Marshfield Clinic®
Research Foundation

Research Committee Policy and Procedure Manual

Committee Charge

The Research Committee is charged by Marshfield Clinic Research Foundation Administration with the task of reviewing and critically assessing research proposals for scientific merit and quality. In addition to proposals for funding through Physician Research and Disease Specific Funds (see **Appendices A & B – Internal Funding Policy and Implementing Procedures**), the Committee is also asked to assess the scientific merit of other proposals. Selected examples include:

- Proposals submitted to the Institutional Review Board that are considered greater than minimal risk that have not previously received scientific merit review by an external body;
- Other research projects, as requested by Foundation Administration, which may seek to use certain other sources of internal funding (e.g., scientist TTS funds, department honoraria, investigator residual funds, etc.).

Finally, the Research Committee is charged with ensuring that funds awarded under the Internal Funding Policy are used responsibly. This is accomplished through periodic continuing reviews of funded research. Redistribution of previously approved funds may be recommended if a project is not progressing at a satisfactory pace, or if the original proposal is amended (with the approval of the Committee).

MEMBERSHIP

Composition

The Research Committee will be comprised of individuals of varying backgrounds in order to provide a thorough review of research activities conducted by the institution. In light of the extensive array of research activities conducted at Marshfield Clinic and the limited time available to both clinicians and scientists for Committee service, the Committee will consist of a small group of voting members supplemented by consultants. The Committee will consist of no fewer than five members and will include (at a minimum) a(n):

- physician with research experience
- laboratory scientist
- non-voting biostatistician
- epidemiologist
- representative of St. Joseph's Hospital

When determining the number of voting members, consideration should be given to potential conflicts in both workload and interest that may arise. This may vary depending on the members selected. If numerous conflicts are anticipated, consideration should be given to increasing the number of members or assigning an alternate for any member who is anticipated to have

frequent conflicts. Voting members will be expected to attend all meetings and will be granted voting and proposal rating privileges.

Consultants with specific expertise will be recruited as needed from among Marshfield Clinic physicians, scientists and staff as well as from other institutions. Consultants will be asked to review proposals in their area of expertise and are encouraged but not required to attend meetings. Consultants do not have voting or proposal rating privileges.

Appointments

The Research Committee Chair will be appointed by the Director of Medical Research for a one-year term, renewable annually. The Research Committee Chairperson may appoint a co-chair at his/her discretion. The Chair of the Research Committee will propose new members, who may be approved/appointed at the discretion of the Director of Medical Research.

Term Limits

Members will be appointed for a three-year term, during which time an attendance rate of 80% is expected. Members will receive regular summaries of their attendance, and will be specifically notified if their attendance is not at the expected level. Members will be asked to improve their attendance if necessary. If an individual member's attendance does not improve within a reasonable time period after notification, the member may be replaced on the Committee. No member may serve more than two consecutive, three-year terms. No limitation on terms of chairpersonship shall exist.

Individuals appointed to complete the term of a resigning member will not be considered to have served a full term, and therefore, this individual is eligible to serve two consecutive three-year terms after completing the term of the resigning member.

No term limits or attendance expectations exist for consultants.

Conflict of Interest

Each member of or consultant to the Research Committee shall exercise utmost integrity in all of their Research Committee responsibilities. Members of the Committee shall not use their position, or the confidential knowledge gained by virtue of their position, to unfairly advance their self interest.

The Research Committee will assume a conflict of interest exists if a Committee member or consultant:

- is named as an investigator (PI or Co-I) on a proposal being reviewed;
- is named as an investigator on a proposal that is competing for the same source of funds as another proposal during the same funding cycle;
- is the spouse or first-degree relative of an investigator named on a proposal; or
- has a supervisory or subordinate relationship with the principal investigator.

Any member (or consultant) with an assumed conflict of interest may answer questions from the Committee but must be recused themselves from the discussion and voting process on the proposal in question.

Members and consultants who feel conflicted on a proposal for reasons other than noted above should declare the conflict. These members may freely participate in the discussion but must refrain from voting.

OPERATIONS/FUNCTIONS

Meeting Schedule

The Research Committee is scheduled to meet the second and fourth Wednesday of each month from 12:00 noon until all business for that meeting agenda is concluded, or until the Chairperson adjourns the meeting, but in no case should the meeting adjourn after 2:00 p.m. Additional meetings may be held as workload demands and as member schedules allow. Members will receive a copy of the agenda approximately one week prior to each meeting. Primary reviewers will receive new proposals, resubmissions, responses and amendments requiring full committee review two weeks prior to the meeting. If a meeting is not going to be held, members will receive a cancellation notice two weeks prior to the scheduled meeting date.

Quorum/Approval Requirements

The Research Committee will not typically convene a meeting of the full Committee to review proposed or ongoing research unless a majority (more than one-half) of the standing members are in attendance at the meeting. In no case may a vote be taken with fewer than five voting members present.

Proposal Format

Proposals submitted for internal funding should be written in a manner that is understandable to a broad audience. A proposal is expected to stand on its own without verbal defense or clarification by its author. Proposals must be written in the format noted below and each area (A. through J.) must be addressed. Proposals that do not address each area will be returned as incomplete. Proposals must be complete without reference to attachments. Applicable portions of relevant manuscripts and other documents should be summarized or otherwise detailed within the appropriate section of the proposal.

A. Research goal: Express in a clear concise fashion the broad research goal or hypothesis to be tested.

B. Specific Aims: Specific aims should be stated in a clear concise fashion and include the relationship to the overall goal. In sentence format, list what the specific research proposed in this application is intended to accomplish. One page is recommended.

