



## Clinical Research Unit (CRU)

### STUDY PARTICIPANT RULES AND REGULATIONS

**SITE OF INVESTIGATION:**

Austin CRU

7551 Metro Center Dr., Ste. 200  
Austin, TX 78744

**24 HOUR TELEPHONE NUMBER:**

(512) 447-2985

We sincerely appreciate your willingness to join Trialmed on this journey to help bring new treatments to those who need them. Your safety and well-being are our top priorities. This guide outlines the rules, responsibilities, and expectations associated with screening, enrollment, and participation in our clinical research studies. Please read this carefully to ensure a smooth and successful experience.

---

#### 1. Informed Consent

- The Informed Consent confirms your voluntary agreement to participate in the clinical trial (study).
- You may withdraw your consent at any time.
- It is required that you read, understand, and sign the Informed Consent Form (ICF) before any study-related procedures.

---

#### 2. Photo ID & Study Integrity

- A valid photo ID is required at every visit (screening, check-in, outpatient, etc.).
- Failure to present ID will result in being turned away and may delay compensation or lead to disqualification.
- A photograph may also be taken and stored securely to verify your identity during your stay.

---

#### 3. Medication Disclosure

- All medications, supplements, or substances must be disclosed.
- Taking unauthorized substances (prescription, OTC, herbal, illicit, etc.) may result in serious medical risks and disqualification.

---

#### 4. Personal Searches & Belongings

- Thorough, gender-appropriate searches will be conducted at check-in (removal of clothing down to undergarments) and may occur throughout your stay.

- Personal items will be inspected. Contraband will be stored and returned to you at check-out.
  - Do not bring valuables; Trialmed is not responsible for lost/damaged items.
- 

### 5. Allowed/Prohibited Items

- Refer to **Attachment A** for a full list of allowed and prohibited items.
  - Concealing contraband may result in a minimum of \$150.00 withholding from completion bonus, removal from the current study, and possible exclusion from future studies.
  - Tobacco use is not allowed unless permitted by the study protocol.
- 

### 6. Electronics & Privacy

- Electronics must be powered off between 12:00 AM – 8:00 AM. Repeated misuse may result in confiscation.
  - You are responsible for your personal property, including electronics. Trialmed is not liable for damage or loss.
  - For privacy reasons the use of audio or video recording devices of any kind is strictly prohibited within the clinic, including wearable recording devices (e.g., Meta Glasses or similar devices).
  - Tamper-resistant tape will be used to cover all device cameras.
    - Tampering may result in withholding from completion bonus, confiscation of device, removal from the current study, and possible exclusion from future studies.
- 

### 7. Reporting Adverse Events (AE) and concomitant medications

- Immediate and complete reporting of any **adverse event (AE)**, whether in-house or between visits, is required at all times and is critical to participant safety and study integrity, no matter how minor it may seem.
  - All **concomitant medications** must be reported promptly, including prescription, over-the-counter, vitamins, and herbal supplements, whether taken before, during, or between study visits.
  - **Follow-up phone calls** are required for safety purposes and must be completed.
  - Failure to report **AEs, concomitant medications, answer or respond to follow-up calls** in a timely manner may result in forfeiture of the completion bonus and disqualification from current and future studies.
- 

### 8. Emergency Medical Alert Devices (EMA)

- Located throughout the facility (beds, bathrooms), EMA devices are for medical emergencies only.
  - Misuse may result in a \$200 withholding from completion bonus and future study disqualification.
- 

### 9. Identification wristbands & Study Attire

- For safety reasons you will receive a wristband and study-issued attire (t-shirt and/or scrubs), which **MUST** be worn and visible at all times during your stay. Failure to comply with this policy may result in withholding from completion bonus.
  - Shoes must also be worn in all common areas for safety purposes.
- 

### 10. Housing & Curfew

- You must sleep in your assigned bed. Privacy tents and switching beds are not allowed.
- Curfew is at 12:00 AM (lights out at 11:45pm) unless study procedures may require otherwise.

