**TMPL\_055 Potential breaches reporting log**

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| Study Title: |  | | |
| R&D Reference Number: |  | Version no: |  |
| EudraCT number (where applicable): |  | Report Date: |  |

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| --- | --- | --- | --- |
| Potential breach (data/safety/GCP) | Occasions after which agreed need to report to Sponsor for assessment | Justification | Sponsor Oversight during the trial (e.g. quarterly review/review during routine monitoring visits etc) |
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| **Understood and approved by:** | | | |
| **Chief Investigator:** |  | **Date:** |  |
| **Lead Applicant:** |  | **Date:** |  |
| **Sponsor representative:** |  | **Date:** |  |