**Tool Summary Sheet**

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| **Tool:** | Reportable Events Table Template |
| **Purpose:** | To provide a template for organization of study-specific safety reporting requirements and a sample table for reference. |
| **Audience/User:** | Principal Investigators and Site Staff |
| **Details:** | This template provides a table to organize study-specific safety definitions of all reportable events and relevant examples, including how and when each event must be reported. An example table is included to provide guidance for formatting and sample content for reference. |
| **Best Practice Recommendations:** | * The example table includes **SAMPLE** text for your reference. Use the blank template to enter your study-specific information. Your study’s custom Reportable Events Table should contain the specific safety definitions, notification requirements, and reporting timelines from your current protocol or Manual of Procedures. * Add rows for any additional reportable events and delete any rows/events listed that are not applicable to your study. * The optional Study-Specific Examples column provides a location to enter examples that are relevant for your study for each type of reportable event. * Forms listed in the example table are available for use through Clinical Tool Box and/or the NIDCR Toolkit for Clinical Researchers. Include relevant and/or study-specific forms in your custom table as appropriate. * Multi-center studies may require a unique Reportable Events Table for each site. * Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate. * Ensure that all placeholder and example text is replaced with the study-specific information. * If the protocol is revised, update this tool to reflect any changes in the safety reporting requirements. * The Reportable Events Table can be included as an Appendix to your Manual of Procedures (MOP). * Please retain the Tool version identifier in the lower left hand section of the footer. You may choose to add “Based on” in front of “Tool Version”. * Delete this Tool Summary Sheet and the sample table after development of the study-specific table for your study team’s use. |

**Tool Revision History:**

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| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| 1.0 | 29Jan2014 | First approved version. |

| **Reportable Event** | **Definitions** | **Group/Site to be Notified** | **Timeline** | **Forms** | **Study-Specific Examples (Optional)** |
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| **Serious Adverse Event (SAE)** | SAEs are any adverse events / experiences occurring the course of the study that result in any of the following outcomes:   * Death * Life threatening (subject at immediate risk of death) * Requires inpatient hospitalization or prolongation of existing hospitalization * Results in congenital anomaly/birth defect * Results in persistent or significant disability or incapacity | 1. Independent Study Monitor (ISM) 2. Other Study Site 3. IRBs 4. NIDCR Safety Coordination Center, which will notify the NIDCR Program Official and Medical Monitor | Deaths and immediately life-threatening events: within 24 hours.  All other SAEs: within 72 hours of site awareness.  Yearly reports of SAEs will be made to the DSMB. | Serious Adverse Event Form | Hospitalization for dehydration  Dislodgement of dental restoration during study oral exam and aspiration  Bone fracture |
| **Unanticipated Problem (UP)** | Unanticipated problems involving risks to participants or others is defined as:   1. the information is unexpected in terms of nature, severity or frequency; **and** 2. related or possibly related to participation in the research; **and** 3. the information indicates that participants or others are at greater risk of harm than was previously known or recognized. | Dependent on whether the UP is also an SAE or AE:   1. ISM 2. Other Study Site 3. IRBs 4. NIDCR Safety Coordination Center | UPs that are also SAEs should be reported as both.  UPs that are SAEs should be reported as UPs to the IRB and to NIDCR within 5 working days of the PIs becoming aware of the event.  All other UPs should be reported to the IRB and to NIDCR within 2 weeks of the investigator becoming aware of the problem. | Unanticipated Problem Form | Laptop computer with subject information is lost  Dosing error  Product contamination  Allergic reaction to medication during study procedure |
| **Adverse Event (AE)** | AEs are any untoward medical occurrence in a participant administered a pharmaceutical product regardless of its causal relationship to the study treatment. | 1. Other Study Site 2. IRBs | AEs (that are not SAEs) will be reported to the other site at the monthly Safety Committee meetings.  AEs will be reported to both site IRBs at the time of continuing renewal. |  | Rash  Nausea  Headache  Wound infection  Joint sprain  Anemia |
| **Protocol Deviation (PD)** | Deviations from the most recent version of the approved study protocol; these PDs involve risks to subjects or others, or affect the scientific soundness of the research plan. | 1. Other Study Site 2. IRBs 3. NIDCR:   [NIDCR\_Reports@rhoworld.com](mailto:NIDCR_Reports@rhoworld.com) | No later than 5 days after the situation occurred or the study team became aware of the PD to the Other Study Site and IRBs.  Monthly to NIDCR on the first of the month. | NIDCR Protocol Deviation Form  Protocol Deviation Tracking Log | Missed procedure or assessment  Dose amount error  Lab or dosing completed out of window  Enrollment of ineligible subject |

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| **Serious Adverse Event (SAE)** |  |  |  |  |  |
| **Unanticipated Problem (UP)** |  |  |  |  |  |
| **Adverse Event (AE)** |  |  |  |  |  |
| **Protocol Deviation (PD)** |  |  |  |  |  |
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