

Eastern Virginia Medical School
Policy and Procedure for Chesapeake Research Review, Inc. (CRR)
Protocol Submissions

I. Policy

- A. Eastern Virginia Medical School (EVMS) has designated the Chesapeake Research Review, Inc. (CRR) as a third EVMS IRB for investigators to use for review of studies involving human subjects.
- B. All costs associated with the submission and review of a protocol through CRR is the responsibility of the Principal Investigator. (See Appendix 1 for fees.) If funds are not available to support the review, the EVMS investigator must use one of two in-house EVMS IRBs.
- C. EVMS IRB administration will determine if the protocol may be submitted to the CRR. EVMS reserves the right to keep local level review for any submission. It is strongly recommended the site contact the EVMS IRB office **before** completing the CRR forms.

Local review will be required for certain studies. Examples are as those conducted in a local school setting; emergency research; emergency use of a product; studies involving a waiver of consent. This list is not inclusive and the site should contact the IRB office for an official determination. It may be necessary for the site to provide a copy of the protocol in order for a decision to be made on the use of CRR services.

II. Procedures

- A. **Principal Investigator responsibilities:** After determining if the principal investigator (PI) wants to utilize the services of the Chesapeake Research Review, Inc., the PI or their designee will:
 - 1. Prepare the CRR submission utilizing CRR forms. CRR staff will assist the PI with questions regarding the proper completion of forms.
 - 2. Complete the EVMS "Submission Cover Sheet / Chesapeake Research Review Inc." (This form is only required for NEW submissions. Once CRR approves a protocol, the investigator may submit amendments, continuing review and other study requests directly to CRR.)
 - 3. Submits materials to department chair for approval.
 - 4. Forwards ALL completed documents to the EVMS IRB after signature.
- B. **EVMS IRB responsibilities:**
Designated EVMS IRB staff member(s):
 - 1. Upon receipt of CRR submission, conducts administrative/facilitated review to occur within two business days. This review will determine if the request for CRR review can be granted.
 - 2. If CRR review is accepted, the IRB staff:
 - Assigns a tracking number; inputs information into the IRB Manager database, noting the CRR as the IRB of record.
 - Forwards the application to CRR for review.
 - 3. If CRR review is not approved, the site will be notified to submit the protocol to one of the EVMS IRBs, which will require completion of the EVMS IRB forms.

- In such cases, the PI may appeal the decision to the Associate Dean for Research Subject Protections.

C. **CRR I responsibilities:**

1. Work directly with the site to ensure the proper completion of all forms.
2. Review submissions.
3. Notify the EVMS IRB office and PI of any actions on the protocol.

D. **Adverse Event Reporting:** The PI should send a copy of any local SAE reports to the EVMS IRB office at the same time as it is submitted to CRR I. Use of the SAE Submission form is required.

E. **Consent form:** The CRR I has developed an EVMS model consent form. Sites must use this model consent for developing their study consents.

F. **Key EVMS IRB Personnel**

IRB Administrators, IRB Manager, Associate Dean for Research Subjects Protections.

APPENDIX 1: EVMS Fee Schedule for CRR1 Reviews

	<u>Fee</u>
Initial Review of Protocol and One Site	\$2900.00
Each Additional Site	\$735.00
Additional Locations for Approved Site	\$160.00
Translations	Pass-through
Recruitment Material (per piece)	\$135.00
Documentation to Site (per piece)	\$50.00
Federally-Funded Study (additional, per year)	\$790.00
Continuing Review: Protocol and One Site	\$2900.00
Each Additional Site	\$735.00
Modification Review: Protocol and One Site	\$900.00
Each Additional Site	\$160.00
Informed Consent (per site)	\$265.00
Priority Review	Available upon request Contact the EVMS IRB Office

Please contact the EVMS IRB with any questions regarding fees for IRB services

This Fee Schedule is effective November 20, 2006. Changes may occur at any time without notice.