Guidelines and Helpful Tips for Sarcoidosis Patients Interested in Clinical Trials

Purpose: This guide is designed to help people living with sarcoidosis make informed, confident decisions about whether a clinical trial may be right for them. It is not medical advice; patients should discuss all trial decisions with their sarcoidosis specialist, primary care clinician, and research team.

1. Start with the Basics

A clinical trial is a research study that tests a medical approach, such as a medication, device, procedure, monitoring strategy, or behavioral intervention. In sarcoidosis, trials may focus on lung, heart, skin, eye, neurologic, or multi-organ disease; symptom relief; imaging or biomarkers; steroid-sparing therapies; or quality of life. Clinical trials can advance understanding of sarcoidosis even when an individual participant does not directly benefit.

- Ask what the trial is testing and why it matters for sarcoidosis.
- Find out the trial phase, study length, number of visits, and whether there is a placebo or comparison group.
- Confirm whether participation would change your current sarcoidosis care plan.

2. Talk with Your Healthcare Team First

Before enrolling, review the trial with the clinician who knows your sarcoidosis history. Bring the trial listing, eligibility criteria, medication list, recent test results, and questions. Open communication with healthcare providers helps ensure symptoms, organ involvement, treatment goals, and changes in condition are monitored and addressed.

- Ask whether your organ involvement, disease activity, and current treatment make the trial appropriate for you.
- Discuss whether steroid use, immune-suppressing medicines, infections, pregnancy plans, heart rhythm issues, eye disease, or other health conditions could affect eligibility or safety.
- Clarify what standard treatments remain available if you join, do not qualify, or decide to leave the study.

3. Understand Your Rights and the Consent Process

Informed consent is more than a signature. It is a conversation that should help you understand the study's purpose, procedures, expected time commitment, possible risks, possible benefits, alternatives, costs, confidentiality protections, whom to contact with questions, and your right to stop participating. U.S. informed-consent regulations require that participation be voluntary and that a participant may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

- Take time to read the consent form; do not feel rushed.
- Ask for plain-language explanations of medical terms, procedures, risks, and alternatives.
- Request copies of the consent form and contact information for the study team and institutional review board.
- Ask what happens if your sarcoidosis worsens, you develop side effects, or you need urgent care during the trial.

4. Questions to Ask Before You Enroll

Topic	Questions to ask
Purpose	What is the trial trying to learn? Why are sarcoidosis patients being studied?
Eligibility	What tests determine whether I qualify? Which sarcoidosis organs or disease features are required?
Treatment	What treatment, placebo, procedure, or monitoring will I receive? Can I stay on my current medicines?
Risks and benefits	What side effects are known or possible? What benefits are realistic, and what benefits are uncertain?
Time and travel	How many visits are required? Are any visits remote? Who pays for travel, lodging, parking, or childcare?
Costs	What does the sponsor cover? What might be billed to insurance? Could I have out-of-pocket expenses?
Follow-up	Will I receive study results? What happens after the trial ends?
Safety	Who do I contact after hours? What symptoms should I report immediately?

5. Weigh Potential Benefits and Risks

Possible benefits may include closer monitoring, access to sarcoidosis experts, additional testing, and the chance to contribute to future treatments. Possible risks may include side effects, extra appointments, uncertainty about whether the study treatment will help, privacy considerations, and burdens on work, family, or finances. Patients should carefully weigh potential risks against possible benefits and should ask questions when reviewing trial details.

- Consider how stable or active your sarcoidosis is right now.
- Think about how the trial schedule fits your energy level, transportation, caregiving responsibilities, work, and finances.
- Ask whether joining would delay or limit treatments you may need outside the trial.
- Discuss whether the trial includes emergency plans for breathing problems, chest pain, vision changes, neurologic symptoms, infection symptoms, or severe medication reactions.

6. Prepare for Screening and Enrollment

- Make a one-page health summary listing your sarcoidosis diagnosis date, organs affected, major test results, hospitalizations, allergies, and current symptoms.
- Bring an up-to-date medication list, including prednisone or other steroids, methotrexate, azathioprine, mycophenolate, infliximab or other biologics, supplements, and over-the-counter medicines.
- Ask whether recent imaging, pulmonary function tests, ECGs, echocardiograms, eye exams, lab results, or biopsy reports are needed.
- Keep a symptom diary before screening so you can describe changes clearly.
- Identify a trusted family member or friend who can help review information, travel with you, or take notes.

