

	<b>Standard Operating Procedures</b>
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Procedure Category:	Study Activities
Procedure CLN-04-07:	Patient Visit Scheduling Procedures

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in scheduling patient visits.

**Responsible Individuals**

Qualified MICHHR personnel (including, but not limited to, Study Coordinator and Research Assistant); Investigators, General Clinical Research Center (GCRC); Director, MICHHR

**Procedure**

1. After a subject has been determined to be eligible for the targeted protocol (See SOP CLN-03-10), MICHHR personnel generate the Protocol Visit Calendar (see Appendix 1), to be used if the sponsor does not provide a predesigned template. Any allowed deviations should be clarified with the sponsor (e.g. +/- 3 days of calculated visit date).
2. Utilizing the Protocol Visit Calendar, MICHHR personnel schedule the patient's appointment times at General Clinical Research Center (GCRC) or other clinics for all required visits. A notation should be added to indicate the protocol name, protocol number, investigator and study visit number. The scheduled visits or planned visits are then entered into the RSC database.
3. To minimize scheduling problems, MICHHR personnel contact the relevant facilities weekly to confirm the visit schedule.
4. Each week MICHHR personnel creates a Visit Report (see Appendix 2 and contacts subjects via telephone, email, or mail (see Appendix 3) to confirm scheduled visits within two days prior to each visit. This reminder should include the date, time, and location for the visit, any scheduled procedures and related instructions, contact information and special reminders (e.g., 12 hour fast, bring study medication, bring current patient diary). This visit report is located and filed in the patient visit QA binder.
5. If the use of Appendix 3 is anticipated as a method of reminding patients of their pending study visits, a copy of the Appendix 3 (visit reminder letter template) must be attached on the New Project Application and sent to the IRB for approval.

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6. Following each scheduled study visit, MICHHR personnel will provide the patient with a copy of the "Visit Information letter" (Appendix 4). The information letter will include date, time and location for the next visit, any scheduled procedures and related instructions, length of visit, and special reminders.
7. If a subject is continually absent for appointments, MICHHR personnel will try to contact him/her by phone or letter to determine any scheduling conflicts, transportation issues, concerns, and, if possible, reschedules the missed appointments. If attempts at follow-up fail to convince the subject to report for scheduled appointments the subject must be withdrawn from the study (See SOP CLN 04-08).

### Documentation

Documentation for this procedure includes documentation generated by the Recruitment Log, Patient Visit Calendars, subject source documents, subject visit letters and institutional visit reports.

### Deviation Approval

The Director, MICHHR or designee, must approve deviation from this procedure. The Director, MICHHR or designee, must store documentation of the deviation approval.

### Appendices

- Appendix 1 Protocol Visit Calendar Sample
- Appendix 2 Visit Report Template
- Appendix 3 Visit Reminder Letter Template
- Appendix 4 Visit Information Letter Template

### Procedure Author

Manager, Research Support Core

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