SCIENTIFIC REVIEW COMMITTEE (SRC)

The Maine Medical Center (MMC) SRC supports the Institutional Review Board (IRB) review process and provides scientific review for projects seeking internal funding. The SRC also serves a mentoring role, by providing constructive advice and feedback to investigators. There are three pathways to SRC review, as follows:

1. **Scientific Review Only**: The SRC assists the IRB by evaluating the scientific merit of investigator-initiated studies that are conducted at MMC and which carry more than a minimal risk to human subjects and have not otherwise been reviewed adequately for scientific merit. Risk determination is performed by the IRB and may occur after a proposal has been submitted for IRB review, or when requested by the Investigator prior to IRB submission. The IRB forwards these proposals to the SRC for review. After receiving SRC approval and making any recommended revisions, the investigator may then submit/re-submit their proposal for IRB review.

2. **Mentored Research Grant Applications**: The SRC provides scientific review and makes recommendations about funding for projects proposed by trainees and junior faculty who are working with a MMC mentor. These studies must be submitted to the SRC for review prior to any IRB submission. The application process is managed by the SeQUR team (Support of Education and Quality Improvement for Researchers) within the Office of Research Ethics and Compliance. Funding decisions for Mentored Research Grants are made by MMCRI’s VP Research. Once funding has been approved, it is the Investigator’s responsibility to complete their IRB/IACUC submission (as appropriate).

3. **Scientific Review plus funding recommendations for internally funded faculty research projects**: On request, the SRC may provide scientific review and make recommendations about funding for MMC programs that periodically announce a Request for Applications (RFA). Funding decisions are made by the department/program offering the grant opportunity. These studies must be submitted to the SRC for review prior to any IRB/IACUC submission.

Visit the SRC webpage for SRC Meeting dates and submission deadlines, as well as a list of the current and past Scientific Review Committee Members

SCIENTIFIC REVIEW PROCESS

**What does an application for SRC review involve?**

All proposals that require SRC review, whether submitted as a request for Mentored Research Grant (MRG) Funding or following a risk determination by the IRB, must be submitted electronically, together with all necessary application forms and documents, to SRC@mmc.org. Detailed instructions begin on page 4 of this document. For more information, contact the Office of Research Ethics and Compliance at 207-661-4474 or at SRC@mmc.org. For more information on SRC’s membership, review process, and method for evaluating scientific merit see the SRC webpage.
How often does the SRC meet?
The SRC meets on the first Tuesday of February, May, August, and November; the SRC’s schedule is posted on the SRC webpage (Research Services & Resources/Research Compliance Services). For a proposal to be considered at a given meeting, all application documents must be received three weeks prior to the scheduled meeting date. If you require an exception to this submission schedule, please contact Daniel Spratt MD, SRC chair at spratd@mmc.org.

What happens if the SRC recommends revision before approving my proposal for funding?
Historically, most proposals require revision and resubmission before they are approved for further action. This factor should be considered when planning your project’s timeline. If the SRC determines that the proposal requires revision, the Investigator will be given the opportunity to meet with a subgroup of SRC members to discuss the requested changes.

What happens after the SRC approves my proposal?
All SRC decisions regarding the action of the committee are communicated to the study’s Principal Investigator in an e-mail from the SRC Chair within five business days of the SRC meeting. The decision, together with Reviewers’ comments, is also communicated to the IRB or IACUC (Institutional Animal Care and Use Committee) as appropriate, and/or to the department providing funding. Formal IRB/IACUC submissions must occur after a funding decision has been made.
MENTORED RESEARCH GRANT (MRG) PROGRAM

Application:
Begin by meeting with a Research Navigator to discuss your research proposal; submit a request for assistance online at MMCRI Navigation. A proposal guidance document is available on the IRB webpage (Forms & Documents).

- Detailed instructions for submitting an application begin on page 4 of this document.
- Completed applications should be submitted electronically to the SRC at SRC@mmc.org.

Funding Priorities:
The Mentored Research Internal Funding program places a high priority on trainee/junior faculty research and on original investigations into new areas. Its goal is to provide “seed” support for 12-month projects with high potential to result in publication or presentation of results at a regional or national meeting.

Eligibility & Budget:
The Principal Investigator (PI) must be an:

- MMC Resident and Fellow Physicians
- MMC Junior Providers (i.e. medicine, nursing, pharmacy, dietary, therapy) defined as within 5 years of terminal degree
- MMCRI Post-doctoral fellows doing clinical research (can be combined with translational or basic components)

All applications must have a Co-Principal Investigator who is a member of the attending or scientific advisory staff to act as the applicant’s Mentor. It is the expectation that the applicant will be with the organization for the full 12-month funding period.

