University of Rochester
Institutional Biosafety Committee
Human Gene Transfer Submission Checklist

Principal Investigator____________________________

Study Identifier (Brief Title or Protocol #):___________________________________________

Date Received____________________  Reviewer:____________________________________

Documentation Checklist: √

   Human Gene Transfer Studies Checklist

   Virus Vector Registration Form

   Copy of any RAC review comments and proof of RAC Review

   Scientific Abstract

   Non-Technical Abstract

   The Proposed Clinical Protocol with Tables, Figures, Manuscripts

   Responses to Appendices M-II through M-V

   The Proposed Informed Consent Document

   Names of all personnel who will administer recombinant DNA to subjects and those who will collect and analyze samples from study subjects with their laboratory-specific training and OSHA training including dates

   Publicly available adverse event reports related to DNA molecule

   Expected adverse events based on pre-clinical information related to DNA molecule

   Investigator Brochure

   CV(s) of Principal Investigator(s)

COMMENTS:______________________________________________________________

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1/30/03