# Augusta University Institutional Biosafety Committee (IBC)

## Checklist for Human Gene Transfer/Therapy and/or DNA Vaccine Clinical Trial Protocols

The following is a list of requirements needed to comply with the NIH Recombinant DNA Guidelines, Appendix M for clinical trial protocols. http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_M.htm

- *Approval by another Institutional Biosafety Committee does not guarantee approval by Augusta University's IBC.*
- *All communications between a study sponsor and the IBC must be through the Principal Investigator or designee*

**Submit documents below, including this checklist to biosafety@augusta.edu.**

| | Requirements | Resource | Status |
|---|---|---|---|
| **1** | Biosafety Protocol (BSP) "Full" Application (A new one must be completed for each study, specific to that study. For these types of trials, one application cannot cover multiple studies, each requires a new application). | http://www.augusta.edu/research/ibc/apps.php<br><br>If electronic signature is not possible, mail an original signature page. | |
| **2** | Curriculum vitae of PI and co-PI | HGT studies must have a co-PI | |
| **3** | Responses to NIH Recombinant DNA Guidelines, Appendix M | Must be PI and site-specific<br>http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf | |
| **4** | FDA Approval | Explain if not applicable | |
| **5** | Relevant Correspondence with FDA | Explain if not applicable | |
| **6** | Investigator's Brochure | Explain if not applicable | |
| **7** | Information regarding rDNA and Standard Operating Procedures for its receipt, handling, transfer/transport, administration and proper disposal | Must be site-specific | |
| **8** | Preclinical Animal Data (if Phase 1) | Explain if not applicable | |
| **9** | Previous Human Data with Recombinant DNA | Explain if not applicable | |
| **10** | Clinical Protocol for the FDA | Explain if not applicable | |
| **11** | Consent Forms | Must be site-specific | |
| **12** | Annual Renewal Requirements | See Appendix M-I-C-3 | |

**Contact EH&S Biosafety at 706-721-2663 or biosafety@augusta.edu for consultation as needed.**