

# Documenting the efficacy, safety, and acceptability of medication abortion up to 97 days

2025 Request for proposals

## **Purpose**

Medication abortion is an <u>effective and safe method of abortion care</u>, and in 2023, it comprised <u>63% of all abortions</u> in the formal US healthcare system. While the FDA has approved the use of mifepristone with misoprostol for medication abortion through 70 days of gestation, clinical guidance from <u>national</u> and <u>international</u> organizations affirms its effective and safe use beyond 70 days.

Recognizing that pregnant people may want or need medication abortion after 70 days, rigorous research on the efficacy, safety, and acceptability of medication abortion at different estimated gestational durations is crucial to advancing evidence-informed and person-centered clinical care. To this end, the Society of Family Planning is offering the *Documenting the efficacy, safety, and acceptability of medication abortion up to 97 days* funding opportunity. This funding opportunity aims to build upon the existing knowledge base by generating data that further advances evidence-informed and person-centered medication abortion care.

The deadline for proposals is February 3, 2026 at 8:59 pm PT/11:59 pm ET. Awards will be announced in March and funds will be available for immediate use.

## Research focus

**Study design**: The Society seeks to fund one prospective non-inferiority cohort study that compares outcomes of mifepristone and misoprostol medication abortion among individuals at different estimated gestational durations who are receiving in-person ultrasound. Proposed research must compare a comparison group receiving care within the FDA-approved estimated gestational duration (≤70 days of gestation) to a study group extending from 71 days up to an endpoint chosen by the study team that is ≤97 days of gestation. Study teams are responsible for defining and justifying the specific estimated gestational duration for each group within these parameters. Proposals must clearly state and justify the chosen non-inferiority margin, and include a detailed statistical plan that demonstrates the study is sufficiently powered and accounts for potential confounding variables.

**Setting**: The proposed research must be a multi-site study conducted in outpatient clinical settings in the US. The study team must justify the number of sites, address the feasibility of data collection at the sites, and discuss the generalizability of the sites, including how they will reach relevant subpopulations.

**Outcomes:** The primary outcome is efficacy. Study teams must include a detailed justification for how they define and will measure this outcome, narrating alignment with standardized definitions (eg, MARE, STAR, PAIRS, FDA), and provide a clear rationale for the timing of assessing efficacy to minimize measurement error. Secondary outcomes must include measures of safety and acceptability, and study teams must narrate alignment with standardized definitions (eg, MARE, STAR, PAIRS, FDA). Secondary outcomes should include, but are not limited to, adverse events, side effects and symptoms, care-seeking after receipt of medications, need for and use of additional misoprostol, and experiences with fetal tissue viewing and disposal. Proposals may include additional outcomes or data collection efforts (eg, alignment between self-assessed and ultrasound-estimated gestational duration, alignment between preferences and care after receipt of medications), provided that these are feasible within the study's resources.

**Regimen**: Study teams must use an evidence-based regimen for mifepristone and misoprostol medication abortion at the estimated gestational durations, and define and justify the regimen in their proposal.

# Research focus (continued)

Enrollment and follow-up procedures: Study participants must undergo an ultrasound to confirm an estimated gestational duration of ≤97 days. The timing of mifepristone intake relative to the ultrasound is at the discretion of the study team; however, the medication must be taken at ≤97 days of gestation, all participants must take the medication within a one-week period following the ultrasound, and a mechanism must be in place to document the exact date of medication intake. All study participants must receive in-person follow-up via ultrasound or quantitative HCG test to confirm abortion completion. The timing of the follow-up must be justified.

**Remuneration**: Recognizing that in-person follow-up presents significant barriers to study participants, study teams must outline a remuneration plan that directly addresses and mitigates these challenges.

Other considerations: Proposals must be positioned to produce empirical evidence with a clear, concrete, and strategic path to influencing clinical practice, public policy, and/or health services delivery. We encourage study teams to provide a brief assessment of how, if at all, existing laws restricting medication abortion in states relevant to the proposed study influence study design. In addition, recognizing that institutionalized racism, both past and present, has hindered the full participation of people of color in science and medicine, the Society aims to support the full range of individuals advancing the science and medicine of abortion and contraception, in alignment with our Diversity, Equity, and Inclusion Vision. We actively seek teams that reflect on the relationship between their identities and lived experiences and the proposed project.

#### Funds and duration

We invite proposals for research studies with budgets up to \$950,000 that can be completed within 36 months. We anticipate supporting one research project via this funding opportunity. Funding is also available to cover processing fees associated with six open-access publications, provided the work is published within two years of grant completion.

