EARLY CLINICAL INVESTIGATOR GRANT
MRF GRANT REGULATIONS & GUIDELINES
FOR ADMINISTRATION OF GRANTS AWARDED BY THE MEDICAL RESEARCH FOUNDATION COMMITTEE OF OREGON

REGULATIONS

1. Medical Research Foundation (MRF) Early Clinical Investigator (ECI) grants are awarded to institutions. The grantee institution will account for expenditures at the close of the grant period.

2. Funds will be used for the purposes stated in the application.

3. MRF ECI grants do not include indirect costs, but an institution's cost of employee benefit programs may be included for personnel. For OHSU awardees, MRF grants cannot be used to cover Overhead Cost Allocation.

4. Unencumbered balances at the end of the grant period or when an incumbent resigns will be returned to MRF.

5. If funding from another source is received for the project being supported by an MRF grant, notify the MRF Committee. Uncommitted funds are to be returned to MRF for use in supporting other projects.

6. Due to the training nature of the ECI grant, extension requests beyond the one-year grant period are discouraged. However, extensions will be considered and may be granted, if justified, under unusual circumstances.
   a) Prior to the grant expiration date, the PI **and mentor** must submit a **co-signed** letter requesting an extension to OHSU Office of Proposal and Award Management (OPAM) or outside institution's equivalent department.
   b) OPAM will send the signed request letter to the MRF Committee.
   c) The MRF Committee will consider the request and, if authorized, will communicate the authorization to the principal investigator and OPAM prior to the expiration date.

7. The awardee investigator will submit a brief written report of results to MRF within 90 days after the grant period. This summary should be no longer than one double-spaced typed page, written in lay language.

8. For OHSU applicants: No clearance request forms need to be submitted.

GUIDELINES

1. Early Clinical Investigator (ECI) awards are intended to further the development of young investigators who interact with human subjects and who are interested in a career in clinical research. Clinical research is defined as research conducted with human subjects or on material of human origin such as tissues, specimens, and/or clinical, cognitive, or behavioral data. Research on animal models will be considered only if there is obvious relevance to human health/disease, and the animal studies have a high probability of leading to research on human subjects or specimens.

2. Research involving human subjects, animals or recombinant DNA must be approved by the appropriate institutional review board (IRB / IACUC/ IBC). Investigators are encouraged to submit this application simultaneously but it is not a requirement. Note that no funds will be distributed until IRB/IACUC/IBC approval is obtained.

3. The principal investigator must be a post-doctoral trainee or fellow with specific plans for a career in clinical research.

4. Grants are not made for expensive items of equipment. However, requests will be considered when such equipment will enjoy wide use by a number of investigators or when it will make possible research of unique value. All equipment becomes the property of the grantee institution.

5. No funds are awarded for indirect costs, secretarial support or tuition. Funds may be used for travel if directly related to the conduct of the approved project. Funds may also be requested for travel to present research findings at a meeting (limit of $2,000). Proof of program acceptance must be provided to the MRF administrator for approval of funds. Requests for PI salary support must be justified.

6. The research facility with which the applicant is affiliated must be fully prepared to accommodate the project in terms of the principal investigator's salary and space.

7. Proposals should not overlap with established funding.

8. Applications must include a letter from the Department Chair addressing the applicant's qualifications for a career in clinical research and the proposed training plan. The Chair should comment on the commitment of the Department/Division to the applicant's research and career goals to develop a career in human investigation and on the availability of time to perform the proposed project. The Department Chair should commit to the applicant's training plan for a minimum of one year. The letter should also discuss any additional support for the applicant, such as core research facilities, laboratory space, course work, etc. This document is to be sent **separately** by the Department Chair.

9. Applications must include a letter and biosketch from the mentor that comments on the applicant's qualifications and career plans. The mentor should describe in some detail the proposed training and career development program that is being proposed to foster career independence. The mentor should address his or her track record as a mentor, current funding and the research facilities available to the applicant. The mentor shall include a statement confirming the applicant wrote the research proposal and describe the mentor's contribution. The mentor shall included a statement confirming the applicant wrote the research proposal and describe the mentor's contribution. In addition, the mentor must fill out the **Applicant Qualifications Form**. These documents are to be sent **separately** by the mentor.

10. All applicants must address their intentions to pursue clinical research through applying for future grants, such as a career development award or other federal funding. Describe the plan to use the data collected under this award to apply for future grants. For applicants who are not US citizens or do not have permanent resident status, they must address their plans about citizenship status, as this will affect their eligibility for future grant applications. They should also discuss their plans to remain in the United States and conduct clinical research.

11. Strong preference is given to proposals having the potential to evolve into ongoing, nationally supported career development awards.

