

# Health and Science Research

## Request for Proposals

### TOPIC

## Nicotine Pouch Products: Implications for Tobacco Cessation and Harm Reduction

Issue date	Tuesday, May 16, 2023
Closing date	Monday, July 10, 2023
Closing time	12 Noon – UK Time
Submit proposals to	(See submission instructions in RFP)
Financing instrument	Grant
Financing amount	Amount consistent with proposal and work plan (paid in US dollars)
Financing duration	Maximum of 12 months, consistent with proposal and work plan
Contact information	<a href="mailto:support@smokefreeworld.org">support@smokefreeworld.org</a>

### Background

Although the prevalence of combustible tobacco smoking has decreased overall, smoking remains a leading cause of death and disease worldwide.<sup>1</sup> Noncombustible nicotine products are available to smokers to reduce the harm associated with smoking.<sup>2</sup> A relatively new noncombustible nicotine product category is nicotine pouches (NPs). NPs are placed between the upper lip and gum so that nicotine is absorbed through the oral mucosa. Use of NPs does not require spitting.<sup>3</sup> NPs have properties similar to Swedish snus, with the notable difference that NPs do not contain tobacco.<sup>3</sup>

NPs have been available in some countries since the mid-2010s.<sup>4</sup> Seven companies currently offer NPs, representing 0.3% of the world tobacco market (in value terms) in 2021.<sup>5</sup> Even though NPs are not widely available globally, several surveys of retail sales and product use show that NP prevalence is increasing in the US and in other high- and middle-income countries.<sup>6,7</sup>

Studies have demonstrated the reduced-harm potential of tobacco-containing traditional Swedish snus.<sup>8,9,10</sup> Because NPs are similar to Swedish snus but contain no tobacco leaf, it is not surprising that initial studies have shown they have similar or even greater harm-reduction potential than traditional snus.<sup>11</sup> Some research has indicated that NPs also have lower levels of toxic compounds compared to traditional Swedish snus products. NPs and nicotine replacement therapy (NRT) products have similarly low levels of harmful and potentially harmful constituents,<sup>12</sup> further suggesting NPs occupy a position close to NRTs on the tobacco and nicotine product toxicant delivery continuum.<sup>10,13</sup> Other early evaluations have shown that NPs can deliver nicotine levels similar to those delivered by cigarette smoking<sup>14</sup> and provide smokers with a more satisfying level of nicotine than NRTs.<sup>15</sup> According to one study, the most common reasons for NP use are health concerns and ease of use.<sup>16</sup>

Because NPs are a relatively new product category, the current research assessing their potential harms and benefits is insufficient. More data on NP use are required to better understand their reduced-risk potential in comparison with other tobacco and nicotine products.<sup>11,17</sup> Given the uncertainties surrounding this novel product, a well-designed study is necessary to understand its characteristics and its implications for tobacco cessation and harm reduction.

## **Objective**

The Foundation for a Smoke-Free World (“the Foundation”) seeks proposals to explore the safety and efficacy of NPs and to understand their implications for tobacco cessation and harm reduction. The research proposal should address fundamental gaps in knowledge related to NPs and propose analyses that are innovative, based on prior evidence and/or theory, and, where

appropriate, use methods that plausibly identify causal relationships. Applicants are expected to complete the research within the stipulated period. Research topics may include (but are not limited to) the following:

- Assessments of NP characteristics in comparison with other tobacco products, particularly oral tobacco products; this may involve evaluating their chemical and physical attributes or biological interactions
- Assessments and comparisons of the consumer knowledge and the demographic, socioeconomic, and other distinctive characteristics of NP users and users of other nicotine products, including smokers
- Descriptive or analytical investigations to evaluate user interest in, and awareness or usage patterns of, different nicotine products (including NPs) across diverse populations categorized by age, gender, race, geography, socioeconomic status, or psychological condition
- Effects of NP use, as well as dual and poly use of various nicotine products (including NPs), on tobacco cessation and harm reduction

The research areas listed above are only a few examples of topics that are aligned with the Foundation's mission and are not meant to be exhaustive or exclusive. The Foundation encourages applicants to propose innovative and creative research questions that will advance knowledge about NPs.

The Foundation will consider appropriate methodologies best suited for the applicant's chosen area(s) of research. However, the proposal must demonstrate a complete understanding of the research area and include a rationale for using the particular methodology. The research may cover one or more areas according to the expertise and capacity of the respective applicant.

## **Eligibility**

Eligible institutions include academic, health-related, research, and science centers and institutions, and other collaborating centers and institutions with experience in epidemiology, behavioral health, public health, or clinical studies. Research experience in addiction or tobacco use is desirable.

Proposals should be submitted by entities registered in their country of origin with the 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 preference will be given to proposals that include research associated with locations in which NPs are legally available and NP prevalence is relatively high or potentially in flux.

## **Estimated Budget and Duration**

**Duration:** The scope of the proposed project should determine the project duration. Maximum duration not to exceed 12 months.

**Budget:** Application budgets consistent with proposal and work plan

## **Evaluation Criteria**

Applicants are advised to read and understand the [Foundation's Strategic Plan](#). All study objectives must align with the Foundation's goals.

