Please complete a breach report for any incident which deviates from the principles of GCP or the approved protocol and had the potential to affect to a significant degree:

1. The safety, physical or mental integrity of the participant(s) of the research project; or
2. The scientific value of the research project

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of incident:** | |  | | | | **Site where breach occurred:** | | |  | |
| **Date reported to trial office:** | |  | | | |
|  | | | | | | | | | | |
| **Name of person reporting breach to sponsor:** |  | | | | **Tel No:** | |  | | | |
| **Email:** | |  | | | |
|  | | | | | | | | | | |
| **Detail of the breach (please specify if a patient safety/data integrity issue or both):** | | | | | | | | | | |
|  | | | | | | | | | | |
| **Corrective and Preventive Action (CAPA) Implemented by Site Staff:** | | | | | | | | | | |
|  | | | | | | | | | | |
|  | | | | | | | | | | |
| ***FOR TRIAL OFFICE USE ONLY*** | | | | | | | | | | |
| **Non-Serious Breach:** | **Serious Breach:** | | | **Date Breach Report received:** | | | | | |  |
| **Date CAPA(s) completed:** |  | | | | | | | | | |
| **Date of Breach Assessment:**  **(or date BAT convened if applicable)** | | |  | | | | | | | |
| **Date of notification to REC:** |  | | | **Date of notification to MHRA: *(if applicable)*** | | | | | |  |
| **Notifications made by:** |  | | | | | | | | | |
| **Signature:** |  | | | | | **Date of signature:** | |  | | |
| ***For Serious Breach CAPA, please refer to Breach Assessment Team Report.*** | | | | | | | | | | |