

FMLA & Clinical Trials: What Clinicians Need to Know

Identifying Workplace Barriers to Clinical Trial Participation

Foundation for Sarcoidosis Research (FSR) developed a national, IRB-approved, survey for Black and African American patients to better understand their perspective on clinical trials participation, as well as the barriers and motivators that influence their decisions. Among the top barriers reported were job-related challenges and financial burden. These findings aligned with other studies on participation.

Nearly 30% of U.S. clinical trial participants drop out, often citing scheduling conflicts tied to work and family responsibilities as key stressors.¹

Building on the data from the Black sarcoidosis patient community and broader research across patient populations, FSR sought to address job-related barriers, by advocating for job-protected leave for clinical trial participants, leveraging the **Family Medical Leave Act (FMLA)** as a pathway.

Using FMLA to Overcome Barriers to Clinical Trial Participation

In August of 2023, the Foundation for Sarcoidosis Research (FSR) submitted a Request for Opinion Letter on Clinical Trials and FMLA to the U.S. Department of Labor (DOL). To build on this effort, FSR launched the Coalition to Transform Clinical Trial Engagement to address barriers in practical yet transformative ways.

After a year of advocacy, the launch of the 27-member coalition, and over 40 Hill visits garnering bi-partisan support, FSR received a response.

FSR received a letter of clarification from the DOL that ensures employee access to FMLA benefits when participating in clinical trials.

This clarification removes job-related barriers to care and helps patients—especially those from underserved communities—access innovative therapies without risking job loss.

WHAT IS FMLA?

The Family and Medical Leave Act (FMLA) is a federal law that gives eligible employees up to 12 weeks of unpaid, job-protected leave each year for certain medical and family reasons. During this time, employers must continue the employee's group health insurance coverage. FMLA leave can be taken all at once or in smaller blocks, such as for individual medical appointments.

Thanks to this clarification, FMLA benefits:

- Extend to participant and family caregiver of participant
- Can be used even if patient's participation is 'voluntary'
- Expands the definition of "therapeutic" under the FMLA to include experimental treatments and placebos
- Can be used without fear of risking:
 - Job assignments
 - Promotions
 - Training opportunities
 - Health insurance



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See page 2 to learn how to help your patients navigate the FMLA application process.



How to Help Your Patient Get Started Using FMLA for a Clinical Trial

Talk to Your Patients About Clinical Trials

- **Set the tone:** Create a two-way conversation by sharing and actively listening.
- **Explain simply:** Describe the purpose, goals, and potential risks/benefits in clear, jargon-free language.
- **Review logistics:** Outline time commitments, travel needs, and potential impact on patient's daily life.
- **Provide support:** Make space for questions and share resources patients can reference later.
- **Encourage conversations with others:** Suggest patients talk with family, friends, or caregivers to help them make an informed, supported decision.

Forms and resources can be found at stopsarcoidosis.org/FMLA

Support the FMLA Application Process

- Inform patient about FMLA job-protected leave.
- Direct patient to FSR's website for FMLA resources and the DOL hotline for questions or concerns before engaging their Human Resource (HR) department. Patient should inquire about state-specific labor requirements or information during this process.
- Encourage patient to follow instructions provided by DOL and print the appropriate FMLA Certification Form.
 - HR issues WH-380-E (for the patient) or WH-380-F (for a family member)
- Complete the form on behalf of patient.
 - Confirm health condition, describe frequency and duration, indicate type of leave needed (e.g. intermittent), return completed form to patient.
- Refer patient to speak with HR to request leave and provide the appropriate FMLA Certification Form. Some HR departments may require additional steps or forms.

Potential Benefits to Emphasize with Patients

- **Closer medical oversight.** Patients in trials are monitored regularly by specialists and research staff, often with more frequent check-ins than in standard care.
- **Access to new therapies.** Participation may provide early access to promising treatments not yet available outside the trial.
- **Regular health monitoring.** Frequent labs, imaging, or evaluations may help identify health issues earlier.
- **Contribution to research.** Participation helps advance understanding of the disease and may improve care for future patients.
- **Support services.** Some trials provide assistance with travel, stipends, or patient navigation, which can help ease the burden of participation.

Visit
stopsarcoidosis.org/participate-in-a-clinical-trial
for a list of active clinical trials on sarcoidosis.