



## GRANT POLICIES AND PROCEDURES

### OUR PURPOSE

The purpose of the Foundation is to improve global health by ending smoking with the goal of eliminating the use of cigarettes and other forms of combustible tobacco in this generation, that is, over the next 10 to 20 years (the “Foundation’s Purpose”).

The Foundation supports independent medical, agricultural and scientific research that advances smoking cessation and the field of tobacco harm reduction and that addresses the impact of the reduced world-wide demand for tobacco, free from the influence of any commercial entity that may be affected by the outcome of the research.

In furtherance, the Foundation will:

- Make grants to appropriately qualified organizations and institutions to conduct research or analysis on topics relevant to the Foundation’s Purpose, including:
  - Data on the epidemiology of smoking and use of other nicotine products and associated behaviors; public perceptions and opinions on harms related to smoking, tobacco, and nicotine; public perceptions on smoking cessation and harm reduction; public perceptions and beliefs regarding products and services related to smoking, nicotine use, smoking cessation, and harm reduction;
  - Data on the broader context for smoking, cessation, and harm reduction, including but not limited to the regulatory environment, product availability and pricing, and media activity;
  - Alternatives to cigarettes and other combustible tobacco products;
  - The development of innovative and therapeutic products and services related to smoking cessation and harm reduction (for example, biomarkers, apps, et cetera);
  - Assessments of the impact of harm reduction products and associated interventions on public health outcomes;
  - Monitoring and publishing reports on activities of the tobacco industry and other commercial entities in relation to a smoke-free world and advancing the field of tobacco harm reduction;

- Assessment of the effect of the reduced demand for leaf tobacco on farmers;
  - Exploration and promotion of sustainable agricultural and nutritional alternatives for tobacco farmers and the land devoted to growing tobacco; and
  - Building the capacity of researchers in areas related to harm reduction, innovation and alternatives to tobacco agriculture.
- Fund organizations and collaborate with other organizations, as appropriate, to conduct global conferences, forums, panels and similar programs to focus on the evolving science regarding alternatives to cigarettes and other combustible tobacco products and how to best realize a smoke-free world.
  - Fund, as appropriate, projects that will further the efforts of research organizations to undertake activities aligned with the Foundation’s Purpose (for example, projects that improve general access to relevant data or facilitate engagement with smokers and users of nicotine products).

## OUR CORE PRINCIPLES

The scientific integrity of the Foundation’s grant program is described in Article IX of the Foundation’s Bylaws

([https://www.smokefreeworld.org/sites/default/files/uploads/foundation\\_for\\_a\\_smoke-free\\_world\\_inc.\\_-first\\_amended\\_and\\_restated\\_bylaws.pdf](https://www.smokefreeworld.org/sites/default/files/uploads/foundation_for_a_smoke-free_world_inc._-first_amended_and_restated_bylaws.pdf)) which includes:

- **Independent Research Agenda:** The Foundation’s goal is to promote and support significant scientific research that advances the field of smoking cessation and of tobacco harm reduction and reduces the public health burden of smoking-related diseases. *The Foundation will not take into account the potential impact of that research on the tobacco industry or any other industry or commercial entity.*
- **Governance:** The Foundation’s research program is guided by experienced researchers, scientists and policy experts in accordance with the Foundation’s goals.

The Foundation has established a Science Oversight Committee as well as two grant review committees: The Health, Science, and Technology Grant Committee and the Agriculture and Livelihood Grant Committee.

- **Transparency and Independence:** The process for screening, reviewing and awarding grants is conducted in a transparent manner and includes explicit and clear guidelines for grant applicants. The grant selection process is conducted by the Foundation, supported by independent peer review with no influence, involvement or participation from the tobacco industry or any other industry or commercial entity.
- **Competitive Funding Process:** The Foundation employs a competitive funding process in screening, reviewing and awarding grants that ensures that the grant selection process is based on explicit, well established scientific criteria.

- **Protection Against Conflicts of Interest:** The Foundation maintains a written conflicts of interest policy which includes adequate protections in place to guard against potential conflicts of interest on the part of grantees and grant application reviewers. The conflicts of interest policy will govern the disclosure of relevant financial relationships, including, but not limited to, salary or wages, remuneration, consulting fees, honoraria, expert testimony fees or speaking engagement fees received by grantees or grant application reviewers from the tobacco industry or any other industry or commercial entity.
- **Ownership of Data and Freedom to Publish:** To safeguard the scientific integrity of each research endeavor the Foundation ensures, unless prohibited by law, that grantees have the freedom to publish their findings, studies and results in the form submitted to the Foundation. To the extent legally possible, the Foundation requires grantees to make their raw research data available for secondary analyses and review on an open-access platform.

