

Worldwide Clinical Trials

In-House Facility Rules

Participation in all Worldwide Clinical Trials studies requires strict adherence to the facility rules. These rules exist to assure good study data for each participant and to maintain harmony among the participants. Please assist staff members and fellow study participants by complying with the following procedures:

COVID 19 Safety Requirements

Worldwide Clinical Trials is committed to the safety and health of our participants and staff. During any visit or in-house stay, you will be required to wear a face mask or face covering. It is mandatory to wear the mask when interacting with staff and other participants. You will not have to wear the mask when you sleep, shower or while eating a required meal/snack. If you do not bring a mask, one will be provided.

During your visits and stay, we ask that you maintain 6 feet of social distancing, including limiting the number of people in an area, leaving enough space between yourself and others in common areas and throughout the facility.

While participating in a study, clean your hands often with either soap and water or hand sanitizer containing at least 60% alcohol. Hand sanitizer stations are available for use in common areas and throughout the facility.

PARKING

Worldwide Clinical Trials recommends that you arrange to be dropped off and picked up for your in-house periods; however ample parking is available if needed. Participant parking is not allowed in the covered parking areas or the front parking lot. Worldwide Clinical Trials will not assume responsibility for theft or damage to any vehicles parked in the parking lot.

IDENTIFICATION

Upon check-in arrival to the facility, you will be identified with a wrist band and a bed will be assigned to you. Once you have been checked in, you will not be permitted to leave the facility until the end of each housing period. You will also be provided a colored t-shirt for study identification. Your t-shirt must be worn at all times and will be re-collected at the end of the study period.

BEDDING/CLOTHING

Bedding (sheets, pillow and blanket) as well as 2 towels and a facecloth will be provided to you at check-in. New towels will be provided every 4th day and new bedding will be provided every 7th day during the study. Sleeping arrangements will be pre-assigned; please do not switch these during the check-in process. You will be required to strip the linens from your assigned bed prior to leaving the facility.

Bring comfortable and appropriate clothes for your stay; clothes and shoes will be required to be worn at all times. You are encouraged to bring shower shoes, a light jacket and a blanket. Vital signs procedures require use of your bare arm, so a zippered jacket is recommended. If you are a light sleeper you should bring earplugs as you will be sleeping in a dormitory setting.

Laundry services will be provided once per week for studies with housing stays longer than 5 nights.

WHAT TO BRING/PERSONAL ITEMS

Upon arrival, all personal items will be searched and inspected as well as the clothing you are wearing.

If you are uncertain about any item you want to bring, consult with your coordinator prior to admission.

If you bring an item that is not allowed, especially medications, you may be discontinued from the study. This includes over the counter and/or prescription medications.

ALLOWABLE ITEMS

- Non-medicated mouthwash
- Shampoo, conditioner soap (non-medicated and in original container)
- Books, magazines
- Pillows, blankets, towels
- Laptops and tablets
- Toothpaste (cannot be a whitening toothpaste or contain peroxide)
- Deodorant
- Board games/cards
- Cellular telephones
- Hairdryers
- Chapstick (non-medicated)
- Vaseline lip therapy

ITEMS NOT ALLOWED

- Any substance containing hemp
- Carmex, Blistex
- Medicated items – Prescription or Over-the-counter (OTC) (mouthwash, creams, powders, cough drops, shampoos, acne medications, aspirin, antacids), or nutritional supplements
- Cameras (cameras on phones, or any electronic device will be covered with tamper-evident tape)
- Weapons, knives, scissors, or sharp objects
- Sexually explicit material (magazines, books, films) or offensive clothing
- Hair clippers
- Matches & lighters
- Tobacco (any form) or electronic cigarette devices
- Food or beverages (includes candy & gum)
- Amplifiers, drums, or stereo equipment
- Unlabeled items (i.e. plastic containers or baggies)
- White-out or glue (any type)
- Condoms
- Drug paraphernalia
- Any substance containing Vitamin E or Aloe
- Any substance containing SPF
- Network Cables
- Heating pads and electric blankets

Should you accidentally bring a non-allowed item to your check in, the item(s) will be confiscated and held until study completion. Any confiscated items not claimed within 14 days of study completion will be disposed.

Worldwide Clinical Trials is not responsible for loss or theft of personal items. Lockers are available, however you will need to bring your own lock.

Random searches of your person and belongings may be conducted during your in house stay.

ELECTRONIC DEVICES

All personal electronics may be used only with headphones/earphones and are to be turned off in the dormitory areas between 10pm and 8am; bedtime in the facility is midnight unless you are involved in study procedures. There should be no use of

cell phones in the dormitories, quiet areas or while procedures are being conducted. Cameras on any electronic devices will be covered with tamper evident tape; this tape must not be removed.

