

# STUDY # B7451032

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

---

### **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. No use of Depo Provera

**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. Do not use hormonal contraception, and or utilize hormone replacement therapy. No products containing marijuana or poppy seeds prior to screening through end of study. No hormonal forms of oral contraception. Notify physician of **any** medications used within 28 days of check-in

**7 days prior to dosing:** Stop use of non-prescription drugs, vitamins and dietary supplements. Stop eating/drinking grapefruit or grapefruit containing products and red wine. Inform the clinic if you are required to take any prescription drugs.

**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 and follow up visit:** Stop alcohol use.

**24 hours prior to dosing:** Stop tobacco and caffeine use.

**Check-in:** Do not bring to the unit any unapproved medications or products containing any form of medication, vitamins or dietary supplements or you may be disqualified from the study.

**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 Part A

Part A Group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	<b>Admission</b>	<b>W</b>	<b>14Aug2019</b>	<b>12:00</b>		<b>4 Hour Fast</b>
1	Dosing Day	Th	15Aug2019	Inpatient		
2-11	Inpatient	N/A	16Aug2019 – 25Aug2019	Inpatient		
12	Discharge	M	26Aug2019	approximately 12:00	\$2280	
<b>Follow-up Phone Call</b>		M	23Sep2019	Between 8am-4pm	\$1120	

\* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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\*

Part A Group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	<b>Admission</b>	<b>Th</b>	<b>15Aug2019</b>	<b>12:00</b>		<b>4 Hour Fast</b>
1	Dosing Day	F	16Aug2019	Inpatient		
2-11	Inpatient	N/A	17Aug2019 – 26Aug2019	Inpatient		
12	Discharge	T	27Aug2019	approximately 12:00	\$2280	
<b>Follow-up Phone Call</b>		M	23Sep2019	Between 8am-4pm	\$1120	

\* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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\*

## Study Schedule Part B

Part B Group 1						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	Su	29Sep2019	12:00		4 Hour Fast
1	Dosing Day	M	30Sep2019	Inpatient		
2-5	Inpatient	Tu-Fri	01Oct2019 – 04Oct2019	Inpatient		
6	Discharge	S	05Oct2019	approximately 12:00	\$1200	
Follow-up Phone Call		Th	31Oct2019	Between 8am-4pm	\$850	
<p>* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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”</p>						

Part B Group 2						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	Admission	TBD	TBD	12:00		4 Hour Fast
1	Dosing Day	TBD	TBD	Inpatient		
2-5	Inpatient	TBD	TBD	Inpatient		
6	Discharge	TBD	TBD	approximately 12:00	\$1200	
Follow-up Phone Call		TBD	TBD	Between 8am-4pm	\$850	
<p>* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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”</p>						

Part B Group 3						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	<b>Admission</b>	TBD	TBD	<b>12:00</b>		<b>4 Hour Fast</b>
1	Dosing Day	TBD	TBD	Inpatient		
2-5	Inpatient	TBD	TBD	Inpatient		
6	Discharge	TBD	TBD	approximately 12:00	\$1200	
<b>Follow-up Phone Call</b>		TBD	TBD	Between 8am-4pm	\$850	
<p>* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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”</p>						

Part B Group 4						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	<b>Admission</b>	TBD	TBD	<b>12:00</b>		<b>4 Hour Fast</b>
1	Dosing Day	TBD	TBD	Inpatient		
2-5	Inpatient	TBD	TBD	Inpatient		
6	Discharge	TBD	TBD	approximately 12:00	\$1200	
<b>Follow-up Phone Call</b>		TBD	TBD	Between 8am-4pm	\$850	
<p>* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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”</p>						

Part B Group 5						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	<b>Admission</b>	TBD	TBD	<b>12:00</b>		<b>4 Hour Fast</b>
1	Dosing Day	TBD	TBD	Inpatient		
2-5	Inpatient	TBD	TBD	Inpatient		
6	Discharge	TBD	TBD	approximately 12:00	\$1200	
<b>Follow-up Phone Call</b>		TBD	TBD	Between 8am-4pm	\$850	
<p>* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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”</p>						

Part B Group 6						
Day	Purpose of Visit	Date		Time	Partial Payment Planned*	Fasting Required
0	<b>Admission</b>	TBD	TBD	<b>12:00</b>		<b>4 Hour Fast</b>
1	Dosing Day	TBD	TBD	Inpatient		
2-5	Inpatient	TBD	TBD	Inpatient		
6	Discharge	TBD	TBD	approximately 12:00	\$1200	
<b>Follow-up Phone Call</b>		TBD	TBD	Between 8am-4pm	\$850	
<p>* Planned partial payments may be provided on a loadable debit card or by paper check within 2 weeks after the completion of the visit. 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”</p>						