*An overview of the Foundation's grant-making policies and procedures is presented below.*

*Additional information about the Foundation can be found at [www.smokefreeworld.org](http://www.smokefreeworld.org).*



## GRANT POLICIES AND PROCEDURES

*This section provides an overview of the policies and procedures that guide the Foundation's grant-making activities from submission through implementation.*

### GRANT SOLICITATION, REVIEW AND APPROVAL PROCESS

#### ***Grant Solicitation and Application***

- The Foundation directly solicits early-phase concept memos and proposals from organizations known to be well suited to perform the mission and programs of the Foundation.
- The Foundation also coordinates grant solicitations by issuing periodic calls for:
  - Letters of intent to provide short-term detailed scoping grants to inform and guide the Foundation's research initiatives and priorities;
  - Proposals for multi-year research on topics related to smoking cessation and harm reduction and associated products; and
  - Proposals for building capacity of researchers and other stakeholders related to the mission of the Foundation.
- The Foundation does not accept unsolicited proposals.
- Requests for proposals and letters of intent (the "grant applications") are submitted through the Foundation's online grants submission system, which provides explicit and clear guidelines to grant applicants.
- Grant applicants are required to provide the following information on prescribed templates:
  - Applicant Information (including organization name, address, telephone number, website, organization mission, geographic focus, contact name for organization, contact email and mailing addresses and contact telephone number);
  - Organizational Documents of the Applicant (including governing documents, most recent financial statements, list of names of board of

directors or trustees and key staff, most recent government filing and/or annual report);

- Tax-Exempt Status of the Applicant (including copy of exemption ruling)

Foreign Applicants are required to provide additional information related to tax status, governing documents, operations and financial support;

- Detailed Proposal including the background or *curriculum vitae* of the key personnel who will participate in and be directly responsible for the research supported by the grant;
- Detailed Budget; and
- Detailed Work Plan.

- The Foundation maintains separate files for each grant applicant in which all correspondence and other information are retained.

### ***Grant Application Review and Approval***

- All grant applications are evaluated by either the Health, Science, and Technology Grant Committee or the Agriculture and Livelihood Grant Committee. This evaluation also includes a review of the applicant's ability to appropriately administer the grant.
- In addition to the Grant Committees, the Foundation has other systems and processes in place providing various levels of leadership and oversight, including: the Foundation's Board of Directors, a scientific advisory board, and a best-in-class legal team.
- Grant applicants selected for further consideration will be contacted to further develop the parameters of the proposal.
- All grant applicants are advised of the outcome of their applications on the date and timelines announced with the call for proposals.
- The terms and conditions of all grants awarded under this process are memorialized in a formal grant agreement.

### **DISCLOSURE OF POTENTIAL CONFLICTS**

- The Foundation maintains a Conflict of Interest Policy, which can be found in Article VIII of the Foundation's Bylaws, ([https://www.smokefreeworld.org/sites/default/files/uploads/foundation\\_for\\_a\\_smoke-free\\_world\\_inc.\\_-first\\_amended\\_and\\_restated\\_bylaws.pdf](https://www.smokefreeworld.org/sites/default/files/uploads/foundation_for_a_smoke-free_world_inc._-first_amended_and_restated_bylaws.pdf)). As part of the grant application process, each applicant is required to disclose in writing:
  - any direct or indirect ownership or investment interest in, or any past or present financial relationship, including, but not limited to, salary or wages,

remuneration, consulting fees, honoraria, expert testimony fees or speaking engagement fees received from, a tobacco company or any commercial entity involved in the development and/or commercialization of nicotine-containing products or the tobacco reduction or smoking cessation field or that otherwise may be affected by the scientific research conducted or funded by the Foundation.

## **ETHICAL GUIDELINES IN BIOMEDICAL RESEARCH<sup>1</sup>**

### ***Introduction***

- Bioethics is a broad field that connects biological sciences with ethical concerns. Research ethics is a subfield of bioethics that focuses on issues related to basic and clinical research. In this Grant Policies and Procedures the term “research” refers to any systematic investigation designed to develop or contribute to generalizable knowledge. This includes, but is not limited to, medical experiments, surveys and observational studies, neuroimaging and genetic studies. (These ethical guidelines do not apply to marketing research which involves insight survey, polls, or focus group.)

### ***Background***

- At the request of the United States Congress in 1974, experts in medicine, law and ethics came together to form the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research (*i.e.*, the “National Commission”). As part of its findings, the National Commission stated that research involving humans should be guided by three (3) ethical principles: beneficence, respect for persons, and justice.

### ***Beneficence***

- *Beneficence* provides that all research must be done for the good of both the participants and the broader community. Implied in the term beneficence is another principle, called nonmaleficence, which holds that research should not result in harm.

### ***Respect for Persons***

- *Respect for persons*, sometimes called “respect for autonomy,” emphasizes the importance of informed consent from competent individuals, and special protection for vulnerable populations (described below).

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<sup>1</sup> Ethical issues related to harm reduction, and how those issues are to be addressed, will be added to a revised version of this Grant Policies and Procedures later in 2018.

## ***Justice***

- *Justice in human subjects* research means that the goods or benefits derived from research must be distributed fairly.

The order of these principles does not indicate the importance of one over another; they are understood to conflict at times and must be balanced and weighed accordingly.

## **ETHICAL STANDARDS**

- The ethical standards governing the research on human beings can be divided into three subfields: (1) standards relating to research protocol; (2) standards relating to the selection and treatment of research subjects; and (3) standards regarding the relationships with the communities in which the research is conducted.

### ***Standards Relating to Research Protocols***

- Scientific validity
  - A precondition of exposing human subjects even to minimal risk in research is that the research design can be scientifically valid. This requires attention to the basic scientific structure of the research and the competence of the research team, and a realistic appraisal of the research team's ability to enroll a sufficient number of subjects, in reasonable time, to complete a study with statistical power; and of the feasibility of carrying the study to completion within the political or cultural contexts in which the research is to be conducted.
- Risk – Benefit Ratio
  - Researchers need to assess the risks and benefits of their research to their study population. A research study poses only “minimal risk” to human subjects when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Minimal-risk studies may be justified by relatively small benefits to the study population, but as risk and inconvenience increase, studies need to be justified by greater benefits to study subjects or to their communities.
- Social Value – Aims of Study
  - Researchers must assess the social value of their research separately from their assessment of the risk benefit balance faced by potential human subjects. Who will benefit from the research, and in what way?

