

Center Number: _____ Participant Number: _____ Participant's Initials: _____
first middle last

Protocol Deviation

Please indicate below any deviations from the Calerie Protocol taken for this participant.

Check all that apply (one participant per form):

Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24

Date of deviation: ____/____/____
day month year

- | | |
|-------------------------------------------------------------|-----------------------------------------------------------------------|
| <input type="checkbox"/> Informed Consent | <input type="checkbox"/> Study/laboratory procedures (specify): _____ |
| <input type="checkbox"/> Inclusion/Exclusion criteria | <input type="checkbox"/> Participant non-fasting |
| <input type="checkbox"/> Randomization/treatment assignment | <input type="checkbox"/> Participant safety (specify): _____ |
| <input type="checkbox"/> Concomitant Medications | <input type="checkbox"/> Other (specify): _____ |

Brief explanation of deviation: _____

Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24

Date of deviation: ____/____/____
day month year

- | | |
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Brief explanation of deviation: _____

Submission date: ____/____/____ ____/____/____ ____/____/____
day month year day month year day month year