---

## 11. Meals & Fasting

- It is important to understand that nutrition and calorie intake are monitored and measured. This ensures **standardization** and **control** across participants to draw valid conclusions.
- Participants must be willing and may be **required to eat the full meal**, including **all condiments**, because all calories count for accurate data collection. *Please see [Attachment B](#) for a sample menu.*
- Fasting periods may be required (no food or drink other than water).
- Only study-provided meals are allowed during your stay in the clinic, no outside food or drinks permitted.
- Sharing food is prohibited.

---

## 12. Hygiene & Physical Activity

- Daily showers are required unless exempted by your study.
- Complimentary laundry service is available for in-house stays of seven (7) days or longer.
- Exercise and strenuous activity are prohibited unless permitted by protocol.

---

## 13. Internet & Phone Access

- Wi-Fi and computer access are available during non-curfew hours.
- Viewing pornography or inappropriate content is prohibited.

---

## 14. Mail & Deliveries

- You may NOT receive packages or mail during your stay.
- You may send mail (letters) if you bring your own stamps. Outgoing mailboxes are available on-site.

---

## 15. Parking

- Designated parking is available.
- Unauthorized or unregistered parking may result in \$50 penalties per violation.
- Trialmed is not responsible for vehicle damage, personal property or theft.

---

## 16. Procedures & Timepoints

- All procedures, including urine drug screenings, may be observed/monitored by staff to uphold data integrity.
- Be on time (arrive 3–5 minutes early) for all scheduled procedures.
- Repeat lateness will incur escalating withholdings from your completion bonus.
- For outpatient visits (OPVs), arrive 30 minutes early. Late arrival or rescheduling may lead to withholdings from your completion bonus (see withholding structure below).

---

## 17. Check-In & Attendance Exceptions

Your completion bonus is calculated based on the successful completion of the study. Exceptions may occur when these key time points and requirements are not met.

### A. No-Show (missed appointment)

<b>Incident</b>	<b>Screening</b>	<b>Check-In</b>
1 <sup>st</sup>	Warning	3-month ban

<b>Incident</b>	<b>Screening</b>	<b>Check-In</b>
2 <sup>nd</sup>	Warning	9-month ban
3 <sup>rd</sup>	6-month ban	9-month ban

**B. Lateness (Non-Dosing / OPV)**

<b>Incident</b>	<b>Withholdings</b>	<b>Cumulative Total</b>
1 <sup>st</sup>	Warning	\$0
2 <sup>nd</sup>	\$10	\$10
3 <sup>rd</sup>	\$20	\$30
4 <sup>th</sup>	\$30	\$60
5 <sup>th</sup>	\$40	\$100
6 <sup>th</sup>	\$50	\$150
7 <sup>th</sup>	\$60	\$210

**C. Lateness (Dosing / Rescheduled OPV)**

<b>Incident</b>	<b>Withholdings</b>	<b>Cumulative Total</b>
1 <sup>st</sup>	\$50	\$50
2 <sup>nd</sup>	\$100	\$150
3 <sup>rd</sup>	\$150	\$300
4 <sup>th</sup>	\$200	\$500
5 <sup>th</sup>	\$250	\$750

---

**18. Study Conduct Expectations**

Any violation of these expectations *including but not limited to the following* may result in removal from the study, disqualification from current and future studies, and forfeiture of any completion bonus.

- Failure to disclose or inaccurate reporting of medical history
- Unsafe behavior, harassment, or theft
- Drug/alcohol use
- Profanity, gambling, or inappropriate behavior
- Physical or verbal altercations
- Displays of affection
- Any sexual activity, whether alone or with others

---

**19. Violation Examples - include but are not limited to the following**

<b>Violation</b>	<b>Withholding</b>
Property damage	Cost of repairs
Verbal altercations	\$200 (& or possible removal)
Physical altercations	Result = 2.00 compensation per night & permanent exclusion
Sexual activity	Minimum \$150 & removal
Profanity	\$25 per incident
Unauthorized activities	Minimum \$50
Curfew violations	Start at \$25; increase by \$25 per incident

---

## 20. Payment

- Payments are expected to be processed within 3 weeks of completion date *and all study requirements*.
- If you earn \$2,000 or more annually, a 1099-MISC will be issued for tax purposes.
- Participants are not Trialmed employees; all study compensation is reported to the IRS as *non-employee income*.

