

## CERTIFICATIONS AT CCRC

**Declaration of Helsinki** – Recommendations guiding medical doctors in biomedical research involving human subjects

**Belmont Report** – Ethical principles and guidelines for the protection of human subjects of research

- 21CFR50 – Protection of Human Subjects
- 21CFR54 – Financial Disclosure by Clinical Investigators
- 21CFR56 – Institutional Review Boards
- 21CFR312 – Investigational New Drug Application
- 21CFR812 – Investigational Device Exemptions
- ICH E2A – Clinical Safety Data Management
- ICH E6 – Good Clinical Practice: Consolidated Guidance
- FDA Information Sheets – Information Sheets from the FDA that offer regulatory guidance and information

### **Health Insurance Portability and Accountability Act (HIPPA)**

Coastal Carolina Research Center as a dedicated research site is considered a “non-covered” entity under the The Privacy Rule and HIPPA. We do however honor the spirit of the HIPPA guidelines and understand the indirect relationship we have in working with other physicians, who do fall under the auspice of HIPPA, requires constant vigilance that we protect an individual’s Personal Health Information (PHI) under all circumstances.

Our President, Nancy Dinsmore, acts as our HIPPA compliance officer and has received a certification of training by Barnett International.

### **CLIA**

Coastal Carolina Research Center has a Certificate of Provider-Performed Microscopy Procedures authorized from the Centers For Medicare & Medicaid Services and the Clinical Laboratory Improvement Amendments otherwise know as CLIA.

**Please see CLIA certificate for Mount Pleasant**

### **Hazardous Material Training (HAZMAT)**

Each member of the study staff which includes Study Coordinators, Research Assistants and Laboratory staff are required to complete and maintain a certificate of the “Record of Training for the Transportation of Dangerous Goods” by Saf-T-Pak.

### **OSHA**

Annually are staff is instructed on the safety requirements and standards under OSHA.