# **APPENDIX D:**Single-site Sample Protocol Deviation Log

Version\_November 2020

## SAMPLE PROTOCOL DEVIATION LOG

Protocol Title:

Protocol Number: Principal Investigator:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Deviation Code** | **Participant ID#** | **Date Deviation Occurred**(mm/dd/yyyy) | **Date Deviation Discovered**(mm/dd/yyyy) | **Date Deviation Form Completed** (mm/dd/yyyy) | **Date Deviation Reported to IRB** (mm/dd/yyyy) | **Impacts Participant Safety**Y=Yes / N=No (if Y, enter date in next column) | **Date Deviation Reported to NIAMS** (mm/dd/yyyy) | **Contact Person**(if applicable) |
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## SAMPLE PROTOCOL DEVIATION CODES

### Consent Form:

1. Missing or not obtained
2. Not signed and dated by participant
3. Does not contain all required signatures
4. Outdated, current IRB-approved version not used
5. Not protocol specific
6. Does not include updates or information required by the IRB

### Randomization:

1. Ineligible participant enrolled and/or randomized
2. Participant is randomized prior to determining whether eligible for study
3. Occurs outside protocol window

### IRB:

1. Not reporting a serious complication within 24 hours
2. Approvals not kept up-to-date
3. Enrollment and/or treatment occurs prior to IRB approval or during period when “on hold”
4. Reportable serious adverse events not reported to IRB

### Participant

1. Receives wrong treatment
2. Visits occur outside expected follow-up window
3. Entered into another study

### Study Data and/or Forms

1. Missing data and/or forms
2. Missing radiology and/or operative reports
3. Forms or data not sent from clinical site to coordinating center

### Other

1. Other, specify

*\*Please* customize this sample template with study-specific terminology. All protocol deviations (both major and minor) should be recorded on this log. *Protocol deviations that impact participant safety should also be reported to the NIAMS within 48 hours of the investigator becoming aware of the event.*

*SS\_Protocol Deviation Log*

*Version\_November 2020*