EARLY CLINICAL INVESTIGATOR GRANT INSTRUCTIONS

A SUCCESSFUL APPLICATION GENERALLY INCLUDES:

1. A clearly stated and testable hypothesis.
2. A discussion of how the data will be obtained and analyzed.
3. Methods of approach to be used.
4. Alternate approaches should proposed methods fail.
5. The application should include a section entitled “career plans” that provides a description of how the proposed work fits into the applicant's research training and long-range goals. Particular emphasis should be given to how the award may enable the investigator to obtain career development funding in the future.

I. GENERAL INFORMATION

The maximum dollar award for an MRF Early Clinical Investigator Award is $30,000. These grants are made for a period of one year for research conducted in Oregon.

Grants are awarded by the MRF Research and Education Committee following the deadlines below.

Application Deadline Date*	MRF Committee Meeting	Effective date of Grants
April 15	June	Aug 1-Jul 31
Aug 15	October	Dec 1-Nov 30
December 15	February	Apr 1-Mar 31

*If the 15th day falls on a weekend or holiday, the grants are due on the following workday.

Applications are reviewed by the OHSU School of Medicine Research Committee for scientific merit, an evaluation of the trainee, and an evaluation of the mentor and the training environment. The peer-review committee will provide brief critiques of each application. In addition, staff is willing to discuss ways to make an application stronger for resubmission to MRF. Applications are then submitted to the MRF Committee for final funding review and authorization.

Applicants will be advised of the decision by the MRF Committee immediately after the meeting (generally by email).
Only one application per investigator is allowed in any cycle. A single proposal may be submitted a maximum of three times.

II. PREPARATION OF PROPOSAL

1. Applications must be submitted on the MRF Committee’s form with appendices as indicated. The type font should be no smaller than 12 point and side margins of at least one inch should be used for the body of the grant.

2. **Please supply all information requested**. Failure to do so may cause the application to be administratively withdrawn.

3. Descriptions of the general objectives, purposes and plan of the research and the background of those to be engaged in it, while condensed, must be clear enough that the reviewers can make a fair appraisal of its worthiness, capabilities of the personnel, and appropriateness of the project in relation to work of record. The research proposal must be written by the applicant.

4. The MRF Committee must know with as accurate detail as possible what is to be done with the money. This is detailed on the budget page.

5. The "Responsible Official" signing for the institution is a matter of institutional preference. This is generally the Vice President of Research. However, contact OPAM or your Research Office to determine your institution’s preference.

6. After receiving an Institutional Approval signature, application should exist of the following documents **combined into a single pdf**. No “bookmarks” are necessary and no other formats will be accepted. The order of the required documents are as follows:

   a) Cover letter (required for resubmission only; include concise response to previous reviews)
   b) Previous MRF Written Reviews (required, if resubmitting)
   c) Grant Application
   d) Research Plan (six pages maximum)
   e) Literature Cited
   f) IRB/IACUC/IBC approval (if available)
   g) Principal investigator's Biographical Sketch, ideally conforming to the current NIH format.

7. The following documents are to be **sent separately by the Department Chair and mentor**:
   a) Letter from your Department Chair (guideline 8)
   b) Letter from your Mentor, Mentor’s biosketch and Applicant Qualifications Form (guideline 9)

8. When resubmitting, any materials associated with the original application, including support letters and forms, must be resubmitted by the original, required sender (noted above) **concurrent** with the resubmission. **No previously submitted materials will be transferred to a resubmission.** It is strongly recommended that any such support materials be updated for the current submission rather than re-used from a previous submission.

9. **The following naming conventions are required:** Application: Last, First, Submission Deadline, Grant Type (example: **Doe, John, August 2016, Early Clinical Investigator**) Support Letter: Applicant Last, First, “Support Letter,” Writer Last (example: **Doe, John, Support Letter, Jones**)

10. Application and supporting documents are to be submitted through CAP at **ohsu.inforeadv4.com**. For questions, contact **mrfsubmit@ohsu.edu**.

Applications received by 5:00 p.m. on the deadline date will be accepted for the related review meeting. **Late or incomplete applications will not be reviewed and will be returned.**

EARLY CLINICAL INVESTIGATOR (ECI) GRANT SCORING GUIDELINES

#1 Evaluation of the trainee (score 1.0 – 9.0, then x 0.25)

- Potential for research (academic record, comments in letters of support)
- Track record to date (research experience, publications)
- Is there a clear rationale supporting need for proposed training
- Are career plans specified (to be covered in specific section of application)

#2 Evaluation of the mentor and training program/environment (score 1.0 – 9.0, then x 0.25)

- Is mentor an independent investigator (current funding, publications)?
- Track record of successful mentorship (mentor will be asked to put one paragraph in his or her letter of support addressing accomplishments as a mentor).
- Quality of the training program that will facilitate the applicant's progress towards his/her research career goals (described by the mentor in his/her letter)

#3 Evaluation of the proposal (score 1.0 – 9.0, then x 0.5)

