**For applications submitted in eProtocol, it is preferred that a serious breach report is completed and submitted in eProtocol. For applications submitted in REGIS, the report will need to be provided through REGIS.**

**If a third party (e.g. individual/institution) wishes to report a PVR/Serious breach without reporting through the sponsor, please use the Serious breaches report form – Third party (MAR F3.1.2).**

|  |  |
| --- | --- |
| HREC reference number: |  |

|  |  |
| --- | --- |
| Project title: |  |

|  |  |
| --- | --- |
| Coordinating Principal Investigator: |  |

|  |  |
| --- | --- |
| Date of report:  *(This date must be the date of submission – please complete as the last step before submission.)* |  |

|  |  |
| --- | --- |
| Date of event: |  |

|  |  |
| --- | --- |
| Participant's ID/s (if applicable): |  |

|  |
| --- |
| Provide an explanation of where, how and when the serious breach occurred, how it was identified, and any other relevant information (e.g. project status): |
|  |

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| --- |
| Any investigations you/others are conducting and the outcome of those investigations if completed (or details of when they will be available/reported): |
|  |

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| --- |
| Detail the impact of the serious breach on participant safety, rights, and reliability and robustness of data: |
|  |
| Any corrective and preventative action (CAPA) implemented to ensure the serious breach does not occur again.(If the investigation or the corrective/preventative action is ongoing at the time of this report, please indicate your plans with projected timelines for completion and provide any further information in a follow-up report)  Please also comment on how the serious breach will be reported in the final report/publication? |
|  |

If the report is by a third party (e.g. trial site) has the sponsor been informed of the breach?

Yes No N/A

|  |  |
| --- | --- |
| Date sponsor confirmed breach: |  |

|  |
| --- |
| It is important to accurately name the attachments as you want them to appear in the approval letter. |
|  |

The Principal Investigator has read and agrees that the above information is true.