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***Sample PROTOCOL DEVIATION TRACKING AND REPORTING LOG***

Deviations must be reported to the IRB. Use of these sample templates is optional. See the policy Deviations from Protocol and/or Standard Operating Procedures for definitions and examples of minor vs major.

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| **Study Title:** |  | | |
| **PI:** |  | **IRB #:** |  |

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| **MINOR Deviations** | | | | | | |
| **Date site aware** | **Date occurred** | **Cause of deviation & how discovered** | **Participant ID# and Summary of deviation** | **Why did this not increase risk or harm?** | **State corrective action taken,**  **change in practice,**  **&/or education to reduce recurrence** | **Date sent to the IRB** |
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***Pick a template below for major deviations:***

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| **MAJOR Deviations- should be reported at the time site is aware** | | | | | | |
| **Date site aware** | **Date occurred** | **Cause of deviation & how discovered** | **Participant ID# and**  **Summary** **of deviation** | **Explain increase risk or harm; compromised scientific integrity; &/or noncompliance** | **State corrective action taken,**  **change in practice,**  **&/or education to reduce recurrence. Will participant(s) be notified?** | **Date IRB and sponsor notified** |
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| **MAJOR Deviations- should be reported at the time site is aware** | | | | | | | |
| **Date site aware** |  | **Date happened** |  | **Date IRB and**  **sponsor notified** |  | **Participant code#** |  |
| **Cause of deviation & how discovered** |  | | **Explain increase risk or harm; compromised scientific integrity; &/or noncompliance** |  | | | |
| **Summary of deviation** |  | | | | | | |
| **State corrective action taken** |  | | | | | | |
| **State corrective action taken,**  **change in practice,**  **&/or education to reduce recurrence** |  | | | | | | |
| **Will participant(s) be notified?** |  | | | | | | |
| **PI name, signature, and date** |  | | | | | | |