- Social Value – Publication
  - The social value of research is enhanced by its broad dissemination. Related to publication, the World Health Organization (“WHO”) has called for a minimal set of information on all clinical trials to be registered in a public database. The Foundation accepts the WHO’s mandate, and therefore requires that, for each trial on human subjects undertaken by its grantees, before the enrollment of any subjects begins, all elements of the WHO’s Trial Registration Data Set must be registered.
- Conflicts of Interest
  - A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. The Institute of Medicine defines a conflict of interest as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.” Primary interests of concern include promoting and protecting the integrity of research and the welfare of subjects. Secondary interests “may include not only financial gain but also the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues.”

### ***Ethical Standards Relating to Human Participants***

- Respect for Study Subjects
  - Study designers and researchers must respect research subjects. This includes not only respect for the decisional autonomy of subjects or their surrogates, but also respect for their role in and centrality to the research enterprise, and sensitivity to their cultural norms.
- Fair Selection of Subjects
  - The study population must be recruited and selected not only in a way that ensures the scientific validity of the research, but also in a way that ensures the just distribution of the benefits and burdens of research. Care should be taken to ensure that particular sub-populations (whether or not they are identified as “vulnerable,” see below) are neither excessively recruited into research nor excluded from it.

➤ Informed Consent

- Grantees must obtain the voluntary informed consent of all subjects, or, in the case of subjects who are not capable of giving informed consent, the permission of a legally authorized surrogate decision-maker. Informed consent should normally be documented in writing.

For these purposes, vulnerable human beings are persons who are incapable of protecting their own interests because they lack sufficient power, intelligence, education, resources or other attributes needed to protect their own interests. Vulnerable subjects include (among others) children, pregnant women and their developing fetuses, persons from impoverished communities, persons who lack capacity, prisoners, severely ill persons, and subordinate members of hierarchical groups.

***Ethical Standards Relating to the Community***

- All research on human subjects must be approved in advance by one or more scientific and ethical review committees or Institutional Review Boards (“IRB”). Review committees must be independent of the grantee’s research team, and no benefit they may derive from the research should be contingent on the outcome of their review. Review committees should conduct periodic reviews of all research they have approved, including monitoring study progress.
- When research is conducted outside the U.S., and especially when research is conducted on vulnerable populations, it is preferable that a national or local ethical review should be conducted by a committee that has established ties to the community where the research will be conducted, and to the subject population. Advice from local authorities can help avoid unnecessary problems and expense. All research must be approved by a locally approved IRB or equivalent AND approved through a corporate review process.

**GRANT AGREEMENT**

***General Terms***

- Each grant is made generally pursuant to a written grant agreement which specifies, among other terms:
  - The purposes of the grant, including the proposed protocol, budget and work plan, with specified targets as may be appropriate;
  - The length of time of the grant;
  - The pay-out schedule of funds; and
  - Eligible and ineligible costs under the grant.

- The grant agreement requires that the grant funds be kept in a separate, segregated account for the exclusive use of the grant.
- The grant agreement requires the grantee to repay any portion of the grant funds which are not used for the purposes of the grant and to return any excess (unexpended) grant funds to the Foundation.
- The grant agreement requires the grantee to:
  - Use valid and scientifically rigorous study protocols designed to yield results that advance scientific or medical knowledge;
  - Present and interpret its study results accurately;
  - Subject any resulting publications to appropriate peer review; and
  - Disclose that the Foundation is the source of the grant in any resulting publication.

### ***Grant Funds***

- The grant agreement provides that grant funds may not be used:
  - For any purpose other than the charitable, scientific or educational purposes specified in the grant agreement;
  - To carry on propaganda, or otherwise attempt to influence legislation (*i.e.*, lobbying);
  - To influence the outcome of any specific election or to carry on, directly or indirectly, any voter registration drive;
  - To make any grant to an individual for travel, study or other similar purposes; or
  - To make grants to organizations unless certain requirements are met, as specifically provided in the grant agreement.
- The grant agreement requires that grant funds only be used for the purpose of the grant and in accordance with the grant application and as detailed by the project budget.
- The grant agreement requires that the grantee not make any expenditures of grant funds above or below 10% of the amounts for any line item in the budget, and also requires the grantee to notify the Foundation of any actual or expected line item expenditure changes of 10% or more. Any changes to expenditure levels for any line items will be made only to promote the grant's purpose more efficiently or effectively.

- The grant agreement allows grantees to use grant funds to make payments to third parties, provided the funds are used only for the grant's purpose and provided further, that the grantee obtains prior approval from the Foundation for any payment of more than \$10,000 to a third party not previously disclosed in the grant application and approved by the Foundation.

