

Memorandum of Understanding (MOU)

I understand that approval of this project is for one year only. Annual reports as to the study's progress must be submitted to the Institutional Biosafety Officer on the anniversary of the signature date. Failure to provide the report will result in termination of the approval and notification of appropriate federal authorities. The report must include a listing patient accrual, progress and adverse events.

All adverse events related to gene transfer must be reported to the Committee on Microbiological Safety within two weeks. NOTE: Approval by another Institutional Biosafety Committee does not guarantee approval by the Harvard Biosafety Committee.

All communications between a study sponsor and COMS must be through the Principal Investigator.

I am familiar with and agree to abide by the NIH Guidelines, OSHA standards, and other federal, state and local regulations relating to this project.

I accept responsibility for training all personnel involved in the proposed project in matters of potential biohazards, relevant Biosafety practices, techniques and emergency procedures.

I will not carry out the work described in this registration until it has been approved by the Committee on Microbiological Safety.