University of Rochester Institutional Biosafety Committee
Checklist for Human Gene Transfer Studies

Information about biosafety assessment and the Institutional Biosafety Committee (IBC) can be found on the IBC web site http://www.safety.rochester.edu/ibc/

P.I. _________________________________ Dept. ____________________ Phone______________________
Office Location ________________________ e-mail_______________________________________________
Study Title________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
Study Coordinator ___________________________________ Phone ______________________________
Office Location _______________________ e-mail_______________________________________________
Study Sponsor______________________________________________________________________________

Patient Safety Reviewed by (circle one):  University RSRB   Western IRB

Names of UR staff involved in study (e.g. diluting or preparing study material, administering study material, collecting specimens for analysis, specimen analysis). Please correlate tasks with individual UR personnel.
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

Documentation supporting this study must be submitted to the IBC Executive Secretary, RC Box 278878.
Please refer to the IBC website for a list of required documents and contact information:
http://www.safety.rochester.edu/ibc/ibchuman.htm

Please complete the following questions for all human gene transfer research studies:

1. What, if any, is the infectious agent or virus vector with which you are working?________________

2. What is the biosafety level assessment suggested by NIH for the unmodified, wild-type, infectious agent (from which your vector may have been derived)?____________________________________

3. What is the biosafety level assessment provided by the sponsor (if different from the above)?

4. Will you use a risk group 2, 3 or 4 virus or bacterial vector? (Yes/No)
   If yes, will:
   A. Greater than 2/3 of the wild-type genome be used? (Yes/No)
   B. Helper virus or packaging cells be used? (Yes/No)
   C. Will your experiment enhance pathogenicity (e.g., insert oncogene or extend host range)? (Yes/No)

5. Is the study material received through the SMH Pharmacy? _________________________________
6. Where is the study material stored at the University? Room numbers: ____________________________

7. Will the study material be stored in a refrigerator or freezer that is NOT used for food/drink? _________

8. Is the study material supplied in single dose vials? ________________________________

9. Is the study material diluted at the University? If yes, where is it diluted? Room: ________________

10. Where will the study material be administered? Room number: ______________________________

11. If the study material is administered via injection, is a safety needle used? Refer to the Exposure Control Plan for Bloodborne Pathogens, Appendix VIII for more information. ________________________________

12. Is the needle/syringe connection a Leur-Lok? __________________________________________

13. Are needle/syringe assemblies disposed of immediately in a hospital approved sharps container? ______

14. If study material is administered via routes other than injection, please describe route of administration and methods used to prevent environmental contamination. ________________________________

15. What disinfectant will be used for the patient area used for study material administration? __________

16. How is residual study material handled? _________________________________________________

17. What personal protective equipment will the clinical staff wear? 
   During study material administration?
   During specimen collection? ________________________________

18. Have clinical staff completed appropriate training including SMH In-Service Training? Please provide documentation of this training. ________________________________

19. Will UR laboratories be utilized for study material preparation (e.g. dilution, syringe loading, etc.) or for specimen analysis? If yes, please indicate which tasks will be performed which UR labs, correlate task with room number. Use an additional sheet if necessary. ________________________________

20. If laboratory staff are involved in the study, have they received annual lab safety training provided by Environmental Health & Safety? ________________________________
IF UR laboratory staff are involved either in preparation of the study material (e.g. dilutions, syringe loading, etc.) or in analysis of patient specimens, please continue to complete the attached checklist, sign below, and send through intramural mail to IBC Executive Secretary, RC Box 278878.

If the laboratory work will not be performed at the University, please sign below and send through intramural mail to IBC Executive Secretary, RC Box 278878.

I understand that the attached forms are subject to approval by the Institutional Biosafety Committee. A site visit is part of the approval process if UR laboratories are involved. If there are any changes to the protocol, I understand that it is my responsibility to notify the Institutional Biosafety Committee in writing.

________________________________________________________________________  ___________________________________________________________________
Principal Investigator                                           Date
The documentation has been reviewed and is adequate and consistent with the appropriate guidelines. If UR laboratories are used, they have been surveyed and found to be in compliance with appropriate guidelines.

_________________________________________   ________________________________
Biosafety Officer       Date

_________________________________________   ________________________________
IBC HGTR Coordinator      Date

_________________________________________   ________________________________
IBC Chair (Required for BSL-2)     Date

Final IBC approval granted on ____________________________________________________________
Additional Instructions for Use of Recombinant Virus Vector Systems

If you are intending to use recombinant virus vector systems, the vectors must be registered with the IBC using our on-line virus vector registration form.

This form is completed online at: http://www.safety.rochester.edu/ibc/ibcvirus.htm

Instructions for Laboratory Portion of Checklist

Please read carefully and check yes or no. Feel free to add notes of explanation in the margins.

- **Personal protective equipment (PPE) must be provided to employees, and must be suitable for the task(s) performed.** PPE includes lab coats, gloves, face protection (if appropriate/necessary) and other protective measures (if appropriate/necessary).

- **A plan for containment of sharps should be in place** (e.g., use of sharps containers; no re-capping of needles, etc).

- **Changes in the proposed use of recombinant DNA materials or biohazards within this project must be documented.** Provide summary of changes to Janet Ives at Environmental Health & Safety, RC BOX 278878.