### ***Reports, Recordkeeping, Monitoring and Evaluation***

- The grant agreement requires the grantee to keep accurate records and accounts of the grant implementation in a manner that shows the grant funds separately on the grantee's books of account.
- The grant agreement requires the grantee to provide narrative and financial reports, at least annually, on the use of grant funds and the progress toward completing the project. The financial report should reflect expenditures of the grant funds, and any income earned thereon, according to the categories of the approved budget. These reports are reviewed by the Foundation to determine if the grant is progressing as anticipated and to verify that the expenditures are in accordance with the grant proposal, budget and work plan.
- The grant agreement requires the grantee to provide a final report no later than 90 days after the grant term has ended that describes how the grant funds were used, identifies any third parties receiving grant funds from the grantee and describes the progress made toward meeting the grant's goals.
- The grant agreement generally requires the grantee to engage the services of a qualified auditor to conduct an annual audit of the grant to be submitted to the Foundation within 90 days after the completion of each year of the grant agreement.
- The grant agreement requires the grantee to retain copies of accounting records and reports submitted to the Foundation for at least four years after completion of the use of grant funds with such records and reports to be made available to the Foundation for examination upon request.
- The grant agreement provides for monitoring and evaluation by the Foundation which may include:
  - Allowing the Foundation's staff, consultants or agents to verify, by examining documents or by means of site checks, the implementation of the grant and conduct a full evaluation at the end of the grant by an independent third party; and
  - Giving appropriate access to the Foundation's staff, consultants or agents or the independent third party to the sites and locations at which the grant is being implemented, including information systems, as well as documents and databases concerning the technical and financial management of the grant.

### ***Intellectual Property and Publishing***

- The grant agreement establishes the appropriate ownership of any intellectual property developed under the grant.
- The grant agreement provides, to the extent legally possible, that the grantee will make its raw research data available for secondary analyses and review on an open access platform.
- The grant agreement provides, unless prohibited by law, that the grantee will have the freedom to publish its findings, studies and results in the form submitted to the Foundation.
- Grantees shall publish only under the auspices of their research organizations.
- If the grantee has ownership of the intellectual property under the grant agreement, the Foundation will be provided a non-exclusive, royalty-free, worldwide, perpetual license to all of grantee's rights in all means and media now known or hereafter developed to reproduce, distribute, publicly display and perform and create derivative works from all works developed by grantee as part of the grant.

### ***Publicity***

- Any publication relating or referring to the Foundation, in whatever form or by whatever means or medium, including internet, must include the following statement: *'Produced with the help of a grant from the Foundation for a Smoke-Free World, Inc. The contents, selection and presentation of facts, as well as any opinions expressed herein are the sole responsibility of the authors and under no circumstances shall be regarded as reflecting the positions of the Foundation for a Smoke-Free World, Inc.'*
- Grantees shall provide accessibility to all data and control of statistical analysis by investigators, auditors, and reviewers.
- Grantees shall take all necessary measures to publicize the fact that the Foundation has financed its research activities. The grantee shall acknowledge the Foundation's grant in its internal and annual reports, and in any exchanges with the media.
- Grantee specifically authorizes the Foundation to publish its name, address, the purpose of the grant and the maximum amount of the grant.

### ***Anti-Terrorist Financing Laws and Anti-Corruption Policy***

- The Foundation must comply with anti-terrorist financing laws, including U.S. Executive Order 13224 and the USA Patriot Act, which prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. The grantee must take all reasonable steps necessary to ensure that none of the grant funds shall be used in support of or to promote violence, terrorist activity, or related training, whether directly through its own activities and programs, or indirectly through its support of or cooperation with, other persons and organizations known to support terrorism or that are

involved in money laundering activities. These efforts by grantee shall include, but not be limited to, taking all reasonable steps necessary to ensure that none of the grant funds are paid to any person or organization identified on the terrorist-related lists promulgated by the U.S. Government, which are currently accessible through the following U.S. Treasury Department website: <https://www.treasury.gov/ofac/downloads/sdnlist.pdf>

- The grantee is required to certify in the grant agreement compliance with the requirements of the Foundation’s Anti-Corruption Policy.

### **EXPENDITURE RESPONSIBILITY AND EQUIVALENCY DETERMINATIONS**

- The Foundation, as a private foundation, exercises “expenditure responsibility” in accordance with Section 4945(h) of the Internal Revenue Code of 1986, as amended, with respect to the making of a grant to an organization, domestic or foreign, that is not a public charity. Expenditure responsibility requires a private foundation to exert all reasonable efforts and establish adequate procedures to see that a grant is spent solely for the purpose for which it was made, obtain full and complete reports from the grantee on how funds were spent and make full and detailed reports with respect to such expenditures on an annual basis on the private foundation’s Form 990-PF filed with the U.S. Internal Revenue Service.
- The general requirements for expenditure responsibility are a pre-grant inquiry regarding the grantee, a written agreement, and annual reports from the grantee. The grant-making procedures the Foundation has established, as outlined above, including the application process, the terms of the grant agreement and the required reporting and recordkeeping by the grantee, shall comply with the requirements of “expenditure responsibility.”
- Alternatively, with respect to the making of a grant to a foreign organization that is the equivalent of a public charity under U.S. law, in lieu of exercising expenditure responsibility, the Foundation may make an “equivalency determination.” An equivalency determination involves a determination that a foreign charity is the equivalent of a public charity under U.S. law based on a legal opinion analyzing the foreign organization’s ability to qualify as such, which involves an analysis of financial information, governing documents, programs and activities and other relevant information.



