16, 2026



What we'll cover *today*

- 01 Purpose & scope
- 02 Regulatory framework
- 03 Key definitions
- 04 Roles & responsibilities
- 05 IRB review & approval
- 06 Informed consent
- 07 Subject eligibility & screening
- 08 Protocol compliance & deviations
- 09 AE / SAE reporting

- 10 Investigational product mgmt
- 11 Data & documentation
- 12 Monitoring & audits
- 13 Investigator site file / regulatory binder
- 14 Confidentiality & privacy
- 15 Training requirements
- 16 Financial disclosure & COI
- 17 Study closeout

01

Purpose & *scope*

SOP objectives & who it applies to

Purpose & scope

PURPOSE

This SOP establishes requirements and procedures for protecting human subjects and ensuring adherence to Good Clinical Practice (GCP) principles at this clinical trial site.

All clinical research must comply with applicable:

- Applicable regulations & regulatory requirements
- Ethical principles governing human subjects research
- Sponsor requirements and protocol specifications

SCOPE

Applies to ALL research staff involved in clinical research activities at this site:

- Principal Investigators (PIs)
- Sub-Investigators
- Clinical Research Coordinators (CRCs)
- All Site Staff in Research Activities

COVERS

All research involving regulated by FDA or subject to *ICH GCP guidelines*

02

Regulatory *framework*

ICH GCP, CFR, Helsinki & Belmont

02

SECTION 02

Regulatory & ethical framework

The foundation of everything we do

ICH E6(R2/R3) International GCP Standard	2016 addendum (R2) + 2023 final guideline (R3). The global benchmark for designing, conducting, recording & reporting clinical trials.
21 CFR PART 50 – FDA Protection of Human Subjects	Governs informed consent requirements. Defines the rights of research participants and essential consent documentation standards.
21 CFR PART 56 – FDA Institutional Review Boards	Establishes IRB composition, operations, and review requirements. Mandates independent oversight of research involving human subjects.
21 CFR PARTS 312 & 812 IND & IDE Requirements	Governs Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications, sponsor obligations, and site responsibilities.
45 CFR PART 46 – HHS The Common Rule	Federal policy for protection of human subjects in federally funded research. Sets baseline ethical & procedural standards across U.S. agencies.
ETHICAL FOUNDATIONS <i>Declaration of Helsinki & Belmont Report</i>	Foundational ethical principles: respect for persons, beneficence & justice. The moral bedrock underlying all GCP regulations worldwide.

03

Key definitions

AE, SAE, GCP, PI, IRB & more

Key definitions

AE Adverse Event	Any untoward medical occurrence in a participant given an investigational product; does not require a causal relationship with treatment.	Sub-Investigator	Clinical trial team member designated and supervised by the PI to perform critical trial-related procedures.
SAE Serious Adverse Event	An AE resulting in death, a life-threatening condition, inpatient hospitalization, persistent disability, or congenital anomaly / birth defect.	Clinical Trial	Research study where human subjects are prospectively assigned to interventions to evaluate health-related outcomes.
GCP Good Clinical Practice	International quality standard for designing, conducting, recording, and reporting clinical trials — ensuring data integrity and subject protection.	Protocol	Document describing the objective(s), design, methodology, statistical considerations, and organization of a trial.
IFC Informed Consent	Process by which a subject voluntarily confirms willingness to participate after being informed of all relevant aspects of the study — risks, benefits, and alternatives.	Source Documents	Original records from which data are captured — hospital records, charts, lab notes, subject diaries.
IRB Institutional Review Board	Independent body ensuring the protection of rights, safety, and well-being of human subjects enrolled or recruited to participate in clinical research.	Sponsor	Individual, company, institution, or organization responsible for the initiation, management, or financing of a trial.
PI Principal Investigator	Individual responsible for the overall conduct of the trial at the site.	DSMB Data Safety Monitoring Board	Independent committee monitoring participant safety and study integrity.

These definitions apply to all clinical research staff covered under SOP-001. Familiarity is required before performing any study-related activities.

