

**Austin Clinical Research Unit (CRU)  
SUBJECT RULES AND REGULATIONS**

**SITE OF INVESTIGATION:**

Austin CRU  
7551 Metro Center Dr., Ste. 200  
Austin, Texas 78744

**24 HOUR TELEPHONE NUMBER:**

(512) 447-2985

**I. SCREENING PROCEDURES**

- A. To participate in any procedures at PPD, you must read, review and sign an Informed Consent Form. The screening procedures required for your study/generic screening are described in the Informed Consent Form. The total screening process may consist of 2 (or more) visits.
- B. Prior to screening for the study, you may be required to have your photo taken by a study staff member. Your photo will be used as a means of verifying your identification and will be saved in PPD's internal database for future reference. Only the study doctor and study staff who have access to the database will be able to view your photo.
- C. If you meet the criteria listed for the initial screening visit, you will be required to return for the additional screening procedure(s) described in the Informed Consent Form (such as physical exam, etc.).
- D. The decision to admit you into a study is based upon results of pre-study requirements. Compensation for the screening process is not guaranteed for every study. No one is assured a place in the study until the first dosing is completed.

***\*Please Note: All return visits to our facility (repeat blood draws, screening procedures, and all out-patient visits) will require that you present a photo ID. In the absence of a photo ID, you WILL be turned away, and no procedures will be performed. This could result in your disqualification for a study, or a delay in your study payment.***

**II. STUDY REQUIREMENTS AND FACILITY RULES**

**Violation of any of the following may result in a financial penalty.** Any serious violations may result in your dismissal from the study and your exclusion from participation in PPD studies in the future.

- A. Due to the unknown effects which may be caused by combining drugs, you should be aware that the use of any drug (over-the-counter, herbal, prescription, investigational or illicit) other than the study medication anytime during the study without approval of the investigator, could result in serious and even life-threatening reactions. Contact a member of the Research Team assigned to your study before taking any medications. For your safety, you must disclose all medications you have taken pre-study including any medications taken at other research facilities.
- B. If you are enrolled in a study which requires at home dosing, you are required to have a reliable and consistent residence. All study material and supplies are intended for you. You are responsible to ensure that you are the only person exposed to this investigational product.
- C. You must report to PPD on time for all your study visits. Your extreme punctuality is required. When you arrive at the facility for an overnight stay, a complete search of your person and your belongings will be conducted. This search requires removal of clothes down to your undergarments.

- D. You will only be allowed to bring two pieces of luggage into the facility; this includes backpacks and totes that in total can fit into a 21" space. If luggage does not fit in a 21" space, it may not be allowed in the facility. If any items are found that are not allowed, they will be placed in a bag with your name on it. They will be returned to you when you check out of the facility. (*See Attachment A for a list of allowable items.*)
- E. You will be issued an Identification Bracelet upon check-in. This Bracelet may not be removed prior to discharge. You will also be issued a color-coded T-shirt to identify your study group upon check-in. You will be provided with a clean shirt to wear each day you are in-house. The shirt must be visible and worn over any other clothing. You must also wear shoes at all times. Laundry will be provided approximately once a week for studies in house 7 or more days..
- F. Beds are assigned during check-in; for safety reasons, subjects must sleep in assigned bed. No switching of sleeping arrangements, tenting or making privacy screens with blankets is allowed.
- G. You may be required to fast (*no food or drink other than water*) at various times during the study.
- H. You will be provided meals while housed at PPD. You may be required to eat the entire meal and **no other food or beverages will be allowed in the facility**. All meals will be served in the dining area. No food is to leave the dining area. Sharing of food with other study participants is not allowed. (*See Attachment C for a copy of our example menu.*) Please note that your study may require variations to the standard menu. This menu is provided only as a sample to help you determine if you can comply with the typical diet served at PPD.
- I. You will be required to shower at least once a day during your in-house stay, unless otherwise required by your specific study.
- J. A specific unit will be assigned to each study group; subjects must remain in that unit of the building, unless escorted by assigned PPD personnel.
- K. You will not be allowed to participate in any strenuous physical activities for the duration of the study. You will also not be allowed to use tobacco products during the study unless permitted by the protocol.
- L. We have both male and female subjects in-house. We require that female subjects stay out of the male subjects' dorm rooms and male subjects stay out of female subjects' dorm rooms. Subjects are expected to abstain from sexual activity while housed in the facility.
- M. Inappropriate behavior toward, or harassment of subjects or staff will not be tolerated.
- N. We have computers for internet access. Wireless internet is available to study volunteers as well (except during the hours of 11:30 PM to 5:00 AM). You will be responsible for ensuring no pornographic sites are visited. If infractions occur your internet access may be restricted and/or you may be permanently excluded from future PPD studies.
- O. The phones in each housing unit have specific purposes: the red phone to contact a Paramedic Staff Member and the black phone to contact a Research Technician Coordinator.
- P. You will not be able to have mail, including "packages", mailed to you (e.g. FedEx, UPS or U.S. Mail) while housed at the Austin CRU.

