



Welcome to Rochester Clinical Research.

We believe that a strong relationship begins with clear communication by all parties. We have outlined for you our operational procedures in an effort to help facilitate a productive working relationship.

1. Monitors are welcome from M-TH, 7:30am to 4:45pm. You will not have access to the suite, staff, copier or fax machine before or after regular office hours. Fridays we are open only until 12:00 PM. All monitor rooms are located on the second floor in Suite 265. Free WIFI is available.

Please check in with the front desk in Suite LL20 to obtain your key fob.

- Your Monitor Room Fob/Key must be returned to Suite LL20 by 4:45PM each day
- When you leave for the day, all charts must be placed back on the cart in order by subject number. All charts must follow the Patient Charts – Organizational Information sheet.

2. We are expecting you to arrive alone. If you are going to bring someone with you, please notify us in advance. If we have room to accommodate the request we will let you know.

3. Please let us know which charts you are planning to review on which day and we will have them ready. Please leave the charts as you found them. There is an index in this binder that outlines the order the charts will be in when given to you. If you need temperature logs or calibration certificates, please include that in your confirmation appointment, or know the request may take 24 – 48 hours to process. Thank you for this courtesy!

4. To aid you and us with Regulatory Binder review, we have added a blue colored sheet of paper to our correspondence binders to be inserted after each visit as a place marker. Please sign and date the sheet upon review.

5. To respect the confidentiality of all of our sponsors we ask that you do not enter the study coordinator offices. Please use the intercom system to get any help you need from the study coordinators/ research assistants or front desk. Intercom #110 is the front desk; staff directory is located in this binder.

6. Our staff is busy in the mornings but will be available for time after lunch or an hour before leaving at 4:45. The research assistant should be available to answer questions throughout the day. If it is your first visit for the study the study coordinator/administrative assistant will orient you to the process and office logistics upon your arrival.

7. Please ask your study coordinator for IP and the nurse manager will bring it to you.

8. Dr. Davis makes daily rounds with the monitors. Dr. Shlotzhauer and Dr. Mann will be available by appointment in advance.

9. We expect a follow up monitoring letter and will address any outstanding issues. Please cc: to the study coordinator.

10. Per our site's SOP all original source documents including patient recorded source documents, diaries, and the Site Responsibility Log must stay on site for the duration of the study and post closeout. Please see your Study Coordinator or the Regulatory Specialist with any questions.

11. As a reminder, RCR will not be destroying any IP on site. It will be returned to the Sponsor/CRO at the end of the study.

It is our hope that you have found this information useful. Here's to a successful clinical study. Your assigned Research assistant, Study Coordinator and copy code will be given to you at check in.

Thank you,

The Rochester Clinical Research Team