C. Background: A brief sketch of the background leading to the present application must be included in order to critically evaluate existing knowledge. The purpose of this section is to support the significance of the proposed research and methodology by reviewing relevant literature in the area of interest. Two to three pages are recommended. Attaching abstracts/manuscripts in lieu of detailing background within the protocol is not allowed.

D. Significance: State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Specifically identify the gaps in literature that the project is intended to fill. No more than one page.

E. Preliminary Studies and/or Data: Use this section to provide an account of the principal investigator preliminary studies pertinent to the application. Also include information that will help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

Supplementary background graphs, diagrams, tables and charts relevant to the preliminary studies may also be submitted in the appendix. However, if such material is essential to an evaluation of the research plan, incorporate it in the body of the application.

F. Research Design and Methods: Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

Specifically, include a description of the following for each specific aim (for clarity, use subheadings): 1) the methods you will use to recruit (attach a letter of support for collaborative research) and treat case and control subjects, collect data, collect and analyze samples and manage and analyze data; 2) the number of case and control subjects to be studied and how this sample size was chosen (provide historical evidence and demonstrate potential to enroll this number); 3) if applicable, how control subjects will be selected and how they will be matched to case subjects; 4) the key assumptions that were used in designing the study, including recruitment projections and effects size; 5) statistical methods of assuring the quality of data and testing *(Biostatistics and Bioinformatics Core can assist with this section)* and 6) potential pitfall associated with and alternative procedures to accomplish the aim.

The total page limit (A-F) may not exceed 25 pages, including all tables and figures. Applicants are encouraged to be as concise as possible; there is no requirement that all 25 pages allotted be used.

G. Timeline: Include a timeline in chart or graph format that reflects the project activities and notes the time allotted per activity. Since project start dates are uncertain, note the time allotted (e.g., Month 1 through Month 3: Recruitment) versus actual dates (e.g., January – March: Recruitment). While there is no limit on the timeframe from start to completion of a proposal, it is anticipated that most proposals and their related budgets will not exceed two years.

H. Budget: Itemize all expenses into personnel, supplies, equipment and miscellaneous. Include percent of effort to be committed to the project for all individuals, even if no dollars are budgeted. Cost-sharing in other budget categories should be included. Funding requests may not exceed $40,000 per proposal. An inflationary adjustment may be made to this cap as deemed necessary by the Director of Medical Research. In exceptional circumstances, when necessary to meet Marshfield Clinic research priorities, the Director of Medical Research, with approval of the Board of Trustees, may grant an exception to the cap. Principal and Co-Investigators who actively practice at Marshfield Clinic and possess a terminal degree (i.e., MD, DO, etc.) may also apply for funding up to an additional amount of $15,000 to fund their time conducting research projects deemed scientifically meritorious by the Research Committee.

Include a justification and sufficient detail on each item to determine how you arrived at the requested figure.

I. Literature Cited: List all references. Limit references to relevant and current literature. Each reference should include the title, names of authors, book or journal, volume number, page numbers and year of publication. For publicly available citations, URL's or PMC submission identification numbers should accompany the full reference.

J. Biographical Sketch: All investigators must have a **current** biographical sketch included for review. The biographical sketch may not be more than five pages in length. Include only those publications most relevant to the proposal being submitted.

Proposals should include a version date, which should be adjusted if/when the proposal is revised.

New Proposal Review Process

Projects requesting funds and those requesting only scientific merit review undergo the same basic review using the established criteria to evaluate scientific merit. The review process is explained in detail below.

Biostatistical Pre-Review The non-voting biostatistician member will review the proposal prior to submission of the study and will work out any concerns with statistical design/analysis with the statistician named on the project. If the two disagree, a third biostatistician (the director of the biostatistical core unless he is named on the project) will mediate and make a final decision on the best statistical design/analysis plan. If the PI and the statistician on the project do not agree on design/analysis issues, the disagreement will be taken to the Feasibility Board for consideration. Office of Research Integrity & Protections will send the proposal to the statistician member of the Research Committee at the same time the proposal is sent to the primary reviewers. While the intent is that the statistician will have seen the proposal prior to submission, this will ensure that the statistician has the earliest opportunity to review it in case this does not occur.

Staff Review The Office of Research Integrity and Protections staff reviews applications to ensure required materials are included. This includes ensuring that: 1) the application form is complete and includes required signatures; 2) a proposal addressing each of the areas in the proposal format (i.e., research goal, specific aims, background, etc.) is attached; 3) all attachments referenced in the proposal are included; 4) a list of references is attached; 5) a budget and budget justification is included, reviewed and approved by the Sponsored Programs Office; and 6) a copy of the principal investigator's curriculum vitae is included. Research Integrity and Protections staff will contact the investigator to obtain any missing information. An application is not considered complete until all missing information is received in the Office of Research Integrity and Protections. Complete applications are scheduled for review in the order they are received. In general, no more than two new proposals will be scheduled for any one meeting.

Primary Reviewer Assignments and Review At least two individuals are assigned to each proposal as primary reviewers. At least one of these individuals must be a voting member of the Committee. Primary reviewers will receive a copy of the proposal two weeks prior to the meeting at which the proposal is scheduled for review along with a copy of the New Protocol Review

Form (**Appendix D**). Primary reviewers are strongly encouraged to send issues of concern and questions identified during their review to the Committee Coordinator in the Office of Research Integrity and Protections at least four working days in advance of the meeting. These concerns/questions will be sent anonymously to the investigator who will be asked to provide a response prior to the meeting. Investigators will be cautioned that additional questions will likely arise during the meeting.

If a member receives an application from the Committee Coordinator for which s/he feels uncomfortable or unqualified to act as a primary reviewer, the member should return the application to the Coordinator for reassignment. Primary reviewers may, at their discretion, ask for a written statistical review by a member of the Biomedical Informatics Research Center.