If you plan to write letters or send mail during your in-house stay, please bring your own stamps and stationery. There will be out-going mail boxes in the cafeteria, and pickups are scheduled at

2:00PM daily, except weekends and holidays. Mail picked up at 2:00PM does not go out until next business day.

- Q. **Parking Policy:** PPD provides approx. 45 spaces in the front of the building near the volunteer entrance designated for visits no longer than 3 hours (i.e. screenings, outpatients, and physical exams) and only available between the hours of 6:00 AM - 9:00 PM. No overnight parking will be allowed in these marked spaces. PPD also provides “OPEN” parking which is located in the upper parking lot (southwest) behind the building and does not require a parking permit. This lot is available to all subjects, employees, and any other PPD visitors. Volunteers are expected to register their vehicles that they intend to park at the facility for their In-house stay. Registration is to be completed on or before check-in for the first In-house stay. Volunteers leaving their car overnight must register their vehicles and park ONLY in the “OPEN” parking lot. In the event that the parking policy is violated the volunteer will be docked \$50.00 from their payment for each parking violation. It should be emphasized that PPD will not be held liable in the event of vandalism. PPD strongly discourages leaving your vehicle overnight. Leaving valuables in your car is also discouraged. You will be parking in the PPD parking lot AT YOUR OWN RISK. You will not be able to enter your car or test the ignition while you are participating in the study. In the event that it is necessary for you to retrieve items from your car, you will be accompanied by a staff member.
- R. Please do not bring any valuable items with you. PPD cannot assume responsibility for your belongings. At scheduled times, staff members may need to enter your dorm for maintenance purposes. Random searches of person and belongings, to check for any contraband, may occur at any time while housed in the unit. Sunglasses may not be worn while you are housed inside the clinic facility unless medically necessary.
- S. You will not be allowed to discuss any aspect of the data contained on your clipboard with any other subject. This includes adverse experiences and vital signs. **Any subject caught discussing any data will be warned once and then docked for each subsequent incident and may be withdrawn from the study and excluded from future participation. Any subject that does not report a side effect in a timely manner may be docked and may be withdrawn from the study or excluded from future participation in other PPD studies.**
- T. You will not be allowed to communicate by telephone or any other electronic means such as social media or text messaging any aspect of the study or data contained on your clipboard with any person other than PPD staff. **Any subject caught communicating any study information or data may be withdrawn from the study, refused payment and excluded from future participation.**
- U. If you damage or destroy any PPD property, you will be required to pay for repairs and/or replacement of damaged items, (this includes any attempt to move fixed furniture and any graffiti found on walls or fixtures). Damage or destruction of PPD’s property will prevent you from participating in any future studies at PPD.
- V. Stealing PPD property, the property of your fellow subjects, or employees will automatically disqualify you from participation in any future studies. **Any person caught stealing will be prosecuted to the full extent of the law.**
- W. All personal electronics or anything in a closed box will be opened at check- in. You will be responsible for bringing the necessary tools to open them. Any tools you bring will be confiscated and returned to you at check-out. All personal electronics may only be used with headphones and are to be turned off in the DORM areas between midnight and 8:00am. After receiving 2 warnings and/or reminders for using electronics after hours or when otherwise prohibited, the device may be confiscated upon the 3rd warning/reminder. Confiscated items are kept until check out.