04

Roles & *responsibilities*

PI, Sub-I, CRC, Nurses & IRB

Roles & *responsibilities*

PI

Principal Investigator

- Overall site responsibility for trial conduct
- Ensures GCP compliance & protocol adherence
- Oversees all delegated duties & qualifications
- Reports SAEs to sponsor, IRB, & regulators
- Oversees & documents informed consent process

SUB-I

Sub-Investigators

- Perform PI-delegated clinical procedures
- Document all activities per GCP standards
- Report AEs & protocol deviations to PI
- Maintain current GCP & protocol-specific training
- Act only within scope of delegation log

CRC

Clinical Research Coordinator

- Manages day-to-day trial operations
- Maintains ISF / Regulatory Binder
- Enters & verifies CRF data per guidelines
- Tracks milestones, deviations & timelines
- Ensures investigational product accountability

Roles & *responsibilities*

RN / STAFF

Research Nurses / Study Staff

- Perform nursing procedures & assessments
- Document contemporaneously in source records
- Report AEs to PI immediately upon awareness
- Adhere strictly to protocol & delegation log
- Maintain current training before performing tasks

DIRECTOR

Site Director / Research Manager

- Oversees site-level SOP compliance
- Manages staffing & resource allocation
- Ensures all staff training is current & documented
- Conducts internal audits & quality reviews
- Escalation point for site-level compliance issues

IRB

Institutional Review Board

- Reviews & approves protocols & amendments
- Reviews & approves all consent form versions
- Conducts continuing review before expiration
- Receives unanticipated problem & SAE reports
- Provides written approval documentation for ISF

Principal Investigator’s responsibilities

REGULATORY BASIS

PI responsibilities are mandated under 21 CFR §312.60, ICH E6(R2) Section 4, and the signed FDA Form 1572. Failure to meet these obligations may result in clinical hold, warning letter, or debarment.

- 01

Overall responsibility for trial conduct at the site — non-delegable authority
- 02

Ensure trial conducted per signed protocol, GCP, and applicable regulations
- 03

Supervise all delegated duties — ensure staff are qualified and trained before performing tasks
- 04

Sign and date delegation log and all required regulatory documents personally
- 05

Ensure adequate resources: qualified staff, appropriate facilities, and functioning equipment
- 06

Report ALL SAEs & unanticipated problems to IRB, sponsor & regulatory authorities within required timelines
- 07

Oversee the informed consent process and ensure proper documentation for every subject
- 08

Complete FDA Financial Disclosure Forms (FDA 3454 or 3455) prior to study start and at closeout

05

IRB review & *approval*

Submissions, renewals & amendments

IRB review & approval

No research begins without *prior written IRB approval*

1

Submit to IRB Before Study Initiation

Complete protocol + all amendments
Informed consent forms & recruitment materials
Investigator’s Brochure (IB), if applicable
CVs & training records for key personnel

2

Obtain Written IRB Approval

MANDATORY GATE

3

Continuing Review

TIME SENSITIVE
If approval lapses → study MUST be suspended immediately

4

Protocol Amendments

PRIOR APPROVAL REQ.
Exception: Changes to eliminate immediate hazard to subjects

5

Unanticipated Problems

10 BUSINESS DAYS
— or per sponsor instructions, whichever is sooner

Study must stop if IRB approval lapses — no exceptions.

Any lapse in approval requires immediate suspension of all study activities until re-approval is obtained in writing.

06

Informed *consent*

Process, elements & special populations

Informed consent — *the process*

■ 1	Private Setting	Consent discussion conducted in private, in the language the subject understands, free of coercion or undue influence.
■ 2	Explain All Elements	Purpose, procedures, risks, benefits, alternatives, confidentiality, compensation/injury treatment, contact info, and right to withdraw — all must be covered.
■ 3	Adequate Time	Subject / LAR given adequate time to review, ask questions, and consult family or advisors before signing. No rushing or pressure.
■ 4	Signature	Signed and dated consent obtained BEFORE any study procedures or screening assessments begin. No exceptions.
■ 5	Copy to Subject	A copy of the signed and dated consent form must be provided to the participant at the time of signing.
■ 6	Re-consent Required	Required when new information arises (protocol amendment, new safety data). Re-consent must be documented in the subject's file.
■ 7	Special Populations	Minors / cognitively impaired subjects require LAR consent + subject assent where developmentally appropriate. Document both.

