Permanent Discontinuation from CR Intervention

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)*:

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

Participant's Details:

Date of birth: ___ ___ /___ ___ ___ /___ ___ ___ ___ (day / month / year)

Gender: ☐ Male ☐ Female

Height: ___ ___ ___ . ___ cm

Weight: ___ ___ ___ . ___ kg

BMI *(if applicable)*: _____

Relevant Medical History:

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

Permanent Discontinuation from CR Intervention

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
				__ __/__ __ __/__ __ __ __ day month year	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ day month year
				__ __/__ __ __/__ __ __ __ day month year	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ day month year
				__ __/__ __ __/__ __ __ __ day month year	☐0 No ☐1 Yes	__ __/__ __ __/__ __ __ __ day month year

Relevant Lab Tests:

Test	Date	Value/Results	Normal Range
	__ __/__ __ __/__ __ __ __ day month year		
	__ __/__ __ __/__ __ __ __ day month year		
	__ __/__ __ __/__ __ __ __ day month year		
	__ __/__ __ __/__ __ __ __ day month year		

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

Investigator's Signature

Investigator: _____ (signature) **Date:** __ __/__ __ __/__ __ __ __ (day month year)

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