- X. Bedtime rules: Unless you are involved in late night procedures, **bedtime is midnight.**
- Y. You may not participate in any form of gambling during your in-house stay (i.e. cards for money, betting on sports events or pool games).
- Z. In the case of an emergency, such as a fire, you will be required to report to the designated area in your Unit. You will be escorted out of the building by a PPD staff member.
- AA. All used gauze must be disposed of in the proper receptacles.
- AB. If ECGs are required for the study, men must shave so that their chest is completely free of hair and females should refrain from wearing underwire bras, as this can cause artifact on an ECG.
- AC. If pulse ox is required for the study, you may not have long and/or artificial nails (i.e. acrylic, shellac, gel, etc.), and they must not have polish. If polish is present, it may require removal.
- AD. If you need to cancel or reschedule your appointment, you must call PPD at least 24 hours prior to your scheduled date. Failure to call and cancel your appointment will result in the following:

#### **PENALTIES FOR NO SHOWS (SCREENING APPOINTMENTS)**

<b>Incident</b>	<b>Consequence</b>
#1	Warning #1
#2	Warning #2
#3	6 Month Ban

#### **PENALTIES FOR NO SHOWS (CHECK-IN)**

<b>Incident</b>	<b>Consequence</b>
Initial Check-in #1	3 month ban
Initial Check-in #2	9 month ban
Subsequent Period Check-in	9 month ban

- AE. You must arrive 3-5 minutes early for all procedures (i.e. blood draws, vital signs). Continual tardiness will result in a financial penalty. You will receive **one** warning. Any violations after that time will result in a deduction from your payment as indicated below. **NOTE: You are required to be on time for “Not Time Dependent” (NTD) procedures. The NTD wording on the DCS is for staff use only.**

#### **PENALTIES FOR LATES (NON-DOSING PROCEDURES)**

<b>Incident</b>	<b>Cumulative Total</b>
#1. Warning	-0-
#2. \$10.00	\$ 10.00
#3. \$20.00	\$ 30.00
#4. \$30.00	\$ 60.00
#5. \$40.00	\$ 100.00
#6. \$50.00	\$ 150.00
#7. \$60.00	\$ 210.00

- AF. Late to Dose: Subjects who do not show up at least 3 minutes prior to their dosing procedure will be penalized (penalties listed below). This includes all dosing procedures throughout the study.

#### **PENALTIES FOR LATES (DOSING PROCEDURES)**

<b>Incident</b>	<b>Cumulative Total</b>
-----------------	-------------------------

#1. \$50.00	\$ 50.00
#2. \$100.00	\$ 150.00
#3. \$150.00	\$ 300.00
#4. \$200.00	\$ 500.00
#5. \$250.00	\$ 750.00

**GUIDELINES FOR PENALTIES FOR INFRACTIONS (ALL ARE SUBJECT TO STAFF DISCRETION):**

Property Damage (PPD's or personal – Payment of Repairs)

Fighting (Physical or Verbal Altercations) - \$200.00 and/or removal from study

Profanity - \$25.00

Unauthorized Activities – a minimum of \$50.00

Knowingly Bringing Contraband into the Clinic – a minimum of \$150.00 and/or removal from the study.

You may also be excluded from future participation.

Violating Curfew - \$25.00 and will increase in increments of \$25.00 for future violations. For example:

Incident	Cumulative Total
#1. \$25.00	\$ 25.00
#2. \$50.00	\$ 75.00
#3. \$75.00	\$ 150.00

**Emergency Medical Alert (EMA) Devices:** EMA devices are installed at every bed, shower, toilet and urinal located in the clinic's 2nd floor subject areas. These may be activated by either a push button, pull string, or sliding switch located on the face of the device for when a subject feels that their circumstances/situation seem serious or dire and/or there is an inability to call for medical help via red phone or direct communication with staff. This device is for the protection of subjects and any misuse by subjects for any reason other than a medical emergency will result in a financial penalty of \$200.00 and may negatively impact their future participation status.

