

**TITLE: Clinical Research Conducted in Campus Facilities**

**1.0 OBJECTIVE:**

- 1.1 This Standard Operating Procedure (SOP) describes the requirements for conducting clinical research in campus facilities for the Medical College of Georgia (MCG).
- 1.2 This procedure is intended to meet the following regulations while recognizing that these regulations may override the procedure:
  - Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814)
  - Department of Health and Human Services (DHHS) Regulations (45 CFR Subparts A, B, C, and D)
  - International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines
  - Medical College of Georgia (MCG), Medical College of Georgia Health, Inc. (MCGHI), and Medical College of Georgia Research Institute (MCGRI) guidelines.

**2.0 RESPONSIBILITIES:**

- 2.1 The Principal Investigator (PI) is responsible for ensuring that all human subject research takes place in locations that meet the minimum standards as outlined in this standard operating procedure.
- 2.3.1 The Medical College of Georgia (MCG) Office of Human Research Protection (OHRP) is responsible for monitoring compliance with Clinical Research SOPs at the Medical College of Georgia and Medical College of Georgia Health, Inc.
- 2.4 The MCG OHRP is responsible for posting these SOPs on their website as a reference material.

**3.0 PROCEDURES:**

- 3.1 Preparing the campus facility for clinical research that does not place the research subject at any additional risk based on the subject population pool:
  - 3.1.1 The PI is responsible for ensuring that the research is conducted in a campus facility that has an appropriate emergency plan.
  - 3.1.2 The PI will designate the campus facility by building name, building code and room number(s).
    - 3.1.2.1 Access to the emergency system by providing the location of the nearest telephone for calling 1911 for local emergency medical assistance.
    - 3.1.2.2 Access to the emergency system by providing the location of the

nearest telephone for calling 12911 to notify appropriate campus personnel of the need for external assistance.

- 3.1.2.3 Appropriate signage and location of other individuals during the emergency call to promptly guide emergency medical personnel.
- 3.1.2.4 Basic cardiac life support (BCLS) training should be provided to all research team members.
- 3.1.2.5 Documented training of all research team members regarding these procedures.
- 3.1.2.6 Documented communication plan of these procedures to include all research team members.

3.2 When the planned clinical research places the research subject at any additional risk based on the subject population pool, the emergency plan for the campus facility may require additional measures as determined by the Institutional Review Board (IRB) of record:

- 3.2.1 These measures may include a crash cart for specifically trained individuals only.
- 3.2.2 Other measures may also be required.

3.3 Definitions:

- 3.3.1 Campus research facility: An area that is not part of the hospital or clinic area and may include such terms such as an academic site, non-hospital site or the practice sites for the Schools of Allied Health Sciences or Nursing or others.