Research Support Proposal

APPLICATION INSTRUCTIONS

Research Project Letters of Intent are currently accepted on a ROLLING SUBMISSION basis.

*Your application in its entirety (to include Biosketches, Letters of Support, etc.) MUST be scanned into ONE PDF file; however, the following pages must also be submitted in Word: Abstract Page, Purpose and Specific Aims/Innovation Page, and Pages 2-7.

Sparrow Health System/Michigan State University*Center for Innovation and Research
Sparrow Hospital*1215 E. Michigan Ave, 3 South, Lansing, MI 48912
Phone: 517-364-5738*Fax: 517-364-5735
Email: cfir@msu.edu
Website: http://sparrowmsuinovations.msu.edu/
RESEARCH PROPOSAL GUIDELINES

DEADLINE DATES:
- Rolling Submissions
- Submit by email to: Center for Innovation and Research at: Sharon.Baer@Sparrow.org
- Notification of Funding: Approximately eight (8) weeks following due date.
- Funding Available: Typically up to $50,000.00

PURPOSE OF GRANT:
The purpose of the Center for Innovation and Research is to support health care delivery research that will affect patient outcomes, safety, quality and cost. Research projects may include pilot or feasibility studies or a new area of research. The research must address the Mission and Vision of the Center of Innovation and Research.

All research grant awards are typically up to $50,000. Grants target specific areas of focus.

There are no indirects.

The intent of these funds are to obtain preliminary work to lead to federal level funding (NIH, NSF, DOD).

Training grants, marketing, staffing, or equipment purchase grants will not be supported. These funds are not to be used for instrument development nor developing software apps.

ELIGIBILITY:
The principal investigator must actively be a clinician or researcher from MSU or Sparrow. Active team members must be from each site. (Consultants are not generally considered active key personnel.) Funding preference will be given to research projects that focus on health care quality, patient outcomes (including safety), and cost. Outcome variables must be specific and clear, and questions or Aims clear.

FUNDING PERIOD:
The maximum funding period is one (1) year from the receipt of the award notification. “No cost” extensions will be considered on a case-by-case basis. Requests for no-cost extensions should be made during the final three months of the grant project.

GENERAL INSTRUCTIONS:
- All projects should have a scientist as a co-investigator who has an established track record of independent (extramural) research funding. The team must include investigators from MSU and Sparrow.
- One of the goals of the Center for Innovation and Research is to develop partnerships of researchers/clinicians at MSU and Sparrow who can go on to submit grant proposals for external/extramural funding. (National Institute of Health [NIH], Agency for Healthcare Research and Quality [AHRQ], Department of Defense [DoD], National Science Foundation [NSF], Blue Cross Foundation, Heart Failure Society of America, American Lung Association, and other Foundations.)
- Partners from MSU and Sparrow need to have a specific and active role and not just be a consultant or receive an honorarium. They need to be an integral, active, and on-going team member. (See Role of Contributor(s) section below).
- Consultants can be included; they just do not count as the desired partnership.
- Data should be stored on a secure network drive with appropriate back-up and intrusion protection.
- Patient data for CFIR research must be kept for three (3) years, and the CFIR must retain a copy of the data. Ownership of the data resides with the CFIR.
  - Patient consents should be kept in a locked location. Locked files are available at the CFIR office.
  - Hard Copy/Patient Consents must be filed and locked in a separate location from other data.
  - Other information, separate from the patient consents, can also be stored in locked files in the CFIR office.
ROLE OF CONTRIBUTOR(S)
• Substantial contributions to the conception or design of the project; or the acquisition, analysis, or interpretation of data for the work; AND
• Drafting the proposal or revising it critically for important intellectual content; AND
• Final approval of the version to be submitted; AND
• Agreement to be accountable for all aspects of the proposal in ensuring that questions related to the accuracy or integrity of any part of the project are appropriately investigated and resolved.

EXPECTATIONS FOR RECIPIENTS
Two major reports are due for all projects, a six-month report and a final report.

ADDITIONAL REPORTS
Reports are to be provided to the CFIR at requested intervals and will be distributed to the CFIR Advisory Board and the CFIR Governing Board.

• Reports may be requested at more frequent intervals by Advisory Board and/or Governing Board.

