

Advarra IRB approved: 09Aug2021
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**PPD DEVELOPMENT, LP  
SUBJECT RULES AND REGULATIONS**

**SPONSOR:** PPD Development, LP

**SITE OF INVESTIGATION:** PPD Development, LP  
8285 W. Arby Avenue, Suite 331  
Las Vegas, NV 89113

**24 HOUR TELEPHONE NUMBER:** (702) 963-1600

**I. SCREENING PROCEDURES**

- A. You have reported to our office at PPD Development, 8285 W. Arby Avenue, Ste. 331, Las Vegas NV, 89113, for your initial screening visit. To participate in any procedures at PPD, you must read, review and sign an Informed Consent Document. The screening procedures required for your study are described in the Informed Consent. The total screening process will consist of 2 (or more) visits.
- B. Prior to screening for the study, your photo will be used as a means of verifying your identification and will be saved in the 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 (such as physical exam, etc.).
- D. The decision to admit you into a study is based upon results of pre-study Requirements. There is no 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 current government issued 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 event 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.**

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- B. 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.
- C. You will only be allowed to bring two pieces of luggage into the facility; this includes backpack 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 for a list of allowable items.)
- D. You will be issued an Identification Bracelet upon check-in. This Bracelet may not be removed prior to discharge. You will be issued scrubs to identify your study group upon check-in. You will be provided with a clean scrub 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. (See Attachment B for our information regarding Laundry Service provided to participants staying in-house for long term studies greater than 7 days). Laundry will be provided approximately once a week.
- E. If you are enrolled in a study which requires at home dosing, you are required to have a reliable and consistent residence. All study materials and supplies are intended for only you. You are responsible to ensure that you are the only person exposed to this investigational product.
- F. Beds are assigned during check-in, 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, except for studies that require bed confinement. No food is to leave the dining area. Sharing of food with other participant is not allowed. *(A menu in a separate document will be given to you. You will be required to sign and date the menu to confirm that you are able to adhere to the planned menu).* Please note that your study may require variations to the standard menu. This menu is provided only as 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.

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- K. You will not be allowed to participate in any strenuous physical activities for the duration of the study, unless allowed per protocol. You will not be allowed to use tobacco products during the study unless permitted by the protocol, tobacco products are not allowed during any period at the PPD unit.
- L. Inappropriate behavior toward, or harassment of subjects or staff will not be tolerated, and may result with disqualification from study participation
- M. We have both male and female subjects in-house. The dorm rooms may be co-ed. Subjects are expected to abstain from sexual activity while housed in the facilities.
- N. We have compatible 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. You may be required to limit your internet access at times. If infractions occur your internet access may be restricted and/or you may be permanently excluded from future PPD studies. **You will need to bring your own computer disks and paper if you plan to use our computer.**
- O. PPD Las Vegas does not supply phones for personal calls. In case of an emergency, you may discuss use of a PPD phone with the Research Staff.
- P. If you plan to write letters or send mail during your in-house stay, please bring your own Stamps and stationery.

All in-coming mail should be addressed as follows:

**PPD**

**Attention: Project Manager - \_\_\_\_\_(name),**

**Subject Name: \_\_\_\_\_**

**Subject #: \_\_\_\_\_,**

**8285 W. Arby Ave, Suite 331 Las Vegas, NV 89113**

All in-coming mail will be sorted by the staff and searched for unallowable items. Mail will then be distributed daily, except weekends and holidays. Outgoing mail may be given to the front desk, except weekends and holidays. Mail picked up at 2:00PM does not go out until next business day.

You will not be able to have “packages” mailed to you (e.g. FedEx, UPS or U.S. Mail) While housed at the PPD, Las Vegas Clinical Research Unit.

- Q. **Parking Policy:** Parking is provided in front and to the East of our building. 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. 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

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for any contraband, may occur at any time while housed in the unit. Contraband items include: any food; medications; cameras (including cell phones and laptops with cameras), sexually explicit books, magazines, and films; and any items considered to be inappropriate for the study. Any items not allowed in the facility will be placed in a bag with your name on it and returned during check-out. (*See Attachment A for a list of allowable items*) 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 source documents with any other subject. This includes adverse experiences and vital signs. **Any subject caught discussing any data will be warned once and then financially 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 financially penalized 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 source documents 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 or cabinet 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. 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**

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**Time Dependent” (NTD) procedures. The NTD wording on the source documents is for staff use only.**

- AC. 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.
- AD. 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.

