

## Study Participation Guidelines, Restrictions, and Quick Reference Dates

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### **IMPORTANT!!!**

Please follow the guidelines/restrictions below in order to be counted as a qualified participant in the study. Use the dates below as a reference to know when to begin each restriction. **Failure to do so may disqualify you.**

### **Guidelines and Restrictions**

**6 months prior to screening:** No excessive alcohol use.

**60 days prior to dosing:** No blood donation.

**30 days prior to dosing:** No dosing on any other clinical trial, at any location.

**28 days prior to dosing:** Stop use of herbal supplements. No products containing poppy seeds prior to screening through end of study. Notify physician of **any** medications used within 28 days of check-in.

**7 days prior to dosing:** Stop use of prescription or nonprescription drugs, vitamins, and dietary supplements. Stop eating/drinking grapefruit or grapefruit-containing products.

**48 hours prior to check-in:** Stop strenuous activity - heavy lifting (e.g., moving furniture, shoveling snow), weight training, calisthenics, aerobics, etc.

**24 hours prior to check-in:** Stop alcohol use.

**24 hours prior to dosing:** No use of caffeine, tobacco, or nicotine-containing products.

**Please call the Clinical Research Unit** if you are planning on leaving the country at any time, either before checking in or between dosing periods.

## Study Schedule

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Group 1

Period 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission	Tues	29Jan2019	12:00		4-hour Fast
1	Dosing Day	Wed	30Jan2019	Inpatient		
Period 2						
1	Dosing Day	Wed	06Feb2019	Inpatient		
5	Discharge	Sun	10Feb2019	approximately 10:00am	\$2400.00	
Follow-up Phone Call		Wed	06Mar2019	Between 9am and 4pm	\$1000.00	

December 21, 2018  
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\*Planned partial payments may be provided on a loadable debit card or by paper check. Pfizer New Haven Clinical Research Unit reserves the right to determine method of payment. Please know payment amounts may be reduced for missed visits and docking offenses. Refer to the NHCRU House Rules and Informed Consent Document for details.

Group 2

Period 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission	Mon	11Feb2019	12:00		4-hour Fast
1	Dosing Day	Tues	12Feb2019	Inpatient		
Period 2						
1	Dosing Day	Tues	19Feb2019	Inpatient		
5	Discharge	Sat	23Feb2019	approximately 10:00am	\$2400.00	
Follow-up Phone Call		Tues	19Mar2019	Between 9am and 4pm	\$1000.00	

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Group 3

Period 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
-1	Admission	Thurs	21Feb2019	12:00		4-hour Fast
1	Dosing Day	Fri	22Feb2019	Inpatient		
Period 2						
1	Dosing Day	Fri	01Mar2019	Inpatient		
5	Discharge	Tues	05Mar2019	approximately 10:00am	\$2400.00	
Follow-up Phone Call		Fri	29Mar2019	Between 9am and 4pm	\$1000.00	

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Group 4

Period 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Requirements
-1	Admission	Mon	25Feb2019	12:00		4-hour Fast
1	Dosing Day	Tues	26Feb2019	Inpatient		
Period 2						
1	Dosing Day	Tues	05Mar2019	Inpatient		
5	Discharge	Sat	09Mar2019	Approximately 10:00am	\$2400.00	
Follow-up Phone Call		Tues	02Apr2019	Between 9am and 4pm	\$1000.00	
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