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| *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.**

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| **[ ]** *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:* |       |       |

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