### Payment Examples:

Please note, these are examples only and the dollar amounts listed may vary by study. You must refer to your specific Informed Consent Form (ICF) for the exact payment amounts applicable to your study.

- Backup Overnight – If you stay in the facility overnight but not needed for dosing in the study: \$250
- Backup, Not Needed - If you perform check-in procedures but not needed for dosing and discharged the same day: \$100
- Screening Extra/Standby – If you are requested to remain at the facility and active as a Screening Extra/Standby and do not perform check-in procedures: \$50

---

## 21. Substance Use Policies

- Alcohol/Nicotine: Positive test after screening = 90-day exclusion
- Cannabinoids:
  - **1st Screening** Positive test = **3-month** exclusion (any subsequent positive results = Permanent exclusion)
  - **1st Check-In** Positive = **6-month** exclusion (any subsequent positive results = Permanent exclusion)
  - Positive at Check-In = **Permanent** exclusion from future participation
- Other positive drug screen result = **Permanent exclusion** (examples: Cocaine, MDMA, Benzodiazepines and Amphetamines)
- You must abstain from any alcohol, drugs, and exercise for 7 business days after the study, unless your Informed Consent states otherwise.

---

## 22. Final Notes

- *Admission to the study is not guaranteed until after your first dose is complete.*
- Trialmed may exclude any participant at any time for behavior *including but not limited to* disruptive conduct, noncompliance or safety concerns.

- For safety reasons, **female** participants who become **pregnant** after dosing or during the study despite having agreed to use the required methods of contraception, as documented in the Informed Consent Form and source data will not be eligible to participate in any future studies.
- Children are not allowed at the facility at any time for safety reasons.
- You may be required to re-consent if there are significant changes to the study design.

---

If you have any questions about these policies, procedures, or your participation, please contact your Study Coordinator. Your understanding and cooperation are essential to the success of this research and the safety of all involved. By signing below, you agree to the requirements of these Rules and Regulations.

X  
\_\_\_\_\_  
Participant's signature

\_\_\_\_\_  
Date

## **Attachment A**

### **ITEMS NOT ALLOWED IN CRU**

(Items are subject to site discretion)

For your safety and the safety of others, all luggage, clothing, and personal belongings will be thoroughly searched during check-in. **Please check your bags carefully before arriving at the clinic to ensure no prohibited items are inside.**

- Prescription or over-the-counter items (e.g., creams, powders, cough drops, shampoos, acne treatments, aspirin, antacids) are not permitted unless instructed by Trialmed staff or stated otherwise in your Informed Consent
  - *If instructed to bring your prescription or over-the-counter medication, it must be documented and released to staff prior to your check-in search procedure*
- Anything labeled “medicated”
- Unlabeled items (e.g., plastic containers or baggies)
- Ingestible items such as gum, seasonings, or any food items
- **If primary ingredients (within the first five) or 100% is stated on the label these items will not be allowed:**
  - Alpha-hydroxy acids, vitamin-enriched or anti-aging products
  - Vitamins, herbs, Aloe, tea tree oil, olive oil, green tea, coconut oil,
- Charcoal-containing products
- Carmex or other medicated lip balm
- Lotions or products containing sunblock/SPF
- Nail polish remover
- Perfume, body spray, air fresheners or any scented products
- Teeth-whitening products (e.g., strips, adapters, solutions)
- Tobacco/nicotine products, e-cigarettes, vapes
- Matches or lighters

- Heating devices such as heating pads/heated blankets
- White-Out or glue (any type)
- Cameras/recording devices
- Instruments, stereos, speakers, televisions, desktop computers, projectors or co-axial cables
- Sexually explicit magazines, movies, etc.
- Weapons, replica weapons, guns of any type, knives, sharp objects, mace, pepper spray, tools
- Ankle monitors or breathalyzers
- Valuables such as expensive jewelry or large sums of cash
- Pets

### **Participant Device & Compliance Policy**

Participants with ankle monitors and/or breathalyzers will not be enrolled in studies due to legal obligations and possible safety concerns. Once the device has been removed and all legal obligations have been fulfilled, official documentation may be provided in consideration for possible reinstatement.

