

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

### Permanent Discontinuation

**1** Date of permanent discontinuation: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

**2** Reason(s) for discontinuation (check only one):

- <sub>1</sub> Persistent potassium level > 5.0 mEq/L resistant to one month of treatment
- <sub>2</sub> Persistent potassium level ≥ 5.5 mEq/L after CR was temporarily discontinued and restarted
- <sub>3</sub> Persistent anemia (anemia still not improving or worsening one month after temporary discontinuation)
- <sub>4</sub> Ventricular ischemia confirmed by stress image
- <sub>5</sub> Decrease in BMD at the hip or spine of 5% or greater from baseline at any time during first 12 months of CR
- <sub>6</sub> Decrease in BMD at the hip or spine of 10% or greater from baseline at any time during months 12–24 of CR
- <sub>7</sub> BMD t-score at any site (hip, femoral neck, or total spine) of less than -2.5 at any time during study
- <sub>8</sub> Eating disorder (including anorexia nervosa, bulimia nervosa or binge eating OR experiencing a sub-threshold eating disorder)
- <sub>9</sub> Further decrease in BMI after 1 month of increase calorie intake OR temporary discontinuation of CR intervention OR persistent decrease in BMI (< 18.5) after CR intervention restarted
- <sub>10</sub> Psychiatric disorder (including severe depression)
- <sub>11</sub> Reoccurrence of moderate depression (BDI still > 20) after CR intervention restarted OR moderate depression that is not improving or is worsening (BDI ≥ 30) after temporary discontinuation of CR intervention
- <sub>12</sub> Major illness or disease (e.g., cancer)
- <sub>13</sub> Trauma requiring prolonged hospitalization or bed rest for more than one month
- <sub>14</sub> Menstrual irregularities or acyclicity for more than one year (women only)
- <sub>15</sub> Pregnancy (women only)
- <sub>16</sub> Participant withdrew consent
- <sub>17</sub> Personal reasons (specify): \_\_\_\_\_
- <sub>98</sub> Other: \_\_\_\_\_

**Participant's Details:**

Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

Height: \_\_\_\_\_ . \_\_\_\_ cm

Gender:  Male  Female

Weight: \_\_\_\_\_ . \_\_\_\_ kg

BMI (if applicable): \_\_\_\_\_

**Relevant Medical History:**

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

### Permanent Discontinuation (continued)

Relevant Concomitant Medication (do not list medication administered to treat this event):

| Medication | Dose & Unit | Frequency | Route | Start Date                                      | Continued   | Stop Date                                       |
|------------|-------------|-----------|-------|---|---|---|
|            |             |           |       | ____/____/____<br><small>day month year</small> | <input type="checkbox"/> No<br><input type="checkbox"/> Yes | ____/____/____<br><small>day month year</small> |
|            |             |           |       | ____/____/____<br><small>day month year</small> | <input type="checkbox"/> No<br><input type="checkbox"/> Yes | ____/____/____<br><small>day month year</small> |
|            |             |           |       | ____/____/____<br><small>day month year</small> | <input type="checkbox"/> No<br><input type="checkbox"/> Yes | ____/____/____<br><small>day month year</small> |

Relevant Lab Tests:

| Test | Date  | Value/Results | Normal Range |
|------|---|---------------|--------------|
|      | ____/____/____<br><small>day month year</small> |               |              |
|      | ____/____/____<br><small>day month year</small> |               |              |
|      | ____/____/____<br><small>day month year</small> |               |              |
|      | ____/____/____<br><small>day month year</small> |               |              |

Please describe any additional action taken (e.g., observation or seek medical attention outside study):

### Investigator's Signature

Investigator: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
signature day month year