Cedar Ridge Clinical Research Institute

Research Site 0142 · 1400 Cedar Ridge Parkway, Suite 220, Fairhaven, ST 58027
Study coordinator 555-0184 (Mon–Fri 8:00 a.m.–5:00 p.m.) · 24-hour study line 555-0188
Sponsor: Vantera Therapeutics, Inc. · Protocol VTX-1042-301

PARTICIPANT SAFETY CONTACT CARD

Card version
2.0, dated 14 January 2027
IRB approved
06 February 2027 · expires 05 February 2028
IRB protocol
MC-2027-0184 · Site 0142
24-hour study line
555-0188

When and How to Contact the Study Team

Three contact routes, what to have ready, a wallet card to carry, and a log for what you reported

IN A LIFE-THREATENING EMERGENCY, CALL 911 FIRST — THEN CALL 555-0188

The study team does not provide emergency care and never replaces emergency services or your own doctor. Get help first; tell the study team within 24 hours.

PARTICIPANT ID	PROTOCOL	PRINCIPAL INVESTIGATOR	SITE
VTX-1042-301-0142-0037	**VTX-1042-301**	**Imogen T. Race, MD**	**Cedar Ridge Clinical Research Institute, Site 0142**
EMERGENCY	URGENT, 24 HOURS	ROUTINE, BUSINESS HOURS	IRB
911 or local emergency services	**555-0188**	**555-0184**	**Midland Central IRB · 1-888-555-0191**

THREE ROUTES — PICK BY URGENCY, NOT BY TOPIC

ROUTE	CALL	WHEN TO USE IT	EXAMPLES	HOW FAST
EMERGENCY	911 first, then 555-0188 within 24 hours	Anything that could be life-threatening or needs care right now	Trouble breathing; swelling of the face, lips, or throat; chest pain; fainting; severe bleeding; a seizure; sudden confusion or weakness	Immediately
URGENT	24-hour study line 555-0188	A new or clearly worsening problem that is not an emergency but should not wait	Temperature of 100.4°F (38.0°C) or higher; an injection-site reaction that is spreading or painful; a rash; persistent vomiting; a possible pregnancy; any hospital stay or emergency visit; a new prescription from another clinician	Same day, within 24 hours
ROUTINE	Coordinator 555-0184, Mon–Fri 8:00 a.m.–5:00 p.m.	Anything about logistics, paperwork, or the study process	Scheduling and rescheduling; diary questions; reimbursement and mileage; supplies; travel plans; questions about the consent form; requesting a copy of a document	Next business day, within 2 business days

When you are not sure which route fits, use the higher one. No one at this site has ever been told they called the 24-hour line unnecessarily.

HAVE THIS READY BEFORE YOU DIAL

- ☐ Your participant ID: VTX-1042-301-0142-0037
- ☐ The protocol number: VTX-1042-301
- ☐ The investigator's name: Imogen T. Race, MD
- ☐ The date and time the problem started
- ☐ What you noticed, in your own words
- ☐ What you did about it, including anything you took
- ☐ Whether it is getting better, worse, or staying the same
- ☐ A current list of all your medicines and supplements
- ☐ The name and number of any other clinician involved
- ☐ Your wallet card, or a photo of it on your phone

Write the date, the time, who you spoke with, and what you were told. The log on the next page is for exactly that.

WHAT THE STUDY TEAM WILL AND WILL NOT DO

Will do:

- Answer the 24-hour line and reach the on-call investigator
- Decide with you whether you need to be seen and where
- Record what you report in the study safety record
- Tell any other clinician what they need to know about the study

Will not do:

- Provide emergency care, or replace 911 or an emergency department
- Replace your regular doctor for conditions unrelated to the study
- Diagnose you over the phone or tell you what is causing a symptom
- Tell you whether you are receiving VTX-1042 or placebo, except when unblinding is medically necessary

WALLET CARD — CUT ALONG THE OUTER BORDER AND CARRY BOTH SIDES

FRONT

I AM TAKING PART IN A RESEARCH STUDY **VTX-1042-301**	PARTICIPANT ID **VTX-1042-301-0142-0037**
INVESTIGATIONAL PRODUCT **VTX-1042 or placebo, blinded**	PRINCIPAL INVESTIGATOR **Imogen T. Race, MD**
SITE **Cedar Ridge Clinical Research Institute, Site 0142**	SITE ADDRESS **1400 Cedar Ridge Parkway, Suite 220, Fairhaven, ST 58027**