**Out-patient Visits:** Subjects who are required to report to PPD for out-patient visits must report to the facility 30 minutes before scheduled time. Arriving late (**2 hours past your scheduled time**) to an out-patient visit can result in a financial penalty and will be figured in addition to any existing financial penalties and violations and will be based on above formula. Failure to report to an out-patient visit within 2 hours of our scheduled time will result in loss of compensation for that out-patient visit as stated in the Informed Consent Form plus a \$100.00 financial penalty **and** may result in discontinuation from the study or possible exclusion from future studies.

**Study Check-In:** Subjects who are required to report to PPD for check-in to the study must report to the facility at the scheduled time. Arriving late (30 minutes or more past the scheduled time) to the study check-in can result in a financial penalty of \$100.00 and may impact your participation in the study or possible exclusion from future studies.

**Penalties for Serious Infractions:** If at any time during the study, you test positive for drugs or substances other than the study drug, or, if you engage in disruptive behavior, including but not limited to: destruction of property, stealing, verbal abuse, profanity, bodily or verbal threats, sexual harassment, you will forfeit the scheduled study payment and you will be paid \$2.00 per night or outpatient visit for the time you were in the study. You will be withdrawn from the study and you may not be allowed to participate in other studies. Female subjects who dosed in a study and are later determined to have been pregnant or who become pregnant during the study will be permanently excluded from future studies.

### **III. BREACH OF CONTRACT**

You must follow the study guidelines and the rules of the facility. Breach of any of the items mentioned in this document may result in a forfeiture of your study payment as described above. Agreement to this document indicates that you understand and are willing to abide by the study guidelines and the rules of the facility.

#### IV. **CHANGES IN STUDY**

From time to time, it may be necessary for the sponsor company or the FDA to initiate a change in the study design (**i.e. changes in procedures, length of stay, or compensation**). If changes are necessary for this study, you will be made aware of them as they occur, and you will be asked to sign a new Informed Consent Form at that time. It is still your right to withdraw from any study at any time.

#### V. **PAYMENT INFORMATION**

- A. You may expect payment within three weeks after you complete the study and all of its requirements. Depending on the design of the study, you may receive a portion of your compensation before the study is completed. If you do not qualify for entrance into the study, you will receive no financial compensation. If you are dropped from the study by the investigator, due to an adverse experience, you will be fairly compensated.
- B. If you receive a total of \$600.00 or more in any given year, PPD is required by law to send you a 1099-MISC return and report this income to the IRS. If you receive less than \$600.00 total in any given year, PPD is not required to send you a 1099-MISC return. However, you are required to report all income received each year on your tax return, no matter the amount of compensation. Any income received from PPD is considered Non- Employee Compensation by the IRS.
- C. If you are an employee of PPD your payment for compensation will be included in your regular pay check with taxes taken out.
- D. As a study volunteer, you must realize that you are not employed by PPD, and have no job duties or assigned tasks, only the responsibilities of the study requirements. You must also realize that you receive payment for voluntary participation as a study subject; this is solely in order to compensate you for any inconvenience that may result from your participation.
- E. The decision to admit you into a study is based upon results of pre-study requirements. **No one is assured a place in the study until the first dosing is completed.** If you are a backup volunteer who is required to stay in the facility overnight, you will be compensated a total sum of \$100.00. If you are not required to stay overnight, you will be compensated a total sum of \$50.00.
- F. Your participation as a subject is not completed until all of your exit requirements and clinical laboratory results have been approved by the investigator and the sponsor. For this purpose, you must abstain from alcohol, exercise, and illicit drug use for at least 7 business days following your release from your last in-house period or out-patient visit. If your coordinator has not contacted you within 7 days following your last visit, you may consider yourself completed. However, it is your responsibility to ensure that your coordinator has an active and current telephone number to reach you. Your final payment will be mailed to you when all of your exit requirements have been met and the Investigator has cleared you from all study procedures. Any questions at all concerning your status should be directed to your coordinator.
- G. It is your responsibility to notify PPD of any change in your address as soon as possible. A \$30.00 fee will be charged if you request "stop payment" on a check. PPD will deduct the \$30.00 from the reissued check.

