

# HOUSE RULES

**Not abiding by these house rules could result in you being fined, excused from the study and/or impact your participation in future studies at the ACPRU.**

## ADMISSION

### Arrival Time

- You must arrive at the ACPRU at your scheduled appointment time.
- In the event of an EMERGENCY, call the ACPRU as soon as possible at (847) 935-4400, or if there is no answer, call 1-800-827-2778 and leave a message to inform the staff that you will be late.
- If we cannot accommodate a late arrival time, you **will** be informed not to check in.

### Inspection of Personal Belongings

- Upon arrival at the ACPRU, you will be required to change into scrub tops and pants which are to be worn throughout the study. All street clothes, including footwear, will be inspected. At check in, only undergarments will be allowed to be worn under the scrubs. A limited amount of clothing will be allowed to be brought upstairs: clothes that you plan to wear at check-out, additional undergarments, sleepwear and an additional sweatshirt/long sleeve shirt or sweater.
- All items that you bring to the ACPRU will be inspected by the staff. Any personal items that you may need during the study must be transferred into **one** ACPRU issued storage container.
- Personal belongings will be inspected at any time that the staff deems necessary and at the end of confinement.
- You may bring small, personal electronic items such as a laptop computer, personal gaming system (e.g., playstation) or a portable media player (e.g., MP3 player, CD player) to the ACPRU for personal use as long as it fits into the one ACPRU issued storage container.
- Prohibited electronic items include but are not limited to fans, heaters and hair dryers. If you are unsure or have a question about an item, please check with the ACPRU staff **BEFORE** your arrival.
- The ACPRU staff reserves the right to prohibit any item at any time.

- Receiving packages larger than a standard 8.5x11 mailer will not be permitted. If a package should arrive the package may be rejected and returned to sender.

### **Prohibited Items**

- FOOD, CANDY, GUM and BEVERAGES are not to be brought to the confinement area of the ACPRU. In the event that they are, they will be disposed of.
- MEDICATIONS OR MEDICATED PRODUCTS (*e.g.*, aspirin, Tylenol, Tums, vitamins, medicated creams, powders, lotions, herbal supplements) are not to be brought to the ACPRU. In the event that they are, the product may be disposed of and/or you may not be allowed to check-in for the study.
- Personal hygiene items must be in original container with listed ingredients.
- No cameras (whether reported as functional or not functional) are allowed. AbbVie does not allow any type of photo or videos to be taken on the unit for privacy of all study participants and protection of private company information.
  - Not abiding by this could result in your device being surrendered until end of confinement.
  - Items with a camera will be required to have security tape placed over the camera lens. Security tape will be checked daily. If the security tape falls off, inform staff immediately to have it replaced.
- Weapons or items considered to be potentially dangerous are not allowed to be brought to the ACPRU and will be confiscated at check-in.
- Items that are deemed inappropriate by ACPRU staff will be held with your luggage until the end of your confinement.
- Bed linens (including pillows) and stuffed animals, will not be allowed on the 2<sup>nd</sup> floor of the ACPRU. One small personal blanket will be allowed.

### **Storage of Valuables**

- A locker, lock and key will be assigned to you upon your request for storage of your valuables (highly recommended). You are responsible for maintaining the security of your assigned key.
  - Money, wallets, purses, credit cards and valuables **are not** to be kept in your stored luggage.
- No personal locking devices are allowed to be used at the ACPRU.
- You are responsible for promptly returning your lock and key to the staff at the end of confinement. A \$50 fine will be charged if the lock and key are not returned.
- **THE ACPRU IS NOT RESPONSIBLE FOR LOSS OR THEFT OF PERSONAL PROPERTY.**

## SAFETY MONITORING

Your safety and the outcome of the study depend upon accurate and timely reporting of your health status.

### Side Effects

- You must tell the study staff about all side effects you experience.
- You must not discuss your side effects with other study participants.

### Adverse Event Checks

- An announcement will be made indicating the time and location of scheduled adverse event checks. However, you are responsible for reporting to the study nurse whenever you are not feeling well or when you are experiencing anything unusual.

