**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 comments  ACTION TAKEN | RESOLVED  yes 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…..