

PARTICIPATING IN CLINICAL TRIALS

From a coordinator perspective

University of Rochester

What is a Research Coordinator?

A research coordinator is a professional who manages and oversees the operational aspects of a research study or project. This role typically involves organizing, supporting, and facilitating research activities, often in academic, clinical, or scientific settings. The responsibilities of a research coordinator can vary depending on the type of research

Key Responsibilities:

- Care and Management of the volunteer
- Study Management
- Data Collection & Management
- Participant Recruitment and Communication
- Compliance and Documentation
- Collaboration with the Provider and Research team

What is a clinical trial?

- Research with human volunteers to answer specific health questions.
- Carefully conducted clinical trials are the safest and fastest way to find effective treatments, and new ways to improve health.

Types of Clinical Trials

- Study new treatments
 - How safe is a new treatments? (Phase 1)
 - What is the best dose? (Phase 2)
 - How well does a new treatments work (Phase 3)
 - How safe is a new treatment in lots of people over long periods of time (Phase 4)
- Study causes of disease
- Study how people do with regular care (prospective/observational)
- Study how people did in the past (retrospective studies)

What is it like being in a clinical trial

- Clinical trials are meant to be just like regular medical care
- With much more emphasis on accurate and multiple measurements of how you are doing!
- Usually longer and more frequent visits than regular care
- Can involve new treatments or regular treatments or no treatments

What is it like being in a clinical trial

- First Step – Tell your doctor you want to help with research
- Your doctor will tell research team about your interest
- Research team helps identify trials that are a good fit
(Prescreening)
- Research team or your doctor (clinical team) can give you details about trial – and if you think it is a good fit ->
- Informed Consent!

Step 2 – Consent and Screening

- Informed Consent – full details of everything in the trial
- Time to ask lots of questions of research team
- Research is Voluntary! Can “withdraw” anytime for any reason
- Screening – making sure you can help us answer the question we are studying – (inclusion/exclusion criteria)



Clinical Trial Preparation

Pre-Screening Stage :

Review of medical history, medications, prior lab results, demographics and disease status to determine your eligibility to participate in a study

Screening/Randomization:

Review all information obtained during the previous (pre-screen) phase, obtain consent, bloodwork, urine and imaging based on study requirements.

This information will determine your eligibility to start on a clinical trial which can take up to 28 days

On-Study Visit:

Overview of information obtained during the screening/randomization phase for any updates or changes, questionnaires, bloodwork, assessments, study treatment and stipend

Your participation is voluntary, and you will not be penalized if you choose to withdraw at anytime.



BENEFITS OF PARTICIPATING IN A LUPUS CLINICAL TRIAL

• **Help other people with lupus!**

- Help develop new treatments
- Help better understand disease -> better treatments, healthier people

• **Help yourself**

- Develop a deeper understanding of your disease – access to experts to ask questions
- Access to an extra team of experts to help – research team – much more face time with your team than usual clinical care!
- Early access to new treatments


How do I learn more about trials?

- <https://www.urmc.rochester.edu/research/health-research/clinical-trials.aspx>
- <https://clinicaltrials.gov/>
- <https://lupustherapeutics.org/current-partner-studies/>



How do I start participating?

- Tell your doctor at your next visit “How can I help with research”!



AIR RESEARCH TEAM

COORDINATORS

Manager



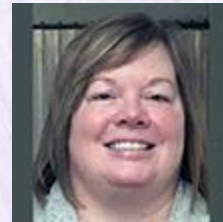
Tyler Cavin, MPH



Maria Allen



Nichole Turner



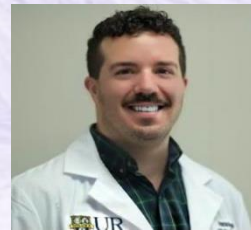
Sally Thomas



Jaclyn Zona



Layla Wynn



Patrick Kingsley



Chelsea Lo Monaco

PROVIDERS



Jennifer Anolik, MD, PhD



Christopher Ritchlin, MD, MPH



Christopher Palma, MD, ScM



R. John Looney, MD



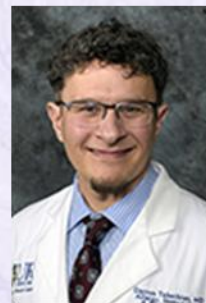
Ummara Shah, MD



Norman Madsen, BMBS, MSc



Jennifer Barnas, MD, PhD



Darren Tabechian MD



Ilana Y. Abeles, M.D., Ph.D.



Benjamin Korman, MD



Allen Anandarajah, MBBS



Ralf Thiel, MD



Christopher Richardson, MD, PhD



Shadefai Goldsmith, NP



Let's Talk About It...