• Six (6) Month Progress Reports: For all funded projects, a progress report is required for release of final funds. Guidelines for submitting these reports will be provided to all grant recipients.
  - Writing progress reports is the responsibility of the Principal Investigator. Reports should be submitted to the Center for Innovation and Research for their office files.
    - Sparrow Reports should be submitted to the IRB (as part of the continued review, if necessary, prior to the annual report)
  - Six (6) month Progress Reports are to include the following information:
    - Date of report.
    - Timeline progress.
    - Report on activities in statement of work and details on status of project.
    - Budget spending progress.
    - Summary of achieving Specific Aims.
    - Barriers to implementing study.

• Final Reports
  - A final report of expenditures and a final scientific report must be submitted 30 days following the end of the project funding period. Unexpended funds revert to the Center for Innovation and Research.
    - Narrative Report – Writing the required narrative report is the responsibility of the Principal Investigator.
    - Financial Report – MSU will prepare the final financial report. The Administrative Assistant will receive a copy of the financial report for review prior to submission to the study sponsor.
    - Reports should be submitted to the Center for Innovation and Research for their files.

Recipients will agree to complete a follow-up survey at one, three, and five years after the completion of the funding project addressing future activities and funding related to seed funds. The purpose of the survey is to track dissemination activities.

ACKNOWLEDGEMENT OF FUNDING: Investigators must acknowledge that this research was funded by the Sparrow Health System/Michigan State University Center for Innovation and Research. This must be on all dissemination formats, posters, manuscripts, presentations, etc. Poster templates are available at the CFIR office, and are also hosted on the CFIR website: http://sparrowmsuinnovations.msu.edu/.
NOTE:
*Prior to finalization of the budget, you should make contact with Nancy Miller, Director of Research, Sparrow Clinical Research Institute (SCRI). She can assist with activities that occur at Sparrow or involving Sparrow medical records that may or may not have related budget issues. Nancy.Miller@Sparrow.org Nancy.Miller@Sparrow.org

PLEASE ALLOW FOR A MINIMUM TWO WEEKS LEAD TIME FOR PROCESSING AND INCLUDE SPARROW BUDGET NEEDS.

INSTRUCTIONS FOR COMPLETION OF THE APPLICATION: Please see the CFIR Website for the Application Instruction Packet information located under the Resources tab at http://sparrowmsuinnovations.msu.edu/.

*Please use the provided formats of the attached templates to complete these sections.

COVER PAGE:
- Name of the applicant(s), to include any credentials.
- Team of Investigators with Institutional affiliation and Department/Unit for each person identified, to include any credentials.

ACKNOWLEDGEMENT CHECK OFF LIST (See Forms Section)

ABSTRACT:
Provide the following information on the project: (See Forms Section)
- At the top of the abstract page, list the title of the project. Limit to 75 characters.
- The abstract should be limited to one page (500 words), using a 1 inch or ½ inch margin. Indicate the number of words in the abstract at the bottom of the page.
- Name of the applicant(s).
- Team of Investigators with Institutional affiliation for each person identified.
- Purpose/Specific Aims/Innovations.
- Rationale/Significance of Study.
- Approaches, Design, Setting, Sample, Methods. Outcomes should be specified.
- Future Funding Opportunity, be specific.

PROPOSAL:
Format:
- Include the Purpose/Specific Aims/Innovation through Data Analysis.
- The narrative is not to exceed 6 single-spaced typewritten pages using an 11-point font (preferably Times New Roman, Arial, or Courier)
- Half-inch margins top/bottom, right, and a ¾ inch left margin.
- The consistent use of one format (American Psychological Association [APA], American Medical Association [AMA], etc.) for the text, citations and reference list is required.
- Please number all pages of the narrative.

PRESENT THE PROJECT NARRATIVE INFORMATION IN THE FOLLOWING ORDER:

TITLE OF PROJECT. Limit to 75 characters.

Purpose/Specific Aims and Innovation Sections
• Purpose and Specific Aims. (See Forms Section – ½ PAGE)
  • Clearly state the purpose of the study and list specific aims in numerical sequence. This needs to be in the form of research questions or research aims, not goals and objectives of projects that are not research in nature.
• Innovation: How will this transform Care? Evidence that this deals with a gap in existing science. (See Forms Section – ½ PAGE)
  • Describe how the project challenges existing paradigms or clinical practice; addresses an innovative hypothesis or critical barrier to progress in the field. Describe how the project develops or employs
novel concepts, approaches, methodologies, tools or technologies. The service /care recipients need to be in the Sparrow Health Care System.

Background Significance, Rationale, and Review of Literature Approach – *(See Forms Section, Proposal Pages 2-7)*.

