ADMINISTRATIVE, STUDY, OR SCIENTIFIC REVIEWS

1. Are there any exceptions to Departmental Study Review and Administrative Review?

Yes. Those research proposals that meet the requirement for exemption from IRB review.

2. What is the purpose of these reviews?

- To provide an opportunity to review a study for feasibility;
- To determine if the design and objectives meet your research mission, and;
- To determine if this is an appropriate study for your research subject/patient population and/or will help to answer a research question that may benefit future research subjects or patients.

3. What are the accepted guidelines for the conduction of a departmental administrative/study review?

The review must take place during a convened meeting of your research team who have received a copy of the research plan and informed consent document who:

- Has the knowledge (either by education or experience) to understand the background, aims and methods of the proposed study;
- Understands the research mission and research subject population that will be studied;
- Are from a variety of disciplines, if applicable.

4. Who needs to sign the form?

The Departmental Administrative/Study Review Form must be signed by the Chief or Practice Administrator (or designee) prior to IRB review. Designees must have the authority to commit the department or practice resources.

5. Why are we asking the departments or practice administrator's to sign?

Research studies with MMC subjects (e.g. in-patients, out-patients, employees, students, and staff)

The department chief (or designee) or practice administrator of the principal investigator must agree, by signing the Form, to support the principal investigator in conducting the proposed study. If the department must commit resources (e.g. principal investigator time or other employee time) for the success of the project, it is critical that the department formally agree to that commitment.

Studies with Non-MMC subjects

The practice administrator, staff president or other person with the authority to commit the practice from which subjects will be recruited must agree, by completing the form, to support the principal investigator in conducting the proposed study.

6. What should be provided to the Department Chief or Practice Administrator in order for them to be assured that a thorough review has taken place?

- The first section of the Departmental Administrative Form should be completed by the principal investigator and research team and provided to the department chair or practice administrator for their approval. We recommend that this review takes place at the same time as your study review.
- If applicable, please include a copy of any COI Disclosures, a completed Departmental Administrative/Study Review Form and Internal Service Checklist(s) that shows other ancillary departments have agreed to the use of their resources (found in the IRB application).
- If you are collaborating with others, please get prior sign-off from that Department Chief/Practice Administrator. The final sign-off should be by the principal investigator's department chief or practice administrator.

7. **What if my study is greater than minimal risk and has not received an adequate scientific review elsewhere?**

These studies will have to receive a review by the Scientific Review Group at Maine Medical Center Research Institute.