|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PROTOCOL DEVIATION/VIOLATION REPORT FORM**  ***\*\* DO NOT SEND IDENTIFIABLE DATA WITH THIS FORM \*\**** | | | | | | |
| **REPORT DETAILS** | | | | | | |
| **Study title:** | | |  | |  | |
| **Site number:** | | |  | |  | |
| **Participant number:** | | |  | |  | |
| **Date occurred:** | | |  | |  | |
| **Could this occurrence have an impact on:** | | | | | | |
| **Safety of participant** | | | **Yes** | **🞎** | **Details:** | |
| **No** | **🞎** |
| **Study Outcomes** | | | **Yes** | **🞎** | **Details:** | |
| **No** | **🞎** |
| **If the answer is “Yes” to both of these questions –**  **this event is a serious violation and must be reported to the approving HREC**  **Now complete the following sections where applicable:** | | | | | | |
| **ASSESSMENT TO CONFIRM DEVIATION** | | | | | | |
| A potential participant does not meet, or only partially meets, one of the eligibility criteria | | | **Yes** | **🞎** | **Details:** | |
| **No** | **🞎** |
| A protocol visit date deviation outside the study visit window, or not conducted | | | **Yes** | **🞎** | **Details:** | |
| **No** | **🞎** |
| Isolated incident of a missed or incomplete study procedure (e.g., laboratory test, study evaluation or questionnaire) | | | **Yes** | **🞎** | **Details:** | |
| **No** | **🞎** |
| ***Other deviation*** | | | **Yes** | **🞎** | **Details:** | |
| **No** | **🞎** |
| **PROTOCOL DEVIATION/VIOLATION REPORT FORM (cont.)**  ***\*\*DO NOT SEND IDENTIFIABLE DATA WITH THIS FORM\*\**** | | | | | | |
| **ASSESSMENT TO CONFIRM VIOLATION** | | | | | | |
| **Description of violation** |  | | | | | |
| **ACTIONS TAKEN** | | | | | | |
| **Date** |  | | | | | |
| **Corrective action** |  | | | | | |
| **Preventative action** |  | | | | | |
| **Action required** | **Participant(s) to remain on trial** | | | | **🞎** | |
| **Participant(s) to be withdrawn from trial** | | | | **🞎** | |
| **INFORMATION SOURCE** | | | | | | |
| **Name, address and telephone number of Principal Investigator or designee** |  | | | | | |
| **Signature of Principal Investigator or designee** |  | | | | | |
| **Dated** |  | | | | | |
| **This form must be sent to IMPACCT Trials Coordination Centre within 3 days**  **of any trial site member becoming aware of Deviation/Violation of Protocol**  **Email:** [**itcc@uts.edu.au**](mailto:itcc@uts.edu.au) | | | | | | |