- The research will contribute to the understanding of human responses and to advances in science or clinical practice. Description should indicate effect on patient outcomes, cost, and quality of care.
- The research should present a succinct, focused, and critical review and synthesis of the literature that provides rationale for need of the study and lack of current evidence.
- The research should identify how the study will address a knowledge gap and contribute to the patient care at Sparrow Health System

Preliminary Work.
Describe any previous research on the topic that has been done by the PI or research team and provide preliminary findings to demonstrate how this is the next step.

Approach, Methods and Design. Use the following subheadings:

- **Design.** Describe the research design in detail.
- Indicate if the project is a pilot study and the need for a pilot study. Some reasons for conducting a pilot study include: feasibility, protocol development, safety determination.

- **Sample and Settings.** Describe the number and type of participants and all sampling and assignment procedures. Provide evidence that patients are available and would participate is important. Indicate the rationale for the sampling process and sample size. Eligibility criteria should be specified. If a power analysis was conducted to justify the sample size, include the results of this analysis.

- **Describe the process for recruitment** of participants. Identify potential problem areas and include alternative strategies. Provide a rationale for the use of the selected setting(s) and patient population.

- **Experimental Variables (experimental and quasi-experimental designs).** Describe the independent and dependent variables in sufficient detail to allow evaluation of its strength of the measure and clinical soundness. Outcomes and measures have to be clear. A more complete description of the intervention or experimental manipulation may be appended for further clarification. Existing and validated measures should be used.

- **Instruments.** List and describe all instruments and measures, and include a discussion of the validity and reliability of each or other psychometric properties. Describe the scoring methods. Append a copy of all instruments.

- **Data Collection Schedule and Procedures.** Describe how and when data will be collected and any procedures for data collection.

- **Data Analysis and Interpretation.** Describe the statistical or analytic techniques that will be used to answer each research question of the project. Include the name of the statistical support person and their role.

OTHER COMPONENTS OF THE PROPOSAL SUBMISSION PROCESS: (Not part of the 6-page narrative)

**Research Priorities and Implications for Practice and Research.** *(See Forms Section)*
Describe how the project addresses the Priorities of the Center for Innovation and Research.

- Describe the implications for quality, patient care outcome, cost, and safety.
- Describe how this project will provide the groundwork for seeking additional funding in the future.
Future Funding (See Forms Section)

- Be specific and detailed about funding source, including institutes and/or foundations, RFA number or Program announcement number, or page of instructions and strategic plan. Identify future research that may develop from this project. What is the potential for garnering future, extramural support?
- Detail fully how completion of this project will lead to further extramural funding or support, inventions and/or intellectual property, or other benefits to Sparrow and MSU.

Provide 1-2 paragraphs addressing each of the following areas:

- **Research on Human/Animal Subjects.** The principal investigator must obtain approval from an Institutional Review Board (IRB) or Animal Welfare Committee if the proposed project pertains to human or animal research. The IRB must be registered with the office for Human Research Protections, DHHS and the assurance identification number must be provided as instructed in the application submission process. If approval has been received, list the approval date and upload the approval letter. If approval is pending, indicate this in the appropriate place in the submission process and upload proof of submission to the IRB.
- Describe how informed consent will be obtained and steps taken to protect participants’ rights or the welfare of animals. Identify any potential risks associated with participation in the project.
- **Women, Children and Minority Inclusion in Clinical Research.** The inclusion of women, children and minorities must be addressed in developing a research design appropriate to the scientific objectives of the study. Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic group. Provide a rationale for selection of such subjects.
- **Facilities and Resources [Environment].** Describe the facilities and resources available to carry out the project at all research sites, e.g., computers, statistical and data management support, access to patients, if relevant.

**APPENDICES** (Not included as part of the 6-page narrative)

- **Reference List.** The reference list should follow the format chosen for the project narrative (APA, AMA, Chicago, etc.).

- **Timetable for Accomplishing the Work.**
  The project should be confined to a maximum of one year. Please include a time line with details for benchmarks. The timetable should reflect a realistic work schedule so the project can be completed within the funding period. Include milestones. All major activities should be on the timeline.

