

Human Gene Transfer Submission Checklist
For University of Miami Institutional Biosafety Committee

Last updated on 5/20/2009

- All documents submitted to and received from OBA (e.g., Appendix M-I-A, RAC comments, letter of approval, etc)
- Investigational Brochure and Sponsor's Protocol
- Diagrams of Operating Room and Pharmacy
 - Include location of spill kits
- Scientific Overview with references (2-3 Pages)
- Inspection and approval of facilities by Environmental and Safety Officer
 - Inspections to include Operating Room, Pharmacy, Storage and qualifications of participating staff. Approval is conditional on the inspection and approval of facilities
- IBC Gene Transfer submission form

Please note that if a study has multiple phases, each phase of the study must be submitted to the OBA and the IBC.

Please contact the IBC Associate Director if you need additional information about human subject research involving recombinant DNA.