

Center Number: \_\_\_\_\_ Participant Number: \_\_\_\_\_ Participant's Initials: \_\_\_\_\_  
first middle last

### Excessive Weight Loss Episode

Excessive weight loss is defined as a BMI < 18.5 kg/m<sup>2</sup>. This report is completed for each episode of excessive weight loss. Reporting starts when the BMI level is first observed to be < 18.5 kg/m<sup>2</sup>, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention as a direct result of this episode.

#### A Identifying information

1 Date of initial report: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

2 Name of person making this report: \_\_\_\_\_

#### B BMI below 18.5 kg/m<sup>2</sup>

3 Date of threshold value: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

4 Height: \_\_\_\_\_ cm (from original measurement at Screening)

5 Weight: \_\_\_\_\_ kg

6 Calculated BMI: \_\_\_\_\_ kg/m<sup>2</sup>

#### C Temporary Discontinuation

If BMI < 18.5 kg/m<sup>2</sup>, the participant is advised about the risks of excessive weight loss and is prescribed a diet plan with increased number of calories up to the baseline level for up to one month.

7 Was CR temporarily discontinued and a diet plan prescribed?

No → If No: Indicate the reason why it was not temporarily discontinued: \_\_\_\_\_

Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to section D below.

#### D Follow-up BMI Value

The CR intervention is only restarted if the BMI increases to 18.5 kg/m<sup>2</sup> or higher after one month of treatment.

8 Date of follow-up value: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

9 Weight: \_\_\_\_\_ kg

10 Calculated BMI: \_\_\_\_\_ kg/m<sup>2</sup>

#### E Permanent Discontinuation

If BMI is still < 18.5 kg/m<sup>2</sup> after one month of increased calorie intake, CR intervention is permanently discontinued.

11 Was the participant permanently discontinued from the CR intervention?

No → If No: Indicate the reason CR was not permanently discontinued (check only one):

BMI returned to 18.5 kg/m<sup>2</sup> or higher

Other (specify): \_\_\_\_\_

Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

**Note that a participant is permanently discontinued from the CR intervention if a BMI < 18.5 kg/m<sup>2</sup> occurs at any point after the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.**

**Fax to Safety Surveillance at 1-866-668-7138**

# Excessive Weight Loss Episode Report

Center Number: \_\_\_\_ Participant Number: \_\_\_\_ Participant's Initials: first middle last \_\_\_\_

## Excessive Weight Loss Episode (continued)

**F Please provide a description of this episode including actions taken:**

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## Study Manager's Signature

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year