calerie Phase 2

Temporary Discontinuation from CR Intervention

Check one: ☐ Initial ☐ Follow-up

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

Temporary Discontinuation

Note: Complete one form per reason for discontinuation.

1 Date of temporary discontinuation: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
day month year

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

☐1 Persistent potassium level > 5.5 mEq/L and < 6.0 mEq/L at any point during study, confirmed by repeat testing at 1 week

☐2 Persistent potassium level ≥ 6.1 mEq/L at any point during study, confirmed by repeat testing at 48 hours
if second level is above 5.5 mEq/L

☐3 Treatment resistant anemia *(anemia has not improved after one month of treatment)*

☐4 Ventricular ischemia observed with exercise *(stress image performed in 2 weeks)*

☐5 Decrease in BMI to <18.5 at any time

☐6 Moderate depression *(BDI ≥ 20)*

☐7 Personal reasons *(specify)*: _____

☐8 Other *(includes any other disease or condition that requires temporary discontinuation from intervention such as recovery from trauma, surgery, or severe infections)* *(specify)*: _____

Participant's Details:

Date of birth: ___ ___ / ___ ___ ___ / ___ ___ ___ ___   Height: ___ ___ ___ . ___ cm
day month year

Gender: ☐ Male ☐ Female   Weight: ___ ___ ___ . ___ kg

BMI *(if applicable)*: _____

Relevant Medical History:

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		

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

Temporary Discontinuation from CR Intervention

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

Temporary Discontinuation (continued)

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

Intervention Resumption

Was intervention resumed? If No: Fill out Permanent Discontinuation from CR Intervention form

If Yes: Date intervention was resumed: __ __ /__ __ __ /__ __ __ __
day   month   year

Investigator's Signature

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