- Is there a high probability the data generated will enable the trainee to obtain career development funding in the future. [This is most important – "dead-end" proposals with regards to career development should not be funded.]
- Is there a clearly stated and testable hypothesis
- Is there a description of the methods to be used
- Does the proposal involve human subjects or material of human origin.
- If the proposal is an animal model, is there an obvious relevance to human health or disease
- Is there a discussion of how the data will be collected and analyzed (viewed from the stand-point of a high quality pilot project, keeping in mind that a 1 year clinical study supported by $20,000 will rarely be adequately powered)
- Is the study feasible (preliminary data not as critical as for an established investigator)
- Are appropriate resources available
- Are alternate approaches discussed
- Is it clear how the proposal fits into the applicants training and long-range goals
- [Note novelty or importance of the research is not listed as a specific criterion for scoring. The ECI grant is a substrate for training, not requiring the uniqueness of an RO1-level award.]

Final score (sum of 1 + 2 + 3)

ECI GRANT APPLICATION 1

MEDICAL RESEARCH FOUNDATION OF OREGON – EARLY CLINICAL INVESTIGATOR AWARD
1121 SW SALMON ST, STE 200
PORTLAND, OR 97205-2021

APPLICATION FROM: _____
NAME OF INSTITUTION

Amount requested: $_____ From_____ Through_____
DATE DATE

Brief descriptive title of project:

In 250 words or less, summarize the proposed work in space below using lay language.

INSTITUTIONAL APPROVAL

_____
Signature of Responsible Official

_____
Name

_____
Title

_____
Address / Mail Code

_____
Telephone Number Date

PRINCIPAL INVESTIGATOR

_____
Signature of Principal Investigator

_____
Name

_____
Title and Department

_____
Address / Mail Code

_____
Telephone Number E-mail Address

(Form revised 02/03/2016)

ECI GRANT APPLICATION 2

I. **Name and title of the principal investigator:**

II. Names and titles of associated personnel: (Do not list anyone included in the personnel category of the budget)

1. Number of times investigator has applied for this project:
1st (●) 2nd ( ) 3rd ( )
2. Have you received previous MRF Awards?
Yes ( ) No ( )
3.If Yes, which award type and which year?

III. Proposed budget for 12 months or less. Please provide justification of all major items in the budget (Append as necessary).

1. For personnel (Include fringe benefit as separate amount.)

$ _____

2. For permanent equipment (itemize and justify.)

$ _____

3. For expendable supplies and services (itemize and justify.)

$ _____

TOTAL BUDGET **$** _____

IV. Other support: (Append as necessary)

1. List sources of current research support you now receive for all research projects: project titles, amount of annual budget, number of years, dates, and role in the project.

2. List sources of pending support for all research projects: project titles, amount of annual budget, number of years, dates, and role in the project.

3. Append budget pages and abstracts for all current and pending support for all research projects for which you are the principal investigator or a co-investigator.

V. Research plan and other supporting information:

Using **no more than six (6)** single-spaced additional pages, in a font no smaller than 12 point and side margins of at least one inch, please give your research plan in detail sufficient to permit determination of merit. This six–page limit includes graphics and other illustrations. It does not include literature cited in the research plan or questionnaires. Recognize that many of the reviewers are not expert in your field. The plan should include background, preliminary studies if applicable, methods, feasibility & time line, and discussion as to how data will be interpreted.

Include a brief discussion outlying the PI's career development plans in Clinical Research. How will the proposed project advance your plans?

VI. Other information and attachments:

You must include with your application and proposal the following items:

- Principal investigator's Biographical Sketch ideally conforming to the NIH format.
- Letters from your Department Chair and Mentor – see the Guidelines section #'s 8 and 9 for information which should be included in these letters.
- Mentor's Biosketch **(Chair and Mentor documents are to be submitted separately.)**

Please refer to the Application Instructions section titled "Preparation of Proposal" for the order in which these items should be attached.

VII. Will human subjects be involved in this project? ☐ Yes ☐ No

If "Yes," does this application include IRB approval? ☐ Yes ☐ No ☐ Pending

VIII. Will vertebrate animals be involved? ☐ Yes ☐ No

If "Yes," does the application include approval by your institution's Animal Care and Use Committee? ☐ Yes ☐ No ☐ Pending

IX. Will recombinant DNA /infectious agents or biologically-derived toxins be involved? ☐ Yes ☐ No

If "Yes," does the application include approval by your institution's Biosafety Committee? ☐ Yes ☐ No ☐ Pending

Funds will not be made available until IRB / IACUC / IBC approval is provided to the institution's Sponsored Projects Administration Office.

For all institutions ***except*** OHSU, please complete the following information regarding the responsible financial official at your institution.

Name _____

Title _____

Address _____

Telephone Number _____