

# Deficiency Investigation Worksheet

CRA/Other: \_\_\_\_\_

Date(s) of investigation: \_\_\_\_\_

## **Section 1 - Demographics:**

Date of initial incident: \_\_\_\_\_

Investigator's name: \_\_\_\_\_

Site contact name: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

## **Section 2 – Describe the Deficiency:**

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## **Section 3 – Provide Example(s):** (Provide grouped examples of similar or related events across subjects or within a subject's treatment)

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

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### Section 4 - Compliance Category:

**Deficiency Involves:** (Mark one compliance category)

- Investigational Product
- Subject safety, rights, welfare
- Data integrity

**Deficiency Sub-Type:** (Mark deficiency sub-types or describe "other" sub-type identified)

<input type="checkbox"/> Investigational product related deficiencies <ul style="list-style-type: none"> <li>• Includes unreported, late, or incomplete Serious Adverse Event reporting and/or</li> </ul>	<input type="checkbox"/> Repeated deviations of the same type: <ul style="list-style-type: none"> <li><input type="checkbox"/> Investigational product</li> <li><input type="checkbox"/> Safety, welfare, rights</li> <li><input type="checkbox"/> Data integrity</li> </ul>
<input type="checkbox"/> Investigational product related documentation deficiencies <ul style="list-style-type: none"> <li>• Documentation cannot reconstruct IP use</li> </ul>	
<input type="checkbox"/> Investigational product used by someone not authorized to receive	
<input type="checkbox"/> Investigational product improper storage/access	
<input type="checkbox"/> Unanticipated problems involving risks to human subjects or others	<input type="checkbox"/> Informed consent related deficiencies
<input type="checkbox"/> Unperformed safety testing [Labs, ECG, diagnostic testing] or confirmed safety-related result such as pregnancy	
<input type="checkbox"/> Other safety concern related to subjects	
<input type="checkbox"/> Improper delegation of authority	<input type="checkbox"/> IRB/Ethic's Committee or regulatory inspection history
<input type="checkbox"/> Lack of approvals and IRB/EC status	<input type="checkbox"/> Data integrity concerns with efficacy data
<input type="checkbox"/> Lack of investigator involvement	<input type="checkbox"/> Data integrity concerns with safety data
<input type="checkbox"/> Unreported general adverse events that continue unresolved	<input type="checkbox"/> Suspect clinical data misconduct
<input type="checkbox"/> Unreported medical, surgical, or medication use histories	<input type="checkbox"/> Sponsor confidentiality security breach
<input type="checkbox"/> Medical license concerns with investigator and/or subinvestigator(s)	<input type="checkbox"/> Regulatory or IRB/EC inspections/suspension/termination <ul style="list-style-type: none"> <li>• This includes issuance of the Form FDA 483, Warning letters, NIDPOE Letters, Disqualified/Totally Restricted Lists, Debarment List, OHRP Determination Letters or Office of Research Integrity Actions</li> </ul>
<input type="checkbox"/> Conflict of interest with investigator or study team member	<input type="checkbox"/> Death or change in clinical investigators
<input type="checkbox"/> Improper qualifications of staff	<input type="checkbox"/> Other: Describe: _____ <ul style="list-style-type: none"> <li>• Any other problem needing prompt reporting or investigation</li> </ul>

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### **Section 5 – History of Deficiency:**

- New item not covered in prior monitoring reports
- Previous item covered in monitoring reports

Date of Issue: \_\_\_\_\_

Timeline Dates of Issue: \_\_\_\_\_

### **Section 6 – Current Status of Identified Deficiency:**

- Ongoing - Previously Reported in Monitoring Report(s)
- Closed - All Corrective Actions Listed Below
- Partially closed – Additional Corrective Actions Deemed Necessary Not Previously Listed in Monitoring Reports
- Escalation warranted

Visit Dates: \_\_\_\_\_

### **Section 7 – The deficiency violates:**

- Protocol: \_\_\_\_\_ (section/page numbers)
- Regulation(s): \_\_\_\_\_
- IRB requirement: \_\_\_\_\_
- Recommendation(s) or guideline(s): \_\_\_\_\_
- Sound medical practice: \_\_\_\_\_
- Sponsor requirement: \_\_\_\_\_
- Monitoring Plan: \_\_\_\_\_
- Data Completion Guidelines: \_\_\_\_\_
- Suspected misconduct: \_\_\_\_\_
- No direct reference: \_\_\_\_\_ (MM/CRA still concerned)

### **Section 8 – System Grading:** (Indicate how often the deficiency is occurring)

- Isolated
- Periodic
- Pervasive

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**Section 9 - Current Documentation Actions:** (Research monitoring reports and identify all prior corrective actions)

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**Section 10 - Recommendation(s) and Additional Actions:** (Concise statements)

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**Note: If Escalation Deemed Necessary: (Describe escalation needs and contact(s) that received report of complaint) – Follow Escalation SOP**

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