

CALERIE Phase 2 CORE TEMPERATURE DATA HANDLING DOCUMENT

This document outlines the definitions for core temperature data that qualifies for inclusion in the data file.

- 1) Core temperature measured within 1 month plus or minus the date of the RMR is acceptable for use as the core temperature for that particular time point.
- 2) Usable' minutes are those measurements with a temperature between >35 and <39 degrees centigrade
- 3) Definitions for Day time Temperature = 8 am to 10:30 pm
Night time Temperature = 2 am to 5 am

- 4) For a core temperature measurement to be included in the analyses the minimum number of useable minutes that would be required is as follows:

Please note 24 hour average, daytime temperature and night time temperature will be computed separately and will be examined as separate variables

Average 24 hour temperature should have a minimum of 50% of usable data for that period (720 minutes)

Daytime Temperature – should have at least 25% of useable data for that Period (220 minutes)

Nighttime Temperature– should have at least 25% of useable data for that period (45 minutes)

- 5) Always exclude the first 30 minutes after “the first useable minute i.e. >35 and <39 degrees centigrade ”
- 6) For subjects who have more than 24 hours of usable data:
 - Data that is recorded prior to capsule ingestion should be deleted for all subjects for the analysis files
 - Data for the first 30 minutes after the first useable minute should be deleted for all subjects.
 - Data in excess of the first useable 25 hours at the 6 month time point and 26 hours at baseline, 12 and 24 months should be deleted for all subjects