NIDCR Unanticipated Problem (UP) Form

Protocol #:	PI Name/Site #:	List Participant ID # of All Affected Participants:
_____	_____	_____

1. Date Unanticipated Problem (UP) identified: _____ (DD/MMM/YYYY)
2. Identify UP: _____
3. The event was unexpected in terms of nature, severity, or frequency: ☐ Yes ☐ No
4. The event is related or possibly related to participation in the research: ☐ Yes ☐ No
5. The event suggests that the research places participants or others at a greater risk of harm than was previously known or recognized: ☐ Yes ☐ No

If the answers to items 3-5 above are ALL Yes, report the event as an Unanticipated Problem to NIDCR (and IRB if applicable). If any answer is No to items 3-5 above, do not use this form to report the event.

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

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

☐ Revision of protocol to eliminate apparent immediate hazards to participants

☐ Modification of inclusion or exclusion criteria to mitigate newly identified risks

☐ Implementation of additional procedures for monitoring participants

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

☐ Suspension of enrollment of new participants

☐ Notification of currently enrolled participants

☐ Suspension of research procedures in currently enrolled participants

☐ Provision of additional information about newly recognized risks to previously enrolled participants

☐ Other: _____

_____

☐ No action taken; rationale: _____

_____

8. Is the UP a serious adverse event (SAE)? ☐ Yes ☐ No

If the UP is an SAE, submit this form <u>and</u> complete and submit the SAE Form.

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

Investigator Signature	*Date (DD/MMM/YYYY)*
Name of Person Completing Form	*Date (DD/MMM/YYYY)*

Email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to Rho Product Safety.