

Appendix E2. EHS Biosafety Inspection Checklist for Human Gene Transfer (2/12)

A. Laboratory and/or Clinic Identification

1. PI's name _____, Department _____
Site Contact _____ Highest Protocol Biosafety Level _____
Phone _____ Email _____
Sponsor _____ Sponsor Contact Information _____
Building _____ Room # _____ BSL _____ Description _____
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Building _____ Room # _____ BSL _____ Description _____
2. Protocol(s) source: IBC ACUC IRB Other: _____
3. IBC approval number(s) _____ ACUC Number(s) _____ IRB Number(s) _____
List risk(s): Biohazardous materials: prion genomic sequence viroid virus
 HGT bacteria parasite plant(s) rDNA
Pathogens: animals human human/primate blood human fluids, cells and tissues
 (OPIM) other potential infectious material: specify: _____
4. Emergency Procedures poster: Yes No
5. Emergency Notification signage: Yes No N/A

B. Study Related Activities

1. Shipping or Receiving of Agent Yes No N/A
2. Agent Storage Yes No N/A
3. Agent Administration Yes No N/A
4. Disposal of used vials/unused agent Yes No N/A
5. Biopsy post agent administration Yes No N/A
6. Collection of subject samples post agent administration Yes No N/A
7. Other biological materials handled on-site Yes No N/A

C. Administrative Information

1. PI familiar with BMBL and NIH Guidelines Yes No N/A
2. PI will report serious adverse events to IBC, IRB, and NIH Yes No N/A
3. PI will report any significant problems and/or violations of the protocol or NIH Guidelines in 30 days Yes No N/A
4. PI is aware of responsibility for staff training Yes No N/A
5. Site Specific Biosafety Manual is available Yes No N/A
6. Site Specific Biosafety manual Covers:
 1. General Information on agent Yes No N/A
 2. Routes of transmission Yes No N/A
 3. Recommended vaccinations Yes No N/A
 4. Signs and symptoms of disease exposure Yes No N/A

- 5. PPE required Yes No N/A
- 6. Waste handling procedures Yes No N/A
- 7. Spill procedures and containment Yes No N/A
- 8. Exposure follow-up procedures Yes No N/A
- 9. Aerosol control procedures Yes No N/A

- 7. Staff offered Hepatitis B vaccination, recommended
Vaccinations for the agent, or declined via waiver Yes No N/A
- 8. Process to educate staff regarding agent risks? Yes No N/A

D. Gene Transfer Product – Shipping, Receiving, Storage, and Preparation Areas

- 1. PI familiar with BMBL and NIH Guidelines Yes No N/A
- 2. Biosafety signage and labels in lab & at entrance to lab Yes No N/A
- 3. Is the Exposure Control Plan completed (if required) Yes No N/A
- 4. Blood borne Pathogen Training current Yes No N/A
- 5. Training, medical monitoring (if needed), associated
risks provided to all individuals with access to pathogens Yes No N/A
- 6. DOT Training records current with dates of last training Yes No N/A
- 7. No eating, drinking, smoking, applying cosmetics or food Yes No N/A
- 8. Sealable container with biohazard symbol for transport Yes No N/A
- 9. On-site transport of subject samples is safely via SOP Yes No N/A
- 10. Off-site transport in accordance of DOT or IATA Yes No N/A
- 11. Eye-wash station available? Plumbed or not? Checked? Yes No N/A
- 12. Pest control program implemented? Vendor? Yes No N/A
- 13. Work surfaces decontaminated after use? Disinfectant? Yes No N/A
- 14. Any other HGT studies are done in demarcated areas Yes No N/A

E. Gene Transfer Product – Subject Administration and Monitoring Area

- 1. Consideration given to separate patients from N/A staff Yes No N/A
- 2. Agent administration is done in a private exam room Yes No N/A
- 3. Access to agent is limited or restricted by the PI Yes No N/A
- 4. Windows have screens or do not open Yes No N/A
- 5. Hand washing facilities are available Yes No N/A
- 6. If no hand-washing, alcohol based foaming rub is used Yes No N/A
- 7. PPE available in areas of preparation and administration Yes No N/A
 - 1. PPE Available? (Examples gown, gloves, etc.)
- 8. Puncture proof sharps container for sharps disposal Yes No N/A
- 9. Staff aware of regulations for disposal of biowaste Yes No N/A

F. Facility/Equipment

- 1. Biosafety cabinet in use Yes No N/A
Make Model, size, and serial # _____
- 2. Negative-pressure thimble connection/biosafety cabinet Yes No N/A

3. Biosafety cabinet certification required Yes No N/A
4. Date of last certification _____
5. Decontamination of biosafety cabinet BEFORE use Yes No N/A
6. Decontamination of biosafety cabinet AFTER use Yes No N/A
7. Clutter on grate in biosafety cabinet Yes No N/A
8. Neat uncluttered work area in biosafety cabinet Yes No N/A
9. HEPA filter on vacuum line Yes No N/A
10. Is the suction flask more than ½ full? Yes No N/A
11. Autoclave in use? Yes No N/A
- Make _ _ _ , Model, _ _ _ , Room _ _ _
- Frequency of autoclave calibration _____ Log available for each run _____
12. Centrifuge available: Yes No N/A
13. Make, _____ Model, _____ condition of centrifuge bucket, _____,
condition of centrifuge rotors (cracks), _____ condition of centrifuge interior (residue), _____
Usage log available: _____
14. Spill-kit availability Yes No N/A
15. Windows meet NIH & BMBL guidelines Yes No N/A
16. Cleanable surfaces—no carpets Yes No N/A
17. BL-2 eyewash and cleanable chairs Yes No N/A
19. BL-2 self closing doors/BL-1 lockable doors Yes No N/A
- Comments: _____

G. Work Practices

1. All aerosol-generating procedures- steps taken to control them Yes No N/A
2. Effective use of biosafety cabinets Yes No N/A
3. Surface decontamination: Yes No N/A
- Disinfectant used _____, contact time _____ (minutes), frequency _____
4. Are lab coats worn and clean Yes No N/A
5. Are safety glasses and PPE available\ worn as recommended Yes No N/A
6. Any evidence of eating\drinking in the lab areas Yes No N/A

H. Biohazard Waste Handling

1. Labeled rigid containers with lids (boxes or tubs) Yes No N/A
2. Red bags & approved containers used for Biohazardous wastes Yes No N/A
3. Appropriate transporting of waste in room(s)\building(s) Yes No N/A
4. Only biohazard waste in red bags\ no liquids Yes No N/A
5. Appropriate labels and information on containers Yes No N/A
6. Sharps containers used and properly labeled Yes No N/A

I. Interview

1. Biosafety knowledge Yes No N/A
2. Hazards of materials in their work place Yes No N/A

- | | | | |
|-------------------------------------------------|------------------------------|-----------------------------|------------------------------|
| 3. Waste disposal practices | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| 4. Special precautions, practices or procedures | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| 5. Personal protective equipment | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| 6. Emergency response procedures | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| 7. Security of materials, storage & in use | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

Comments: _____

Inspected by: _____ Date: _____