## GRANT AGREEMENT

This grant agreement (this “Agreement”) is between Foundation for a Smoke-Free World, Inc., a Delaware non-profit, non-stock corporation (“FSFW”), and [NAME OF GRANTEE], a [JURISDICTION] [ORGANIZATIONAL FORM] (“Grantee”), and dated as of the \_\_\_ day of \_\_\_\_\_, 20\_\_.

In consideration of the mutual covenants and promises of the parties, the parties agree as follows:

### 1. THE GRANT

FSFW agrees to provide a grant (the “Grant”) to Grantee subject to the following terms:

Amount of Grant (the “ <u>Grant Amount</u> ”)	
Purpose of Grant (the “ <u>Purpose</u> ”)	
Time Period and Duration of Grant (the “ <u>Grant Term</u> ”)	

### 2. GRANT PAYMENT SCHEDULE

FSFW shall follow the following payment schedule:

Grant Payment Schedule	Amount	Reporting Schedule
Initial Payment	___% of Grant Amount	Upon execution of Agreement.
Second Payment	___% of Grant Amount	Upon receipt and approval of 1 <sup>st</sup> Interim Narrative and Financial Reports due on _____ for the reporting period of _____ through _____.
Third Payment	___% of Grant Amount	Upon receipt and approval of 2 <sup>nd</sup> Interim Narrative and Financial Reports due on _____ for the reporting period of _____ through _____.
Final Payment	___% of Grant Amount	Upon receipt and approval of 3 <sup>rd</sup> Interim Narrative and Financial Reports due on _____ for the reporting period of _____ through _____.

**3. ADDITIONAL TERMS AND CONDITIONS**

This Agreement is subject to all Additional Terms and Conditions listed on Attachment A, all of which are expressly incorporated in, and made a part of, this Agreement.

**4. AUTHORITY**

Each of FSFW and Grantee has the full legal right, power and authority to enter into and perform its obligations under this Agreement. The persons executing this Agreement represent that they have been duly authorized to execute this Agreement on behalf of FSFW or Grantee, as applicable.

**IN WITNESS WHEREOF**, the undersigned have caused this Grant Agreement to be duly executed as of the date first set forth above.

**FOUNDATION FOR A SMOKE-FREE WORLD, INC.**

By: \_\_\_\_\_  
Name:  
Title:  
Date:

**[NAME OF GRANTEE]**

By: \_\_\_\_\_  
Name:  
Title:  
Date:

## ATTACHMENT A

### ADDITIONAL TERMS AND CONDITIONS

#### 1. GRANT ADMINISTRATION AND FINANCIAL PROVISIONS

##### 1.1 Use of Funds.

- (a) No Grant funds may be used:
  - (i) To carry on propaganda, or otherwise to attempt, to influence legislation;
  - (ii) To influence the outcome of any specific public election, or to carry on, directly or indirectly, any voter registration drive;
  - (iii) To make any grant to an individual for travel, study or other similar purposes;
  - (iv) To make any grant to an organization unless:
    - (A) such organization is described in sections 509(a)(1) or (2) of the U.S. Internal Revenue Code of 1986, as amended and in effect (the “Code”);
    - (B) such organization is described in Code section 509(a)(3) (other than an organization described in clause (i) or (ii) of Code section 4942(g)(4)(A));
    - (C) such organization is an exempt operating foundation as defined in Code section 4940(d)(2)); or
    - (D) the Grantee exercises expenditure responsibility with respect to such grant in accordance with Code section 4945(h); and
  - (v) To undertake any activity for any purpose other than one specified in Code section 170(c)(2)(B) (*i.e.*, charitable, scientific or educational purposes).<sup>1</sup>

All funds must be used in compliance with the laws of the country in which Grantee is conducting the activities that are the subject of this Grant.

- (b) Grant funds may be used only for the Purpose and according to Grantee’s grant application, as revised by the parties, which is attached hereto and incorporated herein by reference as Exhibit A and as detailed by the project

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<sup>1</sup> Excerpts of the Code sections referenced above are available upon request from FSFW.

budget, attached hereto and incorporated herein by reference as Exhibit B (the "Budget"). Grantee shall not make any expenditures of Grant funds above or below 10% of the amounts for any line item in the Budget, and shall immediately notify FSFW of any actual or expected line item expenditure changes of 10% or more. The parties acknowledge and agree that any changes to the expenditure levels for any line item shall be made only to promote the Purpose more efficiently or effectively.

- (c) Grantee may use Grant funds to make payments to third parties, provided such funds are used only for the Purpose provided, however, that Grantee must obtain prior approval from FSFW for any payment of more than \$10,000 to any third parties not already disclosed in the application and approval process.
- (d) If Grantee expends or commits any part of the Grant funds for purposes or activities other than the Purpose, without prior written consent from FSFW, Grantee must repay such amount, plus interest in the amount of one-month Libor plus 1%, to FSFW.
- (e) The Grant Funds may be used only for the charitable, scientific or educational purposes described in the Work Plan in Exhibit C and are to be spent within the Grant Term. Any funds not expended or committed for the purposes of the Grant, or within the period specified, shall be returned to FSFW.
- (f) The total amount paid by FSFW to Grantee shall not exceed the maximum amount set forth in the Budget, even if the total actual eligible expenditures exceed the Budget. If the eligible costs at the end of this project are less than the Budget, Grantee will return to FSFW any un-expended funds and any funds expended on ineligible costs. Grantee accepts that the Grant can under no circumstances result in a profit for Grantee and that expenditures must be limited to eligible costs.
- (g) Grantee shall ensure that Grant funds are kept in an institutional account separate from any other funds for the exclusive use of the Grant. Grantee shall have access to these funds on an immediate basis.
- (h) Any Grant funds not used or committed by Grantee for the Purpose, within the specified time period stated above must be returned to FSFW unless FSFW in writing authorizes Grantee to use the funds in some other manner or extends the time period of this Agreement.
- (i) Grantee must not use funds corruptly in order to obtain or retain business or secure an improper advantage from a foreign government official. Grantee

certifies that it is in compliance with the requirements of FSFW's Anti-Corruption Policy and Certification, attached hereto as Exhibit D.

