# NIDCR Protocol Deviation Reporting Form COMPLETION INSTRUCTIONS

**Please send the completed Protocol Deviation Form to** [**NIDCR\_Reports@rhoworld.com**](mailto:NIDCR_Reports@rhoworld.com) **along with your Safety Oversight Committee Report or Medical Monitor Oversight Report. If you have general questions about Protocol Deviation reporting, you may contact your assigned CROMS Point of Contact or email** [**NIDCR\_Reports@rhoworld.com**](mailto:NIDCR_Reports@rhoworld.com)

## Protocol Deviation (PD) Form

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| Date of deviation | For Question 1, select the date that the protocol deviation occurred via the calendar or enter the date directly in the following format (dd/mmm/yyyy). |
| Date deviation identified | For Question 2, select the date that the protocol deviation was identified via the calendar or enter the date directly in the following format (dd/mmm/yyyy). |
| Deviation description | For Question 3, write a brief description of the deviation. |
| Deviation identified by | For Question 4, choose the appropriate team member that identified the deviation from the dropdown menu. Alternately, you may enter the title of the individual beside “other, specify” if the option is not available in the dropdown menu. |
| Type of deviation identified | For Question 5, select the type of deviation from the dropdown menu. Alternately, you may enter the type of deviation beside “other, specify” if the appropriate option is not available in the dropdown menu. |
| Did the protocol deviation result in an AE? | For Question 6, if the protocol deviation resulted in an AE, check Yes. If the deviation resulted in an AE, provide clarification. |
| Did the subject continue the study? | For Question 7, specify whether the subject continued on the study by checking either Yes or No. If subject discontinued, provide clarification. |
| Does the deviation meet IRB reporting requirements? | For Question 8, if the deviation met IRB reporting requirements, check Yes. |
| Date the deviation was reported to the IRB (if applicable) | For Question 9, enter the date the deviation was reported to the IRB, if applicable. |
| Action taken to resolve this deviation (if any) | For Question 10, provide a brief description of any action taken to resolve the deviation. |
| Deviation impact | For Question 11, specify the impact of the deviation on the study. Check all options that apply. |
| Comments | For Question 12, insert any comments that are applicable to the deviation. This field can be used to further clarify the impact of the deviation on the study. |

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