Reporting:
The Mentored Research Grant Program requires an interim progress report every 6 months, with a more detailed final narrative and financial report upon completion of the project. If reports are not received within one month of their due dates, remaining awarded funds may be frozen and unavailable for disbursement until the required reports are submitted.

MRG Grantee Funding Supplement Requests for Travel and Publication Costs:
MRG Grantees may request funds up to $1,000 to support travel and/or publication costs.

- For travel expense requests, please send an email to SRC@mmc.org formally requesting funds. With your email, please attach confirmation of acceptance of your abstract for presentation, a copy of the abstract, and invoices or receipts for travel/lodging reservations. Final approval will be through the MaineHealth VP of Research.
- For publication expense requests, please send an email to SRC@mmc.org formally requesting funds. With your email, please attach confirmation of acceptance of your manuscript, a copy of the manuscript, and invoices for publication costs. Final approval will be through the MaineHealth VP of Research.

An overview of the MRG process is shown in the diagram below. We recommend that you allow 6-9 months, depending on project complexity, for proposal development and approval.

Note that the IRB may require documentation in addition to that submitted to the SRC. SRC-approved projects that involve animals must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC).
Please do not submit your mentored grant projects to the IRB (www.irbnet.org) or to IACUC until you have a letter of acceptance from the Scientific Review Committee and confirmation from MMCRI that you have been awarded funding.

If you have any questions regarding the Mentored Research Grant process, please contact the Office of Research Compliance at 207-661-4474 or at SRC@mmc.org.
Scientific Review only:
(Proposals with greater than minimal risk, referred to SRC by the IRB)
- IRB application form*
- Research Plan/Proposal. Guidance documents are available on the IRB’s webpage.
- Key Personnel Form
- CV or Biosketch for Principal Investigator
- CV or Biosketch for each Co-investigator (if applicable)
- Letter of support from each collaborator (if applicable)
- Any relevant articles that are not available on PubMed (PDF)
- Schedule of Events (budget) (suggested)

Mentored Research Grant applications:
- IRB* or IACUC application form, as appropriate
- Research Plan/Proposal. Guidance documents are available on the IRB’s webpage.
- Key Personnel Form
- Mentee Research Development Plan
- Departmental Chief/Practice Attestation Form (only if submitting an IACUC application)
- CV or Biosketch for Principal Investigator
- CV or Biosketch for each Co-investigator (if applicable)
- CV or Biosketch for Mentor
- Letter of support from each collaborator (if applicable)
- Relevant articles that are not available on PubMed (PDF)
- Schedule of Events (budget) (mandatory)

Scientific Review plus funding recommendations for internally funded faculty research projects:
- IRB* or IACUC application form, as appropriate
- Research Plan/Proposal. Guidance documents are available on the IRB’s webpage.
- Key Personnel Form
- Departmental Chief/Practice Attestation Form (only if submitting an IACUC application)
- CV or Biosketch for Principal Investigator
- CV or Biosketch for each Co-investigator (if applicable)
- Letter of support from each collaborator (if applicable)
- Any relevant articles that are not available on PubMed (PDF)
- Schedule of Events (budget) (mandatory)

*Complete the IRB application “Wizard” (online form) at www.irbnet.org and download in PDF format.
Submit all documentation electronically to the SRC at SRC@mmc.org
1. **IRB or IACUC APPLICATION**

   *If you will be applying for approval of a human subjects or animal study at an institution other than MMC, you may submit that institution’s application form.*

   a. **IRB APPLICATION (HUMAN SUBJECTS RESEARCH).** Instructions and on-line form (“Wizard”) are available at [www.irbnet.org](http://www.irbnet.org); this is the only IRB form that you need to submit to the SRC. Complete the “Wizard” but do not submit it to the IRB at this time; it can be downloaded in PDF format for electronic submission to [SRC@mmc.org](mailto:SRC@mmc.org). A template for your Research Plan can be found on the MMCRI website under IRB Forms & Documents.

   b. **IACUC APPLICATION (ANIMAL RESEARCH).** Application form is available at: [https://mmcri.org/?page_id=355](https://mmcri.org/?page_id=355) (Office of Research Ethics & Compliance).

2. **KEY PERSONNEL FORM** (see p.6)

   Complete this table, providing a list of key personnel, their role, their anticipated percent of time dedicated to the study (% of FTE), and a brief description of their contribution to the study. Also provide the type (CITI/IACUC) and date of each person’s most recent ethics training.