Required elements of *informed consent*

1 Purpose Research purpose clearly stated; subject understands why the study is being conducted.	2 Procedures All study procedures described; experimental ones explicitly identified as such.	3 Risks & Discomforts All reasonably foreseeable risks and discomforts to the participant fully explained.
4 Benefits Expected benefits to the participant or others described; no exaggeration permitted.	5 Alternatives Other available treatments or procedures disclosed so subject can make an informed choice.	6 Confidentiality Extent to which records will remain confidential; who may access identifiable data.
7 Compensation Available treatment for research-related injury and any compensation disclosed (if applicable).	8 Contact Information Who to contact with questions, rights concerns, or in the event of a research-related injury.	9 Voluntariness Participation is voluntary; subject may withdraw at any time without penalty or loss of benefits.

Each element must appear in writing AND be verbally communicated to the subject or LAR before any study procedure begins.

07

Subject eligibility & *screening*

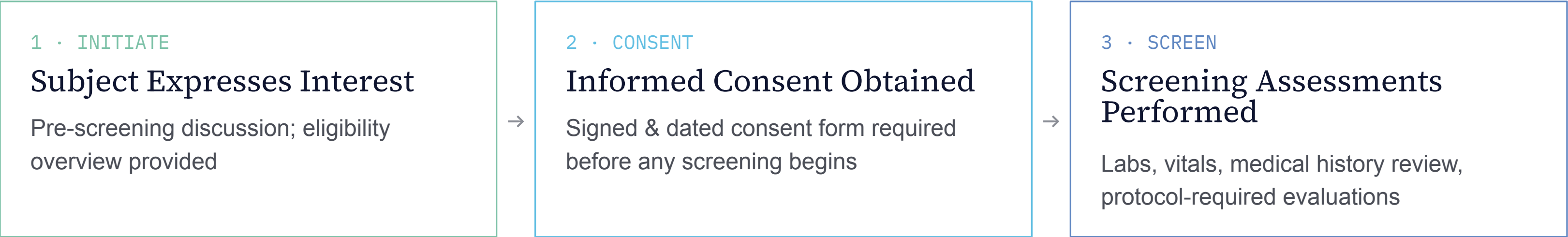
Inclusion/exclusion criteria & enrollment log

Subject eligibility & *screening*

Verify eligibility
rigorously —
every subject, every
time, no exceptions

INCLUSION/EXCLUSION VERIFICATION	Verify ALL inclusion/exclusion criteria for each subject BEFORE enrollment — no exceptions permitted under any circumstance.
SIGNED CONSENT FIRST	All screening assessments must be conducted under a signed and dated consent form — consent precedes every screening activity.
DOCUMENTATION REQUIRED	Eligibility determinations must be documented in source documents prior to enrollment.
ELIGIBILITY WAIVERS	Waivers require PRIOR written approval from the sponsor’s medical monitor — no retroactive waivers accepted.
ENROLLMENT LOG MAINTENANCE	Maintain a subject enrollment log tracking all screened and enrolled subjects — including screen failures with documented reason.

Screening workflow



Eligibility criteria are binary — a subject either qualifies or does not.

■ 4 · ELIGIBLE → ENROLL		■ 4 · SCREEN FAIL → LOG	
a All I/E criteria met	b Document in source + CRF	a Criteria not met	b Document reason
c Assign subject ID	d Randomize/enroll	c Log in enrollment log	d Notify subject

Document every determination. Track every screen failure. No enrollment without documented eligibility.

08

Protocol compliance & *deviations*

Reporting workflow & CAPA process

Protocol compliance & *deviation management*

- DOCUMENT

■ 1

Record the deviation promptly in source documents and CRF (if applicable)
- NOTIFY

■ 2

Notify the PI immediately
- ASSESS

■ 3

Assess impact on subject safety and data integrity

- REPORT TO SPONSOR

■ 4

Report to the sponsor per their instructions
- SUBMIT TO IRB

■ 5

Submit to IRB if required by policy or regulation
- COMPLETE DEVIATION REPORT

■ 6

Complete a Protocol Deviation/Violation Report Form and file in ISF deviation log

All activities must follow the IRB-approved protocol — no unauthorized deviations

RECURRING DEVIATIONS — CAPA REQUIRED

Trigger a CAPA (Corrective and Preventive Action) process — document root cause and corrective steps

EXCEPTION

Deviations to eliminate an immediate hazard to subjects may occur without prior approval — but must be reported immediately to sponsor & IRB

09

AE / SAE reporting

24-hr SAE requirement & documentation

Adverse events (*AE*)