## STUDY-RELATED ACTIVITIES

### Wake-up Time

- You will be awakened approximately 30 minutes before the first morning activity or as directed by staff.

### Study Events

- The dosing and sample collection schedules are available at the nurses' station. You are expected to arrive **5 minutes** before your scheduled activity. **It is YOUR RESPONSIBILITY to be on time for ALL study-related activities.**
- Money will be deducted from your stipend if a scheduled activity is delayed because you were not present at the required time.
- You may be confined in a designated area for **at least 2 hours after dosing**. You must inform staff if you need to use the restroom within the first hour after dosing. You will only be allowed to use the lab restroom with the door open and a curtain for privacy.
- Do not bring any items (e.g. electronic devices, blankets, reading materials, etc.) on your person to scheduled study events. They may be left in the waiting area.

### Waste Disposal

- Gauze pads used with the blood draws must be discarded in the designated **RED** hazardous waste disposable bins only.
- Do not throw regular trash in the hazardous waste bins.

### Meals

- No one may enter the dining room for meals before being called by staff.
- No one can be in the dining room when another study is eating unless allowed by staff.
- Meals must be eaten ONLY in the dining room.
- You are not allowed behind the counter in the dining room.
- Do not touch any food items until instructed by staff.
- The meals and snacks are based on protocol requirements. Therefore, you are not allowed to consume any food not provided by the staff. Additional requirements/expectations will be communicated to you by unit staff.
- You are required to complete your meal within 30 minutes. **DO NOT TRADE, HIDE, SHARE OR SAVE FOOD** items.
- You may request extra condiments **at the time you receive your tray**.
- Do not re-approach the serving line until all other participants have been served.
- The staff will inspect your tray when you are finished with your meal to ensure protocol compliance. Do not discard anything from your tray until the staff has inspected it.
- It is expected that you clean up your eating area after you finish your meal.
- Do not leave the dining room during meals without staff approval.
- Follow staff instructions when entering and exiting the dining area.
- The use of electronic devices (i.e., phones), including hands free, are NOT allowed during meal hours.

### Quiet Hours

- You must be in your bedroom with the lights out **by 11:00 PM**.
- Quiet hours are 11:00 PM – 06:00 AM. Return all borrowed games, movies, and batteries to the nurses' station by 10:30 PM.
- No cell phone or laptop usage is allowed after 11:00 PM. If there is an emergency phone call during quiet hours, leave your room and see the nurse.
- No laundry use is allowed between 10:00 PM and 6:00 AM.
- No shower use is allowed between 10:30 PM and 5:00 AM, or as directed by staff.

### Alcohol and Drug Testing During the Study

- Alcohol and urine drug testing (including a urine screen for tobacco by-products) may be performed at the discretion of the ACPRU Medical Director/Principal Investigator at ANY TIME while you are participating in a study.
- As stated in the Informed Consent, if you have a positive alcohol, drug or nicotine test, **YOUR STIPEND FOR THE STUDY WILL BE REDUCED**, you will be disqualified from the study, and you may not be allowed to participate in future studies.

## **GENERAL**

### **Confidentiality**

- Confidentiality of all study participants , study procedures, adverse events, and study medications are expected to be maintained at all times.

### **Lab Results**

- If you would like a copy of your lab results, while in confinement speak to the nurse on staff.

### **Language**

- Foul, improper or offensive language will not be tolerated. This includes when you are on a personal phone call.

### **Behavior**

- Viewing on AbbVie and personal computers must not be offensive to the average person. This includes, but is not limited to, pornography or other potentially personally offensive material. Please be advised that your computer activity on AbbVie computers may be monitored. Online illegal activities are prohibited.
  - Not abiding by this could result in your personal device being surrendered until end of confinement.
- Any behavior (verbal or physical) directed toward a participant or staff member that is perceived as argumentative, threatening or as sexual harassment will not be tolerated.
- Display of lewd behavior will not be tolerated.
- Display of aggressive behavior (*i.e.*, provoking gestures or speeches) will not be tolerated.
- Common courtesy is expected at all times.
- Theft and vandalism will not be tolerated and can be reported to the local police department. Any participant found to have stolen items will be subject to higher than normal fines.
- Soliciting (*e.g.*, selling, trading, advertising, petitioning) is NOT allowed on the ACPRU premises.

