

Concept notes due: April 10, 2018

Full proposals invited: June 8, 2018

Full proposals due: August 3, 2018

Award decisions: September 4, 2018

See page 4 for details

2018 REQUEST FOR PROPOSALS

Generating Evidence that Contributes to Increasing Access to Medication Abortion in the United States

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Introduction

In 2005, the Society of Family Planning (SFP) was established to advance sexual and reproductive health through research, education, advocacy, and professional development. The grantmaking arm of the organization, the Society of Family Planning Research Fund (SFPRF), was established in 2011. SFPRF aims to provide financial support to scholars working at the forefront of abortion and contraception and to support research studies that ultimately lead to improvements in reproductive health and reductions in unjust disparities.

Since its establishment, <u>SFPRF's grantmaking has grown significantly</u>. To ensure the best use of finite resources, in 2016 we launched an internal evaluation of our approach to grantmaking. This Request for Proposals (RFP) incorporates much of what we learned through our evaluation and through feedback from our members and partners.

For the first time, we are issuing an RFP on a specific topic to inspire scholars from all disciplines to apply their skills and expertise to resolving issues that impede access to medication abortion in the United States (US). To stimulate innovative thinking in this area, SFPRF is particularly interested in the formation of teams that bring established and new researchers and disciplines together to investigate issues related to medication abortion. Consequently, Principal Investigators and Co-Investigators responding to this RFP are not required to be members of SFP at the time of application. To avoid limiting the scope of scientific inquiry, there is no set budget limit for research projects.

Purpose

The overarching question driving this RFP is: What would it take to increase access to medication abortion in the United States—and how might empirical evidence lead to changes in clinical practice, public policy, health services delivery, or cultural understandings? We seek research proposals reflecting disciplinary, methodologic, epistemological, and geographic variation. SFPRF anticipates funding a variety of projects ranging in size, scope, and purpose.

This RFP is a collaborative undertaking with our funders, designed to promote both scientific integrity and outcome utility. In partnership, SFPRF and the funders will select projects with a clearly defined theory of change that describe how the findings could be used to increase access to medication abortion in the US .Investigators will first submit an initial concept note (more information provided in section IV. Instructions, below). A select number of promising projects will be invited to submit a full proposal. Funded projects will launch in the Fall of 2018.

Research findings generated through this mechanism must penetrate beyond the walls of academic publications and the closed-door meetings of scholars. From the early stages of project development, we ask investigators to formulate a plan for how others (e.g., advocates, clinicians, policymakers, voters) will be involved in the research as well as use the findings to affect change. We understand that this request is no small undertaking. An iterative peer review process is designed to help investigators with this challenge through feedback and open communication for those proposals selected to move forward.

Research focus

Advocates heralded that the Federal Drug Administration's (FDA) approval of the mifepristone/ misoprostol regime in 2000 would revolutionize access to abortion in the US. Instead of widespread use outside of traditional abortion settings, persistent barriers including a complicated clinical provision model, high cost to patients, increasingly restrictive state-level abortion policies, and general social stigma toward abortion have stalled advances. Further, the FDA continues to constrain access to mifepristone through its Risk Evaluation and Mitigation Strategy (REMS).

The US differs from other countries which allow greater clinical flexibility in the provision of medication abortion. Most US states allow only physicians to prescribe medication abortion. By comparison, other countries make the drugs available through nurses, pharmacists, and community health workers. In many places around the world, individuals effectively manage medication abortion largely on their own, with little to no formal interaction with the healthcare system. Though medication abortion in the US is currently limited to 10 weeks gestation, second trimester abortions with medication are common in many European countries. Fear of missing a pregnancy located outside the uterus restricts provision in the US to models that include transvaginal ultrasound and expensive serial blood testing. Further, in the US, Rh-negative individuals are administered Rh immune globulin following their abortion; clinical and laboratory research is needed to modernize these practices.

Important gaps remain in understanding nonclinical aspects of the abortion care pathway. Social science methods are essential for increasing understanding of how individuals weigh different options and preferences as they relate to cost, convenience, privacy, pain management, interaction with a health care professional (or not), and the avoidance of a potentially stigmatizing situation. Rigorous research is required to identify and act on modifiable factors that can reduce the economic, racial, and geographic disparities in access to medication abortion.