#### VI. **POSITIVE DRUG SCREEN- CANNABINOIDS**

Any subject that tests positive for cannabinoids at screening will be excluded for 3 months for the first offense and permanently excluded for the second offense.

Any subject that tests positive for cannabinoids at the first check-in for a study will be excluded for at least 6 months for the first offense and permanently excluded for the second offense.

Any subject that tests positive for cannabinoids at any time after the first check-in of a study will be permanently excluded.

## **VII. ADDITIONAL INFORMATION**

You must understand that PPD reserves the right to exclude or discontinue any volunteer from participation in this study or any future studies for reasons including, but not limited to the following: violation of the rules listed above, past or current medical conditions, failure to accurately report medical history, jeopardizing your safety or that of others, positive test results for substances of abuse, for other reasons at the discretion of PPD, or an inability to cooperate with staff and/or fellow study participants.

Any subject that tests positive for alcohol and/or cotinine (nicotine) at screening, check-in, or anytime during the study may be excluded from participating in this study or any future studies for a period of time of at least 90 days.

If you have children, you will not be allowed to bring them to your screening visit or any study procedures such as physical exams or outpatient visits.

**Attachment A****ITEMS NOT ALLOWED IN AUSTIN CRU  
(Items are subject to PPD discretion)**

- Anything labeled “Medicated”
- Prescription or Over-the Counter (creams, powders, cough drops, shampoos, acne, aspirin, antacids)
- Instruments/Stereos/Speakers
- Tobacco/Nicotine Products/E-Cigarettes/” Vapes”
- Food or Beverages (includes candy and gum)
- Co-axial Cables
- White-out or Glue (any type)
- Weapons/Replica Weapons/Knives/Sharp Objects/Mace or Pepper Spray/Tools
- Products containing Hydrogen Peroxide
- Sexually explicit Magazines, Books, Movies, etc.
- Nail polish remover
- Aloe containing products
- Charcoal containing products
- Carmex or other medicated lip balm
- Matches/Lighters
- \*Cameras
- Televisions/Desktop computers
- Unlabeled items (i.e.. plastic containers or baggies)
- Lotions containing sunblock
- Alpha-hydroxy acids or vitamins
- Hair removers/straightener/or permanent hair colors
- Anti-aging products
- Teeth whitening products (i.e. strips, adapters, solutions)
- Vitamins/Herbs/Tea Tree Oil/Olive Oil/Green Tea/Coconut Oil/Alpha-Hydroxy Acids

**ALLOWABLE ITEMS  
(Items are subject to PPD discretion)**

- Nonmedicated mouthwash (< 14% alcohol)
- Deodorant
- Books/Magazines
- Hairdryers
- CD's/DVDs (limit 20)
- Chapstick/Vaseline Lip Therapy
- Heating Pads
- Additional Pillow/Blanket/Towel
- Toothpaste without peroxide (may say “Whitening” on the label)
- Walkman/Discman/Watchman (must have headphones)
- Cellular or Portable Telephones
- Board Games/Cards
- \*Laptops/Self Contained Gaming Systems
- Sunglasses (for safety reasons, cannot be worn inside)
- Lotions (in original container)
- Bar Soap (can be outside of packaging)

Subjects with ankle monitors and/or breathalyzers are excluded from participating in all studies. To be considered for possible reinstatement, subject may provide official records once released from using the device and all legal obligations have been met.

\*For confidentiality reasons, subjects bringing laptops, cell phones, Etc. with picture-taking capabilities must physically remove the camera from the device during in house stay. If that’s not possible, subjects must agree to allow PPD staff to cover the camera with tamper-proof tape for the duration of the study. The presence of the tamperproof tape will be verified periodically throughout the study and again at check-out. In the event that you do not agree, the device will be confiscated. If this tape has been tampered with or removed and you do not immediately notify PPD staff, your device may be confiscated and/or you may be docked \$150.00. You will also be asked by staff to preview any pictures that may have been taken with your device. PPD is not responsible for any damage to laptops or cell phones.

