

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

SITE OF INVESTIGATION: Orlando CRU
100 W Gore Street., Ste. 202
Orlando, FL 32806

24 HOUR TELEPHONE NUMBER: 689-216-3100

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.

- B. The decision to admit you into a study is based upon results of screening requirements. There is not always compensation for the screening process. 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 may require 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 box with your initials 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.
- 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 unless otherwise specified. Sharing of food with other study participants is not allowed.
- 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. 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.
- K. 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.
- L. Inappropriate behavior toward, or harassment of subjects or staff will not be tolerated and may result in your dismissal.
- M. 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 Orlando CRU.
- N. 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.
- O. You will not be allowed to discuss any aspect of the data contained in your binder/chart with any other subject. This includes adverse experiences and vital signs. **Any subject caught discussing any data will be warned once and then penalized 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 withdrawn from the study or excluded from future participation in other PPD studies.**
- P. You will not be allowed to communicate by telephone or any other electronic means such as text messaging any aspect of the study or data contained in your chart with any person other than PPD staff or applicable study partners. The use of social media to communicate any study related means is strictly prohibited. **Any subject caught communicating any study information or data may be withdrawn from the study, refused payment and excluded from future participation.**

- Q. 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 any PPD CRU.
- R. 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.**
- S. All personal electronics or anything in a closed box will be opened at check-in. All personal electronics may only be used with headphones and are to be turned off in patient rooms 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.
- T. Bedtime rules: Unless you are involved in late night procedures, **bedtime is midnight.**
- U. You may not participate in any form of gambling during your in-house stay (i.e. cards for money, betting on sports events).
- V. 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.
- W. All used gauze must be disposed of in the proper receptacles.
- X. If ECGs are required for the study, staff may be required to shave your chest in order to obtain an accurate reading. Females should refrain from wearing underwire bras while in-house, as this can cause artifact on an ECG. You will be asked to remove the bra for this procedure.
- Y. 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.
- Z. 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)

Incident	Consequence
#1	Warning #1
#2	Warning #2
#3	6 Month Ban

PENALTIES FOR NO SHOWS (CHECK-IN)

Incident	Consequence
Initial Check-in #1	3 month ban
Initial Check-in #2	9 month ban
Subsequent Period Check-in	9 month ban

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

Out-patient Visits: Subjects who are required to report to PPD for out-patient visits must report to the facility at their scheduled time. Arriving late (**less than 2 hours past your scheduled time**) to an out-patient visit can result in a penalty. 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 **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 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 (aggressive profanity), fighting, bodily or verbal threats, or 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 as well.

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 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 may not receive financial compensation, depending on the informed consent of study you're participating in. If you are dropped from the study by the Investigator, due to an adverse event, you will be compensated based on the informed consent.
- 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. 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.
- D. 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 all dosing for your group is completed.** If you are a backup volunteer who is required to stay in the facility overnight, you will be compensated depending on the wording of the Informed Consent document that you signed.

- E. 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 or as the protocol requires. 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 may not be issued to you until 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.
- F. It is your responsibility to notify PPD of any change in your address as soon as possible.

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.

If subjects have a legal prescription for cannabinoids and it is allowed per protocol, these consequences will not be applicable.

VII. ADDITIONAL INFORMATION

PPD's Orlando CRU offers open parking in the lot connected to the building. Please do not leave any valuables in your car, as you are parking at your own risk. You will not be able to access your car while confined at the site. In the event that its necessary for you to retrieve items from your car, you will be accompanied by a staff member.

Wi-Fi/Wireless internet is available at the clinic. Instructions regarding how to access the wireless internet will be posted in each room and throughout the building in public areas.

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. . These consequences are not applicable if the protocol allows the result in question.

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.

ITEMS PROHIBITED IN ORLANDO CRU
(Items are subject to PPD discretion)**

- Anything labeled “Medicated”
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- 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
- 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)
- /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 (if desired)
- 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)

All items of value are the responsibility of the volunteer; PPD is not responsible for loss or damage.

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. 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.

** Some of the items listed in the prohibited section of the document may be permitted depending on the trial you are participating in. Please discuss the use of medications and vitamins with a PPD staff member prior to bringing them to the clinic.

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 this may result in removal from the study. You may also be excluded from future participation. Confiscated items are kept until check out.

SUBJECT SIGNATURE

I understand and agree to abide by the rules and regulations 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)