CUH Institutional Review Board (IRB)

# Noncompliance, Unanticipated Problem, and New Information Report Form

This form must be completed by the Principal Investigator (PI) to report any noncompliance, unanticipated problems involving risks to participants or others (UPIRTSO), protocol deviations/violations, breaches of confidentiality, or new information that may affect the conduct of the study or the rights and welfare of participants, in accordance with applicable federal regulations, institutional policies, and IRB requirements.

This form may also be used for institutional documentation and reassessment of activities determined to be Not Human Subjects Research (NHSR), Quality Improvement (QI), or Evidence-Based Practice (EBP), where applicable.

Reportable events should be submitted promptly in accordance with IRB policy. Events involving potential increased risk to participants or others should generally be reported within 5 business days of discovery. Minor deviations or administrative issues should generally be reported within 10 business days.

For guidance on completing this form, please contact the Institutional Review Board (IRB) at irb@chaminade.edu.

| **SECTION A: Study Information** |
|---|
| **Principal Investigator (PI) Name:** |
| **Faculty Sponsor** (if applicable)**:** |
| **Additional Key Personnel** (if applicable)**:** |
| **Protocol ID:** |
| **Protocol Title:** |
| **Department/Affiliation:** |
| **Funding Source** (if applicable)**:** |
| **SECTION A.1: Activity Determination** |
| Was this activity determined to be **Human Subjects Research** under IRB oversight?<br>☐ Yes<br>☐ No – NHSR/QI/EBP/Other<br><br>If No, please explain why this report is being submitted and whether the event or new information may affect the original determination: |

**Response:**

## SECTION B: Report Classification

Select all that apply:

☐ Minor noncompliance
*(Failure to follow IRB requirements, regulations, or institutional policies that does not increase risk to participants or compromise rights/welfare)*
☐ Serious noncompliance
☐ Continuing noncompliance
☐ Protocol deviation/violation
*(Minor or significant departure from approved procedures; may or may not constitute noncompliance)*
☐ Unanticipated Problem (UPIRTSO)
*(Unexpected, related or possibly related to participation, and suggests participants or others are at greater risk than previously known)*
☐ Participant complaint/concern
☐ Breach of confidentiality/data security
☐ Informed consent issue
☐ Enrollment of ineligible participant(s)
☐ Lapse in IRB approval **(Please complete section 1A)**
☐ New information
*(New information that may affect participant safety, study conduct, or willingness to continue participation)*
☐ Other:

**NOTE:** Not all sections below may apply to every report type. Please complete all applicable sections based on the nature and severity of the event. The IRB may request additional information if needed.

## SECTION 1 (Q1): Event Description and Impact

**Q1.1 Describe the event or new information**

Provide a **clear, detailed, and standalone summary** of the event. Your description should be understandable without referring to the protocol.

Include, as applicable:

- Where and when the event occurred
- Timeline of events
- How the event was discovered and by whom
- Number of participants affected (or indicate "No participants affected")
- What should have happened versus what actually happened
- Relevant protocol sections or procedures
- Whether the event has been previously reported elsewhere

**Response:**

**Q1.2 Dates and Timeline**

- **Date(s) of occurrence:**
- **Date PI became aware:**
- **Date submitted to the IRB:**

## SECTION 1A: Additional Questions for Lapse in IRB Approval

(Complete only if "Lapse in IRB Approval" was selected in Section B)

**1A.1 Period of lapse in approval:**

- **From:**
- **To:**

**1A.2 Did any of the following occur during the lapse period?**

(Check all that apply)
☐ Recruitment/enrollment
☐ Interaction/intervention with participants
☐ Collection of identifiable private information
☐ Continued access to identifiable data
☐ Data analysis only
☐ Deidentified data analysis only
☐ Screening activities
☐ No research activities occurred
☐ Other:

**1A.3 Describe all research activities conducted during the lapse period, if applicable:**

**Response:**

**1A.4 Current status of the study:**

(Check all that apply)
☐ Recruitment
☐ Enrollment only
☐ Data collection
☐ Follow-up only
☐ Data analysis
☐ Closed to enrollment
☐ Long-term follow-up only
☐ Completed interactions with participants
☐ Study closed
☐ Other:

**1A.5 Are you currently:**

- Collecting identifiable data? ☐ Yes ☐ No ☐ Not applicable
- Interacting/intervening with participants? ☐ Yes ☐ No ☐ Not applicable

**1A.6 Describe any remaining research activities you hope to complete:**

**Response:**

## SECTION 1 (Q1): Event Description and Impact *(Continued)*

**Q1.3 Impact on the Study**

Describe what effect the event or new information has or may have on the conduct of the study.