A thorough search of all luggage, persons, and clothing is conducted at check-in. If any subject is found purposely concealing items that are not allowed, it will result in a minimum financial penalty of \$150.00



and/or removal from the study. You may also be excluded from future participation. Confiscated items are kept until check out.

**Attachment B****PPD LAUNDRY SERVICE**

Laundry Service is available to subjects who are In-house for long term studies greater than 7 days. Laundry will be provided approximately once a week. Contact your Research Team Leader or a Team Member to arrange for this service. If you qualify, a Personal Laundry Bag will be provided to you by Housekeeping.

**LAUNDRY RULES:**

1. Only 1 load per subject. White and colored garments will be washed together.
2. Your bag must be properly labeled and placed in the hamper located in the assigned shower room on the scheduled day.
3. Same day service is usually provided EXCEPT when a large group is participating.
4. ANY PERSONAL CLOTHING FOUND IN THE HAMPERS WITHOUT A BAG AND LABEL WILL BE DISCARDED.
5. Our laundry uses a non-phosphate detergent and powdered chlorine bleach for whites and a powdered all fabric bleach for colors.

**ACCEPTABLE ITEMS:**

1. Underwear
2. Personal Clothing, EXCEPT SWEATERS AND OTHER ITEMS THAT REQUIRE SPECIALTREATMENT.

**PPD DOES NOT ASSUME RESPONSIBILITY FOR LOST OR DAMAGED ARTICLES OF CLOTHING.**

## Attachment C - Example Menu

### Monday

**Breakfast:** 1 Ham and Cheese Frittata, 1 Plain Bagel, 1 oz. Cream Cheese, 1 ea. (4 oz) Diced Pears, 1 carton (8 fl. oz.) Skim Milk.

**Lunch:** California Chicken Club Sandwich: (1 Hamburger Bun, 1 Uncle G's Chicken Breast, 1 sl. Swiss Cheese, 2 sl. Bacon), 1/4 cup Guacamole, 1 ea. Fresh Fruit Bowl, 1 pkg. Potato Chips, 1 pkt. Light Mayonnaise, 1 pkt. Mustard.

**Dinner:** 1 serving (8 oz.) Italian Meat Lasagna, 1 cup RV Veggie Blend, 1 serving Italian Side Salad, 1 pkt. Fat-Free Italian Dressing, 1 piece (3x2") Yellow Cake with Frosting.

**Snack:** 1 Kind Oats & Honey Bar, 1 bowl Honey Nut Cheerios, 1 carton (8 fl. Oz.) Skim Milk.

KCAL: 2533    PRO: 18.1%    CHO: 50.2%    FAT: 31.7%    Fiber: 20.43g

### Tuesday

**Breakfast:** 1 Buttermilk Biscuit, 1 Turkey Sausage Patty, 1/2 cup Scrambled Eggs, 1 ea. Fresh Fruit Bowl, 2 pkts. Jelly, 1 pkt. Picante Sauce, 1 ea. Chobani Greek Yogurt, 1 carton (8 fl. Oz.) Skim Milk.

**Lunch:** Fresh Made Taco Salad: (3/4 cup browned, taco-seasoned Ground Beef, 3/4 cup Pinto Beans, 1 cup Shredded Lettuce, 1/2 cup Chopped Tomato, 2 T. Shredded Cheddar Cheese), 1 ea. Salsa Cup, 1 pkt. Sour Cream, 1 pkg. Fritos, 1 can (12 fl. Oz.) Fanta.

**Dinner:** 1 serving (6 oz.) King Ranch Casserole, 1/4 cup Pico de Gallo, 1/2 cup Spanish Brown Rice, 3/4 cup Black Beans, 1 Oatmeal Walnut Raisin Cookie.

