

## Cervical Preparation for Dilation & Evacuation Award

### 2012 REQUEST FOR PROPOSALS

#### Introduction

The Society of Family Planning (SFP) was founded in 2004 to bring together professionals committed to the scientific study of family planning, focusing in the areas of contraception and abortion. The SFP Research Fund, an associated corporation launched by SFP in 2011, supports interdisciplinary research in the biological, medical, epidemiological, behavioral, and social sciences

related to family planning. We focus on a wide range of research areas—from improvements in basic conceptual or biomedical knowledge; to design of programs or policies that will provide family planning more safely, efficiently and extensively; to studies of the social and psychological dimensions of family planning services and programs.

#### Multi-site study

The SFP Research Fund is delighted to announce a special request for proposals for a Principal Investigator/Coordinating Center (PI). Results of this study will

inform the practice of future second trimester surgical abortions. The study will be a 12-month project.

#### Budget assumptions

The SFP Research Fund has received approximately \$1.2 million to fund all aspects of this study. At least \$350,000 will be designated for total costs (direct and indirect) for the PI/Coordinating Center. The additional funds will be designated for project management by SFP, and to fund the clinical sites. SFP Research Fund will manage the accounting, distribution of funds, and financial reports monitoring for the sub-awards to participating sites. In addition, the SFP Research Fund will reimburse the successful PI, their monitoring and

project coordination team, and the site representatives for the initial in-person meeting.

Applicants are asked to provide a project budget that will include about 30% dedicated time for the PI salary, site monitoring, project coordination, and data collection and analysis to include salaries and a maximum of 30% for benefits. Indirect costs up to 10% of total direct costs are allowed. Please provide a narrative description and justification for your budget line items.

#### Background

D&E refers to the surgical evacuation of pregnancy with an ultrasound confirmed gestational age greater than or equal to 13 weeks in which cervical preparation and dilation has been achieved by any one or combination of osmotic cervical dilators, mechanical cervical dilation, prostaglandins (including misoprostol), mifepristone, membrane rupture, or oxy-tocics.

D&E is the main method of second-trimester pregnancy termination in the United States. Approximately 10% of abortions occur in the second trimester of which 97% are D & E's. Sixty-four percent of providers offer at least some second-trimester

abortion services (13 weeks or later), and 23% offer abortion after 20 weeks.

Gaps in current knowledge include, but are not limited to, the following:

- Lack of data to permit comparisons of acceptability, complication rates, pain associated with, and costs of different methods of cervical preparation
- Limited data to evaluate the role of misoprostol and/or mifepristone as therapy for cervical preparation
- Limited data to assess the impact of gestational age on acceptability, efficacy and decision making regarding cervical preparation

### Study design

The successful applicant will submit a proposal that demonstrates his/her previous experience in overseeing multi-site trials, and provides a detailed proposed

study design, including the sample size, the timing of procedures, methods included, and the gestational age range to be studied.

### Organizational capacity

Demonstrated organizational capacity to manage site monitoring, data collection and analysis will be essential to a successful proposal. These functions can be managed by the PI's institution or in collaboration with

partner organization(s). Previous specific experience managing these aspects of a similar type of study must be provided.

### Clinical site recruitment and management

The SFP Research Fund will solicit letters of intent from organizations interested in participating in the study as clinical sites in order to collect information on demographics such as volume, gestational age limits, methods used for cervical preparation, and previous

participation in research studies. The PI who is awarded management of the study will oversee the coordination of up to 10 sites and their activities, and thus will be responsible for ensuring that approximately 2,000 patients can be enrolled in the study.

### Review criteria

The SFP Research Fund's goal is to fund the best designed study to accomplish the stated objectives. Expert reviewers will evaluate the proposals based on the following criteria:

- **Overall potential for addressing the main goal of the study:** to improve the quality of care in second trimester pregnancy termination by Dilation and Evacuation (D&E).
- **Research design:** The extent to which the research problem is well-specified and described. The strength and feasibility of the conceptual framework, research methods, and plan for analysis. Acknowledgment of potential problem areas. Sufficient detail to assess feasibility is essential, such as gestational age range and methods of cervical preparation.
- **Innovation:** The extent to which the project employs novel concepts, approaches or methods, challenges existing paradigms or develops new paradigms, or considers an existing problem from a new perspective.

- **Qualifications of investigator(s):** The demonstrated experience and training of the investigative team, as led by the Principal Investigator who documents previous experience with multi-site and/or cervical preparation studies.
- **Organizational capacity:** The extent to which the scientific environment contributes to the project's success. Organizational support for research and use of collaborative arrangements will be assessed.
- **Linkages to existing high volume and/or diverse sites:** While the SFP Research Fund will assist in collecting information from interested sites and guiding site selection, demonstrated experience with existing sites that can assist in ensuring sufficient sample size and a successful outcome is helpful.
- **Budget and timeline:** Reasonable and cost-effective budget with clear justifications and realistic timeline for completion. The SFP Research Fund will look more favorably on applications that use more of the budget on direct expenditures and less on indirect costs.

Go to [grants.societyfp.org](http://grants.societyfp.org) to apply. Application submission opens February 1, 2012 and closes at 5:00 pm EDT, Monday, April 16, 2012. No late materials or changes to your application will be allowed after the cut-off date.