RECORDING RULES

- 01 Record ALL AEs from time of consent through the end of follow-up period defined in the protocol
- 02 Document in source documents AND CRF — both records required
- 03 All AE documentation retained in ISF and subject source file

All untoward medical occurrences — regardless of causality

REQUIRED AE ASSESSMENT FIELDS

- 01 Onset Date
- 02 Description
- 03 Severity (CTCAE Grade)
- 04 Relationship to IP
- 05 Outcome
- 06 Action Taken

Serious adverse events (SAE)

24
h

Report to SPONSOR
within 24 HOURS of PI
awareness — *no
exceptions, no delays*

Report to IRB within 5–10 business days per IRB policy

Forward SUSAR reports received from sponsor to IRB per IRB instructions

All SAE documentation retained in ISF and subject source file

SAE CRITERIA — ANY ONE QUALIFIES

- Death
- Life-Threatening
- Hospitalization
- Persistent Disability
- Congenital Anomaly

10

Investigational product *management*

Receipt, storage, dispensing & return

Investigational product (*IP*) *management*

IP ACCOUNTABILITY IS A CRITICAL GCP REQUIREMENT

Receipt, Storage, Dispensing, Return/Destruction

Authorized personnel only — per signed Delegation of Authority Log. All IP transactions require documentation.

■ Storage Conditions	Must meet protocol and Investigator’s Brochure (IB) specifications (if applicable) — temperature, light, and humidity. Temperature monitoring logs maintained and reviewed daily.
■ IP Accountability Log	Document every unit received, dispensed, returned, and destroyed. Log must be complete, current, and available for inspection at all times.
■ Dispensing	Only to enrolled, subjects under valid prescription, per protocol instructions. No exceptions to eligibility requirements.
■ Returns / Destruction	Unused, expired, or recalled IP returned to sponsor or destroyed per sponsor instructions. Retain all destruction documentation in ISF.



IP accountability — *key rules*

RECEIPT

Log every unit upon arrival

Authorized

Only personnel listed on the current Delegation Log may handle investigational product.

Prescription

Valid prescription required (where applicable) prior to dispensing. File in subject source record.

DISPENSE



Eligible subjects only, per protocol

Temp Log

Temperature excursions must be documented and reported to the sponsor immediately. Do not use affected IP until cleared.

Destruction

Witnessed destruction required. Document witness name, date, method, and quantity. File certificate in ISF.

RETURN / DESTROY



Document & retain all certificates

Every Unit

Each unit of IP must be reconciled: quantity received = dispensed + returned/destroyed. Zero unaccounted units.

IP must NEVER be used for any purpose other than the clinical trial — no exceptions, no deviations.

11

Data & *documentation*

Source docs, CRF & data integrity rules

Data collection, management & *source documentation*

DATA QUALITY & DOCUMENTATION RULES

Record Data: *Promptly · Accurately · Legibly · Contemporaneously*

Data must be recorded at the time of observation — not reconstructed later from memory. Capture in source documents immediately.

Paper Corrections: Single-Line Strikethrough Only

PROHIBITED

Electronic Source Data: Validated Systems Required

Must be captured in validated electronic systems with audit trail functionality. Audit trails must not be disabled or bypassed at any time.

CRF, ACCESS & CONFIDENTIALITY

CRF Completion: Per Sponsor Guidelines & Agreed Timelines

Complete Case Report Forms per the sponsor’s instructions. Submit within the agreed timelines. Address data queries promptly and document all query resolutions.

Source Documents: Always Available for Inspection

Source documents must be available at all times for review by sponsor monitors, auditors, and regulatory inspectors — including unannounced FDA visits.

Confidentiality: Use Subject Identifiers — NEVER Full Names

Use subject numbers and initials only in all data submissions, CRFs, and reports. Full names must never appear in data transmissions to sponsor or regulatory bodies.