There is a glaring gap in implementation science that tests different models for integrating medication abortion into primary care settings. Likewise, novel approaches are needed to overcome barriers related to insurance coverage, billing, or reimbursement. There remains much to be learned from the pioneering provision of medication abortion through telemedicine; evidence-based information is needed to effectively implement or adapt this model in new settings.

Technological innovations could assist individuals in accurately dating the gestation of their pregnancy, or in determining when an abortion has successfully completed. Streamlining the ability to acquire credible information and resources could simplify the abortion care-seeking process for traditionally underserved populations.

Ideologically driven policies regulate access to medication abortion. Robust evidence is needed for litigation to successfully challenge these legal restrictions. For example, though advanced practice nurses provide medication abortion in some states, there is limited published safety or efficacy data. Some states now require providers to counsel women about the possibility of reversing a medication abortion, a practice that is not substantiated in the scientific literature. Finally, statistical modeling for how laws affect low-income and geographically isolated populations is needed to solve the issues that constrain access in these communities.

The examples listed above describe some of the ways that access to medication abortion is hindered by clinical practices, laws, and lack of evidence. These examples are meant to be illustrative of our interest in issuing this RFP, they should not be considered exhaustive of the potential research questions or approaches that might be addressed.

Instructions

The components described below should be considered when developing the concept note.

Study design. When identifying a research question and accompanying project, investigators should consider how empirical evidence will help increase access to abortion in the US. The research question(s) should drive the methods and overall approach of the study design. With no set budget limitations, we ask that teams first identify their research question(s), then propose the methods best suited for answering those questions in rigorous and creative ways, and then build a budget to appropriately resource the project.

Study population. SFPRF believes that by reducing barriers for those most in need, everyone will gain greater access to medication abortion. As such, SFPRF seeks proposals which address the needs of the most underserved and disenfranchised populations, particularly those impacted by institutionalized racism. Investigators should describe their plans to conduct research in a respectful and collaborative way. The identification of the study

GRANT PROGRAM SCHEDULE

- Online submission of concept notes opens February 27, 2018 (see www.societyfp.org/research/applying.asp)
- Concept note deadline: April 10, 2018 at 11:59 PM (EDT)
- Applicants notified of decisions: June 8, 2018
- Online submission of full proposals for selected concept submitters opens June 8, 2018 (see www. societyfp.org/research/applying. asp)
- Application deadline: August 3, 2018 at 11:59 PM (EDT)
- Funding decisions announced: September 4, 2018
- Grant start-up: October 1, 2018

population should be well-justified and should be closely aligned with the framing of the research question(s). Investigators should describe feasible plans for the recruitment and selection of study participants, describing if and how the sample is representative of the overarching population, when possible. For quantitative studies, the proposed sample size should be based on power calculations to ensure that the study is sufficiently powered to answer the questions under investigation and to accommodate the planned analyses. Power calculations should adequately account for the analysis of subgroups of interest within the study sample (e.g., by age, race/ethnicity, education level, location, etc.). Qualitative studies should include thoughtful approaches for determining sample size, such as reaching saturation, predictability, or information power. Qualitative approaches should also account for analyses of subgroups of interest.

Team composition. SFPRF will fund individual investigators or teams as necessitated by the size and scope of the proposed project. We encourage multidisciplinary teams comprised of individuals with complementary skill sets and representing diverse backgrounds, perspectives, and are

inclusive of members at varying levels of career stage. Teams should also include community-based partners, such as those representing local nonprofit organizations, clinics, health care systems, or professional associations, when appropriate. Projects that take place in a setting other than where the research team is located must include a Co-Principal Investigator from the study community. Though highly educated scholars living and working in urban centers have the expertise to implement research with and among disenfranchised populations, we believe that building local capacity for research will enhance the field and the communities we serve.

For instance, if a team of researchers based in Denver wishes to uncover the barriers to access among women of color living in rural Mississippi, then they must collaborate with at least one individual from that community who will serve as a Co-PI. Better yet, a team comprised of women of color scholars, innovators, and/or organizers in Mississippi is the most ideally suited to investigate the issues central to their state or region. Please note that the Co-PIs are not required to have a research background. Rather, they should bring unique expertise or knowledge to the project.

