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To: MIT Principal Investigators
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Subject: Clinical Trials

From time to time the question of conducting clinical trials as part of MIT research arises. We are writing this to clarify MIT policy on the matter. We do conduct research at MIT in which human subjects are involved. However, MIT policy is that we do not accept research agreements for clinical trials. MIT researchers now participate in the non-clinical trial aspects of research along with a cooperating institution which accepts responsibility for the management of the clinical trials and liability for the project. In addition, MIT makes available its unique facilities (such as the nuclear reactor) for clinical trial activities where, although MIT faculty may be involved in the research program, they are not responsible or carry liability for the clinical trial aspects of the project. In these cases researchers must follow appropriate institutional policies, such as those relating to the use of humans as experimental subjects.

There are several reasons for this policy, including the following.

- ◆ MIT is not currently able to provide the extensive oversight that defined clinical trials require; this includes the creation of data safety monitoring boards, ensuring compliance with the formal FDA and NIH good laboratory practices regulations, and the hiring of CROs (nurse affiliates) to manage the clinical trials. We are also concerned that government oversight and regulatory requirements will likely increase in the future.
- ◆ The Institute's insurance coverage could be adversely affected if harm should come to a patient enrolled in the trials. An adverse event could also jeopardize non-clinical research at MIT.
- ◆ Industrial sponsorship of clinical trials often raises issues which are contrary to MIT's policies on intellectual property and freedom to publish research results. It is also not unknown for serious conflict of interest issues to arise.

Generally, institutions that conduct clinical trials do so through associated medical schools and/or hospitals, which do have the substantial infrastructure to carry out clinical trials.. Therefore, if you plan research which may require clinical trials in the future, it would be a good idea to begin to establish a relationship with colleagues in one of the area hospitals so that they may take the lead at the point where clinical trials are undertaken.