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.

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**Regulatory Binder – Social and Behavioral**

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**Protocol**

(Current approved version)

**Previous Protocol Versions**

**Research Consent Form**

(Current approved, stamped version)

**Previous Research Consent Form Versions**

**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 plan of action:

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

 Signature date

**Other Approvals**

(e.g., UCHealth Research Administration, Scientific Advisory and Review Committee (SARC))

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

**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)

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

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

**Unanticipated Problem Involving Risks to Subjects or Others and Adverse Events Guidance:**

[**http://www.hhs.gov/ohrp/policy/advevntguid.html**](http://www.hhs.gov/ohrp/policy/advevntguid.html)

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

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

*(Sample definitions to be revised as applicable)*

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

once Resolved 0 = no action 1 = UAP 1 = IRB within 5 days

intermittent Ongoing 1 = study intervention adjusted 2 = AE 2 = Sponsor

persistent Resolved 2 = study intervention discontinued 3 = Lead site

 with sequelae 4 = IRB at Cont. Review

 Deceased

 Unknown

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| **SUBJECT ID** | **EVENT DESCRIPTION** | **START DATE** | **STOP****DATE** | **UNANTICIPATED?****(Y/N)** | **FREQUENCY** | **OUTCOME** | **ACTION TAKEN** | **CATEGORY** | **REPORTED TO** | **PI INITIAL & DATE** |
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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)

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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 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2 Determine Eligibility 6 Phlebotomy 11 Data Management 14 Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3 Obtain Medical History 7 Source Document Completion 12 Assess Adverse Effects and Unanticipated Problems

4 Perform Physical Exams 8 Source Document Review and Signature

**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, etc.)
* Protocol specific training (e.g., trained on protocol amendments, familiar with inclusion and exclusion criteria, trained on the consent process, trained on administration of measure/survey and scoring methods, etc.)

**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.