NIDCR Unanticipated Problem (UP) Form

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

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

Type of Report: ☐ Initial ☐ Follow-up

Is the research being conducted under an IND/IDE? ☐ Yes ☐ No

Is this study under a single IRB (sIRB)? ☐ Yes ☐ No

IRB/IEC name (or local IRB/IEC if not relying on a sIRB): _____

Required time frame for reporting UP to the IRB: _____

Date event submitted to local or single IRB (DD/MMM/YYYY): _____

Required time frame for reporting UP to the NIDCR: _____

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1. Date Unanticipated Problem (UP) identified: _____ (DD/MMM/YYYY)
2. Identify UP in a few key words: _____

a)	The event was unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied:	☐ Yes	☐ No
b)	The event is related or possibly related to participation in the research *(possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research):	☐ Yes	☐ No
c)	The event suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized:	☐ Yes	☐ No

If the answers to items 2a, 2b, & 2c above are ALL Yes, complete the remaining questions to report the event as an Unanticipated Problem to NIDCR. Utilize IRB reporting forms for reporting to the IRB. If any answer is No to items 2a-c above, this event does not qualify as an unanticipated problem under the OHRP definition and should not be categorized or reported as a UP. Please refer to your data and safety monitoring plan to determine if the event requires prompt reporting to NIDCR and/or your IRB.

3. 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):

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4. 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: _____ _____

5. 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.

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 this form to Rho Product Safety at rho_productsafety@rhoworld.com

Instruction for follow-up: please communicate the IRB determination of the UP to rho_productsafety@rhoworld.com