BACK

24-HOUR STUDY LINE — CALL FOR ANY STUDY QUESTION **555-0188**	STUDY COORDINATOR, BUSINESS HOURS **555-0184**
EMERGENCY **911 or local emergency services**	MIDLAND CENTRAL IRB **1-888-555-0191**
FOR THE TREATING CLINICIAN **Please call the 24-hour line before starting a new medicine or procedure where the timing allows.**	CARD VERSION **2.0 (14 Jan 2027) · IRB approved 06 Feb 2027**

Carry the card at every medical appointment, including dental and urgent care. Show it to anyone who treats you and ask them to call the 24-hour line. Ask the coordinator for a replacement at any visit.

SITUATIONS THAT PEOPLE HESITATE ABOUT — CALL ANYWAY

SITUATION	ROUTE	WHY
Another doctor wants to start a new medicine	Urgent, 555-0188	Some medicines interact with the study drug or are not permitted by the protocol. Follow the treating clinician's instruction, then call.
You were told to stop the study drug by another clinician	Urgent, 555-0188	Follow that clinician's instruction. Then call so the study record is accurate and the investigator can follow up.
You went to an emergency department or were admitted	Urgent, 555-0188	Any hospital visit must be reported within 24 hours, even if it seems unrelated to the study.
You think you or your partner may be pregnant	Urgent, 555-0188	A pregnancy must be reported immediately. Study drug is stopped and follow-up is arranged.
You feel fine but the diary asked about something new	Routine, 555-0184	The diary is not monitored. If something is worth asking about, ask a person.
You want to stop being in the study	Routine, 555-0184	You may stop at any time without explanation. A final safety check is offered, and your regular care is unaffected.
Something feels off and you cannot describe it	Urgent, 555-0188	Describing it is the study team's job, not yours.

CONTACT AND REPORTING LOG — FILL ONE ROW PER CALL

DATE	TIME	WHAT HAPPENED, IN MY WORDS	ROUTE USED	WHO I SPOKE WITH	REFERENCE NUMBER	WHAT I WAS TOLD TO DO	FOLLOW-UP DONE

Bring this log to every visit. It is your record, not the study's, and it is the fastest way for the coordinator to confirm that everything you reported was captured.

SAFETY BOUNDARIES YOU SHOULD KNOW

- The 24-hour line is answered by the study team, not by emergency dispatch. It cannot send an ambulance.
- The study team does not manage conditions unrelated to the study. Keep seeing your own doctor.
- Nothing the study team says on the phone is a diagnosis.
- Do not change how you take the study drug based on a phone conversation unless the investigator tells you to.
- The study is blinded. Neither you nor the site knows your assignment, and the blind is broken only when knowing it would change your medical care.
- Reporting a side effect never removes you from the study by itself, and it never affects your reimbursement.

FOR A CLINICIAN TREATING THIS PARTICIPANT

This person is enrolled in protocol VTX-1042-301 and is receiving either VTX-1042 or a matching placebo. The assignment is blinded to the participant and to the site.

- Call 555-0188 at any hour to reach the on-call investigator.
- Emergency unblinding is available 24 hours a day when the assignment would change management.
- Provide whatever treatment you judge necessary. Do not delay care to reach the study team.
- The study team can supply the investigator's brochure summary and the participant's current study medication record.
- Please report any hospitalization, significant new diagnosis, or new prescription to the 24-hour line.

Consent boundary: Any video, animation, slide, handout, or plain-language summary prepared from this document — including the demonstration video this specimen was built for — **supplements the informed consent discussion and never replaces it**. No material of any kind replaces the conversation with the study team or the signed, IRB-approved consent form. If a summary and the IRB-approved consent form disagree, the consent form controls.

Scope of this document: This card lists contact routes. It does not describe symptoms you should expect, does not tell you what any symptom means, and must never be used to decide whether a symptom is serious. When in doubt, use the more urgent route. In a life-threatening emergency, call local emergency services before calling anyone at the study.

FICTIONAL SPECIMEN. Cedar Ridge Clinical Research Institute, Vantera Therapeutics, Midland Central IRB, protocol VTX-1042-301, the investigator, the coordinator, the participant identifier, the version and approval dates, the study drug, the reported frequencies, the reimbursement amounts, and every telephone number and address shown here are invented for demonstration only. This is not a real informed consent form, protocol, IRB-approved document, schedule of activities, or safety instruction, and nothing in it should be followed, signed, relied on, or reused as a template for a real study or a real participant.