NIDCR Unanticipated Problem (UP) Form

COMPLETION INSTRUCTIONS

Please email (rho_productsafety@rhoworld.com) or fax (1-888-746-3293) this form to NIDCR's CROMS contractor (Rho) via 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	
Type of report	Select Initial or Follow-Up
Is the research being conducted under an IND/IDE?	Select Yes or No
Is this study under a single IRB (sIRB)?	Select Yes or No
IRB/IEC name (or local IRB/IEC if not relying on a sIRB):	If the study is subject to the NIH Single IRB policy, enter the name of the IRB of Record. If the study is not subject to the NIH Single IRB policy, enter the name of the local IRB.
Required time frame for reporting UP to the IRB	Record the per protocol timeline for reporting UP to the IRB in the "IRB/IEC name (or local IRB/IEC if not relying on a sIRB)" field.
Date event submitted to local or single IRB	Record the date the event was submitted to the IRB in YYYY-MM-DD format.
Required time frame for reporting UP to the NIDCR	Record the per protocol timeline for reporting UP to the NIDCR.
1. Date UP identified	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.

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2a. 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	Check Yes or No. If the question is answered No, then this event does not qualify as a UP under the Office for Human Research Protections (OHRP) definition. Refer to the HHS OHRP website for additional guidance about unanticipated problems. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html
2b. 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)	Check Yes or No. If the question is answered No, then this event does not qualify as a UP under the OHRP definition. Refer to the HHS OHRP website for additional guidance about unanticipated problems. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html
2c. 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	Check Yes or No. If the question is answered No, then this event does not qualify as a UP under the OHRP definition. Refer to the HHS OHRP website for additional guidance about unanticipated problems. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html
3. Briefly describe the UP	Briefly describe the incident, experience, or outcome; include the date the event occurred, if known. 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.

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4. What action was taken with the study as a result of the UP?	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.
5. Is the UP a serious adverse event?	Check Yes or No. If Yes is checked, complete and submit a Serious Adverse Event (SAE) Form in addition to the UP Form.
Statement of Investigator and Signature	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.
Instructions for Follow-Up	If the IRB determination differs from that submitted by the Investigator, please communicate this update to rho_productsafety@rhoworld.com.