

Public

Serious Breach (PVR) eProtocol Questions

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 Breach Report Form – Third party (QM F11.1.2).

HREC reference number:

Project title:

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):

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

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., study site) has the sponsor been informed of the breach?

Yes      No      N/A

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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.