### **Confinement**

- You may NOT leave the ACPRU at any time during the study unless escorted by ACPRU personnel when time permits.

### Attire

- Scrub tops and pants are provided and MUST be worn and visible at all times. A T-shirt or light weight shirt may be worn under your scrub top; however, it must be removed if it interferes with planned study activities. If long sleeved, you must be able to pull up the sleeves without bulking. Garments with zippers or buttons may be worn over scrub tops; however, must be removed prior to study activities.
- For your safety, slippers, shoes or sandals with socks must be worn while you are at the ACPRU at all times. When in the blood draw area, closed toe, hard soled shoes must be worn. Flip flops or shower shoes may be worn to and from the shower only.
- Your identification badge must be worn and be visible at all times.
- No sunglasses may be worn while you are at the ACPRU, unless on the balcony.
- Bras and t-shirts must be removed prior to ECG collection.
- Scrub pants must be worn around your waist.
- **You cannot store extra scrubs in your bedrooms.**

### Room Assignments/Room Restrictions

- You are permitted to sleep only in your assigned room. You must not enter any bedrooms other than your own. Any room change must be authorized by a staff member.
- You may only sleep in the bed you are assigned, in the room you are assigned.
- Your mattress must be covered with a sheet and you must sleep on the sheet.
- You cannot store your belongings on an empty bed.

### Personal Hygiene

- You must shower and change your scrubs daily.
- Hair Dryers are provided for your use. You will be sharing these with other study participants.
- Hair clippers may only be used in the bathroom and you must clean-up after yourself.
- If utilizing a flat iron or curling iron, a flat/curling iron holder able to withstand 450 to 500 degrees Fahrenheit or a flat/curling iron mat must be used.
- A flat/curling iron mat will be available to borrow.
- Flat/curling irons can only be used in the main restroom.

### **Restricted Areas**

- You may not enter the NURSES' STATION, STAFF LOUNGE, OFFICE, CONFERENCE ROOM, BEHIND THE COUNTER IN THE DINING ROOM or STORAGE AREAS (e.g., hall cabinets, closets and drawers) at any time.
- The library is a 24-hour quiet area.
- You may not enter the following areas at any time other than for study related events when staff is present:
  - INFIRMARY;
  - LABORATORY;
  - ECG ROOMS;
  - EXAM ROOMS; and
  - STUDY EVENT ROOMS
- Depending on the protocol, staffing, and conditions outside, the staff nurse and the principal investigator will determine if participants may go on the balcony for a maximum of 30 minutes per day when supervised by staff.

### **Electronics: Televisions, DVD Players, Movies, Computers, Etc.**

- No photography or video recording of any sort is permitted.
- The volume level of TVs and electronic devices is to be reasonable. You will be asked to turn the volume down if it disturbs other participants.
- Computers (with internet access) are located in the computer room.
- The ACPRU computer use may be limited to one hour.
- All personal electronic devices must be used with headphones and maintained at a volume that is not disturbing to staff or other participants.

### **Phone Calls**

- Telephones are available for local calls ONLY. Calls must be limited to 15 minutes.
- No incoming or outgoing calls are allowed after 11:00 PM.
- You are expected to respect those around you while on the phone.
- Cell phone use after 11:00PM is NOT permitted
- In the event of an emergency contact the staff.

### **Emergency Procedures**

- Do not block fire exits with chairs or tables.
- In the event of an emergency, you must follow directions provided by the staff on evacuation procedures.
- Adherence to emergencies and/or drills is mandatory.
- The balcony door is not an emergency exit.
- The unit is now equipped with an Emergency Call System (Call Bell). These are located in common areas and individual rooms. These should be activated only in the event of a medical emergency.