**Review procedure**

Proposals will be assigned to a review committee of experts in the field for evaluation of scientific and technical merit using the criteria named above. Each proposal will receive a score based on a scale similar to that used by the National Institutes of Health. A review committee may also decide that an application is not sufficiently competitive and choose not to assign a

score; such an application will not be eligible for funding. The initial review group scores will be one factor in the decision-making process. Together with responsiveness and relevance to the study goals, the score will be used by the SFP Research Fund Board of Directors to fund one proposal. The funding decision will be announced in mid-June, 2012.

**Terms of awards**

Funds may be used for expenses related to the conduct of the approved research project, including salaries and wages, benefits at no more than 30%, consultants,

supplies, project-related travel, fees related to participation of research subjects, and other necessary expenses.

**Ethical considerations**

For studies in humans, human biological materials, or animals, evidence must be provided that the proposed research has been approved by the local Institutional Review Board (IRB) or equivalent ethics committee.

SFP will not transmit any funds until such approval has been given. The first three months of the project timeline can be allocated for IRB approval.

**Eligibility**

The Principal Investigator for this multi-site project must be an SFP Fellow, and a faculty or staff member of the applicant institution. Grants will be made to institutions on behalf of a named principal investigator, not to individuals. Eligible organizations employing SFP fellows include but are not

limited to universities, independent non-profit agencies, community-based organizations, and hospitals. Investigator(s) must have principal investigator status at a non-profit or tax-exempt institution with at least 30% of effort contributed to the proposed study.

**Application procedures**

Applications must be submitted online. (See next page for instructions.) The RFP and application form will be available on February 1, 2012-the date that application submission opens-at grants.societyfp.org. Email submission closes on April 16, 2012 at 5:00 PM (EDT).

To be considered for support, an applicant must be eligible and submit a complete application in accordance with established guidelines. Failure to comply with instructions may result in the return of the application without review. No late materials or changes to your application will be allowed after online submission ends.

**Grant program schedule**

- Online application submission will open on February 1, 2012. Go to [grants.societyfp.org](http://grants.societyfp.org).
- Application deadline: April 16, 2012 at 5:00 PM (EDT). No changes allowed after this time.
- Award decisions: Mid-June, 2012.
- Earliest project start date: July 1, 2012.
- IRB approval no later than October, 1, 2012.

For questions regarding grant requirements, please contact: [mpolonsky@societyfp.org](mailto:mpolonsky@societyfp.org). Instructions for proposal submission are provided on page 4.

**PROPOSAL INSTRUCTIONS. Grant proposals should include the following components:**

- **Study abstract** (300 word limit). Provide a summary description of the proposed research. If the research is funded, the abstract may be used by the SFP Research Fund for informational purposes to describe its program activities. Therefore, do not include proprietary information.
- **Completed application form**, including signature page
- **Proposal narrative** (7 pages). The research proposal narrative should not exceed a total of seven pages . Provide information for each category listed below. Amount of space allocated to each category may vary as needed.
  1. **Specific aims:** Hypothesis to be tested; objectives of proposed study.
  2. **Previous research:** Review the previous significant and relevant research on the topic of cervical preparation for D&E.
  3. **Rationale:** Justification or rationale for the proposed study within the context of present knowledge presented above. If applicable, justify the proposed study in terms of its clinical, demographic, social, or reproductive health impacts, and/or its policy, service, or program relevance.
  4. **Research design and methods:** Describe the research design, control groups, sample size, procedures to be used, methods of data collection and analysis, and potential difficulties that may be encountered. Include specific information and justification for gestational age for enrollment in the study, as well as outcomes to be evaluated such as pain, patient acceptability, complications, cost-effectiveness, and success rates by method.
  5. **Relevant experience:** Previous experience as a PI on cervical preparation and/or multi-site studies. Indicate if the proposed project is linked in any way to other projects in progress.
  6. **Expected outcomes:** Indicate how the study results will be used, and by what means they will be disseminated. Describe how the results are expected to affect health care policies and practices in 2nd trimester abortion care, specifically involving D & E.
- **Budget with justifications** (2 page + separate form). Use the [Cervical Preparation for D&E budget form](#) to provide information on personnel salary and benefits (benefit rate must conform to constraints detailed in the budget form); consulting; supplies and equipment; clinical costs; travel related to completing the project; and other specified expenditures. In addition, include with your proposal a detailed budget narrative that specifically relates each item in the project budget to project activities. If are you seeking or have received other sources of funding for this project, please specify those sources by name, the amount being requested, and the status of the requests.
- **Timeline** (1 page). Proposed sequence or timetable for major project components. Indicate the start/ completion dates.
- **References with complete citations** (2 pages maximum).
- **Biosketch for all key personnel** (4-page NIH style).
- **Appendices** that include description of methodology, tools will be accepted. However, please keep attachments to a minimum. Reviewers will be advised that reading this additional material is optional.
- **Nonprofit research organizations:** Attach a copy of the agency's federal 501(c)(3) status determination letter or proof of tax-exempt status.
- **Type requirements:** Font must be at least 11 points, all margins at least 1 inch, and 1.5 spacing. Applications that do not adhere to these requirements will be disqualified.