### **Search and Confiscation Policy**

- Intentional concealment of prohibited items, including but not limited to those listed, will result in a minimum withholding of **\$150.00** and may warrant immediate dismissal from the study and all future study opportunities.
- Confiscated items will be held securely and returned at check-out.

## **Attachment A**

# **ITEMS ALLOWED IN CRU**

(Items are subject to site discretion)

- New (sealed/unopened) non-medicated mouthwash (less than 14% alcohol)
- Toothpaste without peroxide (may say “whitening” on the label)
- Deodorant
- Bar soap (in original packaging)
- ChapStick or Vaseline Lip Therapy (non-medicated)
- Books and magazines
- Board games/cards
- Hairdryers, curling/flat irons (with responsible use)
- Additional pillows, blanket, or towel
- Sunglasses (However, for safety reasons cannot be worn inside the clinic)
- DVDs and gaming CDs (limit 20)
- Headphones (must be used with all devices)
- Cellphones
- Laptops/incased gaming systems

### **Device Camera Policy for In-House Stays**

For participant privacy and data confidentiality reasons the use of audio or video recording devices of any kind is strictly prohibited within the clinic, including wearable recording devices (e.g., Meta Glasses or similar devices).

- All camera lenses on devices (e.g., cell phones, laptops, tablets) must be covered with tamper-resistant tape provided by Trialmed staff for the duration of the study.
- The presence and condition of tamper-resistant tape will be periodically checked throughout the stay and again at check-out.
- If a participant refuses to comply, the device will be **confiscated**.
- If the tape is found to be tampered with or removed without prior staff notification, the participant's device may **be confiscated** and/or a **\$150.00** withholding from completion bonus may be incurred.
- Participants may also be asked to **preview any photos** taken during the stay for review by staff.
- **Trialmed is not responsible** for damage to personal electronic devices or personal property.

# Attachment B

## Sample Standard Menu

Austin		Las Vegas	
Monday		Monday	
Breakfast:	<u>Ham &amp; Cheese Frittata:</u> Ham & Cheese Frittata Plain Bagel Cream Cheese Diced Pears Orange Juice	Breakfast:	<u>Fit Breakfast:</u> Scrambled Eggs Turkey Sausage Patty Roasted Red Potatoes Mozzarella Cheese Fajita Flour Tortilla Apple Juice
Lunch:	<u>California Chicken Club Sandwich:</u> Chicken Breast Bacon, Swiss Cheese, Guacamole & Mayonnaise Hamburger bun Fresh Fruit Bowl BBQ Chips	Lunch:	<u>Grilled Sirloin:</u> Round Eye Sirloin Sauteed Onions & Bell Peppers Sauteed Mushrooms Red Potato Mash
Dinner:	Spaghetti & Meat Sauce: Spaghetti Noodles Savory Meat Sauce French Bread Stick Parmesan Cheese Italian Side Salad Ranch Dressing	Dinner:	<u>Pesto Chicken Pasta:</u> Grilled Chicken Breast Spaghetti Capers, Yellow Squash & Asparagus Zucchini Pesto Sauce Parmesan Cheese
Snack:	White Cheddar Popcorn Baby Carrots Apple Juice	Snack:	<u>Oatmeal &amp; Fruit:</u> Oatmeal Almond Milk Granola & Honey Mixed Fresh Fruit & Banana

Tuesday		Tuesday	
Breakfast:	Southern Biscuit & Eggs Breakfast: Buttermilk Biscuit Scrambled Eggs Picante Sauce Jelly Fresh Fruit Bowl Apple Juice	Breakfast:	<u>Classic Breakfast:</u> Scrambled Egg Whites Turkey Bacon Grits with Shredded Cheddar Cheese Plain Bagel Jelly & Butter Mixed Fresh Fruit Apple Juice
Lunch:	Taco Salad: Taco-Seasoned Ground Beef Pinto Beans Shredded Lettuce, Chopped Tomato & Corn Shredded Cheddar Cheese Sour Cream & Picante Sauce Fritos Fanta	Lunch:	<u>Turkey Bolognese:</u> Ground Turkey Marinara Sauteed Onions & Bell Peppers Zucchini Noodles Grated Parmesan Cheese Fresh Basil
Dinner:	Bulgogi Beef Plate: Beef Bulgogi Bell Peppers & Onion Fried Brown Rice Garlic Edamame Fresh Fruit Bowl Sugar Cookie	Dinner:	<u>Chicken Mediterrean Wrap:</u> Grilled Chicken Strips Diced Cucumber & Cherry Tomatoes Feta & Grated Parmesan Cheese Chopped Romaine Lettuce Hummus Spinach Tortilla
Snack:	Tropical Trail Mix Watermelon Waterloo	Snack:	<u>Yogurt Parfait:</u> Greek Yogurt Granola & Honey Blueberries & Sliced Strawberries

