University of Rochester
Institutional Biosafety Committee
Preliminary Review of Human Gene Transfer Submission to
Recombinant DNA Advisory Committee (RAC)

Principal Investigator____________________________

Study Identifier (Brief Title or Protocol #):___________________________________________

Date Received____________________ Reviewer:_________________________________

Documentation Checklist: √

Cover Letter
On Institutional Letterhead
Signed by Principal Investigator(s)
Acknowledges documentation submitted complies
with Appendix M-I-A (Requirements for Protocol Submission)
Identifies the IBC Responsible for Review and Approval
Identifies IRB Responsible for Review and Approval
Acknowledges that no research participant will be enrolled
until RAC process has been completed; IBC approval
has been obtained; IRB approval has been obtained;
and all regulatory authorizations have been obtained.

Scientific Abstract

Non-Technical Abstract

The Proposed Clinical Protocol with Tables and Figures

Responses to Appendices M-II through M-V

The Proposed Informed Consent Document

Investigator Brochure (if, applicable)

Curriculum Vitae of Principal Investigator(s) (no more than 2 pages)

Submission does not contain confidential commercial information

OVER
Approved for submission to OBA RAC as submitted

Approved for submission to OBA RAC after modifications noted below

The following issues/concerns need to be addressed before submission to RAC:

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IBC Chair or designee

12/08/00