To protect the anonymity of reviewers, Office of Research Integrity and Protections staff will anonymize reviewer questions/concerns prior to sending them to the principal investigator for response. In addition, the names of the primary reviewers will not be listed on agendas, and minutes will not contain names or references to reviewers or to specific members or consultants who may comment on the application during the meeting.

During the Meeting

The Research Committee will meet in closed session to evaluate each proposal using an established list of criteria (**see Appendix C**). Primary reviewers will present an oral review to the Committee systematically following the New Protocol Review Form (**Appendix D**). This form mirrors the Criteria for Review of Research Proposals and will be kept confidential. Completed forms will be used to aid in the preparation of minutes and follow-up correspondence to investigator(s). Any response to questions submitted to the investigator in advance of the meeting will be distributed and/or summarized and considered as part of the initial review.

When reviewing new proposals, the actions the Committee may take are to approve, approve contingent upon specific actions, invite resubmission or disapprove the proposal. Proposals considered by the Committee to require only limited modification/expansion of the proposal in order to secure approval will typically be approved with one or more contingencies. A determination of whether a contingency is subsequently met may, at the Committee's discretion, be made by the Chairperson and/or primary reviewer(s) through an expedited review mechanism. In most cases, the Research Committee will require that responses from investigators that are more than simple clarifications be incorporated into the proposal before final approval is granted. If the Committee feels a proposal has value but requires substantial modification, the study will typically be invited for resubmission with an indication that major revisions are required. The investigator will be encouraged to revise and resubmit the proposal. If time allows, the revised proposal may be considered in the same cycle. Other proposals approved or approved with satisfied contingencies will move forward for funding consideration. They will not be held awaiting potential revision and review of proposals invited for resubmission. The investigator will receive specific suggestions for modifications in order to secure scientific merit approval. If the Committee feels a proposal will not have scientific merit even with substantial modification, the protocol will typically be disapproved. The investigator will receive comments summarizing the reasons for disapproval.

If the protocol is deemed to be meritorious or deemed to be meritorious after specific contingencies have been met, and funding is requested, the budget, timeline and investigator qualifications are evaluated for appropriateness. For those projects requesting Disease Specific Restricted Funds, the Committee will also assess whether the investigator has requested support from the appropriate fund(s.) The Committee may also recommend additional funding sources as appropriate. Comments regarding these aspects are recorded and forwarded to the funding body. Committee members then individually rate the proposal using an established rating scale (see **Appendix E – Rating Scale**). Only those Research Committee members in attendance during the vote will be allowed to rate the proposal. Each member who rates a proposal must score each element. Proposals must be rated immediately following the vote of approval or contingent approval of scientific merit and turned into Research Integrity and Protections staff by the end of that meeting.

Members who declare a conflict of interest or who have a conflict of interest as defined by Committee policy will not be allowed to rate the project. The name of the Research Committee member must be on the rating form so that Research Integrity and Protections staff may ensure that rules regarding conflict of interest and voting only if in attendance are followed.

After the Meeting

Minutes

Draft minutes are distributed to all members approximately two days after the convened meeting via e-mail. All members are asked to review the draft and submit any additions/corrections to the Committee Coordinator. Information discussed at the meeting and contained within the minutes is confidential. Members are not to share minutes or a verbal summary of the meeting discussions with investigators or anyone who is not a Committee member. A letter summarizing the Committee's discussion and the outcome of the review will be sent to investigators by the Chair as soon as the minutes are reviewed and finalized (within one week of review).

Ratings and Other Approvals

Research Integrity and Protections staff will calculate the average rating for each proposal. Any proposal that receives an average rating between 350 and 500 will not be considered for funding, and the investigator will be informed that the proposal did not meet the minimum rating score.

Proposals that receive an average rating that falls within the range of scores awarded to the top 20% of proposals reviewed by the Research Committee (the reference range is calculated at least annually based upon Research Committee data over the two preceding years) will be triaged for immediate funding. Other projects that will be triaged for immediate funding are any proposal that has no other competition for the same fund or proposals competing for the same fund but where adequate resources are available to support all requests for that fund.

All projects reviewed within a given funding cycle that receive the minimum rating but are not triaged for immediate funding will be ranked in order of their score. The ranked list of projects will be forwarded for a funding decision. Investigators will be informed of the average score of each element for their specific project before the information is presented to the body awarding funds. Research Committee members will be notified of final project ratings once all projects submitted in a cycle have been reviewed.

Investigators will be informed that all institutional approval (e.g., Institutional Review Board, Institutional Animal Care and Use Committee, and/or Institutional Biosafety Committee) must be secured prior to the disbursement of funds and the initiation of the research activity.

No Funding Requested
When conducting scientific merit review only of studies (no Physician Research or Disease Specific Restricted Funds), the review process remains the same with the following exceptions:

- the proposal is not rated; and
- the Committee will ask for assurance that funds are available to conduct the research rather than review the appropriateness of the budget.

If a project is not requesting funds and the scientific merit of the proposal is approved, the investigator is free to start the project as long as all other appropriate reviews have been conducted. Research Integrity and Protections staff will remind the investigator of other necessary reviews (i.e., IRB, IACUC, etc.).

Review Time Frame
Review can usually be conducted within four weeks after receipt of a complete and final proposal in the Office of Research Integrity and Protections.

Changes After Approval
The Research Committee recognizes that circumstances may warrant implementation of changes to an approved research protocol. Such changes could range from minor methodological modifications (e.g., refining laboratory techniques) to major shifts in the scope of the project (e.g., eliminating a group of subjects, compromising the study's statistical power).

Since the Committee has a role in overseeing the appropriate utilization of research funding and in promoting good science, any change to an approved and funded research project that affects the overall goal, specific aims or objectives of the approved proposal, that substantively alters the research methodology or its application in pursuit of the approved purposes of the study, or proposes to change principal or co-investigator(s) must receive prior approval from the Research Committee.