Examples may include:

- Halting enrollment
- Modifying procedures
- Re-consenting participants
- Additional monitoring
- Closing a study arm
- Administrative corrective actions

**Response:**

**Q1.4 Impact on Participant Safety**

Were participants or others placed at increased physical, psychological, social, legal, economic, or privacy/confidentiality risk?

☐ Yes

☐ No

☐ Not applicable

If yes or no, provide **justification**:

- Explain why participant safety was or was not likely affected
- Include any supporting rationale or follow-up actions
- Describe how adverse outcomes were addressed, if applicable

**Response:**

**Q1.5 Impact on Data Integrity**

Was data integrity impacted?
☐ Yes
☐ No
☐ Not applicable

Data integrity includes the **accuracy, completeness, and reliability of data**.

Provide rationale:
- Describe whether data were incomplete, inaccurate, altered, lost, or compromised
- Explain whether study aims or analyses may be affected

**Response:**

## SECTION 2 (Q2): Corrective and Preventive Actions (CAPA)

**Q2.1 Immediate Actions Taken**

Describe any immediate actions taken to mitigate risk and protect participants or data integrity.

Examples:
- Participant notification or re-consent
- Suspension of procedures
- Staff retraining
- Additional monitoring
- Securing data/systems

If no action was taken, please explain why.

**Response:**

**Q2.2 Root Cause Analysis**

(Complete if applicable. The IRB may request additional analysis for serious or continuing noncompliance.)

Describe the underlying cause(s) of the event.

Consider:
- Process failures
- Training gaps
- Communication breakdowns
- System issues
- Human error

**Response:**

**Q2.3 Corrective and Preventive Action Plan (CAPA)**

(Complete if applicable)

Describe actions to prevent recurrence.

Include:

- Corrective actions
- Timeline for implementation
- Monitoring or oversight plans
- Staff education/training

**Response:**

**Q2.4 Will this event result in changes to the study?**

☐ Yes
☐ No
☐ Not applicable

**Q2.4.1 If yes, describe proposed changes:**

- Protocol
- Consent documents
- Study procedures
- Recruitment materials
- Data security measures
- Other:

**Response:**

**Q2.4.2 If no, explain why changes are not necessary:**

Examples:

- Minor administrative issues
- No increased risk
- Study closed
- No participant impacts

**Response:**

## SECTION 3 (Q3): Overall Assessment

**Q3.1 Impact on Risk/Benefit Ratio**

(Complete if applicable.)

Describe how this event affects the overall risk/benefit ratio of the study, if at all.

Consider:

- Whether risks are greater than previously understood
- Whether benefits are reduced
- Whether the study remains ethically justifiable

**Response:**

## SECTION 4: Notifications

Has this event been reported to or discussed with any of the following?

| Entity | Notified? | Date |
|---|---|---|
| IRB | ☐ Yes ☐ No | |
| Faculty Sponsor | ☐ Yes ☐ No ☐ N/A | |
| Department Chair/Dean | ☐ Yes ☐ No ☐ N/A | |
| Funding Source | ☐ Yes ☐ No ☐ N/A | |
| Other: | ☐ Yes ☐ No ☐ N/A | |

## SECTION 5: Supporting Documentation

Attach all applicable materials:

☐ Revised protocol
☐ Consent forms
☐ Recruitment materials
☐ Monitoring/audit reports
☐ Correspondence
☐ Data/security documentation
☐ Faculty Sponsor communication
☐ Project site communication
☐ Other:

## SECTION 6: PI Certification

I certify that the information provided is accurate and complete to the best of my knowledge. I understand that failure to comply with IRB reporting requirements may result in IRB actions, including suspension or termination of approval, when applicable.

**PI Name:**

**Signature:**

**Date:**

## IRB Chair/Vice-Chair Use Only (Do Not Complete)

**Date Received:**

**Review Type:**

☐ Exempt
☐ Expedited
☐ Limited Activity Determination
☐ Full Board
☐ Other:

**Determination**

☐ No noncompliance
☐ Minor noncompliance
☐ Serious noncompliance
☐ Continuing noncompliance
☐ Serious and continuing noncompliance
☐ UPIRTSO
☐ Administrative issue only
☐ NHSR/QI/EBP determination unchanged
☐ NHSR/QI/EBP determination requires reassessment

**Actions:**

☐ None
☐ Modification required
☐ CAPA required
☐ Training required
☐ Monitoring
☐ Suspension
☐ Termination
☐ Report to OHRP/Federal agency (if applicable under reporting requirements)
☐ Report to Sponsor (funding source)
☐ Other: