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

INFORMED CONSENT FORM — KEY INFORMATION

Consent form version
4.2, dated 14 January 2027
IRB approved
06 February 2027
IRB approval expires
05 February 2028
IRB protocol
MC-2027-0184 · Site 0142

Consent to Take Part in a Research Study

Protocol VTX-1042-301 · A randomized, double-blind, placebo-controlled study of VTX-1042 in adults with moderate-to-severe chronic inflammatory joint disease

THIS FORM SUPPLEMENTS THE CONSENT DISCUSSION — IT DOES NOT REPLACE IT

No document, summary, slide, or video replaces the conversation with the study team or the signed consent form. Take as much time as you want, ask every question you have, and take this home before you decide.

PARTICIPANT NAME	PARTICIPANT ID	PRINCIPAL INVESTIGATOR	STUDY COORDINATOR
	VTX-1042-301-0142-____	**Imogen T. Race, MD**	**Naomi Ellsworth, CCRC · 555-0184**
24-HOUR STUDY LINE	IRB CONTACT	RESEARCH PARTICIPANT ADVOCATE	CONSENT VERSION
555-0188	**Midland Central IRB · 1-888-555-0191**	**1-888-555-0193**	**4.2 (14 Jan 2027)**

KEY INFORMATION — READ THIS FIRST

QUESTION	THE SHORT ANSWER
Do I have to take part?	No. Taking part is entirely voluntary. You may decline, and you may stop at any time. Your regular medical care, your relationship with your doctors, and any benefits you are entitled to will not be affected in any way by that choice.
Why is this research being done?	To find out whether VTX-1042, an investigational medicine, reduces disease activity compared with a placebo over 52 weeks, and to learn more about its safety. VTX-1042 is investigational, which means it is not approved for sale and its benefits are not established.
How long will I be in the study?	About 14 months in total: up to 28 days of screening, 52 weeks of treatment across 11 in-person visits and 2 telephone visits, and one safety follow-up about 30 days after the last dose.
What will happen to me?	You will be assigned by chance to VTX-1042 or to placebo in a 2-to-1 ratio, so you have roughly a 2-in-3 chance of receiving VTX-1042. Neither you nor the study team will know which you received. You will have physical examinations, blood and urine tests, electrocardiograms, questionnaires, and a daily electronic diary.
What are the main risks?	The most common effects reported so far are injection-site reactions and headache. Less commonly, changes in liver blood tests and in white blood cell counts have been seen. Rarely, serious allergic reactions and serious infections have occurred. Because VTX-1042 is investigational, there may be risks that are not yet known.
Could this help me?	You may receive no direct benefit. Some participants' symptoms improve and some do not, and if you are assigned to placebo you will not receive the investigational medicine at all. The main purpose is to produce knowledge that may help others.
What are my alternatives?	You do not have to join a study to be treated. Approved medicines, physical therapy, other clinical studies, and continuing your current treatment are all alternatives. Your own doctor can discuss which of these fit your situation.

This Key Information section is a summary. The sections that follow give the complete information, and the study team will go through all of it with you.

IRB APPROVAL RECORD

REVIEWING IRB	IRB PROTOCOL NUMBER	IRB APPROVAL DATE	IRB APPROVAL EXPIRES
Midland Central Institutional Review Board (Midland Central IRB)	**MC-2027-0184**	**06 February 2027**	**05 February 2028**
PROTOCOL	SPONSOR	PRINCIPAL INVESTIGATOR	REGISTRY IDENTIFIER
VTX-1042-301, Protocol Version 3.0, dated 09 December 2026	**Vantera Therapeutics, Inc.**	**Imogen T. Race, MD · Site 0142**	**NCT-SPECIMEN-0142 (fictional; this study is not registered)**

An IRB is an independent committee that reviews research to protect the rights and welfare of the people who take part. A consent form may only be used while its IRB approval is current. Do not sign a version other than the one shown above.

WHAT WILL HAPPEN AT EACH STAGE

STAGE	WHEN	WHAT HAPPENS
Screening	Up to 28 days before Day 1	Review of this consent form and your questions; signature before any study procedure; medical history; physical examination; fasting blood tests; urinalysis; pregnancy test if applicable; electrocardiogram; confirmation that you meet every entry requirement.
Baseline and randomization	Day 1	Final eligibility check; assignment by chance to VTX-1042 or placebo; first dose given at the site; diary device activation and training; questionnaires.
Treatment period	Week 2 through Week 52	Eleven in-person visits and two telephone visits; study drug dispensing and return; safety blood tests; symptom and side-effect review at every contact; daily diary entries at home.
End of treatment	Week 52	Final in-person visit with the full assessment set; return of all study drug and the diary device.
Safety follow-up	About 30 days after the last dose	One telephone or in-person contact to check on any ongoing side effects.

RISKS REPORTED SO FAR, BY HOW OFTEN THEY WERE SEEN

HOW OFTEN	WHAT WAS REPORTED
Very common — more than 1 in 10	Injection-site redness, swelling, or discomfort; headache
Common — between 1 in 100 and 1 in 10	Upper respiratory infection; nausea; tiredness; dizziness
Uncommon — between 1 in 1,000 and 1 in 100	Increased liver blood test values; decreased white blood cell count; rash
Rare — fewer than 1 in 1,000	Serious allergic reaction; serious infection requiring hospital treatment
Not yet known	VTX-1042 is investigational. There may be risks that have not been identified, including risks that appear only after longer use.

Risks also come from the study procedures themselves: bruising, soreness, or fainting from blood draws, and skin irritation from electrocardiogram pads.

PREGNANCY, CONTRACEPTION, AND REPRODUCTIVE RISK

The effect of VTX-1042 on an unborn baby, on a nursing infant, and on fertility is not known. You may not take part if you are pregnant or breastfeeding.

- A pregnancy test is done at screening, at Day 1, and at the visits marked on the schedule.
- Participants who can become pregnant must use a highly effective method of contraception from screening until 30 days after the last dose.
- Participants whose partner can become pregnant must use a barrier method for the same period.
- Tell the study team immediately if you think you or your partner may have become pregnant. Call the 24-hour study line at 555-0188.
- If a pregnancy occurs, study drug is stopped and you will be asked for permission to follow the pregnancy outcome.

COSTS, PAYMENTS, AND WHAT YOUR INSURANCE IS BILLED FOR

ITEM	WHO PAYS	DETAIL
Study drug	Sponsor	VTX-1042 or placebo is provided at no cost to you.
Research-only tests and procedures	Sponsor	Tests done only because of this study, including the pharmacokinetic and biomarker samples, are paid by the sponsor.
Routine care you would have received anyway	You and your insurance	Standard visits, standard laboratory work, and treatment of your condition outside the study are billed in the usual way, including any deductible or copay.
Visit reimbursement	Sponsor	$75.00 for each completed in-person visit, paid to a reloadable card within 10 business days. Telephone visits are not reimbursed.
Travel	Sponsor	Documented mileage at $0.55 per mile and validated parking at each in-person visit.
Research-related injury	See the section below	Immediate medical treatment is arranged. Read the injury section carefully — it does not promise to pay for everything.

IF YOU ARE INJURED BY TAKING PART

If you are injured as a direct result of taking part in this study, get medical care immediately and then call the 24-hour study line at 555-0188.

- The study team will arrange or refer you for the treatment you need.
- The sponsor has agreed to pay the reasonable costs of treating an injury caused directly by the study drug or a study procedure, to the extent those costs are not covered by your insurance or another source.
- No money has been set aside to compensate you for lost wages, discomfort, or other losses.
- You are not giving up any legal right by signing this form.

PRIVACY AND WHO MAY SEE YOUR INFORMATION

Your study records are labeled with a participant identifier rather than your name wherever possible. Your name stays in the site's records and is not sent to the sponsor.

- The sponsor and organizations working for it, for monitoring and analysis
- Midland Central IRB and the research compliance office
- Government agencies that oversee research, including inspectors who may review records
- The central laboratory and the electronic diary provider
- Anyone you authorize in writing

A separate HIPAA authorization describes the health information being used and disclosed. Results may be published or presented, but you will not be identified. Absolute confidentiality cannot be guaranteed.

STOPPING — YOURS AND OURS

WHO STOPS IT	WHY IT MIGHT HAPPEN	WHAT HAPPENS NEXT
You, at any time	Any reason at all, or no reason. You do not have to explain.	Tell the study team so a final safety check can be offered. Data already collected stays in the study. No penalty and no loss of benefits.
The investigator	A safety concern, a new medical condition, pregnancy, or inability to follow the schedule	The reason is explained to you and follow-up care or referral is arranged.
The sponsor or the IRB	New safety information, or the study is stopped for any reason	You are told promptly and given any new information that could affect your willingness to continue.

WHO TO CALL

IF YOUR QUESTION IS ABOUT…	CALL	NUMBER
A side effect, a new symptom, or anything urgent	24-hour study line	555-0188
Scheduling, the diary, reimbursement, or supplies	Naomi Ellsworth, CCRC, study coordinator	555-0184
The study itself or your medical care in it	Imogen T. Race, MD, principal investigator	555-0184
Your rights as a research participant, or a complaint	Midland Central IRB	1-888-555-0191
A concern you would rather not raise with the study team	Research participant advocate	1-888-555-0193
A life-threatening emergency	Local emergency services first, then the study line	911, then 555-0188

SIGNATURE

Sign only after you have read this form, discussed it with the study team, had every question answered, and had as much time as you wanted to decide. You will be given a signed copy.

- ☐ I have read this consent form, or it has been read to me in a language I understand.
- ☐ I have had the chance to ask questions and my questions were answered.
- ☐ I understand that taking part is voluntary and that I may stop at any time.
- ☐ I understand that I may be assigned to placebo and may receive no direct benefit.
- ☐ I agree to the optional biomarker sample described in the procedures section. *(Optional — declining does not affect participation.)*
- ☐ I agree to take part in this research study.

SIGNATURE OF PARTICIPANT	PRINTED NAME	DATE	TIME
SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE	RELATIONSHIP / AUTHORITY	DATE	TIME
SIGNATURE OF PERSON OBTAINING CONSENT	PRINTED NAME AND ROLE	DATE	TIME
WITNESS SIGNATURE (IF REQUIRED)	PRINTED NAME	DATE	CONSENT VERSION SIGNED **4.2 (14 Jan 2027)**

Signing this form does not waive any of your legal rights and does not release any person or organization from liability for negligence.

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.