



## **Advancing Preeclampsia Research in Low and Middle Income Countries: The EMPOWER Program**

### **Goal**

EMPOWER (EMpowering Progress in Obstetric and Women's hEalth Research) was established to create partnerships between mentors and single sites or groups within low- and middle-income countries to improve clinical and health services research into the hypertensive disorders of pregnancy.

### **Key Features of the Program**

1. Independence – A fundamental goal of the program is to build independent capacity for research and effective implementation of research findings.
2. Mentorship – Mentorship by an established investigator and clinician is a critical element of the program. The role of the mentor is to assist the local investigator to identify questions relevant to the local environment that might be studied, to identify critical resources and opportunities that may be unique to the environment, and to guide (but not direct) the development and implementation of a research plan.
3. Objectives – The immediate objective of the program will be the completion of a research project designed by the local investigator and, when appropriate, the dissemination of the results of the study to change practice and improve care. The more fundamental success of the program would be measured by the subsequent success of the research team continuing to perform important work.

### **Detailed Objectives of the Program**

*One or more of the following measurable outcomes will be accomplished per project:*

1. Develop Integrated Hypertension Research Team

Successful research is carried out by stable teams of investigators that include physicians, nurses, coordinators, social workers and other health care professionals. Sustained funding that can be managed by the PI serves to maintain a strong, collaborative team.

2. Support Experienced PI

A PI with demonstrated research productivity provides critical leadership of the team. Independent funding strengthens their credibility locally enhancing their ability to receive additional funding.

3. Develop Young Investigators

Young investigators are critical for the long-term success of a research team. Their growth leverages the capacity of the team to conduct additional projects.

#### 4. Advance knowledge base

Balancing the support and development of a research team is the advancement of knowledge of hypertensive disease in pregnancy relevant to the local community and to the broader international community. Defining results and knowledge translation are important measurements of success.

#### 5. Support research operational infrastructure

Successful research requires an infrastructure of rigorous documentation, protocol review, record keeping, data analysis, and manuscript preparation. Funding of independent research should provide a basis for ongoing investigation.

### **Site Selection/Criteria**

*Most, if not all, of the following criteria must be met for eligibility:*

1. Low- and middle-income countries.
2. Willing to work with a “Champion” sanctioned by ISSHP/ISOM Global Health Committee to serve as a mentor to local PI, meet by WebEx 4-6 times per year, and have site visits conducted by mentor to evaluate site feasibility and study progress.
3. A minimum level of health care resources and community infrastructure must be present to accommodate basic research and care of women with preeclampsia.
4. Facility has sufficient deliveries per year, the ability to recognize and treat preeclampsia/eclampsia, and an ability to initiate the project within three (3) months of funding.
5. On-site Principal Investigator.
6. Commitment to budget accountability, reporting, results measurement and evaluation, and continued role in knowledge translation.
7. Commitment to active listening, learning phase to understand true needs and gaps in preeclampsia health care (e.g., focus groups).
8. Proposed area of study represents *novel* areas of research and is not augmenting or duplicating other funded research.
9. Funding transfer mechanism in place that provides accounting audits, transparency and requires no more than 10% overhead.
10. Preparedness to present outcomes at International meetings

### **Mentor Selection Criteria**

**Qualities of a Mentor** – These characteristics represent ideal circumstances. We recognize that mentors may not be able to fulfill all of these criteria.

- A proven track record of research in hypertensive conditions of pregnancy
- Research and clinical experience mentoring beginning investigators
- General knowledge and experience with research and conditions of clinical care in low resource settings.
- Capacity to commit significant time and effort to the project without direct funding.
- Capacity to periodically visit the research site at least once or twice in two years. Note: EMPOWER program funding will cover travel costs associated with 1-2 site visits over the course of the two-year grant.
- Regular (4-6 times per year) electronic contact (via video/tele-conferencing software provided by EMPOWER sponsors) to ensure site viability and the project’s success.

## **Application Process**

### **Stage 1:**

1. A single page Letter of Intent (LOI) should be submitted outlining the broad area of research and proposed methodology; this should include evidence that the proposal can be carried out successfully at that site.
2. If the applicant already has established links with an appropriate mentor (from outside the LMIC) than a second page should be included. This should be from the proposed mentor and should outline why the mentor believes the project will be successful and how this will advance local research capacity and management of pre-eclampsia
3. The applicant should indicate if no mentor is available in which case the one page LOI would be referred to ISSHP's Global Health Committee to recommend and arrange a suitable mentor who will assist in preparing the grantee application, if invited to do so.
4. All LOIs considered feasible will be invited to submit a full application in coordination with their mentor, as described in Stage 2.