## VISITORS

### Visiting Information

- Visitors may be allowed between 1:30 PM and 6:00 PM Monday through Friday, providing they do not interfere with scheduled study activities.
- Visitors will be asked to leave the clinic floor of the ACPRU during blood draws, dosing, physical exams, vital sign measurements, ECGs, meals and other study-related activities.
- Visitors are restricted to the visitors' area.
- Appropriate behavior must be followed at all times.
- Visitors will be asked to leave if they (children included) become disruptive and cause interference with study activities.
- The number of visitors and visiting duration may be limited at any one time to avoid overcrowding in the visitors' area.
- Visitors may only use the restroom on the first floor.

### Visitor Check-In

- Visitors must check in with a staff member upon arrival to the ACPRU.
- Visitors must sign in and out.
- All purses, coats, packages, backpacks, bags and items with cameras brought to the ACPRU by a visitor will be secured by the staff at the reception center until the visitor leaves the ACPRU.
- The staff will search visitors' (including children's) pockets, shoes and socks. Items brought for the participant will be inspected. Baby baskets/carriers will also be inspected.
- Visitors are not allowed to bring any food or beverages into the ACPRU or to consume any food or beverages while in the ACPRU.
- Children (17 and under) must be accompanied by an adult (aside from the participant they are visiting) and must be supervised at all times.

**Note:** Participants are accountable for their visitors. In the event that prohibited items are brought in by visitors, you may be subject to fines, and the privilege of having visitors may be revoked.

## HOUSEKEEPING

### Bathrooms and Bedrooms

- If your stay is more than several days, you will be periodically provided with clean bed linen in order to change the bed. Place dirty linen (including towels) and scrubs in designated soiled laundry containers.
- You are expected to keep your sleeping area and bathrooms in order. Beds are expected to be made every day.
- Personal items are not to be kept in the bathrooms.
- Keep personal items, except shoes, off of the bedroom floor.
- In order for the housekeeper to properly clean your bedroom, you may be asked to leave your bedroom.
- You may be asked to leave the recreation rooms for a brief period in order for the housekeeper to clean them.
- PLEASE PICK UP AFTER YOURSELF.
- HOUSEKEEPING SERVICES ARE A COURTESY. DO NOT ABUSE.

## DISCHARGE

- Before discharge from the ACPRU, all scrubs and any other property of the ACPRU must be returned. Scrub tops must be worn until bag checks are completed.
- If you do not return the items belonging to the ACPRU, the cost of replacement will be deducted from your stipend.
- Prior to discharge, you must remove the linens (NOT PILLOWS) from your bed and place them in the designated soiled laundry containers provided.
- When rooms are inspected, all participants should be present or as directed.

### Study Follow-Up Procedures

- Any follow-up procedures must be performed only at the ACPRU unless otherwise instructed and must be completed prior to receiving your final payment.

## FINES

- Any staff member may, when warranted, submit a violation form and fines may be incurred with the **typical** range being \$50 - \$75 per violation. Depending on the severity and number of violations reported, fines may be larger.
- Your final payment will be delayed by up to 2 weeks if you incur any fines. After 3 fines, your continued participation in this study may be terminated, at which time you may be paid a reduced stipend.

- I HAVE READ THE ABOVE RULES. THE INFORMATION PRESENTED ABOVE HAS BEEN CLEARLY AND COMPLETELY EXPLAINED TO ME.
- I UNDERSTAND THAT BY SIGNING THESE RULES I HAVE BEEN INFORMED; FINES WILL RESULT IN A MONETARY DEDUCTION IN MY FINAL PAYMENT.
- MY QUESTIONS REGARDING THE ABOVE INFORMATION HAVE BEEN ANSWERED TO MY SATISFACTION.
- I, THE VOLUNTEER, AGREE TO ASSUME FULL RESPONSIBILITY FOR ALL PERSONAL ITEMS I BRING TO THE ACPRU.
- I UNDERSTAND THE HOUSE RULES AND AGREE TO FOLLOW THEM.

Study Number: \_\_\_\_\_

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Printed Name of Subject Participant

Signature of Subject Participant

Date

NOTE: Return signed original to subject participant. Retain copy of signature page.