Human Gene Transfer
Points to Consider In the Exposure Control Plan

Following are some questions/situations that should be addressed in the IBC protocol submission. Answering these questions as clearly and directly as possible will help speed consideration of your protocol. It is imperative that you as the PI establish clear procedure protocols and provide adequate training for involved personnel. These questions are presented as a starting point, not an all inclusive list. Please try to address as many safety issues as possible in your application. If you are unsure how to answer a question, or need assistance developing your procedures/plans, please contact the Biological Safety Officer.

Locations (required in Appendix M-II-B-5-b)
Which operating room, recovery room, hospital room, and procedure room, etc. will be used? If more than one procedure involving gene transfer are scheduled, list for each. Rooms should be designated. If ICU is required, how will containment of the recombinant vector be achieved and other patients protected?

Biohazardous waste (required in Appendix M-II-B-4)
Details of how this will be handled in the operating room, recovery room, hospital room, procedure room, and at the patient's home after discharge. Address both waste disposal and general decontamination procedures. Address specific hazards of each location.

Shedding (required in Appendix M-II-B-4)
Discuss the dissemination within the patient and shedding from the patient of the recombinant virus. Include details of how this will be monitored and criteria used to determine safety of discharging patient to home. Provide as much information as possible (articles, investigator's manual, etc.).

Staff (required in Appendix M II-B-5-a)
A second fully-trained MD should be included as backup. Name all staff (OR, environmental services, recovery room, hospital room, etc.) who will have contact with the patient or will be handling biohazardous waste or cleaning/decontaminating rooms used by patient. Designate responsible persons for patient care for each shift.

How will the health of the staff be monitored or screened? What type of personal protective equipment will be needed when?

Harm to the Patient (required in Appendix M II-B-3-g)
What are the "worst case scenarios" for the patient regarding exposure to this recombinant virus and the risk that these events might occur? (Ex. replication defective virus recombines with an endogenous virus to form a replication competent virus containing the gene to be transferred, recombination of the viral and patient genes, injection of the biologic into the bloodstream, etc).

Training Documents:

Staff Training (required in Appendix M-II-B-4)
Staff must be trained on gene transfer and this particular protocol. Training must
include:

- basic information about the vector (how developed, replication ability, how it is manufactured, without divulging proprietary information)
- Details of the protocol as it relates to each staff member
- Infection control procedures
- Spill procedures
- Exposure control plan that includes the worker's care information, etc.

Please discuss details of the staff training, including name(s) of who will present the information. The Biological Safety Officer must be notified of the date, time, and location of this training with sufficient notice that she can arrange to be present. An attendance sheet documenting who received the training will also be kept in the IBC file. This training must be finished before patients can enroll.

Patient /Family Training (Mandated in Appendix M-II-B-4, M-III)
Instructions patients will receive about wound care, infection control, and care after discharge, etc. should be discussed. Any visitation restrictions and instructions to family members should be discussed. Include a copy of materials prepared for patients or family members. (Ex. The patient is sent home with a drainage tube. Describe how care will be taught. Or, patient will shed virus for up to three weeks post procedure. What restrictions/instructions are given the patient?)