All applications must describe how the research will make a novel contribution, the scientific plausibility of the research question, and the likely validity of the proposed methodology.

The following criteria will be used to evaluate submissions:

- The significance of the research question in the context of the nicotine pouches

- The innovation of the research strategy
- The scientific adequacy of the proposed data and methodology
- The expertise and prior experience of the applicant, including demonstrated experience on similar projects
- Adequate physical and intellectual environment to meet the objectives of the proposed research
- Dissemination plans
- Cost vis-à-vis significance and contribution
- Key organizational documents provided to the Foundation as part of the due diligence process, as outlined in [Grant Solicitation and Application Process](#)

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, and contractors. 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 any 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 supports its mission through three core pillars: Health and Science Research;

Agriculture 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).

## References

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<sup>1</sup> Dai, X., Gakidou, E., & Lopez, A. D. (2022). Evolution of the global smoking epidemic over the past half century: strengthening the evidence base for policy action. *Tobacco control*, 31(2), 129–137. <https://doi.org/10.1136/tobaccocontrol-2021-056535>

<sup>2</sup> Cobb, C. O., Weaver, M. F., & Eissenberg, T. (2010). Evaluating the acute effects of oral, non-combustible potential reduced exposure products marketed to smokers. *Tobacco control*, 19(5), 367–373. <https://doi.org/10.1136/tc.2008.028993>

<sup>3</sup> Robichaud, M. O., Seidenberg, A. B., & Byron, M. J. (2020). Tobacco companies introduce 'tobacco-free' nicotine pouches. *Tobacco control*, 29(e1), e145–e146. <https://doi.org/10.1136/tobaccocontrol-2019-055321>

<sup>4</sup> Azzopardi, D., Haswell, L. E., Frosina, J., McEwan, M., Gale, N., Thissen, J., Meichanetzidis, F., & Hardie, G. (2023). Assessment of biomarkers of exposure and potential harm, and physiological and subjective health measures in exclusive users of nicotine pouches and current, former and never smokers. *Biomarkers : biochemical indicators of exposure, response, and susceptibility to chemicals*, 28(1), 118–129. <https://doi.org/10.1080/1354750X.2022.2148747>

<sup>5</sup> Janazzo, D. (2022, September 30). *Nicotine pouches: geographic footprint, company presence, and legislative snapshot*. Foundation for a Smoke-Free World. <https://www.smokefreeworld.org/nicotine-pouches-geographic-footprint-company-presence-and-legislative-snapshot/>

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- <sup>6</sup> Majmundar, A., Okitondo, C., Xue, A., Asare, S., Bandi, P., & Nargis, N. (2022). Nicotine pouch sales trends in the US by volume and nicotine concentration levels from 2019 to 2022. *JAMA network open*, 5(11), e2242235. <https://doi.org/10.1001/jamanetworkopen.2022.42235>
- <sup>7</sup> Tattan-Birch, H., Jackson, S. E., Dockrell, M., & Brown, J. (2022). Tobacco-free nicotine pouch use in Great Britain: a representative population survey 2020-2021. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*, 24(9), 1509–1512. <https://doi.org/10.1093/ntr/ntac099>
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- <sup>9</sup> Weitkunat, R., Sanders, E., & Lee, P. N. (2007). Meta-analysis of the relation between European and American smokeless tobacco and oral cancer. *BMC public health*, 7, 334. <https://doi.org/10.1186/1471-2458-7-334>
- <sup>10</sup> Luo, J., Ye, W., Zendejdel, K., Adami, J., Adami, H. O., Boffetta, P., & Nyrén, O. (2007). Oral use of Swedish moist snuff (snus) and risk for cancer of the mouth, lung, and pancreas in male construction workers: a retrospective cohort study. *Lancet (London, England)*, 369(9578), 2015–2020. [https://doi.org/10.1016/S0140-6736\(07\)60678-3](https://doi.org/10.1016/S0140-6736(07)60678-3)
- <sup>11</sup> Azzopardi, D., Liu, C., & Murphy, J. (2022). Chemical characterization of tobacco-free "modern" oral nicotine pouches and their position on the toxicant and risk continuums. *Drug and chemical toxicology*, 45(5), 2246–2254. <https://doi.org/10.1080/01480545.2021.1925691>
- <sup>12</sup> Back, S., Masser, A. E., Rutqvist, L. E., & Lindholm, J. (2023). Harmful and potentially harmful constituents (HPHCs) in two novel nicotine pouch products in comparison with regular smokeless tobacco products and pharmaceutical nicotine replacement therapy products (NRTs). *BMC chemistry*, 17(1), 9. <https://doi.org/10.1186/s13065-023-00918-1>

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<sup>15</sup> Azzopardi, D., Ebajemito, J., McEwan, M., Camacho, O. M., Thissen, J., Hardie, G., Voisine, R., Mullard, G., Cohen, Z., & Murphy, J. (2022). A randomised study to assess the nicotine pharmacokinetics of an oral nicotine pouch and two nicotine replacement therapy products. *Scientific reports*, *12*(1), 6949.

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