Changes to the design or methodology of the study which do not significantly change the scope or planned outcomes of the investigation need not receive prior approval, but must be retrospectively reported to the Committee in summary fashion (along with a brief justification for each reported change) at the time of continuing review.

All changes will be processed initially through expedited review, conducted by primary reviewers and/or the Chair. Any concerns initially identified should be submitted to the Committee Coordinator who will anonymously send concerns or questions to the investigator. After consideration of the proposed change and any response from the investigator to issues of concern or questions raised, the expedited reviewers may approve the change or defer the change to Full Committee for review. If deferred to full Committee for review, primary reviewers will receive the amendment two weeks prior to the scheduled meeting.

On a monthly basis, the Full Committee will receive a summary of all items that were approved through expedited review during the preceding month. Any member may request Full Committee reconsideration of an item previously reviewed and approved through the expedited review process.

Changes not requiring prior approval must be explained and justified in the next scheduled continuing review report. The Research Committee reserves the right to request additional reports and information on an as needed basis.

Requests for Additional Funding

Some projects may totally expend awarded funds prior to completion of the proposed project. Principal investigators may apply for additional funds to complete the project; however, the total funds awarded to the project from Physician Research or Disease Specific Funds may not, with rare exception, exceed the established cap.

As part of the request for additional funds, the investigator will be required to provide the Committee with a summary of the results obtained to date, as well as the amount of funds expended to date. Additionally, he/she must provide an explanation of the need for the additional funds, including an explanation of why funds originally approved were not sufficient to complete the study. The request for additional funding must include an itemized budget and an updated timeline, in chart or graph format, for completion of the project. If the additional request for funds involves an amendment to the original protocol, the protocol as modified must be reviewed by the Research Committee to ensure that the project still has adequate merit.

Projects requesting additional funds will compete with new proposal requests and undergo review by the Research Committee at a convened meeting. Primary reviewers will receive requests for additional funds two weeks prior to the scheduled meeting. The Committee will review the request to evaluate: 1) whether the project remains scientifically meritorious; 2) whether the project is making satisfactory progress; and 3) whether the additional funds are justified. If all of these areas are affirmed, the project will retain its original rating score. The same criteria in place for triaging new projects for immediate funding apply to requests for additional funds.

Progress Reports/Continuing Reviews

Requests for reports are initiated by Research Integrity and Protections staff at the time frames detailed below. Investigators will be asked to provide an updated timeline for completion with each continuing review.

Progress reports for projects receiving internal funds will initially be requested four months after funding has been awarded. This first review will be used to determine whether the project is on schedule and whether funding appears appropriate.

If the project is progressing as detailed in the initial timeline, a report will generally be requested twelve months after the funding award date. If, after this second review, the project continues to progress as detailed in the initial or revised timeline, a report will generally be requested one month after the proposed completion of the project or one year from the last review, whichever comes first, until the project is complete.

If, during any continuing review, the Committee determines that a project is not progressing as detailed in the study's timeline and the investigator has failed to provide satisfactory assurance or make appropriate adjustments to ensure the timely completion of the project, the Committee may request a progress report more frequently. In determining the frequency of these reports, the Committee should strive to ensure adequate oversight without placing undue burden on the investigator. Once an investigator's project has been determined to be progressing as detailed in the study's timeline, the schedule for reviews shall revert to that detailed in the prior paragraph.

The Research Committee has the authority to terminate projects that are not making adequate progress.

A project is considered complete when the Research Committee receives:

1. A manuscript which has been submitted for publication,
2. An abstract which has been accepted for presentation,
3. A continuing review report which includes the final results of the project or
4. An adequate explanation of why the project cannot be completed.

Member(s) originally assigned as primary reviewers will be assigned to continuing reviews. If an original primary reviewer is no longer a member of the Committee, another member will be assigned. During continuing reviews, the following points should be considered:

- What results have been obtained to date? Has progress been made since the last report? If not, an explanation of why there has not been progress should be provided. Can the study be closed and funds returned?
- Have there been any deviations from the proposed protocol, which might impact scientific merit or specific aims of the proposed protocol including any unexpected problems, delays, or extenuating circumstances?
- Are there any unexpected changes in the budget? Are remaining funds sufficient to complete the project? If funds are expended, can the study be closed?
- What is the timetable to completion of the project?
- What will the remaining funds be used for?
- Are additional funds needed to complete the study? If so, is a budget and budget justification included?
- What are the plans for the information gathered from the study (i.e., publication, change in clinical practice, etc.)?

The committee will also ask for copies of any abstracts or articles published or submitted.

If the Committee requests additional clarification by approving continuation of the project contingent upon specific actions, or tables the report, the investigator will be given three weeks to provide a response to a contingent approval. If a response is received within that time period, it may be reviewed through the expedited review process with final approval given by the original primary reviewers and/or Committee Chair, if deemed appropriate by the Committee. If a response has not been received within that three-week time frame, he/she will be given a one-week extension. If, after that time, a response has still not been received, the lack of response will be brought back to the committee for review and possible study termination.

Appendix A

Internal Funding Policy-Physician Research and Disease Specific Restricted Funds

1. Purpose

This policy was created to honor the desires of Marshfield Clinic and donors by allowing for the equitable distribution of limited resources in support of scholarly research, scientific inquiry and research involving inventive technology. This policy establishes rules for the distribution of funds to scientifically meritorious proposals.

2. Background

Marshfield Clinic and Marshfield Clinic Research Foundation (MCRF) leadership strongly believes that it is important to provide funds to support internal researchers in conducting scholarly research, scientific inquiry, or research involving inventive technology. Projects designed to subsequently generate extramural funding or other revenue are encouraged since they allow Marshfield Clinic and MCRF to continue to grow its research mission.