Accurate, contemporaneous data is the foundation of clinical research integrity

SECTION 11

If it wasn't
documented, *it didn't
happen.*

12

Monitoring & *audits*

Sponsor visits, audits & FDA inspections

Monitoring & *audits*

COOPERATE FULLY

Sponsor Monitoring Visits

Provide access to source documents, CRFs, IP records & regulatory files

Address all monitoring findings, queries & action items promptly

Document & resolve in CRF or ISF as directed by monitor

COOPERATE FULLY

Sponsor Audits

Do NOT obstruct, mislead, or limit access to study documentation

All documents must be immediately accessible upon request

Answer questions truthfully & completely — provide full context

HIGH ALERT

Regulatory Inspections FDA / EMA

Cooperate fully — provide all requested documentation

UNANNOUNCED FDA Inspection: Immediately contact sponsor’s regulatory affairs team — do not delay

YOUR ROLE

Your Rights & Obligations

Right: Consult with the site director at any time

Obligation: Provide complete, accurate records

NEVER alter or backdate any study document

In the case of an unannounced FDA inspection:

Stop all non-urgent activities — immediately notify the sponsor’s regulatory affairs team. Do not answer regulatory questions without guidance.

13

Investigator site file / *regulatory binder*

Establish and maintain

Investigator site file (ISF) / *regulatory binder*

REQUIRED CONTENTS

01	IRB approvals and correspondence	08	IP accountability records
02	Signed protocol and all amendments	09	Subject enrollment log
03	Signed informed consent forms	10	Protocol deviation log
04	Delegation of authority log	11	Monitoring visit reports & correspondence
05	Staff training records and CVs	12	SAE reports & correspondence
06	Financial disclosure forms	13	Lab certifications, normal ranges & sponsor agreements
07	Investigator’s Brochure / package insert & updates		

An ISF must be established and maintained for every clinical trial

RETENTION RULE – 21 CFR 312.62

2 YEARS MIN.

Records must be retained for a minimum of 2 years after last marketing application approval, OR 2 years after investigation is discontinued and FDA notified — whichever is later, or longer per sponsor agreement. ISF must be stored securely — accessible only to authorized personnel.

Delegation of *authority* log

01 Signed & Dated Log Required for Every Study

Every clinical trial site must maintain a signed and dated Delegation of Authority Log — it is a GCP essential document and must be present in the ISF at all times.

04 Tasks Only After Name, Initials, Signature & Training Are on Record

Tasks may ONLY be performed once the individual’s name, initials, and signature appear on the log AND all required training has been completed and documented.

02 Log Identifies Staff, Qualifications & Authorized Tasks

The log must list all study staff members, their qualifications, and the specific tasks they are authorized to perform under the direction of the Principal Investigator.

05 Update Log When Staff or Roles Change

The log must be updated promptly whenever staff are added or removed from the study, or when role assignments or task delegations change. An outdated log is a GCP finding.

03 PI Must Personally Sign the Log

The Principal Investigator must personally sign the log — confirming that each listed individual is qualified and trained for their assigned responsibilities. No proxy signatures are acceptable.

06 Maintained in ISF Throughout Trial & Retention Period

The Delegation Log must remain in the ISF throughout the entire trial and be retained for the full records retention period — accessible to monitors, auditors, and FDA inspectors at all times.

No training documentation = No authorization to perform tasks

PI signature is mandatory — delegation is not valid without it

14

Confidentiality & *privacy*

Subject confidentiality & *privacy*

01 Identity Protection Subject identities kept confidential in ALL study documentation Only authorized parties may access identifiable records: Sponsor · Monitors · Auditors · IRB · Regulatory Authorities No unauthorized disclosure — ever	02 Secure Data Storage Electronic files: Password-protected with access controls Audit trails required for all validated electronic systems Paper records: Locked cabinets in restricted-access areas only Unauthorized access must be reported immediately	03 HIPAA Compliance All staff must comply with HIPAA and all applicable privacy regulations Data use, storage, and sharing must be disclosed in consent form HIPAA Authorization obtained when required by regulation Breaches must be reported per institutional and regulatory policy	04 Identifiers in Data Use subject numbers & initials ONLY in all submissions Never use full names in data, reports, or CRF entries Subject identification log linking codes to names: secured separately Applies to emails, queries, monitoring logs, and correspondence
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Protecting participant identity is a legal and ethical obligation

Consent form must clearly explain how subject data will be used, stored, and shared — prior to any research activity.

15

Training *requirements*

Training *requirements*

All personnel must be trained BEFORE performing any study-related activities

TRAINING		WHEN REQUIRED	MAINTENANCE
■ 01	GCP training — ICH E6	Required BEFORE study start	Refresher: Every 3 years or per sponsor/IRB requirement
■ 02	Protocol-specific training	Required BEFORE any trial procedures	Documented in delegation & training log
■ 03	CITI Program — human subjects	Required per IRB requirements	Must be kept current — no lapsed certifications

No training documentation = *no authorization to perform study tasks.*

All training records must be filed in the ISF and personnel file BEFORE any study activities begin.