- **Mandatory Letters of Support:**
  - Partners from MSU and Sparrow need to have a specific and active role and not just be a consultant or receive an honorarium. They need to be an integral, active, and on-going team member.
  - Consultants can be included; they just do not count as the desired partnership.
  - Include letters of support from key administrators and consultants, as necessary, about time and fund allocation.
  - Letters of support should document access to performance sites and research participants, institutional resources committed to the project, and matching funds, if any.
  - Any consultants should describe their role and involvement with the research project.
  - Salary Support or in-kind Personnel. [If requesting salary support for the PI or Co-PI, submit a letter from the individual’s immediate supervisor] that gives assurance that release time will be provided from existing job responsibilities.
  - The period of release time must be specified. The percentage of release time must reflect and discuss the percentage of salary support requested in the budget and/or in-kind personnel contributions.
  - Provide a letter from an appropriate administrator that shows effort will be supported.
  - If there is going to be a change in the kind of personnel used in a department (a new type of personnel), a letter of support from the Department Manager must be supplied.
- Biographical Sketches for All Key Personnel. *(See Forms Section)*
  - (Investigators) Use the PHS Form 398 (6/09) biographical sketch form. Submit a biosketch for the PI and any key participants, e.g., all co-investigator(s), consultant(s), clinician collaborators and mentors. Each biosketch is limited to 2-4 pages. Note that the biosketch personnel statement needs to include the contributions (role) of that person to the grant proposal. (Consultants and statisticians)
  - Name the one individual who is primarily responsible for implementing this proposal and for reporting. Enter your position and institutional address.

- Instrument(s). Include all instruments or interview schedules that will be used to collect data. Include any letters of permission to use a copyrighted instrument.

**Budget:** Please use the budget template posted on the CFIR website. NOTE: There are two pages, one for MSU purposes and one for Sparrow purposes.

The budget is typically $50,000.00. There are no indirects. Other sources of support must be indicated to assure that funding to support the project’s activities, which are in excess of the grant funding, will be met and will not hinder the completion of the project.

The budget must be consistent with the role of the team member and not their current salary. Ex: If their role is as an interviewer, payment will be at the interviewer level, not that of a unit manager.

**The Center for Innovation and Research will not support:**
- Payment of tuition
- Publication costs
- Journal subscriptions or books
- Travel costs to professional meetings
- Institutional indirect costs
- Travel for conference attendance or presentation
- Patient Care Costs
- Educational Training
- Equipment purchase, except in situations where that will support better patient outcomes and is central to the proposal. Equipment must be justified and directly related to care.
- Marketing or advertising
- Licenses

**Total Budget Requested.** The budget is typically up to $50,000.00. See the section entitled “Line Item Budget and Budget Justification”. The budget should be planned for one year. Please provide the details of the budget plan.

**No funds will be released until Institutional Review Board [IRB], Institutional Animal Care and Use Committee [IACUC], or other approvals have been confirmed.** If these are intellectual property areas of concern, these will need to be resolved before the proposal is submitted if possible. Funding will not occur until resolved.

**Budget Justification/ Line Item Budget:** *(Please refer to the separate CFIR Budget Worksheet [Excel Spreadsheet] and attach along with the Budget Justification.)*

The justification is a description that includes a justification for all itemized expenses including personnel. Each section of the justification should: (1) list the specific items or project personnel noted below, (2) describe why the items or personnel are essential to the conduct of the study, and (3) include any cost calculations.

One line item budget may be submitted for the entire project or separate budgets are permitted from each performance site. Consortium or contractual arrangements and costs should be itemized. Items labeled as miscellaneous will not be funded. The line item budgets may include the following:
**Personnel:** These funds are not to support summer salaries or salaries to carry over staff while other funding is being sought.

- A description of the activities and role of each person involved in the research project including the principal investigator, co-investigators, consultants, research assistants, secretaries, data collection and data management staff, statistician, etc. Include the percentage of time devoted by each person. If a percentage of any person’s time is to be supported by the institution/another grant or as “in-kind”, indicate and explain in the justification of the budget request for the position.
- All research project personnel, consultants. Include the name, position, % time devoted to project, fringe benefit percent and amount, total fringe requested, and total salary requested.
- Vendors and services, such as survey centers and transcription services, must be HIPAA certified.
- Funds for Sparrow personnel will be provided to Sparrow.

**Subcontracts:**
- Subcontracts with Sparrow may be the mechanism used to pay Sparrow personnel when they are involved.
- Under those circumstances, a Statement of Work (SOW) will be prepared for those personnel covered in the subcontract.
- In addition, a Protocol Statement should be attached, which can come from the IRB document.
- Subcontracts will not be made to companies or vendors that are not registered with Michigan State University and Sparrow Hospital.

