

Date: December 16, 2003

To: Medical Center Deans, Department Chairs, and Faculty

cc: Michael Karpf, M.D., Executive Vice-President for Health Affairs

From: Alfred M. Cohen, M.D., Director, Markey Cancer Center
Jonathan D. Adams, Pharm.D, Assistant Director for Clinical Research,
Markey Cancer Center

Re: Markey Cancer Center Oversight of Cancer-Related Clinical Research

A major goal of the Markey Cancer Center is to become an NCI-designated Comprehensive Cancer Center. To reach this goal the Center must compete for a Cancer Center Support Grant (CCSG). If successful, designation as a Comprehensive Cancer Center indicates that the Markey Cancer Center is recognized nationally as a cancer center that conducts, “long-term multidisciplinary cancer programs in biomedical research, clinical investigations, training and demonstration, and community-oriented programs in detection, diagnosis, education, epidemiology, rehabilitation, and information exchange”. The CCSG provides funds to support research infrastructure, such as program leaders, center administration, shared resources and services, and developmental funds for new initiatives.

One of the many areas the peer-review process will evaluate is the Center’s “mechanism for assuring adequate internal oversight of the scientific and research aspects of **all** the cancer clinical trials in the institution.” Additionally, they will determine that the cancer center has, “a mechanism in place for assuring that its clinical resources are engaged in the best way for scientific purposes.” In order clarify the Markey clinical research oversight process, it was necessary to more formally establish a process to review all cancer-related clinical research within the Medical Center and to require sign-off by the Cancer Center Director (or designee) on all such protocols.

Toward that end, the Cancer Center has worked with program leaders and numerous scientists to arrive at a formal process, referred to as the Protocol Review and Monitoring System (PRMS), for any cancer-related clinical trial proposed by researchers within the Medical Center.

Briefly stated, the Markey Protocol Review and Monitoring System (PRMS) consists of:

- **Disease Specific Clinical Care and Research Teams (CCART):** It is the CCART’s responsibility to set scientific priorities for the cancer center’s research in its respective diseases area. All protocols are evaluated by the appropriate CCART as the first step in the total process.
- **The Scientific Review Committee (SRC):** If a local investigator sponsors the proposed study, CCART will ask the investigator to work with the Cancer Center SRC to assure scientific validity and feasibility of the study design.
- **The Clinical Investigation Steering Committee (CISC):** When a protocol has been discussed with a CCART, approved by the SRC (if needed), it is ready to be sent to the CISC for final Cancer Center acceptance and recommendation for the Director’s signature.

The **Markey Clinical Research Coordinating Center** has been established to serve as the entry point of any cancer-related clinical trial research. The submission of any cancer-related protocol should be coordinated through this Center. Faculty can contact Ms. Karen Bowman at the Center so she can assist with the logistics of sending a protocol through Markey's formalized process. Ms. Bowman is located in the Cancer Center's administrative office, Room 140, Ben Roach Building (telephone 323-1671)

We understand that investigators are busy and requiring them to document Cancer Center research oversight may cause some concern. One of the objectives was to create a process that is transparent to cancer investigators. We believe that our process implemented by an efficient staff will result in a peer-driven research review model that will be a credit to our scientists.

Your cooperation in this effort is appreciated. If you have any questions please feel free to contact Ms. Bowman as indicated above or Dr. Jonathan Adams at 323-9496.