1 PURPOSE
This procedure describes the activities and processes by which patients will have access to adult oncology clinical trials within the Memorial Healthcare System (MHS).

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
The Office of Human Research (OHR) will provide an “Active Protocol Listing” (APL) to all Memorial Cancer Institute (MCI) research physicians during the first week of each month to show the current research trials that are open to enrollment within MHS. All MCI physicians and research personnel are expected to be aware of the current research studies that are available to MCI patients. Patients will be referred to the specific research specialist/investigator involved on the protocol for further information.

3 SPECIFIC PROCEDURES
All potentially eligible patients seen at Memorial Cancer Institute (MCI) will be evaluated for clinical trial participation by their treating physician. The treating physician and research personnel, who have received documented training in the consenting process and who are well versed in the different protocols that are available, will enter into discussions with interested patients about clinical trials which they may be eligible for (Reference SOP 603 Subject Screening and Enrollment). Potential subjects will receive a copy of the informed consent form (ICF) which will be reviewed with them in detail by the research physician or other designated research personnel (Reference SOP 601.1 Obtaining and Documenting Informed Consent and Assent). The ICF will contain more information on clinical trials including patient rights, financial issues, risks, potential benefits, alternatives etc. All their questions will be answered to their satisfaction before enrollment unto a clinical trial will begin (Reference SOP 601, Informed Consent).

Any patient who seeks further information about clinical research within the institution will be directed to the OHR website at www.mhs.net/research which lists the current trials that are available and/or to the research specialist designated for that therapeutic area.
Investigator Standard Operating Procedures  

Several clinical trial information booklets provided by the Office of Human Research and resource library are also available to all potential research participants.

The MCI website will also have a link to "EmergingMed" which is a clinical trial matching service that provides information and access to appropriate clinical trials and trial sites that match the patients' specific diagnosis, stage, symptoms, and treatment history.

DOCUMENTATION:
Any discussions with potential study subjects will be appropriately documented in the patient's electronic medical record.

4 REFERENCES TO OTHER APPLICABLE SOPS

- 601 Informed Consent
- 601.1 Obtaining and Documenting Informed Consent/Assent
- 603 Subject Screening and Enrollment

5 ATTACHMENTS

None

6 APPLICABLE REGULATIONS AND GUIDELINES

- General Requirements for Informed Consent (21 CFR 50.20)
- Elements of Informed Consent (21 CFR 50.25)
- Criteria for IRB approval of Research (21 CFR 56.111)
- Promotion and Charging for Investigational Drugs (21 CFR 312.7)
- IND Content and Format (21 CFR 312.23)
- Prohibition of Promotion and Other Practices (21 CFR 812.7)
- Investigational Device Exemption Application (21 CFR 812.20)
- Communicating with IRB/IEC (ICH E6, Section 4.4)
- Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects (FDA Guidance, March 19, 1999)