

# Same-day preoperative cervical preparation before D&E between 20 and 24 weeks gestation

**2024 Request for proposals** 

# Purpose

The Society of Family Planning recommends preoperative cervical preparation before dilation and evacuation (D&E) procedures between 20 and 24 weeks gestation. While the <u>evidence</u> suggests that one day of overnight cervical preparation with dilators is sufficient to decrease the risk of complications for most D&Es at this gestation, there is evidence suggesting the feasibility of sameday cervical preparation. Same-day cervical preparation has the potential to reduce some of the logistical challenges people may experience obtaining abortion care later in pregnancy (eg, arranging childcare, or time off work). However, there are few studies that document the safety and efficacy of sameday cervical preparation during this gestational window.

To that end, the Society is offering the Same-day preoperative cervical preparation before D&E between 20 and 24 weeks gestation funding opportunity. The purpose of this funding opportunity is to document the safety and efficacy of same-day preoperative cervical preparation before D&E between 20 and 24 weeks gestation across a range of clinical protocols and practice settings.

# **Research focus**

This funding opportunity will support one research project to conduct a multi-site chart review at a sample of sites in the US that offer D&E procedures to patients between 20 and 24 weeks gestation. The Society encourages research proposals focused on documenting a range of same-day preoperative cervical preparation protocols.

Proposals must list the outcomes that will be used to describe safety and efficacy. Recognizing the variability in clinical protocols and volumes of same-day preoperative cervical preparation before D&E during this gestational window, teams must provide a sample size derived from power calculations, prioritizing one outcome of interest for the relevant effect size.

During the award period, the Society will support the selection of study sites with attention to ensuring inclusion of a range of practice settings (eg, hospital, independent clinics, Planned Parenthood affiliates) and geographic regions by the study team. During project implementation, the Society will oversee the enrollment, contracting, and remuneration of participating sites, in collaboration with the study team. Teams are invited but not expected to name desired sites that will be included in the proposed project. In addition to safety and efficacy, proposals are welcome to explore other related topics, if feasible, within the proposed budget and period of support.

Proposed research must be positioned to produce empirical evidence that can be cited by a court or legislative or regulatory body. Teams must be attentive to the Society's <u>Diversity, Equity, and Inclusion Vision statement</u> and how they can be part of bringing that vision to life in their work.

# **Funds and duration**

We invite proposals for research studies with budgets up to \$375,000 that can be completed within 18 months of award. Site incentives need not be included in the project budget, as incentives will be disbursed directly by the Society to participating sites; however, teams should name the proposed cost and structure of site incentives. The Society anticipates five sites, as aligned with sample size calculations, with the potential remuneration to all sites totaling \$100,000. Funding is also available to cover processing fees associated with three open-access publications, provided the work is published within two years of grant completion. We anticipate supporting one research project via this funding opportunity.

# Eligibility

Grants will be made to organizations on behalf of a named principal investigator (PI). Grants are limited, without exception, to tax-exempt organizations. Applicants do not need to be members of the Society. Funding is limited to projects focused on the US.

Application submission opens on

May 1, 2024 and closes July 1, 2024

# **Review process**

All proposals will undergo peer review using specific criteria. The goal of peer review is to make recommendations for enhancing the research proposal and to identify the projects with the greatest potential impact. The funder of these awards may also be involved in the selection of grants; this helps ensure that the research funded through the Society is one of many strategic components working together to strengthen the family planning sector.

All proposals will be reviewed according to the following criteria. For more information about the review process, please see the <u>proposal review guide</u>: <u>https://bit.ly/3JAcJWy</u>

## Methods (70%)

The Society seeks to fund methodologically sound and rigorous projects.

# Team (20%)

The Society seeks to fund projects where the team composition is an asset to the project, including teams that bring together individuals with diverse skill sets, backgrounds, and perspectives. The Society also prioritizes study teams that elevate the expertise and skills of Black and Indigenous researchers and researchers of color.

# Impact (10%)

The Society seeks to fund projects that are positioned to produce empirical evidence that can be cited by a court or legislative or regulatory body.

