

	Standard Operating Procedures
---	--

Procedure Category:	Study Activities
Procedure CLN-04-04:	Patient Recruitment

Procedure Overview

This procedure describes the necessary activities performed by MICHHR personnel in recruiting potential study subjects for participation in a research protocol.

Responsible Individuals

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

Procedure

1. MICHHR personnel utilize the following sources, as permitted by the institution, to identify potential internal study patients:
 - Recruitment reports generated from the volunteer database(s)
 - Charts in physician's offices
 - Queries by diagnosis, drug class use, lab elements from Institutional records
 - Support groups
 - Referrals from physicians, nurses, coordinators, other specialty departments (e.g. Emergency, Radiology, Admitting).

Refer to SOP CLN-03-10, Pre-Screening Patients, for related information.
2. If additional study subjects are needed, the Research Support Core Manager determines if funding is available for advertising and referral fees by reviewing the study budget agreement. Consult with the study sponsor or CRO for advertising funding if this was not included in the initial study budget agreement.
3. MICHHR personnel request study sponsor and IRB approval for planned study advertising via newspaper, radio, television and/or postings based on the available recruitment budget. See Appendix 1 for a list of potential advertising methods.
4. Follow any guidelines set forth by the study sponsor or CRO and the IRB in developing the advertising and obtaining approval for the proposed advertising.
5. After the advertising has been approved by the study sponsor or CRO and the IRB, MICHHR personnel implement the approved advertising. The IRB approval letter and related documentation are filed in the Investigator Study File.
6. MICHHR personnel maintain a Patient Recruitment Log (see SOP CLN-03-10) to determine the method used to recruit each potential subject. These records are used to determine future advertising methods and budget agreements, as well

Version Number: 002	Implementation Date: November 17, 2000
Page 1 of 1	Revision Date: June 30, 2004
	Review Date: June 30, 2005
Approval Signature, Date:	

	Standard Operating Procedures
---	--

Procedure Category:	Study Activities
Procedure CLN-04-04:	Patient Recruitment

as, make adjustments in ongoing advertising to increase the number of subjects available.

7. Recruitment continues until the desired number of subjects has been obtained. Any additional modes of advertising and publicizing, require IRB approval.

Documentation

Documentation for this procedure includes documentation generated to propose and seek approval for various recruiting methods, the Patient Recruitment Log, and study sponsor or CRO and IRB correspondence.

Deviation Approval

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

Relevant Definitions

IRB: Institutional Review Board

Appendices

Appendix 1 Methods of Advertising and Publicizing a Research Study

Procedure Author

Manager, Research Support Core

Version Number: 002	Implementation Date: November 17, 2000
Page 2 of 2	Revision Date: June 30, 2004
	Review Date: June 30, 2005