**Snack:** 1/2 cup Grapes, 1 pkg. Pretzels, 1 box Cran-Grape Juice.

KCAL: 2565    PRO: 18.5%    CHO: 51%    FAT: 30.6%    Fiber: 34.00g

### Wednesday

**Breakfast:** Southwestern Skillet Bowl: (1/2 cup Scrambled Eggs, 3 T. Crumbled Pork Sausage, 1 T. Shredded Cheddar Cheese, 3/4 cup Sautéed Potatoes, 2 T. Diced Bell Pepper), 1 pkt. Picante Sauce, 1 box Orange Juice.

**Lunch:** Original Cheeseburger: (1 Hamburger Bun, 1 Hamburger Patty, 1 sl. Sharp Cheddar Cheese, 1/4 cup Shredded Lettuce, 2 slices Tomato, 1 Fresh Onion Ring, 4 Pickle Chips), 1/2 cup Roasted Potatoes, 1 ea. Fresh Fruit Bowl, 1pkt. Light Mayonnaise, 2 pkts. Mustard, 4 pkts. Ketchup, 1 can (12 fl. Oz.) 7-Up.

**Dinner:** 1 Chicken Teriyaki, 1/2 cup Fried Brown Rice, 1/2 cup Garlic Edamame, 1 cup Asian Veggie Blend, 1 Oatmeal Raisin Walnut Cookie, 1 ea. Fresh Fruit Bowl.

**Snack:** 1 bowl Honey Nut Cheerios, 1 carton (8 fl. Oz.) Skim Milk.

KCAL: 2525    PRO: 19.7%    CHO: 48.9%    FAT: 31.4%    Fiber: 26.90g

### Thursday

**Breakfast:** 2 ea. (2 oz.) Breakfast Kolaches, 1/2 cup Scrambled Eggs, 2 T. Shredded Cheddar Cheese, 1/2 cup Grapes, 2 pkts. Picante Sauce.

**Lunch:** 1 cup Creamy Tomato Basil Bisque, 1 French Breadstick, Chef Salad: (2 cups Tossed Salad, 6 oz. Chopped Turkey, 1 Hard-cooked Egg, 1 T. Shredded Carrots, 1/3 cup Diced Cucumber, 1/3 cup Diced Tomatoes, 3 Red Onion Rings), 2 T. Shredded Cheddar Cheese, 1 pkt. Fat-Free Italian Dressing, 1 pkt. Craisins.

**Dinner:** 1 Chicken Fried Steak, 3/4 cup Homestyle Gravy, 1/2 cup Mashed Potatoes, 1 cup RV Veggie Blend, 1 serving American Side Salad, 1 pkt. Croutons, 1 pkt. Fat-Free Ranch Dressing, 1 ea. Fresh Fruit Bowl.

**Snack:** 1 slice Banana Walnut Bread, 1 carton (8 fl. oz.) Skim Milk.

KCAL: 2547    PRO: 19.1%    CHO: 50.9%    FAT: 30.0%    Fiber: 25.26g

### Friday

**Breakfast:** Bagel Sandwich: (1 Plain Bagel, 1 Egg White Patty, 1 Turkey Sausage Patty, 1 sl. Sharp Cheddar Cheese) 1 ea. Fresh Fruit Bowl.

**Lunch:** Chicken Fajita Tacos: (6 oz. Seasoned Fajita Chicken Strips, 2 Flour Tortillas, 3/4 Ranchero Refried Beans, 4 slices ea. Bell Peppers and Onion), 2 T. Shredded Cheddar Cheese, 1 ea. Salsa Cup, 1/4 cup Guacamole, 1 pkt. Sour Cream, 1 can (12 fl. oz.) 7-Up.

**Dinner:** 1 cup Whole Wheat Spaghetti Noodles, 1 cup Savory Meat Sauce, 1 Texas Toast, 2 pkts. Parmesan Cheese, 1 serving Italian Side Salad, 1 pkt. Golden Italian Dressing, 1 Peanut Butter Cookie.