### **Stage 2:**

*A 2-4 page project proposal should be submitted addressing each of the following areas, including budget, plus a letter of support from the proposed mentor. If any measurement and evaluation mechanisms are intended beyond those required, they should be identified. Total of no more than 5 pages should be sent as one PDF file to [empower@preeclampsia.org](mailto:empower@preeclampsia.org) with "EMPOWER Proposal\_LAST NAME" in the subject field.*

#### **1. Preeclampsia**

The proposal must be clearly relevant to the pathophysiology, the treatment, or impact of preeclampsia on the lives of women and their families. The project should have the potential to improve care and the quality of women's lives and/or provide tools or information to advance the advocacy efforts, public awareness or patient education needed to improve pregnancy outcomes. Whilst preference will be given to studies of preeclampsia, other hypertensive disorders of pregnancy may be considered.

#### **2. Priority needs of the region**

The proposal should identify priority needs for the region/country – based on the most relevant information in the field of: epidemiology, bio-medical, health systems, audits/databases, longitudinal follow up of cohorts, social sciences etc.

#### **3. Feasibility**

The proposal should demonstrate a sufficient knowledge of the clinical and research environment to suggest that the project can be completed in a reasonable amount of time in the context of funding.

#### **4. Protocol**

The research protocol should describe the project(s) to be undertaken including a description of the results that would be "deliverable" at the conclusion of the project(s).

#### **5. Impact**

Successful completion should carry the immediate or future potential for improving the health of mothers and their babies, including direct impact on the clinical environment. Possible interventions or follow-up research should be considered. The proposal should consider how the project would enhance capacity-building in the study of hypertensive disorders of pregnancy.

## 6. Publication & Presentation

The applicant should indicate how he/she will present the research outcomes and demonstrate a commitment to publication in a peer-reviewed journal. Proposals should include a plan for statistical analysis, manuscript writing and publication.

## Budget & Funding Requests

Level of funding available: One project will be funded for two years at up to \$30,000 USD per annum. That is, a total of up to \$60,000 USD.

The budget should describe, in general terms, how the funds will be spent.

- *Principal Investigator:* Funds should not be used to fund the salary or benefits of the PI.
- *Personnel:* Support personnel for the project can be supported. Their support should be justified in the context of the Objectives above.
- *Consumables:* Supplies needed to complete the project and support the team can be funded.
- *Equipment:* Equipment needed for the completion of the specific project can be funded. Equipment should not be a major budget expense and should be clearly justified and evidence of sustainability presented.
- *Travel:* Budget should include costs for the LMIC researcher (awardee) to attend the ISSHP biennial World Congress during training period and for the Mentor to travel to the project site twice during the project period.

## Measurement & Evaluation

- A two-page interim report is due 12 months following release of the initial funding stating progress made, how budget was spent, challenges encountered, and lessons learned, if applicable.
- Preliminary recommendations or opportunities for knowledge translation should be explained.
- Final report at the completion of the 2<sup>nd</sup> year should include complete description of project(s) including methodology, data, discussion of results and conclusion, as well as community impact and recommendations for knowledge translation.
- The project will be submitted for presentation at the ISSHP World Congress and for peer review for a medical journal; the support of the Presenting Organizations – Preeclampsia Foundation, ISSHP and CoLab – as well as any Supporting Organizations, will be acknowledged in these submissions.

## Deadlines

*The EMPOWER program operates on a two-year cycle, as follows:*

**Stage 1 – Deadline for Letters of Intent** is 12 months before the next World Congress of ISSHP. Thus, next round of LOIs are due by November 15<sup>th</sup>, 2015, in anticipation of the October 23-26, 2016 World Congress in Sao Paulo, Brazil. Thereafter, the next round of LOIs will be due October 15<sup>th</sup>, 2017.

- EMPOWER Administrator to respond within 2 months

**Stage 2 – Deadline for detailed Proposal** is 6 months before the next World Congress of ISSHP. Thus, the next round of detailed Proposals are due by April 15<sup>th</sup>, 2016.

- EMPOWER Review Committee to review and select grantee and Mentor
- EMPOWER Administrator to notify the successful and unsuccessful applicants by July 15<sup>th</sup>, 2016.
- Funding to begin in 2016, with second year funding in 2017.

***Announcement of the grant recipient will take place at the Opening Ceremony of ISSHP World Congress.***

### **Presenting Organizations**

Preeclampsia Foundation, the International Society for the Study of Hypertension in pregnancy (ISSHP), and Global Pregnancy Collaboration (CoLab) are the Presenting Organizations for EMPOWER.

### **Supporting Organizations**

New Zealand Action on Preeclampsia, a patient advocacy organization

### **Acronyms Used**

KT	Knowledge translation
LMIC	Low- and Middle-income countries
PI	Principal Investigator
PF	Preeclampsia Foundation ( <a href="http://www.preeclampsia.org">www.preeclampsia.org</a> )
ISSHP	International Society for the Study of Hypertension in Pregnancy ( <a href="http://www.isshp.org">www.isshp.org</a> )
CoLab	Global Pregnancy Collaboration ( <a href="https://pre-empt.cfri.ca/colaboratory/global-pregnancy-collaboration">https://pre-empt.cfri.ca/colaboratory/global-pregnancy-collaboration</a> )
EMPOWER	Empowering Progress in Obstetric and Women’s Health Research