Connecting with local or national abortion advocates. Research projects can be more impactful when they include the ideas and perspectives of advocates who bring unique expertise relevant to their local communities. When brought in during the initial planning stages of a project, advocates can help craft research questions that are salient to the populations they serve and are mindful of ways to package findings to ensure broad application and utility. Insights from advocates may identify potential negative or unforeseen consequences of the research and they can help strategize ways to minimize harmful effects. We encourage teams to explore ways to work with advocates during the development and implementation of the project, as appropriate.

Number of submissions. SFPRF will not limit the number of concept notes submitted or funded by any individual or institution. All concept notes will be reviewed on the merit and rigor of the ideas proposed; those concept notes of the highest quality, with the greatest promise to increasing access, and those demonstrating unique and innovative contributions will be selected to move on to the full proposal stage. Although there is no limit on the number of submissions, SFPRF encourages investigators to weight quality over quantity when developing their concept note(s).

Indicators of impact. SFPRF will fund a number of projects ranging in size, scope, and purpose. SFPRF evaluates the outcomes of our grantmaking as an essential component to improving our impact and the impact of the broader field of family planning research. We use 30 core metrics to regularly evaluate the outcomes of awarded grants. These metrics were developed after a review of the literature and engagement with stakeholders in the field of family planning. It is not expected that all grants achieve impact in all 30 areas, but we do anticipate that projects will successfully accomplish at least three objectives. Investigators should consult SFP's Table of Impact Metrics to identify the indicators of impact most closely aligned with the goals of their project.

Below, we provide some information about how the size and scope of the project correspond with impact indicators that are both feasible and meaningful. The examples listed below are provided to give a sense of the range in the required resources needed to accomplish different levels of research aims and goals. Investigators should not view these predetermined categories, but rather as general guidelines.

- Small: Budgets of \$50,000 or less; projects require 1 to 2 years to complete with a team of 1 to 4 members
 - Proven intervention is replicated in new populations or with new approaches
 - Research is developed and targeted to meet expressed and current needs of stakeholder
 - Research forms partnership with community or other group to address a community-based need
- Medium: Budgets between \$50,000 and \$300,000; projects require 2 to 3 years to complete with a team of 5 to 9 members
 - Research results in the development of a promising intervention
 - Research results in a cost-effective intervention
 - Research results in a clinically effective approach in or modification to the diagnosis, management, or treatment of a disease; disorder; or condition, or results in other improvements in healthcare (e.g., acceptability, effectiveness, performance, quality, or consistency)
- Large: Budgets of \$300,000 or more; projects require 4 to 5 years to complete with a team of 10 or more members
 - Research results in reduced costs in the delivery of health care services
 - Research results in a paradigm shift in a field, leads to a change in understanding of a problem, or leads to a new approach to disease; disorder; or condition
 - Research results in the development of a guideline, is cited in a guideline or textbook, or is cited in a statement issued by a governmental or nongovernmental agency, or by a specialty or medical organization

Review process. Working with SFPRF is a collaborative process and it is our goal to support applicants in the development of strong projects positioned to have the greatest impact. SFPRF will carry out the review of proposals in a two-part process. First, investigators will submit an initial concept note of no more than 10 pages (see Concept Note Guidelines below) that is due on or before Tuesday, April 10, 2018. All concept notes will undergo peer review with a focus on how the work can be strengthened. SFPRF will enlist the support of a wide range of academic and clinical research scholars from myriad disciplines; peer reviewers may also include legal experts, advocates, and lay community members. SFPRF will ensure that each concept note is matched with the appropriate content and methodological expert reviewers. Peer reviewers will offer suggestions for making the work better as well as recommend whether the concept note should move on to the full proposal stage. Accounting for all comments and feedback generated through the peer review process, representatives from the primary funding organizations will then review the concept notes to determine which projects align most closely with their priorities. After an assessment by both peer reviewers and funders, a select number of projects will advance to the next stage.

Comments and feedback from the reviewers and funders will be synthesized and shared with the investigators of each concept note; those moving forward will have approximately two months to write the full proposal. At that time, more detailed instructions will be shared on developing the full proposal, but investigators can anticipate that the proposal will consist of approximately 20 pages which further expounds on the ideas and methods proposed in the concept note, as well as addresses the reviewer and funder comments and recommendations. A designated Review

Committee consisting of SFPRF staff, content, legal, and methodological experts, advocates, and representatives from the primary funding organization will review all proposals. Proposals of the highest caliber and with the most promise to generate data which could increase access to medication abortion will be selected to receive funding. Again, comments and feedback from the Review Committee will be shared with the investigators and there is likely to be one additional round of revisions to finalize the proposal before receiving funds.

