

## Unanticipated Problem (UP)

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

- |   |   |
|---|---|
| <input type="checkbox"/> No action<br><input type="checkbox"/> Revise protocol to eliminate apparent immediate hazards to subjects<br><input type="checkbox"/> Modification of inclusion or exclusion criteria to mitigate newly identified risks<br><input type="checkbox"/> Implementation of additional procedures for monitoring subjects<br><input type="checkbox"/> Suspension of enrollment of new subjects<br><input type="checkbox"/> Notify currently enrolled subjects | <input type="checkbox"/> Suspension of research procedures in currently enrolled subjects<br><input type="checkbox"/> Modification of consent documents to include a description of newly recognized risks (site and/or study wide)<br><input type="checkbox"/> Provision of additional information about newly recognized risks to previously enrolled subjects<br><input type="checkbox"/> Other: _____ |
|---|---|

**Unanticipated Problem (UP)**  
**(continued)**

8. Is the Unanticipated Problem a serious adverse event?  Yes  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.*

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_/\_\_\_/\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Completing the Form

\_\_\_/\_\_\_/\_\_\_\_\_  
Date