Grantee must also take all reasonable steps necessary to ensure that none of the Grant funds shall be used in support of or to promote violence, terrorist activity, or related training, whether directly through its own activities and programs, or indirectly through its support of or cooperation with, other persons and organizations known to support terrorism or that are involved in money laundering activities. These efforts by Grantee shall include but not be limited to taking all reasonable steps necessary to ensure that none of the Grant funds are paid to any person or organization identified on the terrorist-related lists promulgated by the U.S. Government, which are currently accessible through the following U.S. Treasury Department website: <https://www.treasury.gov/ofac/downloads/sdnlist.pdf>

## 1.2 Eligible Costs.

- (a) To be considered as eligible, the direct costs associated with the project must comply with the following rules:
- (i) They must be necessary for carrying out the project, be provided for in the Budget, and comply with the principles of sound financial management, in particular value for money and cost effectiveness;
  - (ii) They must have actually been incurred by Grantee during the Grant Term, and the parties acknowledge and agree that costs incurred during the Grant Term may be eligible costs even if actual payment in respect of such costs is made after the expiration of the Grant Term; and
  - (iii) They must be recorded in the accounts or tax documents of Grantee and must be identifiable, verifiable and backed by original documents of supporting evidence.
- (b) Subject to Section 1.2(a) and subject to the Budget, the following direct costs shall be deemed eligible:
- (i) The costs of staff assigned to the project, corresponding to actual salaries plus fringe benefits and other remuneration related costs; salaries and costs must not exceed those normally borne by Grantee;
  - (ii) Travel and subsistence costs for staff taking part in the project, provided they do not exceed those normally borne by Grantee;
  - (iii) Purchase costs for equipment (new and used) and services, provided they correspond to market rates;

- (iv) Costs of consumables and supplies; and
- (v) Costs deriving directly from the requirements of the Agreement (dissemination of information, evaluation specific to the project, audits, translation, reproduction, insurance, *etc.*) including financial services costs (in particular the costs of bank transfers).

1.3 Ineligible Costs. The following costs are ineligible expenditures for which Grant funds may not be used:

- (a) Debts and provisions for losses or debts;
- (b) Interest owed;
- (c) Items already financed in another framework;
- (d) Sub Grant/Sub contract expenditures;
- (e) Currency exchange losses; and
- (f) Taxes.

1.4 Indirect Costs.

- (a) A lump sum not exceeding 10% of the direct eligible costs of the project may be claimed as indirect costs to cover the administrative overheads incurred by Grantee for the implementation of the project.
- (b) Indirect costs are eligible provided that they do not include costs assigned to another category in the approved Budget.

1.5 Record-Keeping, Audits and Inspections.

- (a) Grantee agrees to keep adequate books and records in a manner approved by FSFW to enable the expenditure of Grant funds to be easily and accurately confirmed and FSFW reserves the right to conduct an audit of Grant funds during or after the Grant Term. At reasonable times, Grantee shall permit FSFW representatives to enter Grantee's premises upon request by FSFW, speak with Grantee staff relating to the Grant and the funded activities, and inspect or copy any documents or materials relating to the Grant or the funded activities.
- (b) Grantee shall keep accurate and regular records and accounts of the implementation of the project using a dedicated double-entry bookkeeping system as part of or as an adjunct to Grantee's main accounts. This

dedicated system shall be managed in accordance with procedures dictated by professional practice.

- (c) Accounting records related to the Grant, as well as copies of the reports submitted to FSFW or its agent(s) shall be kept by each Grantee for at least four (4) years after completion of the use of the Grant funds and shall be made available to FSFW for examination upon request.
- (d) Grantee shall allow FSFW or its agents, staff or consultants to verify, by examining the documents or by means of on-the-spot checks, the implementation of the project and conduct a full evaluation at the end of the project by an independent authority. Furthermore, Grantee shall give appropriate access to FSFW, its agents, staff or consultants or to such independent authority to the sites and locations at which the project is being implemented, including information systems, as well as documents and databases concerning the technical and financial management of the project and take all steps to facilitate their work. Documents must be easily accessible and filed so as to facilitate their examination and Grantee must inform FSFW or its agents, staff or consultants of their precise location.
- (e) Grantee shall engage the services of a qualified auditor to conduct an annual audit of this project. Each annual financial audit report must be submitted to FSFW no later than ninety (90) days after the completion of each year of this Agreement.

#### 1.6 Scientific Integrity.

To safeguard the scientific integrity of the project, Grantee shall:

- (a) Use valid and scientifically rigorous study protocols designed to yield results that advance scientific or medical knowledge;
- (b) Present and interpret its study results accurately; and
- (c) Subject any resulting publications to appropriate peer review.