Worldwide Clinical Trials provides access to the internet via Wi-Fi and our computers in the Internet Café. The internet activity is continuously monitored and logged by Worldwide IT. If any malicious or illegal activity is detected on our network, internet rights will be blocked. Examples of such activities include, but are not limited to: hacking, spamming, illegal downloading or uploading of copyrighted materials (files, movies, music, etc.).

You may be asked to turn off all electronic devices, or your electronic devices may be confiscated, during critical study procedures.

MEALS AND SNACKS

All meals and snacks are standardized based on study requirements. You cannot bring your own food. You are encouraged to eat your entire meal while in house.

Some studies contain critical meals. Critical meals are designed as part of the study to ensure that all participants have a standardized food intake before taking the study medication. If you do not consume all of an identified critical meal, you may be discontinued from the study.

STUDY RESTRICTIONS

Please refer to your study specific Informed Consent Document for study specific restrictions.

Hand washing and showers will not be allowed during the water restriction period. You will also not be allowed to brush your teeth during this time.

Engaging in strenuous activities is not allowed while participating in a study.

Tests for substances of abuse, prohibited medications, tobacco or alcohol may be conducted at random.

If your study requires pulse oximetry monitoring, you may not wear artificial nails or nail polish.

Visitors are not allowed during the in-house stay.

Children and pets are not allowed in the research clinic or clinic outpatient areas.

RESPECT AND BEHAVIOR

As you will be part of a group of people participating in a clinical trial, we ask that you behave accordingly to maintain a pleasant environment.

Inappropriate and aggressive language or behavior towards other participants or staff will not be tolerated and may result in withdrawal from the study and future study participation may be denied. Sexual activity, soliciting or gambling of any kind is strictly prohibited while in-house.

Worldwide Clinical Trials has closed circuit television cameras placed throughout the facility for security purposes. Any damage, destruction or theft of Worldwide property will result in legal actions.

At times you may carry your subject chart or data collection sheets to study procedures with you. Do not destroy or write on any of the data collection sheets.

Study Payments

You will receive either a debit card or direct deposit as payment for participation in the study. Debit card payments will be loaded onto the card within 24-48 hours after you check out of the facility at study end.

Any additional payments (such as study participation bonuses) will be mailed to you within 14 days of study end or loaded onto the debit card within 3-4 days after your last visit. Please keep the debit card as it will be used for payment for future study participation at Worldwide Clinical Trials.

If you do not complete the study, the amount you receive will depend on the portion of the study you completed.

If you are a backup, you will receive payment as outlined in your informed consent document; payments will be made with cash or a debit card.

If you do not follow the in house facility rules or do not arrive on time for a procedure, the following penalties will be applied and your payment will be reduced as applicable:

Penalties for Procedures Not Performed on Time (performed early or late)
You will be considered late if you do not arrive 5 minutes prior to the procedure time

Occurrence	Violation	Total
Blood draw	Any	50.00
Timed Meal (dose or procedure dependent)	Any	50.00
Standard Meal	Any	10.00
Other Procedure	1 st	Free
#Other Procedure	Additional Violations	10.00

Penalties for not following in house facility rules:

<u>Incident</u>	<u>Amount</u>
Failure to wear colored study t-shirt as instructed by staff, each offense	\$50.00
Unauthorized physical activities	\$25.00
Pranks and Physical Altercations	\$25.00 - \$100.00
Noncompliance of facility rules (i.e. ignoring bedtime curfew, using electronics in the dorms between 10 p.m. and 8 a.m., hiding/trading food, not wearing shoes, profanity)	\$25.00 - \$50.00
Disrespectful to staff and other participants	\$25.00 - \$50.00
Premature removal of tamper-evident tape from camera on electronic devices or hiding a device with camera that does not have tamper-evident tape applied	\$150.00
Failure to wear a face mask, or wearing a face mask incorrectly:	
1 st offense	Warning
2 nd offense	\$100.00
3 rd offense	\$200.00 and/or removal from the study and clinic

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In-House Facility Rules

This acknowledges that I, _____ *[Print Name]*, have reviewed the In-House Facility Rules for Worldwide Clinical Trials. Any breach of any of these facility rules will result in negation of the payment contract, may result in a forfeiture of a portion of the study payment and may result in dismissal from the current study and any future studies at Worldwide Clinical Trials.

Signature of Subject

Date

Signature of Worldwide Clinical Trials Staff

Date