**Protocol Deviation and Unanticipated problems Form**

Study title:

EC Refs: N° Eudract-CT: Principal Investigator:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date(dd-mmm-yyy) | Subject number | Non compliance (NC) /Deviation (Dev) / Violation (Viol) / Unanticipated problem (Unantip P)Please specify | Related to (if applicable) | Description and commentsACTION TAKEN | RESOLVEDyes or no |
| .…..-…….-20….. |  | [ ]  NC [ ]  Dev [ ]  Viol [ ]  Unantip P | [ ]  drug [ ]  protocol [ ]  Excl/incl [ ]  NA |  |  |
| .…..-…….-20….. |  | [ ]  NC [ ]  Dev [ ]  Viol [ ]  Unantip P | [ ]  drug [ ]  protocol [ ]  Excl/incl [ ]  NA |  |  |
| .…..-…….-20….. |  | [ ]  NC [ ]  Dev [ ]  Viol [ ]  Unantip P | [ ]  drug [ ]  protocol [ ]  Excl/incl [ ]  NA |  |  |
| .…..-…….-20….. |  | [ ]  NC [ ]  Dev [ ]  Viol [ ]  Unantip P | [ ]  drug [ ]  protocol [ ]  Excl/incl [ ]  NA |  |  |

Principal Investigator : Signature : Date :

Evaluation by the Ethics Committee: [ ]  No feed back [ ]  Feed back [ ]  Plenary session

Name : Signature : Date : .…..-…….-20…..