Two funding sources are available. Marshfield Clinic annually sets aside funds to support the research endeavors of individuals actively practicing at Marshfield Clinic who possess a terminal degree (i.e., MD, DO, clinical PhD, etc.). These funds are referred to as Physician Research Funds.

MCRF has established Disease Specific Restricted Funds, which are available to any staff member or employee of Marshfield Clinic, its divisions, or St. Joseph's Hospital. Funds for disease specific research are received primarily from three sources. The majority of funds are either donated as memorials by relatives and friends or received from grateful patients in recognition of service provided by Clinic physicians. Additional funding is also received from organizations interested in supporting research in a specific disease area. The third source of disease specific funding is honoraria funds that have been designated to disease specific research accounts by Clinic and Foundation personnel.

3. Policy Body

The Director of Medical Research, in conjunction with the Director of Clinical Research and the Director of Sponsored Programs and Fiscal Affairs, shall be responsible for developing a competitive process by which clinicians, scientists and others eligible may request and receive Physician Research and/or Disease Specific Restricted Funds. The process shall be defined in the form of implementing procedures and shall consider and include the following guiding principles and restrictions:

a) Eligibility

i. Requests for support of scholarly research, scientific inquiry or inventive technology will be considered for funding. All requests for funds must be presented with an accompanying research proposal.

ii. Individuals actively practicing at Marshfield Clinic who possess a terminal degree (i.e., MD, DO, clinical PhD, etc.) and who will serve as principal investigators on a proposal are eligible to apply for Physician Research Funds.

iii. Any staff member or employee of Marshfield Clinic or its divisions or St. Joseph's Hospital is eligible for Disease Specific Restricted Funds.

iv. Individuals with temporary positions (e.g., Post Docs, Project Scientists and Residents) who chose to serve as principal investigator on a proposal must have a regular status staff member named as a co-investigator. Individuals with temporary positions must also have plans to be on staff for the length of their proposal as defined by the proposal's timeline plus three months.

b) Proposal Submission and Review

i. Proposals will compete for available funds based on their scientific merit.

ii. The competitive application process shall include a peer review for scientific merit and shall be designed to allow for the most equitable distribution of funds, while preparing investigators for future external submissions.

iii. Whenever possible, the process should be designed to make funds available at various times throughout the year.

iv. The source and amount of funds available must be widely announced a reasonable time period in advance of any established deadline for receipt of proposals.

c) Funding and Award Restrictions

i. Funding requests may not exceed $40,000 per proposal. An inflationary adjustment may be made to this cap beginning in FY 2008, as deemed necessary by the Director of Medical Research. In exceptional circumstances, when necessary to meet Marshfield Clinic research priorities, the Director of Medical Research, with approval of the Board of Trustees, may grant an exception to the cap.

ii. Principal and Co-Investigators who actively practice at MC and possess a terminal degree (i.e. MD, DO, etc.) may also apply for funding up to an additional amount of $15,000 to fund their time conducting research projects deemed scientifically meritorious by the Research Committee. For this purpose, salary and benefit expense would be based on the effective NIH Salary Cap for the actual research time for each funded project as reported via MCRF's time and effort reporting system.

iii. While there is no restriction on the number of new applications/protocols a principal investigator may submit for funds over his or her tenure, investigators are strongly encouraged to limit submissions and seek external funds.

iv. Likewise, while there is no limit on the timeframe from start to completion of a proposal, it is anticipated that most proposals and their related budgets will not exceed two years.

v. Neither Physician Research or Disease Specific Restricted Funds will be utilized to fund the following:

1. Salary and fringe benefits of tenured or tenure-track MD or PhD scientists employed as research scientists;

2. Professional component of patient care related items;

3. Cost of travel to present findings or meet with collaborators;

4. Publication reprints or page charges;

5. Costs not directly related to the proposal; and

6. Costs incurred prior to the proposal award.

vi. Awards of a retroactive nature will not be made; that is, expenses incurred on a proposal prior to the start date of the award will not be reimbursed.

vii. The ultimate decision on funding of meritorious projects competing for Disease Specific Restricted Funds will rest with Marshfield Clinic Research Foundation's Board of Trustees. This decision may be delegated at the Board's discretion.

viii. The ultimate decision on funding of meritorious projects competing for Physician Research Funds will rest with the Director of Medical Research.

ix. Funds may be released only after all necessary regulatory (i.e., Institutional Review Board, Institutional Animal Care and Use Committee, Biosafety Committee, etc.) and Board of Trustee or Director of Medical Research approvals, as applicable.

x. The Director of Medical Research has the authority to grant a one-time per proposal approval of additional funds not to exceed $5,000, as long as the total funds awarded to the proposal from physician research or disease specific funds does not exceed the established per proposal cap in effect at the time of the initial award. The Director shall, whenever possible, grant supplemental funds from the same source utilized in the original funding. If the original funding source is depleted, the Director may utilize another fund as long as that fund is relevant to the proposal.

xi. Only under rare circumstances will awarded funds be transferred out of the institution with a departing investigator. Such transfers require written prior approval from the Director of Medical Research.

d) Monitoring/Closeout

i. A mechanism shall be established for the periodic review of projects awarded funds. This mechanism will ensure funds are being utilized as

described in the proposed application. The body given responsibility and authority to monitor the progress of these projects shall also be given the authority to terminate the projects should adequate progress not be made.

ii. Dollars remaining at the termination of a proposal will revert back to the fund from which they came.

