|  |  |  |
| --- | --- | --- |
| *PROTOCOL DEVIATIONS / VIOLATIONS* | | |
| *IRB rules for reporting protocol deviations/violations to IRB:*  *Deviations, if any, reported to IRB per IRB rules:  Yes  No*  *Deviations, if any, recorded in compliance with protocol requirements:  Yes  No* |  |  |

**The information below is optional. It is not required or collected by ORO. However, several experienced RCO’s have found it to be useful in the auditing process.**

|  |  |  |
| --- | --- | --- |
| *NA*  *Drug INVESTIGATIONAL PRODUCT ACCOUNTABILITY IN INVESTIGATOR REGULATORY BINDER*  *Device* | | |
| *Product accountability records (storage, inventory, dispensing) maintained?  Yes  No  NA Comments:* |  |  |
| *VAF 10-9012 (Summary Drug Information) on file in the Site regulatory file?  Yes  No  NA Comments:* |  |  |
| *Investigator Brochure or Package Insert on File?  Yes  No  NA Comments:* |  |  |
| *Custody & Storage of investigational product (drug and/or device):  N/A  Pharmacy  Investigator  Other*  *Complies with the facility requirements or as stipulated by the IRB/R&D Committee?  Yes  No Comment:* |  |  |

|  |
| --- |
| *Drugs/Biologics:*  *YES - IND Req’d*  *NO - IND not Req’d* |
| *Devices:  YES - IND NSR  NO - IND not Req’d  - IDE not Req’d* |