

Innovations in medication abortion service delivery

2021 Request for proposals

Context

The COVID-19 pandemic has functioned as both an acute stressor on abortion services and as a critical catalyst for innovations in medication abortion service delivery. Changes in clinical protocols and workflows have been made out of necessity in response to patient needs, workforce safety, and population health. At the same time, such changes have presented unexpected opportunities to test more streamlined and patient-centered service delivery models. These changes include reducing in-person clinical visits and shifts in screening, dispensing, and follow-up norms.

Changes on the policy front increased this potential. On July 13, 2020, a federal court enjoined the FDA from enforcing **ETASU B and C**, allowing mifepristone, a medication abortion agent, to be provided remotely (via mail or other delivery service) during the COVID-19 public health crisis. This ruling temporarily created the conditions for reshaping service delivery in a way that had previously been restricted to controlled research studies. While the Supreme Court ruling on January 12, 2021 has halted remote dispensing outside of approved research studies, there is potential for the FDA, under the new presidential administration, to adjust its position. Further, the incoming administration is both valuesaligned on the importance of evidence-based healthcare and responsive to research. The next few years present a critical and fleeting opportunity to align policy and regulatory guidance related to medication abortion with existing and newly captured evidence.

This confluence of events presents a striking opportunity for research primed for impact. Research capturing *in situ* innovations may be uniquely positioned to contribute to the future of medication abortion service delivery. Pairing innovations <u>already or previously in practice</u> with rigorous research holds the potential to generate the evidence needed to advance the delivery of medication abortion towards more patient-centered and potentially accessible models of care.

In an effort to generate this evidence, the Society of Family Planning Research Fund (SFPRF) is offering the Innovations in medication abortion service delivery request for proposals (RFP).

Research focus

SFPRF invites proposals centered on innovations in medication abortion service delivery (eg, at-home pre- and post-treatment consultation and screening; remote dispensing) for US populations. Research related to the following questions will be prioritized:

- Are pandemic-related practices at least as safe as pre-pandemic practices?
- Are pandemic-related practices at least as efficacious as pre-pandemic practices?
- Are pandemic-related practices at least as acceptable to patients as pre-pandemic practices?
- What are best practices in patient-provider communication related to innovations in medication abortion service delivery?
- How, if at all, do pandemic-related practices in medication abortion services shift the accessibility of medication abortion for specific US populations and geographies?

This funding opportunity is best suited for research that can be completed within 12 months of award. Research capitalizing on opportunities to analyze data related to service delivery models currently or previously in use will be prioritized. We strongly encourage the use of methodological approaches that will effectively translate to specifically named policy, legal, and regulatory audiences. Pilot projects, larger projects with the potential to be expedited with additional funding, and projects leveraging existing data are encouraged. Proposed research must be positioned to generate empirical evidence with a clear, concrete, and strategic path to changes in clinical practice, public policy, or health service delivery.

Funds and duration

SFPRF invites proposals for research studies with budgets up to \$100,000 that can be completed within 12 months of award. We anticipate supporting five to ten research projects via this funding opportunity. Investigators are encouraged to leverage existing infrastructure and research efforts, if possible. SFPRF will prioritize funding for projects that are ready for immediate implementation, recognizing the importance of a timely response to the current landscape.

Additional benefits

In addition to receiving funds for research, the investigators and key team members will join a learning community of peers supported by this funding opportunity. The learning community will provide space for additional scientific feedback and capacity building. Specifically, SFPRF will:

- Facilitate discussions of coordination and collaboration among participants.
- Provide information from FDA experts on how research is reviewed.
- Provide information from policy experts about how research can be responsive to policy shifts.
- Share examples from pharmaceutical sponsors on how research is used in requests to the FDA.
- Provide methodological support around the use of subgroup analyses with attention to specific populations (eg, age, race, ethnicity, and socio-economic status).
- Create connections with knowledge brokers in communications, legal, and policy spaces.

< 2 >

Application submission opens on

January 14, 2021 and closes February 25, 2021.

Awards will be announced in April and funds will be available for immediate use.

