

	<b>Standard Operating Procedures</b>
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Procedure Category:	Protocol Review
Procedure CLN-01-04:	Assessing Access to Patient Population

**Procedure Overview**

This procedure describes the necessary activities performed by MICHHR personnel in determining the available subject population. This procedure covers tasks necessary to ensure all resources have been utilized in identifying potential study subjects in order to meet the enrollment objective.

**Responsible Individuals**

Qualified MICHHR personnel; Investigator; Co-Investigator(s); Subinvestigator(s); Director, MICHHR

**Procedure**

1. MICHHR personnel utilize the following sources to identify potential study subjects, as permitted by the institution:
  - Recruitment reports (see Appendix 1) from established internal and external database(s).
  - Patient billing records for study members listed on the 1572. Whenever possible the records are queried by ICD and/or CPT codes based on the targeted protocol disease process or procedure under study.
  - Queries by diagnosis, drug class use, and lab elements from institutional records
2. MICHHR personnel and/or Investigator consult with institutional colleagues, in the targeted therapy group, for additional population identifiers. Consultations should remain in general terms of potential number of subjects. Keep in mind the institutional policies regarding patient confidentiality rules and regulations.
3. MICHHR personnel informs the investigator that he/she should also consult with institutional colleagues for the existence of any competing protocols being conducted that could possibly limit the availability of eligible subjects.
4. MICHHR personnel tabulate the above results to establish estimated patient population from which to recruit for the targeted protocol. See SOP CLN-04-04 for information on Patient Recruitment.
5. MICHHR personnel forward estimates to the investigator for use in sponsor/CRO contract negotiations. Raw data are retained by MICHHR for use during study enrollment.

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Approval Signature, Date:	

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**Documentation**

Documentation for this procedure includes all documentation generated by MICHIR and the institution.

**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.

**Appendices**

Appendix 1 Sample Recruitment Report

This report is for internal use only. Information listed on this document is confidential and cannot be given to the sponsor without prior IRB approval and subject informed consent.

**Procedure Author**

Manager, Research Support Core

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