

## NIDCR Unanticipated Problem (UP) Form

### COMPLETION INSTRUCTIONS

Please email ([rho\\_productsafety@rhoworld.com](mailto: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	
<b>Type of report</b>	Select Initial or Follow-Up
<b>Is the research being conducted under an IND/IDE?</b>	Select Yes or No
<b>Is this study under a single IRB (sIRB)?</b>	Select Yes or No
<b>IRB/IEC name (or local IRB/IEC if not relying on a sIRB):</b>	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.
<b>Required time frame for reporting UP to the IRB</b>	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.
<b>Date event submitted to local or single IRB</b>	Record the date the event was submitted to the IRB in YYYY-MM-DD format.
<b>Required time frame for reporting UP to the NIDCR</b>	Record the per protocol timeline for reporting UP to the NIDCR.
<b>1a-b. Date UP identified</b>	Enter the date that the (a) UP occurred. Enter the date that the (b) UP was identified by the investigator or study team. Record the date in YYYY-MM-DD format.
<b>2. Identify UP</b>	For Item 2, describe the incident, experience, or outcome that occurred.

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<p><b>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</b></p>	<p>Check Yes or No.</p> <p>If the question is answered Yes, then in the box provided, explain how this event is considered unexpected based on the definition above.</p> <p>If the question is answered No, then this event does not qualify as a UP under the Office for Human Research Protections (OHRP) definition. Therefore, this event <u>DOES NOT</u> require prompt reporting to NIDCR. You <u>DO NOT</u> need to complete the remaining items on this form (#3-5) UNLESS it is later determined/ruled that the event meets all three criteria (either by the Medically Responsible Person or the institutional review board (IRB)). Please follow your IRB guidance and policies to determine if this event must be reported separately to your IRB utilizing appropriate institutional or IRB-specific form.</p> <p>Refer to the HHS OHRP website for additional guidance about unanticipated problems.</p> <p><a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html</a></p>
<p><b>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)</b></p>	<p>Check Yes or No.</p> <p>If the question is answered Yes, then in the box provided, please explain how this event is at least possibly related to participation in this research using the definition above.</p> <p>If the question is answered No, then this event does not qualify as a UP under the OHRP definition. Therefore, this event <u>DOES NOT</u> require prompt reporting to NIDCR. You <u>DO NOT</u> need to complete the remaining items on this form (#3-5) UNLESS it is later determined/ruled that the event meets all three criteria (either by the Medically Responsible Person or the institutional review board (IRB)). Please follow your IRB guidance and policies to determine if this event must be reported separately to your IRB utilizing appropriate institutional or IRB-specific form.</p> <p>Refer to the HHS OHRP website for additional guidance about unanticipated problems.</p> <p><a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html</a></p>

<p><b>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</b></p>	<p>Check Yes or No.</p> <p>If the question is answered Yes, then in the box provided, please explain how this event places research participants or others at greater risk of harm than was previously known or recognized.</p> <p>If the question is answered No, then this event does not qualify as a UP under the OHRP definition. Therefore, this event <u>DOES NOT</u> require prompt reporting to NIDCR. You <u>DO NOT</u> need to complete the remaining items on this form (#3-5) UNLESS it is later determined/ruled that the event meets all three criteria (either by the Medically Responsible Person or the institutional review board (IRB)). Please follow your IRB guidance and policies to determine if this event must be reported separately to your IRB utilizing appropriate institutional or IRB-specific form.</p> <p>Refer to the HHS OHRP website for additional guidance about unanticipated problems.</p> <p><a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html</a></p>
<p><b>3. What action was taken with the study as a result of the UP?</b></p>	<p>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, then provide the rationale.</p>

<b>Unanticipated Problem (UP) Form</b>	
<b>4. Briefly describe the UP.</b>	<p>Briefly describe the UP in narrative form and provide any further details relevant to the incident not specified under Items 2a-c above. Be sure to include the nature of the event, outcome or resolution of the incident (or if the event is ongoing), information regarding any corrective and preventative action(s), and whether the participant(s) remains in the study.</p> <p>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.</p>
<b>5. Is the UP a serious adverse event?</b>	<p>Check Yes or No. If Yes is checked, complete and submit a Serious Adverse Event (SAE) Form in addition to the UP Form.</p>
<b>Statement of Investigator and Signature</b>	<p>The investigator signs and dates the form to verify review and agreement with the assessment.</p> <p>Enter the name of the person who completed the form and the date completed.</p>
<b>Instructions for Follow-Up</b>	<p>If the IRB determination differs from that submitted by the Investigator, please communicate this update to <a href="mailto:rho_productsafety@rhoworld.com">rho_productsafety@rhoworld.com</a>.</p>