**Supplies:**
- Details are needed. Supplies are defined as items with a unit cost of $500 or less. Examples include: photocopying, telephone, postage, computer time, paper, envelopes, transcription machines, flash drives, audio recorders, etc.

**Equipment:** Details and Specs are needed.
- Equipment requests should not represent a major portion of the budget or the only budget item. The narrative for equipment requests should: (1) identify the availability of matching funds, if any, or other funds that will contribute to the purchase of the item, (2) explain why the item is absolutely essential to the study, (3) Ownership of the item at the completion of the study will be individually assessed, but will belong to Sparrow or MSU.
- Equipment is defined as items with a unit cost greater than $500.

**Travel:**
- Only travel for data collection and study costs will be considered. Specify the purpose, personnel involved, distance, number of trips, mode of travel, and cost of travel.
- *Conference travel and expenses will not be supported since this is only a one-year project and findings before the end of the project are unlikely.*

**Software:**
- Request purchase of software only if the institution does not provide it. Include the name, version number, and unit cost.

**Other Expenses:**
- Do not list the expenses as miscellaneous. These must be listed specifically, i.e., lab fees or supplies, lab assays, standardized testing, or reimbursement of study participants.

**Other Support:**
- Identify the total amount of other sources of funding for the study. Specify source, amount and funding period.
- Identify any additional funding that has already been awarded for the proposed study, including any funding obtained by a co-investigator. Explain how the work supported by other sources is different from the present request. Overlaps in funding are generally not funded.

**Pending Funding:**
- If there is other pending funding for the proposed project, identify the amount, agency, and date the funding is expected to be initiated, if awarded. If no additional funding is available or pending for the project, write “Not Applicable” in this section of the narrative. The USPHS Form 398 Page entitled, “Other Support” may be submitted.

**Total Funds Requested** – there are no indirect funds.
FORMS — see CFIR Website, Resources Tab, for complete document of Grant Application Instructions with forms:  http://sparrowmsuinovations.msu.edu/
Sparrow/MSU Center for Innovation & Research
Application Instructions Acknowledgement Checklist (to immediately follow the cover page)

We acknowledge that the following information has been reviewed, and confirm that the application has been given proper consideration in the development of the project entitled:

___________________________________________

Principal Investigator: ____________________________________________

Please check the following items as confirmation of your documents review (fillable form):

☐ The Principal Investigator has read the application instructions in their entirety.

☐ We acknowledge that the team includes investigators from both Michigan State University and Sparrow Health System. We have read and agree to the Role of the Contributor(s) definition.

☐ Team member names, including credentials (if any), and their affiliations (Sparrow Health System, Michigan State University, College, Department, Unit, etc.) have been clearly identified.

☐ We acknowledge that all team members have participated in development of this proposal and agree to its content.

☐ We acknowledge that the proposal itself does not exceed 6 single-spaced, typewritten pages (Background Significance, Rationale, and Review of Literature).

☐ We have attached the following pages: Abstract page, Purpose/Specific Aims and Innovation page, and Research Priorities/Implications and Future Funding Sources page.

☐ We have included our budget using the CFIR Budget Worksheet, as well as a budget justification.

☐ We have included Letters of Support for team members from key administrators regarding salary support, and/or in-kind support, which address issues such as release time, salary, responsibilities, etc.

☐ We have included Biosketches (or resumes, if applicable) for the PI and key participants.

☐ We will scan our application in its entirety (to include Biosketches, Letters of Support, etc.) into ONE PDF file.

☐ We will also submit in Word: Abstract Page, Purpose and Specific Aims/Innovation Page, and Pages 2-7.

☐ This project requires Intellectual Property determination.
Abstract (Limited to one page [500 words] – indicate number of words at bottom of page)

To include: 1) Name of Applicant(s)/Institutional affiliation for each person identified. 2) Purpose/Specific Aims. 3) Rationale/Significance of Study. 4) Approaches, Design, Setting, Sample, Methods. 5) Main Research Variable(s). 6) Future Funding.

Number of words:
• Purpose and Specific Aims: (½ page)

• Innovation: How will this transform care? Evidence that this deals with a gap in existing science. (½ page)
Background Significance, Rationale, and Review of Literature
Research Priorities and Implications for Practice and Research. (½ page)

Future Funding Sources. (½ page)
BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
</table>

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central
finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.
BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

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NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

B. Positions and Honors

C. Contribution to Science

D. Research Support