Wednesday		Wednesday	
Breakfast:	Southwestern Breakfast Skillet Bowl: Scrambled Eggs Crumbled Pork Sausage Shredded Cheddar Cheese Sauteed Potatoes, Diced Bell Pepper & Picante Sauce Orange Juice	Breakfast:	Steak & Eggs Scrambled Eggs Beef Round Sirloin Whole Wheat Toast Jelly Butter
Lunch:	Original Cheeseburger: Hamburger Patty & Bun Sharp Cheddar Cheese Shredded Lettuce, Tomato & Pickle Chips Fresh Onion Ring, Mayonnaise & Ketchup Roasted Potatoes Fresh Fruit Bowl Black Cherry Waterloo	Lunch:	<u>Chicken Burrito:</u> Grilled Chicken Spinach Tortilla Sauteed Onions & Bell Peppers Mozzarella Cheese Black Beans Brown Rice Tapatio Sauce
Dinner:	Crispy Breaded Tilapia & Cornbread: Breaded Tilapia Brown Rice Pilaf Tartar Sauce Veggie Blend & Black Beans Oven-Backed Corn Bread Fanta	Dinner:	<u>Turkey Thai Basil:</u> Thai Turkey Spinach Shredded Carrots Sauteed Onions Fresh Basil White Rice
Snack:	Nature Valley Oats Honey Bar Vanilla Almond Milk	Snack:	Blueberry Banana Walnut Muffin Mixed Fresh Fruit

Thursday		Thursday	
Breakfast:	Cini Mini Breakfast: Cini Mini rolls White Frosting Turkey Sausage Patty Fresh Fruit Bowl Grape Juice	Breakfast:	<u>Power Breakfast Burrito:</u> Spinach Tortilla Scrambled Egg Whites & Mozzarella Cheese Turkey Sausage Patty Tapatio Sauce Mixed Fresh Fruit Apple Juice
Lunch:	Soup & Fresh-Made Chef Salad: Creamy Tomato Basil Bisque & French Breadstick Supreme Tossed Salad: Tossed Salad, Shredded Carrots, Diced Cucumber & Tomato Seasoned Fajita Chicken Strips Hard-Cooked Egg & Shredded Cheddar Cheese Fat-Free Ranch Dressing	Lunch:	<u>Chicken Parmesan:</u> Grilled Chicken Mozzarella Cheese & Shredded Parmesan Cheese Marinara Sauce Whole Wheat Penne Pasta Cut Corn
Dinner:	Creamy Chicken Alfredo Pasta & Fresh Caesar Salad: Penne Pasta & Alfredo Sauce Fajita Chicken Parmesan Cheese & Dried Parsley Caesar Salad: Romaine Lettuce, Croutons & Parmesan Cheese Caesar Dressing	Dinner:	<u>Gravy Mushroom Burger:</u> Burger Bun Ground Beef Patty Sautéed Mushrooms & Onions Brown Gravy Green Beans Sweet Potato Mash
Snack:	Apple Raisin Bran Cereal Skim Milk	Snack:	<u>Chicken Caesar Salad:</u> Grilled Chicken Spinach & Romaine Cherry Tomatoes, Cucumbers & Shredded Parmesan Cheese Caesar Dressing Pita Bread & Pretzels

