

# Unanticipated Problem (UP)

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| --- | --- | --- |
| Protocol Name and Number: | Site Name: | Subject ID Number or List of Affected Subjects: |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Date UP Identified: \_ \_ / \_ \_ \_ / \_ \_ \_ \_ (dd/mmm/yyyy)

2. Identify UP:

3. The Unanticipated Problem was unexpected in terms of nature, severity, or frequency: Checkbox. Yes Checkbox. No

4. The Unanticipated Problem is possibly related to participation in the research: Checkbox. Yes Checkbox. No

5. The Unanticipated Problem suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized: Checkbox. Yes Checkbox. No

***If the answers to questions 3–5 are ALL “YES,” report event as an Unanticipated Problem to NCCIH and the institutional review board (if applicable).***

6. Briefly describe the UP. Attach additional pages or supplementary information as necessary. Include date of incident and date of discovery. Describe harm or potential harm that occurred to subject(s), whether the incident is resolved, and whether the subject(s) remains in the study:

7. What action was taken with the study as a result of the Unanticipated Problem? (Check all that apply.)

Checkbox. No action

Checkbox. Revise protocol to eliminate apparent immediate hazards to subjects

Checkbox. Modification of inclusion or exclusion criteria to mitigate newly identified risks

Checkbox. Implementation of additional procedures for monitoring subjects

Checkbox. Suspension of enrollment of new subjects

Checkbox. Notify currently enrolled subjects

Checkbox. Suspension of research procedures in currently enrolled subjects

Checkbox. Modification of consent documents to include a description of newly recognized risks (site and/or study wide)

Checkbox. Provision of additional information about newly recognized risks to previously enrolled subjects

Checkbox. Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. Is the Unanticipated Problem a serious adverse event? Checkbox. Yes Checkbox. No

***If the Unanticipated Problem is a serious adverse event, submit this form and complete the Serious Adverse Event form.***

Statement of Principal Investigator: *I have personally reviewed this report and agree with the above assessment.*

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Signature of Principal Investigator Date

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Name of Person Completing the Form Date