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

Incident	Cumulative Total
#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

**PENALTIES FOR LATES (DOSING PROCEDURES)**

Incident	Cumulative Total
#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

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

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

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**Emergency Medical Alert (EMA) Devices:** EMA devices are installed at every bed, and restroom. 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 communicate directly with research 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 at approximately 9:00 am (subject to change due to clinic capacity). Arriving late (**less than 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 consent form plus a \$100.00 financial penalty, and may result in discontinuation from the study. As a courtesy, if you are unable to keep the appointment or need to cancel or reschedule, please call the facility 24hours prior.

**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.

**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 above may result in a forfeiture of your study payment as described above. Signing 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 consent form at that time. It is still your right to withdraw from any study at any time.

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## V. PAYMENT INFORMATION

- A. Depending on the design of the study, you may receive a portion of your compensation before the study is completed. You may expect payment within three weeks after you complete the study and all of its requirements. 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 \$75.00. If you are not required to stay overnight you will be compensated a total sum of \$25.00.
- 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 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 from the reissued check.

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**VI. POSITIVE DRUG SCREEN- CANNABINOIDS/POSITIVE ALCOHOL BREATH TEST**

Any subject with a positive drug screen, positive for cannabinoids or alcohol breath test at screening will be excluded for 3 months for the first offense and permanently excluded for the second offense. Any subject with a positive drug screen at screening may be permanently excluded from study participation at the discretion of the Investigator.

Any subject with a positive drug screen or alcohol breath test 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 with a positive drug screen or alcohol breath test at any time after the first check-in of a study will be permanently excluded.

**Attachment A**

**ITEMS NOT ALLOWED IN PPD CLINICAL UNIT  
(Items are subject to PPD discretion)**

- |  |  |
|--|--|
| Anything labeled “medicated”   | Carmex or other medicated lip balm                           |
| Prescription or over-the counter (creams, powders, cough drops, shampoos, acne, aspirin, antacids) | Matches/Lighters   |
| Drums, Guitars, Amplifiers, Stereos, Portable speakers   | *Cameras   |
| Cigars/cigarettes/pipes/chewing tobacco  | Televisions  |
| Food or beverages (includes candy and gum)   | Unlabeled items (i.e., plastic containers or baggies)        |
| Co-axial Cables  | Lotions containing sunblock                                  |
| White-out or glue (any type)   | Alpha-hydroxy acids or vitamins                              |
| Weapons/Replica Weapons/Knives/Sharp Objects/ Mace or Pepper Spray/Tools                           | Hair removers/straightener/or permanent hair colors          |
| Products containing Hydrogen Peroxide  | Anti-aging products  |
| Make-up products with vitamins   | Teeth whitening products (i.e., strips, adapters, solutions) |
| Sexually explicit magazines, books, movies, etc.   | Desktop computers  |
| Nail polish remover  | Projectors   |
| Vitamins, herbs, tea tree oil  | Plug-in telephones   |



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

Nonmedicated mouthwash (<14% alcohol)  Deodorant Book's/Magazines Hairdryers Video/Cassette tapes/CD's/DVDs (limit 20) Vaseline Lip Therapy Additional Pillow/Blanket/Towel (if desired) *Tablets	Toothpaste without peroxide (may say "Whitening" on the label) Walkman, Discman, Watchman (must have headphones) *Cellular or portable Telephones Chapstick Board Games/cards *Laptops
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All items of value are the responsibility of the volunteer; PPD is not responsible for loss or damage.

Due to the limited storage space available to accommodate belongings, luggage must be limited to two (2) bags 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 staying longer than 10 days one extra bag/item may be allowed.

Subjects with ankle monitors and/or camera-equipped breathalyzers are excluded from participating in all studies. Subjects will need to provide written documentation that they were released from using the devices or have met all legal obligations to be reinstated.

\*For confidentiality reasons, subjects bringing laptops, tablet or cell phones with picture-taking capabilities must physically remove the camera from the device. 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 tamper-proof 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 financially penalized \$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, tablets 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.

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**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. Laundry bags will be distributed by research staffs along with a checklist on laundry day
3. Laundry bags will be collected a specified time and subject will be informed once laundry is completed for pick up at nurse's station.
4. Same day service is usually provided EXCEPT when a large group is participating.

**ACCEPTABLE  
ITEMS:**

1. Underwear

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

**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.

\_\_\_\_\_  
Printed Name of Study Subject

\_\_\_\_\_  
Time

\_\_\_\_\_  
Signature of Study Subject

\_\_\_\_\_  
Date