

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

### Elevated Potassium Episode

Hyperkalemia is defined as an initial potassium level greater than 5.5 mEq/L followed by a confirmatory value greater than 5.5 mEq/L. This report is completed for each episode of hyperkalemia. Reporting starts when the initial potassium level is greater than 5.5 mEq/L, 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 Initial Elevation in Potassium Level

3 Date of initial elevation: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

4 Potassium level: \_\_\_\_\_ mEq/L

#### C Follow-up Repeat Potassium Level

If the initial potassium level is between 5.5 mEq/L and 6.0 mEq/L (inclusive), the test is repeated in one week; if it is greater than 6.0 mEq/L, it is repeated within 48 hours.

5 Date of follow-up test: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

6 Potassium level: \_\_\_\_\_ mEq/L

#### D Temporary Discontinuation

If the follow-up test is > 5.5 mEq/L, the CR intervention is temporarily discontinued from the CR intervention and the participant is advised to seek medical help outside of the study.

##### 7 Was the participant temporarily discontinued from the CR intervention?

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

Potassium returned to 5.5 mEq/L or lower → If potassium returned to 5.5 mEq/L or lower, then the episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.

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

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

#### E Follow-up Potassium Level

The CR intervention will only be restarted if the potassium level decreases to ≤ 5.0 mEq/L within one month of treatment.

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

9 Potassium level: \_\_\_\_\_ mEq/L

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### Elevated Potassium Episode (continued)

#### F Permanent Discontinuation

*If potassium level is still elevated above 5.0 mEq/L after one month of treatment, the CR intervention is permanently discontinued.*

#### 10 Was the participant permanently discontinued from the CR intervention?

- No → If No: Indicate why CR was not permanently discontinued (check only one):
- Potassium returned to 5.0 mEq/L or lower
  - 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 potassium level of 5.5 mEq/L or higher occurs at any point after the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.**

#### G Please provide a description of this episode including actions taken:

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#### Study Manager's Signature:

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