CDPH IRB Unanticipated Problems, Adverse Events, and Protocol Deviations Report

Project IRB#
Project Title:
Principal Investigator:

PI Telephone:	**PI E-mail**:
PI Mailing Address:	
Home Institution/Organization:	

CDPH IRB requires investigators to promptly report "any unanticipated problems involving risks to subjects or others." **Breaches of confidentiality, unanticipated problems and adverse events that are 1) possibly related to the research and 2) may increase risk to subjects or others must be reported on this form and submitted to CDDH IRB within five working days of knowledge of the event.** Protocol deviations from CDPH IRB approved protocol should also be reported using this form within ten working days of knowledge of the event.
All unanticipated problems as defined below should be reported on this form.

> *Note: Adverse events that are expected, do not involve increased risks to subjects, or are deemed not to be related to the research should not be reported on this form, but should be listed on the annual Progress Report form.*

Researchers are advised to call the CDPH IRB Staff Assistant to discuss the unanticipated problem or adverse event before completing this form if they have questions. If needed, the assistant can put the researcher in touch with the Chair or other IRB members.

I. REPORT TYPE

☐ **Unanticipated Problem:** an incident, experience, or outcome affecting subjects or others that 1) is unexpected given the approved research procedures, informed consent and the characteristics of study subjects; 2) is related or possibly related to participation in the research; and/or 3) may place subjects or others at a greater risk of physical, psychological, economic, or social harm.

☐ **Reportable Adverse Event:** an untoward or unfavorable medical (physical or psychological) occurrence in a human subject (e.g., abnormal sign, symptom, disease, or death) that 1) is unexpected in nature, severity, or frequency; 2) is related or possibly related to participation in the research; and 3) may place subjects at a greater risk of physical or psychological harm.

☐ **Confidentiality Breach** (Examples include, but are not limited to: Lost or stolen laptops or USB thumb drives storing participant information, accessing confidential data or protected information without a *business* need to know, unencrypted email with confidential or protected data, using unsecured protocols, paper with confidential data or protected information not disposed of properly

☐ **Protocol Deviation:** an incident where study activities different from CDPH IRB-Approved Protocol have occurred.

II. DESCRIPTION

A. Please describe the unanticipated problem, adverse event, or protocol deviation, including when and how it occurred, and who was involved.

B. When did the investigator become aware of the unanticipated problem, adverse event, or protocol deviation?

C. Has this type of problem or event occurred previously in this research?

Yes ☑
No ☑
N/A ☑

If yes, describe and provide references:

_____

_____

D. Did this unanticipated problem, adverse event, or protocol deviation require treatment, intervention, or other measures to minimize risks to subjects?

Yes ☐
No ☐
N/A ☐

If yes, explain:

_____

_____

E. Have others been notified of this problem or event?

Yes ☐
No ☐

If yes, please list below:

_____

_____

III. DETERMINING CAUSES AND RISKS

A. Please indicate whether the unanticipated problem, adverse event, or protocol deviation is definitely or possibly related to research procedures.

☐ Definitely Related: It is clearly a direct result of procedures involved in the research.
Explain:

_____

_____

_____

☐ Possibly Related: There is a reasonable possibility that it may have been caused by research procedures.
Explain:

_____

_____

_____

B. Please explain the basis for determining that the unanticipated problem, adverse event, or protocol deviation alters risks to past, present or future subjects:

IV. CONFIDENTIALITY BREACH

A. Please describe what happened:

B. How did it happen:

C. Who was involved:

D. How many subjects were affected:

E. What were the consequences:

F. Describe the notification process for affected individuals and how many subjects were notified:

V. CORRECTIVE ACTIONS OR CHANGES TO STUDY

(Investigators are required to follow up and provide corrective actions)

A. Do study procedures or the study protocol require revision as a result of this unanticipated problem, adverse event, or protocol deviation? Yes ☐ No ☐ N/A ☐

If yes, submit a *Study Amendment Request* which explains the revisions.

B. Do study consent documents require revision as a result of this unanticipated problem or adverse event? Yes ☐ No ☐ N/A ☐

If yes, submit a *Study Amendment Request* along with copies of the revised documents.

C. Describe what corrective action(s) has been/ will be taken to prevent a recurrence.

_____

_____

_____

D. Has this event or problem been reported to the following?

Investigator's home institution
Specify: _____ Yes ☐ No ☐ N/A ☐

The funding agency
Specify: _____ Yes ☐ No ☐ N/A ☐

Others
Specify: _____ Yes ☐ No ☑ N/A ☑

VI. INVESTIGATOR'S STATEMENT:

By submitting this form, I affirm that this report is accurate and complete.

_____		
Print Investigator name		
_____		_____
Investigator Signature		**Date**

Send an electronic copy of this form and all attachments and supporting documents to CDPHIRB@cityofchicago.orgOn the subject line, please indicate adverse event report and include the CDPH Project ID#).