3. **MENTEE RESEARCH DEVELOPMENT PLAN** (see p.7-8)

   *ONLY REQUIRED FOR MENTORED RESEARCH GRANT APPLICATIONS*

   Describe the plan for formal communication between mentor and mentee. This form should be completed by the mentor and must be signed by both mentor and mentee.

4. **DEPARTMENTAL CHIEF/PRACTICE ATTESTATION FORM** (see p. 9).

   *ONLY REQUIRED FOR MENTORED RESEARCH GRANT APPLICATIONS THAT ARE SUBMITTING AN IACUC APPLICATION.* If your study involves human subject research and you are submitting an IRB application form to the SRC, you do not need to complete this form.

5. **CV or BIOSKETCH**

   CV template: [http://medicine.tufts.edu/Faculty-and-Research/Office-of-Faculty-Affairs](http://medicine.tufts.edu/Faculty-and-Research/Office-of-Faculty-Affairs)

   Biosketch template: [https://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf](https://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf)


6. **LETTERS OF SUPPORT**

   Letters of support are needed from each MMC department and/or external collaborator that will be providing support to the study.

7. **ARTICLE(S) NOT AVAILABLE ON PUBMED**

   If you have unpublished preliminary work, or cite articles that are not readily available through PubMed, include PDF versions of these articles.

8. **SCHEDULE OF EVENTS AND BUDGET (Excel File Attached)**

   If you will be applying for funding, completion of a Schedule of Events is required. Instructions for completing a schedule are included in the attached file along with a blank schedule template. Please contact MMCRI Project Management for budget assistance at [ResearchPM@mmc.org](mailto:ResearchPM@mmc.org). Regardless of whether or not you are applying for funding, completion of a Schedule of Events is strongly encouraged as it is a useful tool in the planning and design of your study.
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<tr>
<th>Name</th>
<th>Role¹</th>
<th>% Effort²</th>
<th>Contribution to project</th>
<th>Type of ethics training</th>
<th>Date of most recent ethics training</th>
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<td>Principal Investigator</td>
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<td></td>
<td>Co-Investigator</td>
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¹ E.g.: Principal Investigator, Co-Investigator, Mentor, Consultant, Statistician, Coordinator, Technician; include collaborators from other departments or institutions.

² % of Full Time Equivalent (FTE) that each person will devote to the project (Example: if someone will devote 2 hours per week to the project, that is 2 out of 40 hours/week, or 5% of their time).

³IACUC refers to Dr. Lage’s in-person refresher course at MMCRI
1. Describe your position/employer (if not MMC) and your qualifications as a mentor

2. Describe how you will advise, support and teach the Mentee

3. Describe how Mentor-Mentee meetings and communications will be maintained

4. Describe your approach to the Mentee and project oversight. Address how you will work with the mentee to manage proposal limitations and problems arising during the study

5. Describe how you will provide oversight for the regulatory aspects this project. For example, describe your involvement with and responsibilities for IRB/IACUC submissions and progress reports, Informed Consent process and documentation, and regulatory documentation, as applicable.

6. Describe how you will manage research compliance issues that may arise during the conduct of the research. For example, who will be responsible for reporting any adverse events or protocol violations, as applicable, to the IRB? How will you work with the trainee to ensure that the project is in compliance with pertinent regulations?

7. Describe how you will assist the Mentee in understanding networks, facilities and intellectual resources necessary for the successful completion of their project.
8. Describe training activities that the Mentee will be expected to participate in. Include didactic courses, seminars, meetings etc

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9. Describe how a balance between clinical, teaching and research duties will be fostered, and describe the timeframe available for the Mentee to conduct their project.

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<th>Mentor Name (printed)</th>
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<th>Mentee Name (printed)</th>
<th>Mentee Signature</th>
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## Departmental Chief/Practice Attestation

**Mentored Research Grant Application - IACUC**

*This form is only required only for MRG applicants submitting an IACUC application*

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<th>Project Title:</th>
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<td><strong>Principal Investigator:</strong></td>
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<td>I have reviewed this project and feel that it is consistent with the mission and goals of our organization. I assure that there are appropriate resources in place to conduct this study, that all study staff are appropriately trained, and the study will be conducted according to Good Clinical Practices, and that the investigators have no conflict of interests.</td>
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**Comments:**

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<th>Department Chief/Practice Administrator or Designee Signature</th>
<th>Date</th>
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