

Title: PROCEDURES FOR USING THE HUMAN ASSURANCE COMMITTEE

1.0 OBJECTIVE

- 1.1 This Standard Operating Procedure (SOP) describes the methods for using the Human Assurance Committee (HAC) as the institutional review board (IRB) for a protocol.
- 1.2 This procedure is intended to meet FDA and DHHS regulations, GCP guidelines, state regulations and MCG Health System regulations regarding IRB submissions.

2.0 DEFINITIONS

- 2.1 Chesapeake Research Review, Inc. (CRRI) - Chesapeake Research Review, Inc. an independent IRB available for studies that meet all the following criteria listed in section 2.1.1
 - 2.1.1 Industry Sponsored, Industry Initiated, Multi-Center Clinical Trials that are not conducted at the VAMC.
- 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 Charlie Norwood Veteran's Affairs Medical Center (VAMC) and the Physicians Practice Group (PPG).

3.0 PROCEDURES FOR INITIAL SUBMISSION TO THE HAC

- 3.1 Once the HAC has been chosen as the IRB of record for the protocol, it (the protocol) may not be switched between the HAC and CRRI. If one disapproves a study, the other IRB is notified of the disapproval as per federal regulations.
- 3.2 The investigator must use the HAC forms available on the HAC website.
- 3.3 The investigator should be aware of and committed to ensuring that all applicable fees are paid (Appendix I).
- 3.4 All applicable institutional approvals must be obtained.
- 3.5 The study cannot begin until the investigator receives notification from the appropriate department.
 - 3.5.1 Sponsored studies cannot begin until the PI receives notification from the Division of Sponsored Program Administration (DSPA).
 - 3.5.2 Non-sponsored studies cannot begin until the PI receives the HAC approval letter and all other applicable approvals have been obtained.

4.0 PROCEDURES FOR REPORTING STUDY EVENTS TO THE HAC

- 4.1 Reporting Unanticipated Problems that may include Adverse Events, Serious Adverse Events, Protocol Deviations/Violations or others
 - 4.1.1 The above-listed study reports should be reported to HAC according to their reporting requirements. See the section on “Problems that Investigators Have to Promptly Report to the IRB”
 - 4.1.2 OHRP will receive notification regarding these reports from HAC.

5.0 Reporting Study Amendments

- 5.1.1 All study amendments should be reported to the HAC according to the Protocol Amendments policy.
- 5.1.2 The Division of Sponsored Program Administration should receive notification regarding all HAC approved amendments

APPENDIX I Fees Associated with HAC submissions

Industry sponsored studies with a study budget greater than \$10,000 will be charged a \$1500 HAC submission fee. Effective July 1, 2008, all industry sponsored projects submitted for HAC review will be charged a submission fee of \$2,500 and a continuing review fee of \$500.

The fee is due regardless of study initiation.

The HAC will bill the sponsor directly for the submission fee.

The fee should be included in the study budget.

The fee is not collected for grants or institutionally funded studies.