

Research Visitor – Study Monitor Instructions

Study Monitors are external representatives of the Sponsor who oversee the progress of a clinical study, and ensure that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures, Good Clinical Practice and applicable regulatory requirement(s). If this is the case, please use these Instructions. For other types of visitors and instructions please visit the [intranet](#).

PROCESS:

This process should be completed as close as possible to the Study Monitor's first visit to St. Michael's.

1. Investigator is asked to complete and sign the forms "Research Visitor –Study Monitor Forms for PI".
2. Please provide the completed forms to the Study Monitor prior to In-Person registration.
3. Investigator to provide/email the "Research Visitor- Study Monitor Forms for Monitor" to the Study Monitor for completion.

In-Person Registration

4. Please Instruct the Study Monitor to pre-register by the Sunday before the in-person registration session they are planning to attend at https://www.surveymonkey.com/s/ORA_pre_registration.
5. The Study Monitor must personally bring all PI and Study Monitor forms/documentation to the in-person registration. Study Monitors must arrive promptly at the start of a session with ALL completed paperwork.

REGISTRATION TIMES* & LOCATION:

Tuesdays 10:00 & 2:00

Thursdays 10:00 & 2:00

Location: (250 Yonge Street - 6th floor - Through the glass doors)

*If unable to register during these times, please contact Cordelia Cooper to make an appointment.

6. The Study Monitor will be entered into the Barcode Database and informed of the next steps (i.e., ID Badge, Health and Safety, Training, etc.)
7. PI to retain a copy of all paperwork (PI and Study Monitor) for record keeping purposes.
8. For **Access to Electronic Medical Records (EMR)**. Please see the required forms and instructions for [EMR access](#).

Reminders: The Study Monitor must wear the ID Badge at all times while on hospital premises. On the last day of each visit, the Study Monitor **must** return their ID badge to the PI/delegate for safe-keeping.

Questions? Cordelia Cooper, Research Employment Coordinator (416 864-3077 / cooperc@smh.ca)