# 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.

## **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 project with the greatest potential impact. The funder of these awards may also be involved in the selection process, helping ensure that the research funded by the Society is one of many strategic components working together to strengthen the family planning sector.

Application submission opens on October 21, 2025 and closes February 3, 2026

#### Review criteria

All eligible proposals will be reviewed according to the following criteria. For more information about the review process, please see the proposal <a href="review-guide">review guide</a>: <a href="https://bit.ly/3WE8Nue">https://bit.ly/3WE8Nue</a>

## Study Design (20%)

The Society seeks to fund a methodologically sound and rigorous prospective non-inferiority cohort study.

## Setting (15%)

The Society seeks to fund a project that offers a compelling rationale for its selected multi-site setting and addresses both the feasibility of data collection and the generalizability of its sites.

#### Outcomes (25%)

The Society seeks to fund a project with a well-justified plan for measuring efficacy, safety, and acceptability, and that demonstrates a thorough understanding of relevant clinical and patient-centered outcomes.

## Regimen, enrollment, and follow-up procedures (15%)

The Society seeks to fund a project that utilizes a clearly-defined, evidence-based medication abortion regimen and includes well-justified enrollment and follow-up procedures.

# Participant remuneration (5%)

The Society seeks to fund a project with a thoughtful remuneration plan that addresses barriers to in-person follow-up.

# Impact (5%)

The Society seeks to fund a project that is positioned to produce empirical evidence with a clear, concrete, and strategic path to influencing clinical practice, public policy, and/or health services delivery.

# Team positionality (5%)

The Society seeks to fund a project that demonstrates thoughtful reflection on how team members' race and ethnicity, and other relevant identities and lived experiences, influence the project.

# Team expertise (5%)

The Society seeks to fund a project led by teams with the necessary skills, backgrounds, perspectives, and/or lived experiences to successfully carry out the project.

# **Budget (5%)**

The Society seeks to fund a project up to \$950,000 that can be completed within 36 months of receiving the award.

# **Proposal instructions**

#### 1. Online application form:

Includes contact and demographic information for the PI, and contact information for the institution, study team, and parties responsible for accounts payable and grants management if the project is funded. The <u>application form is linked here</u>, and on page 8.

#### **2.** Summary (250 words):

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

#### 3. Proposal narrative (10-12 pages):

All proposals should include:

Background: Describe the issue and explain how the proposed research project will produce empirical evidence with a clear, concrete, and strategic path to changes in clinical practice, public policy, or health services delivery.

Research question(s): Include the question(s) that will be answered through the proposed project.

Methods: Describe the research methods that will be used to answer the research question(s), with attention to the requirements outlined in the "Research focus" section of this funding opportunity.

Use of research results: Narrate the intended 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.

Timeline: Describe the timeline for conducting research activities. Data collection and analysis must be feasible to complete within 36 months of receiving the award.

Team positionality: Describe how team members' racial and ethnic identities, alongside other relevant identities and lived experiences, influence the proposed project. Explain how these identities and experiences shape the proposed project's design, feasibility, and impact. Please refer to these <u>recommendations</u> for information about positionality.

Team expertise: Describe team members' expertise, specifying their skills, backgrounds, perspectives, and/or lived experiences as they relate to the project.

References: Works cited should be listed as an appendix to the proposal; the reference page is not included in the 10-12 pages of the proposal narrative.

# Proposal instructions (continued)

#### 4. Budget and budget narrative:

The budget maximum for this award is \$950,000. The budget narrative must provide sufficient detail to assess feasibility and suitability during the peer review process and to justify the requested resources' relevance 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, participant incentives), activities related to the use of and dissemination of research results, and similar costs directly supporting research activities. Indirect costs are permitted at no more than 20% of the total direct costs. The Society considers facilities and administrative costs (F&A) to be indirect costs. and these are prohibited from being budgeted as direct costs (including but not limited to: facilities costs, institutional insurance, IT or "network recharge fees"). Indirect costs, whether requested as a flat percentage or not, may not exceed 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 10-12 pages of the proposal narrative.

#### 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. 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. These documents must be included as an appendix and are not included in the 10-12 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. Documentation should also be included for subcontracts with tax-exempt organizations that exceed 20% of the budget. These documents are not included in the 10-12 pages of the proposal narrative.

# **Required formatting**

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>.

## Submission deadline

The deadline for proposals is **February 3, 2026 at 8:59 pm PT/11:59 pm ET**. Awards will be announced in March and funds will be available for immediate use.

#### Questions

The Society welcomes the opportunity to clarify or assist with any application components. Please contact <a href="mailto:Grants@SocietyFP.org">Grants@SocietyFP.org</a>.

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