Appendix B

Implementing Procedures for Internal Funding Policy - Physician Research and Disease Specific Restrict Funds

1. Fund Availability

a. Funds will be available for competition within the following funding cycles:

CYCLES	SUBMISSION PERIOD	FUNDS AWARDED NO LATER THAN
Cycle 1	September 16 through December 15	May 1
Cycle 2	December 16 through March 15	August 1
Cycle 3	March 16 through June 15	November 1
Cycle 4	June 16 through September 15	February 1

b. Both Physician Research (PRF) and Disease Specific Restricted Funds (DSRF) will be available for competition each cycle.

c. The amount of funds available each cycle will be determined as follows:

   i. Ten percent of the total fiscal year PRF budget will be held in reserve and used by the Director of Medical Research to cover unanticipated expenses of previously funded projects, not to exceed $5,000 per project. The remaining PRFs will be available the first cycle. Funds not utilized in the first cycle will be available in the next cycle. This will continue until the last cycle in the fiscal year, at which time any remaining funds will be added to the amount budgeted in the next fiscal year.

   ii. Any Disease Specific fund with a balance in excess of $30,000 will first have 20%, up to a maximum of $10,000, of its fund held in reserve for use by the Director of Medical Research to cover unanticipated expenses of previously funded projects, not to exceed $5,000 per project. The remaining funds will be available the first cycle. Funds not utilized in the first cycle will be available in the next cycle. This will continue until the last cycle in the fiscal year, at which time any remaining funds will be added to the amount budgeted in the next fiscal year.

d. The Director of Sponsored Programs and Fiscal Affairs will announce the amount of funds available and their source a reasonable time period prior to the start of each submission period.

2. Application Submission/Receipt Process

a. Requests for scholarly research, scientific inquiry or inventive technology will be considered for funding. All requests for funds must be presented with a research proposal.

b. Applications for internal funding must be received by the Office of Research Integrity and Protections, routing location 1R4, any time prior to the end of a submission period.

c. Application early in the submission period is strongly encouraged and offers several advantages:
    i. Proposals are scheduled for scientific merit review shortly after their receipt in the order they are received. Proposals that receive scientific merit approval will be triaged for funding immediately as long as one of the following conditions is met:
        1. No other project is competing for the same fund
        2. Other projects are competing for the same fund but adequate resources are available to support all projects requesting the same category of funds.
        3. The proposal receives an average rating that falls within the range of scores awarded to the top 20% of proposals reviewed by the Research Committee (the reference range is to be calculated at least annually based upon two years past Research Committee data).
    ii. Proposals received early in the submission period will be more likely to have adequate time to respond to Research Committee concerns, if any, and gain approval prior to the end of the funding cycle.
d. The Research Committee is normally able to review eight proposals within the time allotted to each funding cycle. While review of the first eight proposals is guaranteed and consideration will be given in the order received, additional proposals will be accepted and a reasonable effort will be made by the Research Committee to review these as well. If more than eight proposals are received and the Committee is unable to review all proposals submitted, the following guidelines will be used:
    i. First, the Research Committee will re-review proposals received within the submission period that were disapproved as initially submitted but considered by the Committee to require only limited modification/expansion of the proposal in order to secure approval.
    ii. Second priority will be given to the review of proposals received within the submission cycle but received after the initial eight.
e. Proposals submitted in excess of eight that the Research Committee is unable to review will be considered in the next funding cycle.
f. An application submitted for internal funding will consist of a fully completed MCRF Research Project Application Form (**Appendix A**), and a formal written proposal addressing each of the areas in the Proposal Format document (**Appendix B**).
g. A principal investigator may submit only one new funding request per cycle. While there is no restriction on the number of new applications/proposals a principal investigator may submit for funds over his or her tenure, investigators are strongly encouraged to limit submissions and seek external funds. Submissions requesting funds to expand or build upon a previously funded study are strongly discouraged. These types of submissions will be considered but priority will be given to new activities.
h. Applications for additional funds to support ongoing research will be considered within the established funding cycles and will compete against new proposals as well as other requests for additional funds. The exception is an active, previously funded proposal that is requesting $5,000 or less to support unanticipated expenses. These requests may be submitted directly to the Director of Medical Research. Applications for additional funds should be requested in advance of depleting funds in study accounts. Fiscal Affairs shall have the authority to temporarily suspend study activity when awarded funds have been depleted and reactivate study activity when additional funds are awarded.

i. If the additional request for funds involves an amendment to the original proposal, the proposal as modified must be reviewed by the Research Committee to ensure that the proposal still has adequate merit. Requests for additional funds in excess of $5,000 are rated using the same criteria established for new proposals and ranked among all funding requests that cycle.

- As part of the application, investigators will be asked to suggest the fund most applicable to their research activity.

3. Scientific Merit Review Process

a. The Research Committee shall review funding requests. The review will include an assessment of the scientific merit of each proposal based on standard criteria and a review of the appropriateness of the budget, timeline and investigator qualifications. If a proposal is deemed to be meritorious and the budget, timelines and investigator qualifications are considered to be appropriate, the Committee will assign a priority rating. The Committee will utilize a standard scale in assigning ratings. The scale will include but not be limited to such considerations as quality of the proposal, potential for garnering future extramural support or income, and likelihood of successfully completing the proposal.

b. Funding requests will be reviewed by the Research Committee in the date order they are received for the first eight proposals submitted and according to the criteria noted in section 3.d. for proposals received beyond the first eight. Reasonable effort shall be made by the Research Committee to conduct a timely review.

c. The Research Committee shall provide the investigator with a list of concerns and/or suggestions for improvement for any proposal not receiving a meritorious vote or not receiving a rating at or above the established minimum.

- The Research Committee may, at its discretion, decide to allow for revision of a proposal(s) within the same funding cycle.