Eligibility. Grants will be made to organizations on behalf of a named Principal Investigator. Grants are limited, without exception, to tax-exempt organizations. A copy of the Internal Revenue Service tax-exempt status determination letter is required from each applying organization. The organization that receives the award may provide a sub-contract to a for-profit organization for specific activities unable to be completed by the primary organization. However, the sub-contract cannot exceed 20% of the budget.

Terms of award. Upon acceptance of the award, the PI and their employing institution will be required to sign an award letter indicating acceptance of the SFPRF award terms and conditions. SFPRF must be notified in advance of and approve any significant changes in research protocols.

IRB and ethical considerations. For studies involving 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. While IRB approval is not required at the time of application, only upon receipt of IRB-related documentation will SFPRF issue funds.

Concept note guidelines

Concept notes are due to the Society of Family Planning Research Fund no later than 11:59pm Eastern Time on Tuesday, April 10, 2018. Concept notes should be no more than 10 pages. Each concept note should address the sections listed below.

- Background: Describe the issue and justify how the proposed research project will generate data needed to increase access to medication abortion in the US
- Research question(s): Include the questions which will be answered through the proposed project.
- Methods: SFPRF seeks projects using qualitative, quantitative, or mixed-methods best suited for answering the research questions at hand. Peer reviewers will carefully assess the rigor of the methods proposed to ensure that only the highest quality science will be funded.
- Study population: The study population must align with the research question(s); sample size should be based on power calculations or other appropriate methods as determined by the study approach; sample size should account for subgroup analyzes as appropriate.
- Theory of change: Investigators should clearly describe how the data generated through this project could be used to increase access to medication abortion. A thoughtful theory of change will connect the dots—starting with the generation of research question(s) and the selection of the study population, to how findings will be disseminated, and ending with a measurable and identifiable outcome. A well-articulated theory of change is an essential component of the concept note.

For more information on developing a theory of change, please consult the following resources:

- Brest, P. (2010). The power of theories of change. Stanford Social Innovation Review, 8(2), 47-51.
- Reisman, J., & Giennap, A. (2004). Theory of change: a practical tool for action, results and learning. Organizational Research Services.
- Taplin, D. H., & Clark, H. (2012). Theory of change basics: A primer on theory of change. New York: Actknowledge.
- Knowledge engagement plan: The concept note should include a brief description of the knowledge engagement plan, including the identification of partners who will be kept apprised of the work throughout all stages and the target audience(s) with whom the findings will be shared.
 SFPRF will fund research that has practical application and a clear vision for how the findings will be packaged and communicated in meaningful ways throughout the life of the project.
- Team composition: SFPRF seeks multidisciplinary teams, including locally based advocates and key stakeholders as appropriate. Please describe how individual members bring complementary and diverse skill sets and represent a wide range of backgrounds and perspectives. NIH-style biosketches, curriculum vitaes (CVs) and/or resumés of team members should be included as an appendix and are not included in the 10-page limit.
- Budget: There is no predetermined budget limit. Investigators should determine the size of the team, propose a timeline, and request the funds needed to accomplish the aims of the project. The review process will carefully assess how well justified the budget request aligns with the needs of the project. At the concept note stage, teams should include preliminary budget estimates with a brief budget narrative describing major line items. Direct project costs should include personnel, research expenses (e.g., equipment, supplies, travel, materials), dissemination activities, and other related costs. Indirect costs are permitted at no more than 20% of total direct costs. For subcontracts 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. Budget documents should be included as an appendix and are not included in the 10 pages of the narrative concept note.
- References: Works cited should be listed as an appendix to the concept note; reference page is not included in the 10 narrative pages of the concept note.
- Agency/institution's federal 501(c)(3) status determination letter or proof of tax-exempt status must be included an appendix and is not included in the 10-page limit.
- Required formatting: Font size must be at least 11 points, and 1.5 line spacing must be used. Please upload as a single PDF file.