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| **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| **Participant(s) to be withdrawn from trial** | **🞎** |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** |