4. Funding

a. The Research Committee will evaluate and comment on the appropriateness of the funds (amount and disease category) requested.

b. The Director of Medical Research may establish a minimum rating required of any proposal to be considered for funding. Proposals receiving a rating at or above any established minimum rating level will be ranked and forwarded to the appropriate funding body for consideration. The ranking and ratings for Physician Research Fund requests will be sent to the Director of Medical Research for the final award decision. The ranking and ratings for Disease Specific Funds must be sent to the Board of Trustees for the final award decision.

- Funds will be released subsequent to all necessary regulatory (i.e., Institutional Review Board, Institutional Animal Care and Use Committee, Biosafety Committee, etc.) and Board of Trustee or Director of Medical Research approvals, as applicable.

5. Monitoring

As a condition of continued funding, the investigator must submit progress reports as required by the Research Committee. All investigators must submit a final report at the completion of the study. The Research Committee has the authority to terminate research that is not making adequate progress.

Appendix C

Standard Review Criteria

The Research Committee uses the following criteria to evaluate the scientific merit of a proposal:

1. **Goal**
   a. Is the research goal or hypothesis to be tested clearly stated?

2. **Specific Aims**
   a. Are the specific aims to be accomplished through the proposed methods clearly outlined? Is the relationship to the overall goal included? Is it clearly stated what the specific research proposed is intended to accomplish?
3. **Background**
   a. Has sufficient information (e.g. literature review) been provided to justify performing the present application; and has existing knowledge been critically evaluated?
   b. Has sufficient information been provided to support the significance of the proposed research and methodology by including relevant literature in the area of interest?

4. **Significance**
   a. Has the importance and health relevance of the research been stated by relating the specific aims to the broad, long-term objectives?
   b. Have the gaps in literature that the project is intended to fill been identified?

5. **Preliminary Studies/ Progress Report**
   a. Has a sufficient account of the principal investigator's and other pertinent preliminary studies been provided in order to establish that the investigator and collaborators are adequately qualified to carry out the study?
   b. Has the investigator outlined factors or qualities that support the likelihood that the project can be accomplished, completed, and converted into a valued endpoint of the research endeavor (e.g. publication)?
   c. If background graphs, diagrams, tables and charts are submitted, are they relevant to the preliminary studies and/or current application?

6. **Experimental Design and Methods**
   a. Are the research design and procedures used to accomplish the specific aims of the project adequately described?
      i. Does the protocol describe how data will be collected, analyzed and interpreted?
      ii. If appropriate, is the advantage of any new methodology described to justify its advantage over existing methodology?
      iii. Have any potential difficulties and limitations of the proposed procedures been discussed as well as any alternative approaches to achieve the aims.
   b. Has a description of the following for each specific aim been provided?
      i. the methods to be used to recruit and treat subjects, collect data, collect and analyze samples, and manage and analyze the data;
      ii. the number of subjects to be studied and how this sample size was chosen (historical evidence should be provided and potential to enroll this number should be demonstrated);

iii. the key assumptions that were used in designing the study, including recruitment projections and effect size;
iv. statistical methods of assuring the quality of data and testing;
v. potential pitfalls associated with and alternative procedures to accomplish each aim.

The Research Committee uses the following criteria to determine the likelihood of successful completion:

7. Timeline

a. Does the application include a timeline which clearly reflects the project's activities and anticipated timeframe of completion (i.e., enrollment, chart abstraction, data analysis)?

Note: While there is no limit on the timeframe from start to completion of a project, it is anticipated that most projects and their related budgets will not exceed two years.

8. Budget (not needed when evaluating studies for **scientific merit only**.)

a. Is the budget complete and realistic?
b. Has percent of effort to be committed to the project for all individuals listed, even if no dollars are budgeted? Is the time commitment of the PI and other researchers appropriate for the work being proposed? Cost sharing in other budget categories should be included.
c. Has sufficient justification and detail been provided to validate the need and cost of each item as well as how the requested figure was arrived at?
d. Are the funds being requested appropriate for the research being proposed?

9. Curriculum Vitae

a. Has an up-to-date bio-sketch been included for the principal investigator and each co-investigator?
b. Are the investigators appropriately trained and well suited to carry out this work?
c. Is the work proposed appropriate to the experience level of the PI and other researchers?
d. Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Appendix D

Marshfield Clinic®
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Research Committee
Review Criteria/Reviewer Form – Projects Requesting Funds

SP Code: _____ **Meeting Date:** _____

Title: _____

Principal Investigator: _____

Date Completed by Reviewer: _____

Primary reviewers are asked to use this form in assessing the scientific merit of new protocols. The form should be completed, **Questionable and Serious Concerns should be raised by the reviewer** at the scheduled meeting, and the form should be handed in after the meeting. If you will be unable to attend the meeting at which this protocol is being reviewed, please submit this form to the **Office of Research Integrity & Protections – 1R4** prior to the meeting. You may contact Linda Exline at extension 9-3578 if you have any questions.

- **No Concerns -** Project may be approved
- **Minor Concerns -** If concerns are minor and won't impact the success of project, the project may be approved—no need to discuss the concerns at the meeting.
- **Questionable Concerns -** If your concerns may or you are uncertain whether your concerns will impact the success of the project, discuss your concerns at the meeting--if resolved to the level of a Minor Concern, the project may be approved
- **Serious Concerns -** Serious concerns are those that are certain to affect the success of the project. Discuss Serious Concerns at the meeting--if Serious Concerns are not resolved to the level of a Minor Concern, the project is not approvable

SCIENTIFIC MERIT REVIEW CRITERIA:

1. **Goal**
   a. Research goal or hypothesis to be tested is clearly stated?

