

Title: PROCEDURES FOR USING CHESAPEAKE RESEARCH REVIEW, INC.

1.0 OBJECTIVE

- 1.1 This Standard Operating Procedure (SOP) describes the methods for using Chesapeake Research Review, Inc. 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 Charlie Norwood 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).

3.0 PROCEDURES FOR INITIAL SUBMISSIONS TO CRRI

- 3.1 Once CRRI has been chosen as the IRB of record for the protocol, it (the protocol) may not be switched between CRRI and the HAC. If one disapproves a study, the other IRB is notified of the disapproval as per federal regulations.
 - 3.1.2 If the study sponsor is using CRRI as the central IRB for the study, MCG sites should submit the study and all appropriate forms according to the procedures outlined in this SOP.
- 3.2 The investigator must use the CRRI- MCG customized forms available on the MCG Office of Human Research Protection (OHRP) web site.
- 3.3 The investigator must copy OHRP and the Division of Sponsored Program Administration (DSPA) on the initial submission correspondence to CRRI.
- 3.4 The investigator should be aware of and committed to ensuring that all applicable fees are paid (Appendix I).
- 3.5 All applicable institutional approvals must be obtained.
- 3.6 The study cannot begin until the PI receives a release letter from OHRP.

4.0 PROCEDURES FOR REPORTING STUDY ACTIVITIES TO CRRRI

- 4.1 Reporting Unanticipated Problems that may include Adverse Events, Serious Adverse Events, Protocol Deviations/Violations or others
 - 4.1.1 Follow CRRRI's policy for prompt reporting (not the HAC) as they might have somewhat different requirements for prompt reporting by investigators.
 - 4.1.2 Investigators must be compliant with Chesapeake's policies when they are the IRB of record.

4.2 Reporting Study Amendments

- 4.2.1 All study amendments should be submitted to CRRRI for their approval according to their guidelines.
- 4.2.2 DSPA should receive notification regarding all CRRRI approved amendments.
- 4.2.3 OHRP will receive notification of study amendments from CRRRI
- 4.3 Requesting a Change in Study Status, Continuing or Expiration
 - 4.3.1 The above-listed study reports should be reported to CRRRI according to their reporting requirements.
 - 4.3.2 OHRP will receive notification regarding these reports from CRRRI.

APPENDIX I **Fees Associated with CRRRI Use**

CRRRI Fees:

Visit the CRRRI web site to access their fee schedule. These fees should be included in the study budget. CRRRI will bill the sponsor directly for the submission and review fees.

OHRP Associated Fees:

OHRP will bill the sponsor directly for the one-time \$750 compliance fee. This fee should be included in the study budget.