**NOTE TO FILE**

|  |  |
| --- | --- |
| Study Title: |  |
| IRB #: |  |
| Principal Investigator: |  |
| Subject Identifier: |  |
| Date: |  |
| Person completing this form: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Check all that apply** | Description | **Corrective Action** | **Date Sponsor Notified** | **Date IRB Notified** |
| [ ]  | Wrong version of consent form signed.  |  |  |  |  |
| [ ]  | The subject did not meet all of the study eligibility requirements or inclusion criteria. |  |  |  |  |
| [ ]  | Protocol deviation.  |  |  |  |  |
| [ ]  | The subject agreed to take part in the study and signed the ICF **post** *study interventions* (or participation in the study). |  |  |  |  |
| [ ]  | Subject non-compliance. |  |  |  |  |
| [ ]  | CV’s and license, and lab certifications are not in binder, in file cabinet. |  | N/A |  |  |
| [ ]  | All contracts and budgets required for a research trial are kept in a central regulatory file in the CCTRO and are maintained by the CCTRO manager.  |  | N/A |  |  |
| [ ]  | Other |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | Date: |  |

**NOTE TO FILE SUBJECT LOG**

|  |  |
| --- | --- |
| Study Title: |  |
| IRB #: |  |
| Subject Identifier: |  |
| Principal Investigator:  |  |
| Person completing this form: |  |

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| --- | --- | --- |
| Date: | Description | **Corrective Action** |
|  |  |
| Date: | Description | **Corrective Action** |
|  |  |
| Date: | Description | **Corrective Action** |
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| **Date:** | **Description** | **Corrective Action** |
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| --- | --- | --- | --- |
| Signature: |  | Date: |  |