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

2. Specific Aims

a. Specific aims to be accomplished through the proposed methods are clearly outlined. The relationship to the overall goal is included. What the specific research proposed is intended to accomplish is clearly stated.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

3. Background

a. Sufficient information (e.g. literature review) has been provided to justify performing the present application, and existing knowledge has been critically evaluated.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

b. Sufficient information has been provided to support the significance of the proposed research and methodology by including relevant literature in the area of interest.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

4. Significance

a. The importance and health relevance of the research has been stated by relating the specific aims to the broad, long-term objectives.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

b. The gaps in the literature that the project is intended to fill have been identified.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

5. Preliminary Studies and/or Data

a. Sufficient account of the principal investigator's pertinent preliminary studies has been provided in order to establish that the investigator and collaborators are adequately qualified to carry out the study.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

b. The investigator has outlined factors or qualities that support the likelihood that the project can be accomplished, completed, and converted into a valued endpoint of the research endeavor (e.g. publication).

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

c. Any background graphs, diagrams, tables and charts submitted are relevant to the preliminary studies and/or current application.

☐ No Concerns
☐ Minor Concerns
☐ Questionable Concerns
☐ Serious Concerns

Points of Discussion

6. Experimental Design and Methods

a. The research design and procedures used to accomplish the specific aims of the project are adequately described.
    i. The protocol describes how data will be collected, analyzed and interpreted.

ii. If appropriate, the advantage of any new methodology is described to justify its advantage over existing methodology.
iii. Any potential difficulties and limitations of the proposed procedures have been discussed as well as any alternative approaches to achieve the aims.

☐No Concerns
☐Minor Concerns
☐Questionable Concerns
☐Serious Concerns

Points of Discussion

b. A description of the following for each specific aim has been provided (including the below listed criteria).
i. the methods to be used to recruit and treat subjects, collect data, collect and analyze samples, and manage and analyze the data;
ii. the number of subjects to be studied and how this sample size was chosen(historical evidence should be provided and potential to enroll this number should be demonstrated);
iii. the key assumptions that were used in designing the study, including recruitment projections and effect size;
iv. statistical methods of assuring the quality of data and testing.
v. potential pitfalls associated with and alternative procedures to accomplish each aim.

☐No Concerns
☐Minor Concerns
☐Questionable Concerns
☐Serious Concerns

Points of Discussion

ADDITIONAL CONSIDERATIONS

7. Timeline

a. Does the application include a timeline which clearly reflects the project's activities and anticipated timeframe of completion (i.e., enrollment, chart abstraction, data analysis)?

☐YES
☐NO (If "No," explain below)

Points of Discussion

8. Budget

a. Is the budget complete and realistic?
☐YES
☐NO

b. Percent of effort to be committed to the project for all individuals listed, even if no dollars are budgeted should be listed. Is the time commitment of the PI and other researchers appropriate for the work being proposed?
☐YES
☐NO

c. Has sufficient justification and detail been provided to validate the need and cost of each item as well as how the requested figure was arrived at?
☐YES
☐NO

d. Are the funds being requested appropriate for the research being proposed?
☐YES
☐NO

Points of Discussion

9. Investigator Qualifications

a. An up-to-date CV should be included for the PI and each Co-I. Are the investigators appropriately trained and well suited to carry out this work?
☐YES
☐NO

b. Is the work proposed appropriate to the experience level of the PI and other researchers?

☐YES
☐NO

c. Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
☐YES
☐NO

Points of Discussion

Appendix E

Marshfield Clinic®
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Internal Funding Request Rating Scale

SP Code: _____ **Date of Meeting:** _____

Study Title: _____

Principal Investigator: _____

RC Member: _____
(First & Last Name)

	Strongly Disagree 500	400	300	200	**Strongly Agree** 100
Element 1 The written protocol is of high quality.	☐	☐	☐	☐	☐
Element 2 The likelihood of successful completion of the study is high (consider researcher expertise and previous experience, difficulty of project implementation, cooperation of colleagues, availability of support staff, and likelihood of publication)	☐	☐	☐	☐	☐
Element 3 *The likelihood of meeting the study enrollment goal is high. Is this element applicable to this study? ☐No ☐Yes (If "Yes," please score)	☐	☐	☐	☐	☐
Element 4 **The potential for garnering future extramural funding or future patent revenue is high.	☐	☐	☐	☐	☐
Element 5 The budget is adequately justified and of a reasonable amount in relation to the potential outcome of the project.	☐	☐	☐	☐	☐

*Committee decides before rating whether this element is applicable. The average rating is calculated accordingly based on the number of elements used.

DESCRIPTION OF RATING SYSTEM:

- Only those projects receiving merit approval will be rated.
- Prior to rating, the committee will decide if the third element regarding enrollment goal is applicable to the project.
- Only those Research Committee members in attendance during the vote on the project will be allowed to rate the project.
- Each member who rates a project must score each element.
- Projects must be rated immediately following the vote of approval or contingent approval of scientific merit and given to Research Integrity & Protections staff by the end of that meeting.
- Members who declare a conflict of interest or who have a conflict of interest as defined by Committee policy will not be allowed to rate the project.
- The name of the Research Committee member must be on the rating form so that Research Integrity & Protections staff may ensure that rules regarding conflict of interest and voting only if in attendance are followed.
- Obvious individual outliers noted on a Committee member's rating form will be brought to the attention of the Chair. The Chair, at his/her discretion, may discuss these with the member.
- Research Integrity & Protections staff will calculate the average rating for each project. Any project that receives an average rating between 350 and 500 will not be considered for funding. The investigator will be told that the project did not meet the minimum rating score. All investigators will be provided the average score of each element for their specific project.
- Projects that were not triaged for immediate funding that meet the minimum rating will be ranked in order from highest to lowest score.
- In the case of identical scores, a project meeting either of the following two factors will be ranked above the other:
    - First time award for the PI
    - Unique projects not previously supported by internal funds (i.e., projects other than requests for additional funds to support ongoing research)
- The ranked list of projects will be forwarded to the appropriate funding body for funding determination