## **2. INTELLECTUAL PROPERTY AND PUBLICITY RELATING TO GRANT**

- 2.1 As between the FSFW and Grantee, all rights in and to any patented matter, copyrights, trade dress, trademarks, and other intellectual property rights that result from the Purpose of the Grant shall vest in the name of the Grantee.
- 2.2 Unless prohibited by law, the Grantee shall have the freedom to publish its findings, studies and results in the form submitted to FSFW. To the extent legally possible,

Grantee shall make its raw research data available for secondary analyses and review on an open-access platform.

- 2.3 Grantee shall take all necessary measures to publicize this Grant and disclose that FSFW is the source of the Grant in any resulting publications, and shall acknowledge the Grant in its internal and annual reports, and in any exchanges with the media. Any publication relating or referring to FSFW, in whatever form or by whatever means or medium, including internet, must include the following statement: *‘Produced with the help of a grant from the Foundation for a Smoke-Free World, Inc. The contents, selection and presentation of facts, as well as any opinions expressed herein are the sole responsibility of the authors and under no circumstances shall be regarded as reflecting the positions of the Foundation for a Smoke-Free World, Inc.’*
- 2.4 Grantee and FSFW shall coordinate efforts to publicize this Grant, the related activities, and related accomplishments. Grantee shall provide FSFW with an opportunity to review and revise the text or content of any proposed press or publicity materials or public statements (“*Publicity Materials*”) of Grantee that in any way refer to the Grant or to FSFW. Grantee shall provide FSFW any proposed Publicity Materials for approval no later than two (2) weeks before the intended release date. Without prior written consent, Grantee shall not issue any such public statements referencing FSFW or any logos, trademarks or service marks of FSFW. But nothing in this paragraph shall restrict Grantee’s ability to publish the results of the research in peer reviewed journals and relevant media.
- 2.5 In its own publicity relating to this Grant or its outcomes, FSFW may use any results from research, photos, information, materials pertaining to Grantee’s activities provided by Grantee or publicly available relating to the Grant including but not limited to Grantee’s name, address, the purpose of the Grant, the maximum amount of the Grant and any Grantee logos or trademarks. FSFW shall make every reasonable effort to consult with Grantee to harmonize the publicity of FSFW and Grantee.
- 2.6 For publicity and other purposes, Grantee also grants FSFW a non-exclusive, royalty-free, worldwide, perpetual license to all of Grantee’s rights in all means and media now known or hereafter developed to reproduce, distribute, publicly display and perform and create derivative works from all works developed by Grantee as part of this Grant or the funded activities.
- 2.7 Subject to Section 2.4, FSFW grants to Grantee a limited license to use and display the trademarks, service marks and/or logos owned by FSFW currently or in the future (the “*Marks*”), solely in connection with the Publicity Materials, and in connection with this Grant. Grantee agrees that it shall not challenge FSFW’s ownership of the Marks, or the validity of the Marks. Grantee agrees that it will

not use any marks or logos that are similar to, resemble or are likely to be confused with the Marks. Grantee's use of the Marks in this manner shall not confer to Grantee any right, title or interest, either direct or indirect, in or to the Marks. Upon termination of this Agreement for any reason whatsoever, Grantee shall cease to use or display the Marks, or any logo or mark of any other party that implies a connection with FSFW or the services or Grant provided under this Agreement.

### 3. NOTIFICATION AND REPORTING

- 3.1 Grantee must immediately notify FSFW if there is any change to the Grant or Grant activities or if at any point during the Grant Term anything happens that affects Grantee's capacity or ability to use the funds for the Purpose, including but not limited to any changes in Grantee's purpose, financial condition, leadership or key project staff, to the Grant's objectives or activities, or to the timing of the activities; or to any significant related factors or circumstances.
- 3.2 Using the Grant Interim Report Form provided by FSFW, Grantee shall provide FSFW with reports ("*Interim Narrative and Financial Reports*"), at least annually and as scheduled in Section 2 of the Agreement above, that describe Grantee's progress toward completing the funded project and achieving its goals, and that describe Grantee's use of the Grant funds received to date and the committed or planned use of any remaining Grant funds, including the identification of any third parties that have received Grant funds or commitments of Grant funds from Grantee. The Interim Narrative and Financial Reports shall also include a representation by Grantee that there has been no improper diversion of Grant funds or use of Grant funds for lobbying or political activities.
- 3.3 Using the Final Grant Report Form provided by FSFW, Grantee shall provide FSFW with a final report no later than ninety (90) days after the Grant Term has ended that describes how the Grant funds were used, identifies any third parties receiving Grant funds from Grantee, and describes the progress made toward meeting the Grant's goals and includes a representation by Grantee that there has been no improper diversion of Grant funds or use of Grant funds for lobbying or political activities.
- 3.4 In addition to the financial and technical narrative reports, written reports on the use of capital equipment purchased with Grant funds shall be submitted to FSFW or its agent(s) as of the end of its fiscal year in which such Grant funds were used to purchase capital equipment and for the next two (2) succeeding fiscal years. No further reports on equipment need be furnished unless requested by FSFW. Each report should confirm that such equipment has not been used for any purpose prohibited by the terms of this Agreement.