7. Watch for Red Flags

- You are pressured to decide immediately or discouraged from talking with your doctor or family.
- The team cannot clearly explain the study purpose, risks, alternatives, costs, or who to contact for problems.
- You are asked to pay large fees to participate in a treatment trial.
- The study lacks clear oversight, consent documents, or safety-monitoring procedures.
- Claims sound guaranteed, such as “cure,” “no risk,” or “works for everyone.”

8. Helpful Resources

- Foundation for Sarcoidosis Research: Find a Clinical Trial
- Foundation for Sarcoidosis Research: Participate in a Clinical Trial
- NIH information on informed consent
- Federal informed-consent elements for FDA-regulated research

Appendix: References and Summaries

This appendix consolidates the document's footnote references into a concise reference list. Duplicate references have been grouped together, and each entry includes a brief summary of how the source supports patient decision-making about sarcoidosis clinical trials.

- Foundation for Sarcoidosis Research: Participate in a Clinical Trial — Provides patient-facing information about participating in sarcoidosis clinical trials, including why trials matter, how patients can get involved, and what to consider before enrolling.
- Sarcoidosis Research Institute: Patient Resources — Offers general resources for people living with sarcoidosis and supports patient education, disease awareness, and conversations with healthcare professionals.
- Foundation for Sarcoidosis Research: Find a Clinical Trial — Helps patients locate sarcoidosis-related clinical trials and understand available research opportunities.
- Foundation for Sarcoidosis Research: Talking to Your Doctor About Sarcoidosis — Emphasizes the importance of preparing questions, discussing symptoms, and maintaining open communication with clinicians.
- Foundation for Sarcoidosis Research: Talking to Your Doctor About Sarcoidosis — Provides similar patient guidance on working with healthcare providers to discuss sarcoidosis symptoms, treatment options, and care planning.
- Clinical Trials Finder: Questions to Ask Your Doctor About Clinical Trials — Lists practical questions patients can ask clinicians before joining a clinical trial, including questions about eligibility, risks, benefits, costs, and logistics.
- FDA: Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors — Explains expectations for informed consent in clinical research, including how information should be presented to potential participants.
- FDA: Clinical Trials Guidance Documents — Provides FDA guidance related to clinical trials and human-subject protections, including regulatory expectations for research conduct and participant safety.
- eCFR: 21 CFR 50.25 — Elements of Informed Consent — Defines required informed-consent elements for FDA-regulated research, including risks, benefits, alternatives, confidentiality, compensation, contacts, and voluntary participation.

- FDA Guidelines: Informed Consent Essentials for FDA-Regulated Clinical Trials and IRB Oversight — Summarizes informed-consent principles and oversight considerations for clinical trials subject to FDA requirements.
- Foley: FDA Draft Guidance on Informed Consent — Discusses updated FDA guidance on informed consent and highlights practical implications for clinical research sponsors and investigators.
- PlainTrial: Patient Rights in Clinical Trials — Provides an accessible overview of participant rights, including voluntary consent, withdrawal from research, and questions patients may ask before enrolling.
- NIH Policy Manual: Informed Consent — Outlines NIH policy expectations for informed consent in human-subject research, including documentation and participant protections.
- NIH Grants: Posting Clinical Trial Informed Consent Forms — Explains NIH requirements and policy context for posting clinical trial informed-consent forms.
- NIH IRBO: Informed Consent — Provides guidance on informed consent as an ongoing communication process between researchers and participants.
- NIH IRBO: Posting Informed Consent Forms for Clinical Trials — Describes expectations for posting informed-consent forms for certain clinical trials and supports transparency in research.
- NIH Notice NOT-OD-19-110: Guidance on Posting Informed Consent Forms — Provides NIH guidance on where and how informed-consent forms should be posted for applicable clinical trials.
- NIH Office of Science Policy: Clinical Research — Provides broader NIH policy resources related to clinical research, participant protections, and research transparency.