

## Deviation Report

**Goodwyn IRB requires reporting of deviations:**  
*Resulted in increased risk to the subject or others*  
*Affected the rights or welfare of the subject*  
*Affects the integrity of the study data*

Sponsor: \_\_\_\_\_ Protocol #: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Contact for additional information about this report: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

Report Date: \_\_\_\_\_ Date Sponsor Notified: \_\_\_\_\_ Date of Deviation: \_\_\_\_\_

### Subject Data

Subject Number: \_\_\_\_\_ Subject Initials: \_\_\_\_\_

### Deviation Description

1. Indicate the type of deviation: *(select the category that is the best fit)*
- Confidentiality Threat** – Access violation, Loss of records, etc.
  - Data Accuracy** – Errors in recording data, etc.
  - Delegation** – Inappropriate delegation of study responsibilities
  - Enrollment** – Violation of Inclusion/Exclusion Criteria
  - Inadvertent Unblinding** – Inadvertent unblinding of research treatment assignment or data
  - Informed Consent** – Informed consent process error, HIPAA error, etc.
  - Investigational Drug/Device** – Incorrect dose or dosing schedule, Improper usage
  - IRB Approval** – Performing study tasks or using advertisements prior to receiving IRB approval
  - Lost Data** – Data not captured in the Case Report Forms, Loss or corruption of study data
  - Product Security** – Test product lost, Not stored or maintained securely  
(including errors in accountability records)
  - Product Storage** – Temperature excursions
  - Prohibited Medication** – Subject took or was given a prohibited medication
  - Reporting** – Requirements for reporting to the Sponsor or IRB not followed
  - Sample Handling** – Incorrect handling, labeling, destruction or shipping of samples
  - Study Procedures** – Procedure not performed / not performed correctly
  - Visit Schedule** – Out of window visit
2. Describe the deviation: *(e.g. time, place, manner, situation, etc.)*



**Corrective Action**

3. Provide details of any corrective action taken or planned to prevent recurrence:

- a. Action(s): \_\_\_\_\_
- b. Study Personnel Responsible for Implementation of Previously Stated Action(s): \_\_\_\_\_
- c. Implementation Date: \_\_\_\_\_

**Additional Information**

4. Did the deviation occur in order to eliminate an apparent hazard to the subject:  Yes  No  
If yes, describe the circumstances surrounding the hazard (e.g., time, place, manner, situation, etc.):  
\_\_\_\_\_

5. Has this type of deviation occurred before or could it happen again:  Yes  No

**Recommendations (Considering this deviation):**

6. Do you recommend any change to the protocol:  Yes  No

If **yes**, attach recommended changes (marked in the protocol or a detailed summary).

7. Do you recommend a change to the consent document/template:  Yes  No

If **yes**, attach the consent changes, marking the changes in the document.

8. Has the study sponsor reviewed these recommended changes:  Yes  No

**Signature of Principal Investigator**

**As Principal Investigator, I understand that deviations from a protocol can have serious effects on the integrity of human research. As the Principal Investigator, I am responsible for oversight of all procedures performed for this protocol and will endeavor to prevent protocol deviations.**

\_\_\_\_\_ Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_