- **If you need help completing this form, contact Janet Ives, Biosafety Officer, jives@safety.rochester.edu, Telephone: 275-3014.**
1. The Principal (Co) Investigator (PI) is familiar with the most current “NIH Guidelines for Research Involving Recombinant DNA molecules” (NIH Guidelines) and with CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”. (Available on-line at [http://www.safety.rochester.edu/ibc/ibclinks.htm](http://www.safety.rochester.edu/ibc/ibclinks.htm))

2. The PI will report within 30 days to the IBC and NIH (ORDA) all significant problems with and violations of the NIH Guidelines and all significant research related accidents and illnesses.

3. Access to the laboratory is limited or restricted at the discretion of the Principal Investigator while experiments are in progress. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

4. A plan for emergencies has been developed and is available to laboratory employees. Emergencies to be planned for include fire, hazardous material spills (chemical, biological, radiological), injuries, and exposures. Spill plans must specifically address the hazards in the laboratory.

5. The PI assures proper instruction of laboratory staff in microbiological techniques, approved protocols, and emergency procedures, and that these instructions are followed. Documentation of training is kept by the PI (contents, trainer, attendees, and date).

6. Laboratory doors are kept closed while experiments are in progress. Closed laboratory doors facilitate directional airflow, special ventilation used to control odors and aerosols.

7. Work surfaces are decontaminated daily and immediately following spills of viable material. The decontaminant used is _______________________.

8. All biological wastes are decontaminated before disposal. Procedure: _____________________________________________________.

9. Other contaminated materials are decontaminated before washing, reuse or disposal.

10. Pipetting by mouth is prohibited. Mechanical pipetting devices are used.

11. Eating, drinking, smoking, applying cosmetics, and food storage are not permitted in the work area.

12. Hand washing facilities are available, and persons wash their hands after handling recombinant DNA or other biohazardous materials and before leaving the laboratory.

13. A plumbed eyewash station is available within 50 feet of the hazard location. The eyewash is activated weekly.

14. Care is taken to minimize the creation of aerosols.

15. Materials decontaminated away from the laboratory are packaged in durable leak-proof containers, which are closed before removal from the laboratory.

16. The use of needles and other sharps are avoided when alternate methods are available.

17. The laboratory is kept neat and clean.

18. The Principal Investigator has established policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements may enter the laboratory or animal rooms.

19. All persons working with human blood, body fluids or tissues receive OSHA Bloodborne Pathogens Training annually and have been offered the hepatitis B vaccination series.
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<td><strong>20.</strong> The universal biohazard sign is posted on all laboratory access doors while experiments are in progress, and is posted on all units used to store organisms containing biohazardous materials. The sign includes agent(s), name and telephone numbers of responsible individuals, and any special entry requirements.</td>
<td>YES</td>
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<td><strong>21.</strong> Lab coats or other protective clothing are worn in the laboratory.</td>
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<td><strong>22.</strong> Gloves are worn and special care is taken to avoid skin contamination.</td>
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<td><strong>23.</strong> Face protection in the form of safety goggles and a mask or a chin-length face shield is worn when a splashing or spraying potential exists.</td>
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<td><strong>24.</strong> Contaminated protective clothing including gloves are not worn outside the laboratory.</td>
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<td><strong>25.</strong> Animals unrelated to the experiments are excluded from the lab.</td>
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<td><strong>26.</strong> Needles and syringes are used only for parenteral injections and fluid aspiration from animals. Only locking or integral-type or syringes are used. Safety needles are required for use with bloodborne pathogens and human materials. (Refer to the Exposure Control Plan for bloodborne pathogens Appendix VIII for further information.)</td>
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<td><strong>27.</strong> Extreme caution is used when handling needles and syringes to avoid autoinculation and the generation of aerosols during use and disposal.</td>
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<td><strong>28.</strong> Contaminated needles are not sheared, bent, or recapped.</td>
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<td><strong>29.</strong> Sharps including needles, razors, scalpels, contaminated broken glass and pasteur pipettes are disposed of in a sharps shelter.</td>
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<td><strong>30.</strong> Concurrent experiments of a lower biosafety level are carried out only in demarcated areas.</td>
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<td><strong>31.</strong> Biosafety cabinets and other containment equipment are used with aerosol producing tasks (blending, grinding, sonicating, shaking, opening containers whose internal pressures may be different from ambient pressure) unless equipment design provides for aerosol containment. List aerosol generating equipment:</td>
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<td><strong>32.</strong> Biosafety cabinets are certified annually:</td>
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<td>Class II Type: __________________________ Serial No.: __________________________</td>
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<td><strong>33.</strong> Centrifuges and microfuges are located within the laboratory.</td>
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<td><strong>34.</strong> Lab specific biosafety information is available, and personnel are required to be familiar with it. Information that should be included: general information regarding biohazardous agent, routes of disease transmission, recommended vaccinations, signs and symptoms of disease, personal protective equipment required, waste handling protocol, spill clean up procedures for inside and outside containment equipment including centrifuges, exposure follow-up procedure, aerosol control procedure, and general biosafety information (NIH Guidelines and/or CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories).</td>
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Revised 1/30/03