

# Health and Science Research Request for Proposal

## TOPIC

### **Long-Term Effects of Tobacco Harm-Reduction (THR) Product Use on People with Chronic Health Conditions**

Issue date	March 31, 2022
Closing date	May 16, 2022
Closing time	12:00 noon, Eastern Standard Time (EST)
Submit proposals to	(See submission instructions in RFP)
Financing instrument	Grant
Financing amount	Budget not to exceed US \$400,000 Paid in US dollars, amount consistent with proposal and work plan
Financing duration	Maximum of 8 months, consistent with proposal and work plan
Contact information	<a href="mailto:support@smokefreeworld.org">support@smokefreeworld.org</a>

## Introduction

It is undisputed that tobacco use has a substantial negative influence on health and disease. Globally, nearly 7.7 million estimated deaths and 200 million disability-adjusted life-years (DALYs) were attributable to tobacco smoking in 2019.<sup>1</sup> Diseases with tobacco use (smoking, chewing, and second-hand exposure) as a major risk factor include cardiovascular disease, cancer, chronic respiratory diseases, respiratory infections and tuberculosis, and diabetes.<sup>2</sup> Without intervention, as the number of smokers continues to increase globally, so too will the attributable burden of disease.

The last decade has brought some hope with the proliferation of tobacco harm-reduction (THR) products (e.g., snus, vaping devices, heated tobacco products), which have been shown to contain significantly lower levels of harmful constituents. For example, preliminary evidence from the Royal College of Physicians in the United Kingdom indicates that e-cigarettes are approximately 95% less harmful to health than traditional cigarettes.<sup>3</sup> At the same time, there is a lack of robust clinical evidence regarding the long-term health effects of THR products relative to combustible and/or oral tobacco. Research evidence in this area is especially lacking for those suffering from chronic health conditions.

The Foundation for a Smoke-Free World (“the Foundation”) is seeking proposals that will lead to the development of clinical trial protocols, with a view to implementation, that will address the research gap identified above and assess the long-term health effects on smokers with chronic health conditions (including noncommunicable and long-term infectious diseases) who switch from combustible or oral tobacco to THR products. Submitted proposals should incorporate recent technologies where relevant to overcome the traditional recruitment/follow-up, data quality, inclusivity, and cost challenges associated with clinical studies. The goal of this RFP is to support independent research that has the potential to build on the current evidence base and

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<sup>1</sup> [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)01169-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01169-7/fulltext)

<sup>2</sup> <https://www.thelancet.com/pb-assets/Lancet/gbd/summaries/risks/tobacco-smoke.pdf>

<sup>3</sup> <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

improve smoker outcomes in areas of unmet need that are aligned with the [Foundation's strategy](#). Work done under this RFP will assist the Foundation in determining what (if any) clinical studies should be carried forward.

**Objective: Develop and publish protocols for clinical research trials to assess the health effects of switching from combustible and oral tobacco to THR products for people living with chronic health conditions, long-term infectious diseases, and lifelong disabilities, with a view toward implementation.**

## **Deliverables**

- Comprehensive literature review of clinical trials conducted for similar work
- Fully developed clinical research protocol for the study
- Study protocol submitted to a peer-reviewed journal or open science journal for publication
- Memorandum of Understanding (MoU) for partnership with clinical partners (if applicable)
- Ethical approval by relevant committee/authority in participating countries

The Foundation will evaluate the protocols for their potential to deliver a scientifically robust clinical study and fund the selected organization(s) to undertake clinical studies.

## **Expected Qualifications**

Eligible institutions include universities, medical/cessation centers, research facilities, and other research partner organizations with strong experience in clinical study design. Clinical research experience in addiction and tobacco cessation is desirable.

Proposals should be submitted by entities registered in their country of origin with an ability to accept research grants from not-for-profit foundations incorporated in the United States.

## **Geographic Focus**

The focus of the work is global, but the Foundation is especially interested in outcomes in low- and middle-income countries (LMICs).

## Estimated Budget and Duration

- Budget not to exceed US \$400,000
- Duration not to exceed 8 months

## Evaluation Criteria

The following criteria will be used to evaluate submissions:

- Expertise and prior experience, including demonstrated experience on similar projects
- Research presence, including in LMICs
- Ability to meet the objectives of the RFP
- Cost and timeline
- Adequate resources (quantity and type) to satisfy project scope and timeline
- Key organizational documents provided to the Foundation as part of the due diligence process, as outlined in [Grant Policies and Procedures](#)

The Foundation will prioritize proposals that demonstrate a commitment to our values, including diversity, equity, and inclusion, and that provide the Foundation with the opportunity to interact with diverse teams, bringing a range of perspectives.

## Submission Instructions

Applications should be submitted through the Foundation's online portal, which can be accessed [here](#). This link will start the new application form. Upon clicking the link, you will be prompted to log in, and then taken to the application form.

The application form has links to three templates, which are also listed here for your convenience:

- [Proposal template](#)
- [Budget template](#)
- [Work plan template](#)

You may save your application at any time by using the Save & Finish Later button at the end of each page.

To return to an in-progress application, [log in to the portal](#).

A list of application portal FAQs can be found [here](#).

If you have any technical issues, please contact the grants management team via [support@smokefreeworld.org](mailto:support@smokefreeworld.org), and we will be happy to help.

## **Key Information**

The Foundation may disclose proposals, documents, communications, and associated materials submitted in response to this RFP to its employees, consultants, legal counsel, contractors, and potential co-funders. The applicant should carefully consider the content of submitted materials if there is any concern about the impact of disclosure of confidential or proprietary information. Although submissions will not be disclosed publicly during the evaluation process, all funded projects (scoping and final awards) will be made public. The Foundation will work with awardees to ensure that any materials made public will not disclose protected information.

To be considered for an award, the applicant agrees that the Foundation may:

- Amend or cancel the RFP, in whole or in part, at any time
- Extend the deadline for submitting responses
- Determine whether a response does or does not substantially comply with the requirements of the RFP
- Issue multiple awards

The applicant must ensure that it has responded to the RFP with complete honesty and accuracy. If information in the applicant's response changes, the applicant will supplement its response in writing with any deletions, additions, or changes within five days of the change. Any material misrepresentation, including omissions, may disqualify the applicant from consideration for an award.

## **About Foundation for a Smoke-Free World**

The Foundation for a Smoke-Free World is an independent, US nonprofit [501\(c\)\(3\)](#) private foundation with the purpose of improving global health by ending smoking in this generation. The Foundation focuses its grantmaking in three broad categories: health and science research, agricultural diversification, and industry transformation. Funded by annual gifts from PMI Global Services Inc. ("PMI"), the Foundation is independent from PMI and operates in a manner that

ensures its independence from the influence of any commercial entity. Under the Foundation's [Pledge Agreement](#) with PMI and [bylaws](#), PMI and the tobacco industry are precluded from having any control or influence over how the Foundation spends its funds or focuses its activities. For more information about the Foundation, please visit [www.smokefreeworld.org](http://www.smokefreeworld.org).