

Title: **IRB SELECTION**

1.0 OBJECTIVE

- 1.1 This Standard Operating Procedure (SOP) describes the methods for choosing an IRB.
- 1.2 This procedure is intended to meet FDA and DHHS regulations, GCP guidelines, state regulations and MCG Health System regulations regarding IRB selection for clinical research.

2.0 DEFINITION

- 2.1 Institutional Review Board- any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects.
- 2.2 Human Assurance Committee (HAC) - the local institutional review board for the Medical College of Georgia (MCG), Medical College of Georgia Health, Inc. (MCGHI), Georgia War Veteran's Nursing Home (GWVNH), and the Augusta Veteran's Affairs Medical Center (VAMC).
- 2.3 Chesapeake Research Review, Inc. (CRRRI) - Chesapeake Research Review, Inc. an independent IRB available for studies that meet **all** the following criteria listed in section 2.3.1
  - 2.3.1 Industry Sponsored, Industry Initiated, Multi-Center Clinical Trials that are not conducted at the VAMC.

3.0 PROCEDURES FOR SELECTING AN IRB

- 3.1 Two Institutional Review Boards (IRB) are available to researchers: The Human Assurance Committee (HAC) is MCG's IRB. Chesapeake Research Review, Inc. (CRRRI) is an independent IRB available for studies that meet **all** the following criteria listed in section 2.1.1
  - 3.1.1 Industry Sponsored, Industry Initiated, Multi-Center Clinical Trials that are not conducted at the VAMC.

- 31.2 Investigators who meet the criteria listed in section 2.1.1 have a choice to use either HAC or CRRI for those specified studies. However, they must use one IRB.
- 32 The use of any other IRBs is not allowed.
- 33 Once an IRB has been chosen, a protocol may not be switched between the two IRBs. If one disapproves a study, the other IRB is notified of the disapproval as per federal regulations.