NIDCR Unanticipated Problem (UP) Form

COMPLETION INSTRUCTIONS

Please email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to Rho Product Safety. If you have general questions about UP reporting, you may contact Rho Product Safety by email or telephone (1-888-746-7231).

Unanticipated Problem (UP) Form	
1. Date UP identified	For Item 1, enter the date that the UP was identified by the investigator.
2. Identify UP	For Item 2, describe the incident, experience, or outcome that occurred.
3. The event was unexpected in terms of nature, severity or frequency	For Item 3, check Yes or No. If the question is answered No, then the event is not considered an unanticipated problem. If the event is not considered an unanticipated problem, reconsider the reporting mechanism; this is not the correct form.
4. The event is related or possibly related to participation in the research	For Item 4, check Yes or No. If the question is answered No, then the event is not considered an unanticipated problem. If the event is not considered an unanticipated problem, reconsider the reporting mechanism; this is not the correct form.
5. The event suggests that the research places participants or others at a greater risk of harm than was previously known or recognized	For Item 5, check Yes or No. If the question is answered No, then the event is not considered an unanticipated problem. If the event is not considered an unanticipated problem, reconsider the reporting mechanism; this is not the correct form.
6. Briefly describe the UP	For Item 6, briefly describe the incident, experience, or outcome. Also include the date the event occurred and/or the date event was discovered. Describe the harm or potential harm that occurred to the participant or multiple participants. Indicate whether the event is resolved and specify if the participant or participants affected remain in the study. If more than one participant was affected, you may list participant IDs in this box if needed due to limited space in the participant ID box in the header. Additional pages or supplementary documents may be attached. Any attached documents should include investigator signature and date.

7. What action was taken with the study as a result of the UP?	For Item 7, record the action taken (if known). There are categories listed to describe the action taken; however, the "Other" option is available to describe the action taken if not available in the list provided. Check more than one action as necessary. If no action was taken, provide the rationale.
8. Is the UP a serious adverse event?	For Item 8, check Yes or No. If Yes is checked, complete and submit a Serious Adverse Event (SAE) Form.
9. Statement of Investigator and Signature	For Item 9, the investigator signs and dates the form to verify review and agreement with the assessment. Enter the name of the person who completed the form and the date completed.