# Additional review considerations (not scored)

Reviewers are also asked to provide feedback on the reasonableness of the proposed budget and period of support; however, these factors are not scored.

# **Proposal instructions**

#### **1.** Online application form:

Includes contact and demographic information for the PI, up to two key team members, institution, and parties responsible for accounts payable and grants management if the project is funded.

### 2. Summary (250 words):

Provide a brief summary of the proposed project. This information may be used in our newsletter and website and for other educational and promotional purposes should the application be funded.

#### 3. Proposal narrative (8-10 pages):

All proposals should include:

Background: Describe the issue and justify how the proposed research project will document the safety and efficacy of same-day preoperative cervical preparation before D&E between 20 and 24 weeks gestation. Name how the proposed research project will generate data that will produce empirical evidence that can be cited by a court or legislative or regulatory body.

Research question(s): Include the question(s) that will be answered through the proposed project, including the different clinical protocols that will be included.

Methods: Describe the research methods that will be used to answer the research question(s) at hand, with attention to: how safety and efficacy will be defined and measured, the number and types of records that will be examined, the time period spanned by the proposed data, and, if applicable, how covariates (eg, patient characteristics, patient comorbidities, type/training of provider, years of provider practice, volume of patients treated) will be defined and measured. The rationale for the proposed sample size must be justified and proposed subgroup analyses must be clearly named. If desired, describe the proposed study sites and populations served by those sites.

Timeline: Describe the timeline for conducting research activities. Data collection and analysis must be feasible to complete within 18 months of receiving the award.

Team composition: Team composition must be an asset to the project, including teams that bring together individuals with diverse skill sets, backgrounds, and perspectives relevant to the proposed project. Elaborate on the expertise and skills of the individuals composing your study team. Describe how the positionality (eg, the social and political context that creates your identity in terms of race, class, gender, sexuality, and ability status) of the team has shaped the proposed project's design, feasibility, and impact. Note that the Society prioritizes study teams that elevate the expertise and skills of Black and Indigenous researchers and researchers of color.

# Proposal instructions, continued

Use of research results: Narrate the target audience(s) with whom you plan to share your research findings, the actions you would like them to take in response to your findings, and the desired outcomes.

References: Works cited should be listed as an appendix to the proposal; reference page is not included in the 8-10 pages of the proposal narrative.

#### 4. Budget narrative:

Budgets should be \$375,000 or less. Funds can be used in combination with already secured or requested funds, but these sources must be named. The budget narrative must provide sufficient detail to justify the relevance of requested resources to the project's success. Direct project costs include personnel, research expenses (eg, equipment, supplies, travel, materials), activities related to use of research results, and other related costs. Site incentives need not be included in the project budget, as incentives will be disbursed directly by the Society to participating sites; however, teams should name the proposed cost and structure of site incentives. Indirect costs are permitted at no more than 20% of total direct costs and sub-awards, the budget itself may include the 20% indirect cost charges, but the subcontract total may not be included in the main budget when calculating the overall indirect cost charges.

#### 5. Team information:

NIH-style biosketches are encouraged for all established scientists. Professional resumes are encouraged for those whose careers have not focused on research. Each submitted biosketch or resume should not exceed 10 pages in length. These documents must be included as an appendix and are not included in the 8-10 pages of the proposal narrative.

### 6. Tax exempt status:

Proof of the agency/institution's tax-exempt status determination letter must be included as an appendix and is not included in the 8-10 pages of the proposal narrative. Documentation should also be included for subcontracts with tax-exempt organizations that exceed 20% of the budget. These documents must be included as an appendix and are not included in the 8-10 pages of the proposal narrative.

# **Required formatting and submission instructions**

Please use a font size that is at least 11 points and 1.5 line spacing. Upload all materials as a single PDF file. All proposals must be submitted electronically through the <u>online application portal</u>.

The deadline for proposals is **July 1, 2024, at 8:59 pm PT/ 11:59 pm ET.** Awards will be announced in August 2024 and funds will be available for immediate use.

The Society welcomes the opportunity to provide clarification around or assistance with any components of the application. Please contact <u>Grants@SocietyFP.org</u>.

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