16

Financial disclosure & *COI*

Financial disclosure & *conflict of interest*

Who must disclose

REQUIRED PERSONNEL

Principal Investigator (PI)

Overall site responsibility — disclosure mandatory

ALL Sub-Investigators

Every sub-investigator listed on the delegation log

REQUIRED FDA FORMS

FDA FORM **3454**
No disclosable financial interests

FDA FORM **3455**
Disclosable financial interests exist

WHEN TO SUBMIT

- 01 Prior to study initiation
- 02 During the study as required (updates)
- 03 At study closeout

Financial disclosure & *conflict of interest*

What must be disclosed

DISCLOSURE SCOPE

Actual or Potential Conflicts of Interest

Any relationship that could bias study conduct or reporting

Significant Financial Interests

Financial interests related to the research or sponsor

DISCLOSED TO

IRB

Institutional Review Board

SPONSOR

Study sponsor / CRO

MANAGEMENT

Managed per site conflict of interest policy

Follow institutional COI management plan if interests identified

Financial disclosure forms are required essential documents and must be filed in the ISF.

17

Study closeout

Study closeout *procedures*

1 Schedule Closeout Visit Coordinate with sponsor/CRO monitor to schedule and conduct the formal site closeout visit.	2 Resolve Outstanding Queries All data queries must be resolved and all CRF data finalized before closeout is complete.	3 IP Reconciliation All remaining investigational product returned to sponsor or destroyed per protocol instructions. Document everything.	4 Notify IRB Submit the final study completion report to the IRB as required by IRB policy and applicable regulations.	5 Archive Records All study records archived per retention schedule. Minimum retention: 2 years after last marketing application approval or 2 years after FDA notification of discontinuation.
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A formal closeout visit with the sponsor/CRO monitor is required upon study completion or termination

*Study closeout is not complete until all documents are archived and the ISF is finalized and secured**

* Per 21 CFR 312.62 — or longer if required by sponsor agreement. Ensure ISF is stored securely and access-controlled.

GOOD CLINICAL PRACTICE

“The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over *interests of science and society*. ”

– ICH E6(R2) Good Clinical Practice

The foundation: *ethical principles*

RESPECT FOR PERSONS

Autonomy & Dignity

Voluntary participation

Informed consent

Vulnerable populations

BENEFICENCE

Do Good. Minimize Harm.

Maximize benefits

Minimize risks

Ongoing safety monitoring

JUSTICE

Fair Distribution

Equitable selection

Fair risk–benefit

No exploitation

These are not just regulations. They are ethical obligations.

Key takeaways — SOP-001

- 01

No research begins without prior written IRB approval.
- 02

Informed consent must be obtained before ANY study procedure.
- 03

All eligibility criteria must be verified and documented before enrollment.
- 04

Protocol deviations must be documented, reported, and tracked immediately.
- 05

SAEs must be reported to sponsor within 24 hours of PI awareness — no exceptions.
- 06

IP must be stored per protocol specifications with daily temperature monitoring.
- 07

Data must be recorded promptly, accurately, and contemporaneously — no white-out.
- 08

Subject identities must remain confidential — use subject numbers, not names.
- 09

All staff must complete GCP & protocol-specific training BEFORE performing any study tasks.
- 10

All study records must be retained per regulations — minimum 2 years post-marketing application.

These principles protect participants, preserve data integrity, and ensure regulatory compliance — every study, every time.

TRAINING COMPLETE

Thank you for completing *SOP-001 training*

Human Subjects Protection & Good Clinical Practice



ACTION REQUIRED

Sign and date your training acknowledgment form and return it to the Site Study Coordinator. Certificates and training records will be filed in the ISF and your personnel file.

QUESTIONS? CONTACT YOUR TEAM

Reach out to your Principal Investigator or Study Coordinator with any questions about SOP-001 or your study activities.

RELATED SOPS

Reference SOP-002 through SOP-003 for procedure-specific guidance covering your assigned study activities and site protocols.

NEXT STEPS: PROTOCOL-SPECIFIC TRAINING

Complete protocol-specific training before performing any study activities. No tasks may begin until training is documented.