# INVESTIGATIONAL PRODUCT SELF-AUDIT TOOL

## PROTOCOL INFORMATION

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## INVESTIGATIONAL/STUDY PRODUCT (Drug or Device)

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| --- | --- | --- |
| **Product Name** | **Product Description (include dose if applicable)** | **Product Location** |
|  |
| *Complete a separate worksheet for each Investigational/Study Product* |

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| --- | --- | --- | --- | --- | --- |
| **Product Handling & Storage** | **Yes** | **No** | **N/A** | **Not** **Reviewed** | **REFERENCES** |
| Is an Investigator’s Brochure (all versions), or instructions for handling investigational / study product(s) (including Instructions for Use) and trial-related materials for each Investigational/Study Product present and up to date?  |  |  |  |  | *ICH GCP E6(R2) 1.14, 1.33, 2.12, 4.1.2, 4.4.2, 5.12, 8.2.1, 8.2.14, 8.3.1**FDA 21 CFR 312.55, 812.140(a)(1) and (b)(4)(i)**IU HRPP Policies: Research Data Management 2.0; Research Personnel Responsibilities 2.7* |
| Are the investigational/study products appropriately packaged and clearly coded and/or labeled? |  |  |  |  | *ICH GCP E6(R2) 5.13, 8.2.13**FDA 21 CFR 312.6, 812.5**IU HRPP Policies: Research Personnel Responsibilities 2.7* |
| Are decoding procedures for blinded trials available? |  |  |  |  | *ICH GCP E6(R2) 1.10, 4.7, 5.13.4, 8.2.17, 8.4.6* |
| Is the Master Randomization list available? |  |  |  |  | *ICH GCP E6(R2) 1.48, 4.7, 8.2.18* |
| Is the investigational product storage area secured? |  |  |  |  | *ICH GCP E6(R2) 5.14.3, 5.18.4(c)(i)**FDA 21 CFR 312.61, 312.69, 812.110(c)**IU HRPP Policies: Research Personnel Responsibilities 2.7* |
| Has a temperature log been kept and maintained (to permit verification of compliance with product storage requirements)? |  |  |  |  | *ICH GCP E6(R2) 2.12, 4.6.1, 4.6.4, 5.13.2, 5.14.3, 5.18.4(c)(i)**IU HRPP Policies: Research Data Management 2.0; Research Personnel Responsibilities 2.7* |

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| **Study Accountability Records** | **Yes** | **No** | **N/A** | **Not Reviewed** | **REFERENCES** |
| Were all product shipments documented as received? Are Shipment invoice(s)/packing slip(s) located for each shipment documented as received?  |  |  |  |  | *ICH GCP E6(R2) 1.33, 4.6.3, 5.18.4 (c)(ii-v), 8.2.15, 8.3.8, 8.3.23, 8.4.1, 8.4.2**FDA 21 CFR 312.57(a), 312.59, 312.60, 312.62, 812.100, 812.110 (e), 812.140(a) and (b)**IU HRPP Policies: Research Data Management 2.0; Research Personnel Responsibilities 2.7* |
| Do recorded shipment amounts, dates and lot/batch number(s) on the Product Accountability Record match the shipment receipts? |  |  |  |  |
| Is the product expiration date tracked, if applicable? |  |  |  |  |
| Is product inventory done routinely and tracked? |  |  |  |  |
| Are the math additions/subtractions within the Product Accountability Record correct?  |  |  |  |  |
| Do Investigational / Study product dispensing dates/doses match subject level source documents? |  |  |  |  |
| Does the physical inventory count match the amount indicated on the Product Accountability Record? |  |  |  |  |
| Was any product destroyed or returned to sponsor? If yes, * did the destruction/disposition of the investigational/study product comply with the approved protocol and applicable regulatory requirements? (e.g. drug lost, device malfunction / failure)
* are the destruction/disposition records on file?
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| **Notes:** |
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Form Completed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_