

## ENRGISE PILOT STUDY: MEDICATION EXCEPTION

Visit Date Completed   /   /

Staff ID

Rev: \_\_\_\_\_

DE: \_\_\_\_\_

Date: \_\_\_\_\_

*Use this form when the study recommended dose is NOT being followed for one or both study medications.*

Losartan/Placebo	Omega 3/Placebo
<p><input type="checkbox"/> Not participating in this arm</p> <p><input type="checkbox"/> Following study recommended dose <i>If you have selected one of the above, do not complete Q1-3 for Losartan/Placebo</i></p>	<p><input type="checkbox"/> Not participating in this arm</p> <p><input type="checkbox"/> Following study recommended dose <i>If you have selected one of the above, do not complete Q1-3 for Omega3/Placebo</i></p>
Dose Change for Losartan/Placebo	Dose Change for Omega 3/Placebo
<p>1. Who is requesting a medication exception for Losartan/Placebo?</p> <p><input type="checkbox"/> Study physician</p> <p><input type="checkbox"/> Participant request</p> <p><input type="checkbox"/> Participant's doctor request</p>	<p>1. Who is requesting a medication exception for Omega3/Placebo?</p> <p><input type="checkbox"/> Study physician</p> <p><input type="checkbox"/> Participant request</p> <p><input type="checkbox"/> Participant's doctor request</p>
<p>2. Why are they [answer to Q1] requesting a medication exception for Losartan/Placebo? <i>(check all that apply)</i></p> <p><input type="checkbox"/> New dizziness or lightheadedness</p> <p><input type="checkbox"/> Blood Pressure</p> <p><input type="checkbox"/> Safety Labs</p> <p><input type="checkbox"/> Adherence issue</p> <p><input type="checkbox"/> Adverse Effects</p> <p><input type="checkbox"/> Other, specify → _____</p> <p>_____</p> <p>_____</p>	<p>2. Why are they [answer to Q1] requesting a medication exception for Omega3/Placebo? <i>(check all that apply)</i></p> <p><input type="checkbox"/> New dizziness or lightheadedness</p> <p><input type="checkbox"/> Blood Pressure</p> <p><input type="checkbox"/> Safety Labs</p> <p><input type="checkbox"/> Adherence issue</p> <p><input type="checkbox"/> Adverse Effects</p> <p><input type="checkbox"/> Other, specify → _____</p> <p>_____</p> <p>_____</p>
<p>3. What dose of Losartan/Placebo is the participant being prescribed at this time?</p> <p><input type="checkbox"/> Discontinue</p> <p><input type="checkbox"/> 100 mg</p> <p><input type="checkbox"/> 50 mg</p> <p><input type="checkbox"/> 25 mg</p>	<p>3. What dose of Omega3/Placebo is the participant being prescribed at this time?</p> <p><input type="checkbox"/> Discontinue</p> <p><input type="checkbox"/> 2.8 g</p> <p><input type="checkbox"/> 1.4 g</p>