

MCO INVESTIGATOR RESPONSIBILITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

- A. Investigators must acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable federal regulations, as well as MCO policies regarding research with human subjects. **It is the responsibility of each investigator to know and understand those regulations and policies prior to initiating any such research.**
- B. Investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations. **Only the MCO IRB can make the determination that a study is exempt**, after review of the proposed research protocols.
- C. Investigators are responsible for **providing a copy of the MCO IRB-approved informed consent document to each subject at the time of consent** and after signing by the subject, unless the IRB has specifically waived this requirement. **All signed consent documents and study records are to be retained in a manner approved by the MCO IRB, and securely kept for 5 years.**
- D. Investigators will **promptly report proposed changes/modifications in previously approved human subject research activities to the MCO IRB**. The proposed changes will not be initiated without MCO IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- E. Investigators are responsible for **reporting progress of approved research to the MCO IRB, as often as and in the manner prescribed by the IRB** on the basis of risks to subjects, but not less than once per year.
- F. Investigators will **promptly report to the MCO IRB any injuries or other unanticipated problems involving risks to subjects or others.**
- G. No investigator will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior MCO IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.
- H. Investigators will advise the MCO IRB, Office of Research & Grants Administration and the appropriate officials of other institutions of the intent to admit human subjects into another institution (e.g., into another hospital) who are involved in research protocols. When such admissions are a planned part of DHHS-supported research, those institutions must possess an applicable Human Research Assurance prior to involvement of such persons as human subjects in those research protocols at those institutions.
- I. **The continuation of research after expiration of IRB approval is a violation of federal regulations. There are no provisions for any grace period beyond the termination date. If IRB approval has expired, research activities must stop** and no new subjects may be enrolled in the study, until IRB review and approval has been obtained.