**Snack:** 1 bowl Honey Nut Cheerios, 1 carton (8 fl. oz.) Skim Milk.

KCAL: 2579    PRO: 18.7%    CHO: 50.3%    FAT: 31.0%    Fiber: 32.16g

### Saturday

**Breakfast:** Tex-Mex Breakfast Bowl: (1/2 cup Ranchero Refried Beans, 3/4 cup Scrambled Eggs, 1 T. Shredded Cheddar Cheese, 1 T. Bacon Bits), 1 ea. Salsa Cup, 1 oz. Tortilla Chips, 1 pkt. Picante Sauce, 1 box Orange Juice, 1 carton (8 fl. oz.) Skim Milk.

**Lunch:** 1 French Fried Onion Chicken, 1 cup RV Veggie Blend, 1/2 cup White Cheddar Mac & Cheese, 1 serving American Side Salad, 1 pkt. Croutons, 1 pkt. Fat-Free Ranch Dressing, 1 ea. Fresh Fruit Bowl, 2 pkts. Ketchup, 1 can (12 fl. oz.) Fanta.

**Dinner:** 2 ea. Beef Enchiladas, 3/4 cup Black Beans, 1/2 cup Spanish Brown Rice, 1/4 cup Shredded Lettuce, 1/4 cup Pico De Gallo, 1 bottle (12 fl. oz.) Blue G2 Gatorade.

**Snack:** 3 oz. Sliced Turkey, 1 stick String Cheese, 1 pkg. Pretzels, 1/2 cup Grapes, 1 box Cran-Grape Juice.

KCAL: 2610    PRO: 19.7%    CHO: 49.8%    FAT: 30.5%    Fiber: 30.38g

### **Sunday**

**Breakfast:** 4 ea. Cini Minis, 2 T. White Frosting, 1 carton (8 fl. oz.) 2% Milk.

**Lunch:** Chicken Marinara: (1 Italian Chicken, 1/4 Marinara Sauce, 2 T. Shredded Parmesan Cheese), 1 cup Green Beans, 1 Texas Toast, 1 serving Italian Side Salad, 1 pkt. Caesar Dressing.

**Dinner:** 4 oz. Blackened Tilapia, 1/2 cup Brown Rice Pilaf, 1 pkt. Tartar Sauce, 1/2 cup KW Veggie Blend, 1 piece Oven-Baked Corn Bread, 3/4 cup Black Beans, 1 can (12 fl. Oz.) 7-Up.

**Snack:** 1 ea. Chobani Greek Yogurt, 1 ea. NutriGrain Bar, 1 ea. Fresh Fruit Bowl.

KCAL: 2571   PRO: 18.9%   CHO: 50.0%   FAT: 31.1%   Fiber: 30.13g

**PPD Clinical Research Unit (CRU)**  
**SUBJECT RULES AND REGULATIONS-**  
**COVID-19 Precautions**

The information in this document explains precautions that have been put into place at the PPD CRUs in Austin, Las Vegas and Orlando in response to COVID-19.

Please note: Financial penalty (minimum of \$250) could occur if you do not follow these precautions. You may also be excluded from future participation. Also, due to the precautions added, all appointments may take longer than expected.

**I. OUTPATIENT VISITS (INCLUDING SCREENING/REPEATS/PHYSICAL & CHECK-IN)**

- A. If you have experienced or have been in close contact with any person that has experienced any fever, upper respiratory, or cold/flu-like symptoms or tested positive for COVID-19 within 14 days of your appointment, please call the 24-hour telephone number below based on your location:

Austin 24-hour telephone number: (512) 447-2985

Las Vegas 24-hour telephone number: (702) 219-4979

Orlando 24-hour telephone number: (407) 955-5400

- B. Only study participants will be allowed in the building. Please do not bring anyone with you

Note: Exceptions can be made for special populations where a caregiver or study partner are necessary

**II. IN HOUSE STAY**

- A. In accordance with current local guidelines and site policy you will be asked to:

- Comply with current social distancing policies which may include, 6-foot social distancing policies, reduced common area access, and anti-loitering policies.

**SUBJECT SIGNATURE**

I understand and agree to abide by the precautions outlined in this document. I have been given the opportunity to ask questions and have received answers to those questions. I understand that I will be given a copy of this document to keep.

\_\_\_\_\_  
Subject Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Subject Name (Printed)