

## Human Gene Transfer Clinical Trial Protocols (GENE THERAPY)

The following is a list of requirements needed to comply with the NIH Recombinant DNA Guidelines, Appendix M for clinical trial protocols.

*Approval by another Institutional Biosafety Committee does not guarantee approval by the UCSD Institutional Biosafety Committee (IBC)*

*All communications between a study sponsor and the IBC must be through the Principal Investigator*

**TWELVE (12) COPIES OF THE PROTOCOL REQUIREMENTS MUST BE SUBMITTED IN BINDERS, DIVIDED BY NUMBERED TABS CORRESPONDING TO THE LIST BELOW:**

### Requirements

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- 1 Printed copy of the on-line BUA Report (found when selecting the BUA Preview link (#9) found under BUA Request)
- 2 Responses to NIH Recombinant DNA Guidelines, Appendix M  
[http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_M.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm)
- 3 Copy of RAC Review and Relevant Correspondence with RAC
- 4 FDA Approval
- 5 Relevant Correspondence with FDA
- 6 Investigator's Brochure
- 7 Information Regarding Recombinant DNA and Standard Operating Procedures to its Handling
- 8 Preclinical Animal Data (if Phase 1)
- 9 Previous Human Data with Recombinant DNA
- 10 Clinical Protocol for the FDA
- 11 Consent Forms
- 12 Annual Renewal Requirements

**Please contact Environment, Health & Safety at (858) 534-5366 for consultation as needed.**