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 of Family Planning. Funding is limited to projects studying US populations.

Review process

All proposals will undergo peer review using <u>specific criteria</u>. The goal of peer review is to make recommendations for enhancing the research proposal and to identify the projects with the greatest potential impact. Funders will also be involved in the selection of grants; this ensures that the research funded through SFPRF is one of many strategic components working together to strengthen the family planning sector. All proposals will be reviewed according to the following criteria:

Impact (25%)

SFPRF seeks to fund projects that are positioned to generate empirical evidence with a clear and strategic path to changes in clinical practice, public policy, or health services delivery. For those projects focused on remote dispensing, projects must be attentive to potential shifts in the policy and regulatory environment.

Relevance (20%)

SFPRF seeks to fund projects that capitalize on opportunities to analyze data related to service delivery models currently or previously in use.

Methods (25%)

SFPRF seeks to fund methodologically sound and rigorous projects.

Study population (10%)

SFPRF seeks to fund projects that focus on study populations that are aligned with the proposed research questions.

Team (10%)

SFPRF 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. SFPRF also prioritizes study teams that leverage the expertise and skills of Black and Indigenous researchers and researchers of color.

Budget (10%)

SFPRF seeks to fund projects with budgets that are fully justified and appropriate in relation to the proposed project.

Timeline (10%)

SFPRF seeks to fund projects that are feasible to complete within 12 months of receiving the award.

Proposal instructions

1. Online application form:

Includes contact and demographic information for the PI, 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, website, and other educational and promotional purposes should the application be funded.

3. Proposal narrative (8 to 10 pages):

All proposals should include:

- **a. Background:** Describe the issue and justify how the proposed research project will generate data that will produce empirical evidence with a clear, concrete, and strategic path to changes in clinical practice, public policy, or health services delivery now and in the future.
- **b. Research question(s):** Include the question(s) that will be answered through the proposed project.
- **c. Methods:** Describe the research methods that will be used to answer the research question(s) at hand. Narrate the external conditions that must be in place to ensure the feasibility of the methodological approach and potential adjustments needed should these conditions change.
- **d. Study population:** Describe the specific 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 analyses as appropriate.
- **e. Timeline:** Describe the timeline for conducting research activities. Data collection and analysis must be feasible to complete within 12 months of receiving the award.
- f. 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. SFPRF will fund research that is attentive to partner engagement, robust dissemination activities, and the translation of knowledge into policy and practice. If applicable, describe how the use of research results might change to respond to policy and regulatory shifts.
- **g. Next phase of research:** Concisely forecast what results of the proposed study would necessitate additional research investment and what results would suggest further research is not needed. For a scenario where additional investment is needed, briefly describe what that investment might look like in terms of study design and potential significance.
- h. 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 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 and its effect on the proposed project's design, feasibility, and impact. Note that SFPRF prioritizes study teams that leverage the expertise and skills of Black and Indigenous researchers and researchers of color.
- **i. References:** Works cited should be listed as an appendix to the proposal; reference page is not included in the 8 to 10 pages of the proposal narrative.

< 4>

Proposal instructions, continued

4. Budget and budget narrative:

Studies should be \$100,000 or less. The budget narrative must provide sufficient detail to assess feasibility and suitability in the peer review process and must justify the relevance of requested resources to the project's success. Additional secured or requested funds for the proposed project must be named, if applicable. Direct project costs include personnel, research expenses (eg, equipment, supplies, travel, materials), activities related to use of research results, 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 8 to 10 pages of the proposal narrative.

5. Biosketches or professional résumés of team members:

NIH-style biosketches are encouraged for all established scientists. Professional résumés are encouraged for those whose careers have not focused on research. Team members can submit the format that works best for the individuals on the team; however, 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 to 10 pages of the proposal narrative.

6. Agency/institution's federal 501(c)(3) status determination letter or proof of 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 to 10 pages of the proposal narrative. Documentation should also be included for subcontracts with tax-exempt organizations that exceed 20% of the budget.

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. All grant applications must be submitted electronically through the <u>online application portal.</u>

SFPRF 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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< 5 >