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 Project Registration No.): ____________________________

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

(OR: if it does, that permission to forward this information to NIH OBA has been obtained from the Sponsor/Manufacturer)
Date Approved for submission to OBA RAC as submitted: __________________________

Date 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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Signature of IBC Chair or designee        Date

Date when the Office of Human Subjects Protection was contacted: _________________________________

Revision Date: 9-04