Purpose:

This document is meant to provide guidance and a template for creating study team standard operating procedures. The document should be modified for study-specific needs/requirements.



**Regulatory Binder – Study Devices**

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**Protocol**

(Current approved version)

**Previous Protocol Versions**

**Research Consent Form**

(Current approved, stamped version)

**Previous Research Consent Form Versions**

**Device Manual**

(Current version, package inserts, reports of prior investigations)

**Previous Device Manuals**

**IRB Submissions, Correspondence and Approvals\***

* Initial Application
* Continuing Reviews
* Amendments
* Unanticipated Problems
* Reports of Noncompliance
* Study Closure

\*Note if documents are saved in InfoEd

note to file

Study title:

IRB #:

PI:

date:

SUBJECT:

Corrective Action plan (when appropriate):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature date

**Other Approvals**

(e.g., UCHealth Research Administration, Scientific Advisory and Review Committee (SARC), Protocol Review and Monitoring System (PRMS), Institutional Biosafety Committee (IBC), Radioactive Drug Research Committee (RDRC), etc.)

**Adverse Device Effects & Unanticipated Problem Guidance and Tools**

**Unanticipated Adverse Device Effect Definition:** [**http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046698.htm**](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046698.htm)

**COMIRB Annual Aggregate Safety Report Form:**

[**http://gcrc.ucdenver.edu/comirb/CF-251-Annual-Safety-Summary-Report-Form.xlsx**](http://gcrc.ucdenver.edu/comirb/CF-251-Annual-Safety-Summary-Report-Form.xlsx)

**Reporting Requirements for Unanticipated Adverse Device Effects:**

[**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.150**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.150)

**How to Submit an Unanticipated Problem (UAP) Report to COMIRB:**

**http://www.ucdenver.edu/research/comirb/submissions/Pages/default.aspx**

**ADVERSE DEVICE EFFECTS (Anticipated and Unanticipated) &**

**UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS LOG**

*(Sample definitions to be revised as applicable)*

**Severity: Causality: Frequency: Outcome: Action taken: Category: Reported to:**

1 = mild 1 = no relation once resolved 0 = no action 1 = UAP 1 = IRB within 5 days

2 = moderate 2 = possibly related intermittent ongoing 1 = study intervention adjusted 2 = ADE 2 = Sponsor

3 = severe 3 = probably related persistent resolved 2 = study intervention discontinued 3 = UADE\* 3 = Lead site

4 = serious 4 = definitely related with sequelae 3 = concomitant medication taken 4 = FDA

deceased 5 = IRB at Cont. Review

unknown

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| **SUBJECT ID** | **EVENT DESCRIPTION** | **START DATE** | **STOP**  **DATE** | **UNANTICIPATED?**  **(Y/N)** | **SEVERITY** | **CAUSALITY** | **FREQUENCY** | **OUTCOME** | **ACTION TAKEN** | **CATEGORY** | **REPORTED TO** | **PI INITIAL & DATE** |
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\*All UADEs are also UAPs, but not all UAPs are UADEs.

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**Noncompliance Guidance and Tools**

(e.g., protocol deviations, protocol violations, noncompliance with regulations, noncompliance with requirements of IRB, noncompliance with institutional policy)

**COMIRB Safety Report Decision Tree (for help determining which noncompliance needs to be reported and when):**

[**http://gcrc.ucdenver.edu/comirb/CF-253-Safety-Report-Decision-Tree.pdf**](http://gcrc.ucdenver.edu/comirb/CF-253-Safety-Report-Decision-Tree.pdf)

**COMIRB Annual Aggregate Protocol Deviation/Noncompliance**

**Report Form:**

[**http://gcrc.ucdenver.edu/comirb/CF-252-Annual-Protocol-Deviation-Summary-template.xlsx**](http://gcrc.ucdenver.edu/comirb/CF-252-Annual-Protocol-Deviation-Summary-template.xlsx)

**Device Management**

(Records of receipt, use and disposition (e.g., dates, quantity, exposure to subjects), Investigational Product Management Plan (when applicable))

**Investigator Records and Reports for Investigational Device Exemptions:**

[**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.140**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.140)

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| **Device Accountability Log** | | | | | | | | | | | | | | | | |
| **Study Title:** | |  | | | | | | | | | | | | | | |
| **IRB #:** | |  | | | | | | | | | | | | | | |
| **PI:** | |  | | | | | | | | | | | | | | |
| **Storage Location:** | |  | | | | | | | | | | | | | | |
| **Device Name:** | |  | | | | | | | | | | | | | | |
| **DEVICE RECEIPT** | | | | | **DEVICE USE** | | | | | **DEVICE RETURN/REPAIR/DESTRUCTION** | | | | | | |
| Date Rec’d | Initials of Receiver | Lot #/ Serial or Model # | Device Type / Batch # | Comments | Date Used | Initials of Device Dispenser | Participant ID | Explant Date | Comments | RET=Returned  DES=Destroyed  REP=Repaired | Date | Initials | Auth # | # of Units | Reason | Comments |
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| **Screening and Enrollment Log** | | | | | | | | | |
| **Study Title:** |  | | | | | | | | |
| **IRB #:** |  | | | | | | | | |
| **PI:** |  | | | | | | | | |
| **Subject Identifier (initials or #)** | **Contact attempts** | **Screen Date** | **Eligible? (Y/N)** | **Consent Date** | **Study intervention start/stop date** | **Subject withdrawn from study? (Y/N)** | **Withdrawal reason, if given** | **Date data collated for Continuing Review** | **Comments** |
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| **Delegation of Duties Log** | | | | | | | | |
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| **Study Title:** |  | | | | | | | |
| **IRB #:** |  | | | | | | | |
| **Print Full Name** | | **Signature** | **Initials** | Study Role | **Key Delegated Study Task(s)\*\*** See Examples Listed Below | **Duration** | | Investigator's Authorization\* |
| **From:** | **To:** |
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\* Duties are delegated in accordance with training, education, recognized institutional practices, state laws and licensure stipulations. This could be documented via a Standard Operating Procedure, Note to File or by the PI signing and dating this log.

\*\* Identify key study tasks when delegated by the investigator. Examples of key delegated study tasks could include:

1 Obtain Informed Consent 5 Vitals 9 Regulatory Submissions 13 Assess Unanticipated Adverse Device Effects

2 Determine Eligibility 6 Phlebotomy 10 Investigational Product Management 14 Assess Unanticipated Problems

3 Obtain Medical History 7 Source Document Completion 11 Data Management 15 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4 Perform Physical Exams 8 Source Document Review and Signature 12 Assess Adverse Device Effects 16 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator Signature (to be signed at study close out):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** \_\_\_\_\_\_\_\_\_\_\_\_ **Page \_\_\_\_ of\_\_\_\_**

**Study Team Meeting/Training Log**

* Protocol specific meetings (e.g., study status, recruitment status, subject status, proposed amendments)
* Protocol specific training (e.g., trained on protocol amendments, familiar with inclusion and exclusion criteria, trained on the consent process)

**Study Team Meeting/Training Log**

Protocol ID/PI Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Attendees: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Discussion Highlights:

Staff Signature/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Trainer Signature/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Study Team Meeting/Training Log** | | |
| **Study Title:** |  | |
| **IRB #:** |  | |
| **PI:** |  | |
| **Date** | **Subject** | **Attendance** |
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**Monitor/Auditor Reports**

**Laboratory Normal Ranges\***

\*Note if maintained on a website and indicate where.