Friday		Friday	
Breakfast:	Bagel Breakfast Sandwich: Plain Bagel Scrambled Eggs Turkey Sausage Patty & Slice of Sharp Cheddar Cheese Fresh Fruit Bowl Apple Juice	Breakfast:	<u>Western Denver Muffin:</u> Large Western Denver Egg Muffin Red Potatoes Apple Juice
Lunch:	Chicken Fajita Tacos: Season Fajita Chicken Strips Flour Tortillas Ranchero Refried Beans Bell Peppers & Onion Shredded Cheddar Cheese, Guacamole & Sour Cream	Lunch:	<u>Teriyaki Salmon:</u> Teriyaki Glazed Salmon Cooked Carrots Brown Rice Mixed Fresh Fruit
Dinner:	Italian Meat Lasagna: Italian Meat Lasagna & Veggie Blend Caesar Salad: Romaine Lettuce Croutons & Parmesan Cheese Caesar Dressing Rice Crispy Brown Butter Treat	Dinner:	<u>Veggie Pasta:</u> Whole Wheat Pasta Capers & Mushrooms Zucchini Squash & Asparagus Shredded Parmesan Cheese Pesto Sauce
Snack:	Homemade Banana Walnut Bread Diced Pears Vanilla Almond Milk	Snack:	Strawberry Banana Protein Muffin Low Fat Milk

Saturday		Saturday	
Breakfast:	Biscuit & Gravy Breakfast: Buttermilk Biscuit Home-Style Gravy Crumbled Pork Sausage Scrambled Eggs Shredded Cheddar Cheese Picante Sauce Diced Peaches Skim Milk	Breakfast:	<u>Garden Scramble:</u> Scrambled Eggs Spinach Mushrooms, Onions & Cheddar Cheese Sweet Potato Turkey Bacon Plain Bagel Butter & Jelly Apple Juice
Lunch:	French Fried Chicken and Mac & Cheese: French Fried Onion Chicken Ketchup Veggie Blend White Cheddar Mac & Cheese American Side Salad Croutons Fat-Free Ranch Dressing Fresh Fruit Bowl	Lunch:	<u>Turkey Chili:</u> Ground Turkey Tomato Sauce Mozzarella Cheese Sautéed Onions & Bell Peppers Chopped Green Onion Kidney Beans & Black Beans Yogurt Mini Cornbread Loaves
Dinner:	BBQ Pulled Pork Tacos: Pulled Pork Flour Tortillas Black Beans Topped with Queso Fresco Spanish Brown Rice Shredded Lettuce Pico de Gallo Black Cherry Waterloo	Dinner:	<u>Chicken Fajitas:</u> Seasoned Chopped Chicken Breast Fajita Tortillas Sautéed Onions & Bell Peppers Black Beans Shredded Cheddar Cheese Yogurt Tapatio Sauce
Snack:	Light N Fit Vanilla Yogurt Nature Valley Granola Bar Blueberries Honey	Snack:	<u>Fruit Bowl:</u> Strawberries Blueberries Kiwi Grapes

Sunday		Sunday	
Breakfast:	Spinach Quiche Breakfast: Spinach Quiche Turkey Sausage Patties Diced Pears Apple Juice	Breakfast:	<u>Pancakes &amp; Turkey Sausage:</u> Turkey Sausage Patty Pancakes & Sugar Free Syrup Blueberries Scrambled Eggs & Mozzarella Cheese
Lunch:	BBQ Chicken Tender Sandwich: Hamburger Bun Chicken Tenders, Pickle Chips & BBQ Dipping Sauce Potato Salad Fresh Fruit Bowl Rice Crispy Brown Butter Treat	Lunch:	<u>Teriyaki Turkey Meatballs:</u> Spinach Teriyaki Glazed Turkey Meatballs Chopped Green Onion White Rice
Dinner:	Teriyaki Salmon & Asian Mixed Salad: Grilled Salmon & Teriyaki Sauce White Rice & Garlic Edamame Asian Mixed Salad: Chopped Romaine, Coleslaw & Carrot Mix Ken's Pan Asian Dressing Peanut Butter Cookie	Dinner:	<u>BBQ Chicken Sandwich:</u> Chicken Breast BBQ Sauce Fried Onions Hamburger Bun Green Beans
Snack:	Pretzels String Cheese Grapes Apple Juice	Snack:	<u>Hummus &amp; Pita:</u> Pita Bread Round Hummus Cucumber, Cherry Tomatoes & Carrot Sticks