#### 4. CONFIDENTIALITY

- 4.1 Grantee shall treat as confidential, during as well as after, the performance of any work under this Agreement, any information, including any personal information defined by FSFW or its agent(s), to which Grantee becomes privy as a result of acting under this Agreement (“Confidential Information”).
- 4.2 Confidential Information shall not include information that, at the time of disclosure: (i) is or becomes generally available to and known by the public other than as a result of, directly or indirectly, any breach of this Section 4 by Grantee; (ii) is or becomes available to Grantee on a non-confidential basis from a third-party source, provided that such third party is not and was not prohibited from disclosing such Confidential Information; (iii) was known by or in the possession of Grantee before being disclosed by or on behalf of FSFW; (iv) was or is independently developed by Grantee without reference to or use, in whole or in part, of any of FSFW’s Confidential Information; or (v) is required to be disclosed under applicable federal, state or local law, regulation or a valid order issued by a court or governmental agency of competent jurisdiction. Grantee shall: (A) protect and safeguard the confidentiality of the Confidential Information with at least the same degree of care as Grantee would protect its own confidential information, but in no event with less than a commercially reasonable degree of care; (B) not use the Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement; and (C) not disclose any such Confidential Information to any person or entity, except to Grantee representatives who need to know the Confidential Information to assist Grantee, or act on its behalf, to exercise its rights or perform its obligations under the Agreement. Grantee shall be responsible for any breach of this Section 4 caused by any of its Representatives. On the expiration or termination of the Agreement, Grantee shall promptly return, and shall require its representatives to return to FSFW all copies, whether in written, electronic or other form or media, of the Confidential Information, or destroy all such copies and certify in writing to FSFW that such Confidential Information has been destroyed. In addition to all other remedies available at law, FSFW may seek equitable relief (including injunctive relief) against Grantee and its representatives to prevent the breach or threatened breach of this Section 4 and to secure its enforcement.

#### 5. TERMINATION OF THE GRANT AGREEMENT

- 5.1 The time period for Grantee’s use of the Grant funds shall be extended, when necessary, to account for any delays made necessary by factors beyond Grantee’s control. FSFW may also change the schedule of Grant payments to correspond with any significant delays in the activities funded by the Grant.

- 5.2 This Agreement may be terminated, in whole or in part, by either party at any time upon forty-five (45) days' prior written notice of termination to the other party.
- 5.3 In the event that any party hereunder shall materially breach any of the terms and conditions contained in this Agreement to be kept, observed or performed by it, then the other party may terminate this Agreement, at its option and without prejudice to any of its other legal or equitable rights, by giving the party who committed the breach thirty (30) days' notice in writing, specifying the breach.
- 5.4 In the event that any party shall become insolvent or shall suspend its operations or shall file a voluntary petition or answer admitting to the jurisdiction of a court as to the material allegations of insolvency, or shall make an assignment for the benefit of creditors, then the other party may thereafter immediately terminate this Agreement by giving written notice of termination to such party or its receiver.
- 5.5 If FSFW determines that any Interim Narrative and Financial Report fails to provide adequate evidence of Grantee's successful progress toward completion of the funded Grant's activities, as described in Exhibit A, FSFW may exercise its right to terminate this Agreement, as set forth herein.
- 5.6 The provisions of Section 4 shall survive the expiration or termination of this Agreement.

## 6. NOTICES

All notices and demands under this Agreement shall be made in writing and shall be communicated by e-mail or conventional mail to the mail address of the receiving party.

## 7. ADDITIONAL PROVISIONS

- 7.1 Grantee shall notify FSFW of any reporting or other legal requirements or restrictions relating to this Grant placed on FSFW by the laws or rules of the country where Grantee is located or the Grant-supported activities take place.
- 7.2 Grantee confirms that no substantial goods or services have been received by FSFW in return for this Grant other than the accomplishment of the Grant Purpose and the receipt of research or other resulting findings.
- 7.3 Grantee may not assign its interest in this Agreement to any third parties without the prior written consent of FSFW.
- 7.4 This Agreement does not create any relationship between the parties other than grantor and grantee, and neither party has the power or authority to speak or act for the other or to bind the other party in any way in any transactions with any third parties. In addition, FSFW shall in no way be responsible for any actions or

omissions of Grantee or its employees, agents, contractors, or licensees relating to this Agreement or the subject project or for any expenses, damages, claims, suits, actions, judgements, injuries or costs whatsoever, including attorney's fees, arising out of, or in any way connected with activities undertaken by Grantee or its employees, agents, contractors, or licensees relating to this Agreement or the subject project.

- 7.5 This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and may not be changed orally, but only by an agreement in writing signed by both parties, as set forth in Section 7.10 below. This Agreement also supersedes any prior understandings, agreements or representations by or among the parties, written or oral, which may have related to the subject matter of this agreement in any way. In the event that this Agreement is translated into another language, this English version shall control in any disputes about the terms of the Agreement or their interpretation and nothing in the translated version shall supersede or amend any of the terms of this Agreement.
- 7.6 The waiver by either party of any breach of any provisions of this Agreement by the other shall not operate or be construed as a waiver by that party of any subsequent breach by the other.
- 7.7 Should FSFW and Grantee extend the time period of this Agreement or if Grantee received additional Grant funds from FSFW, all other provisions of this Agreement will remain in effect unless altered or superseded by a subsequent agreement signed by both parties.
- 7.8 The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.
- 7.9 If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.
- 7.10 This Agreement may only be amended, modified, or supplemented by an agreement in writing signed by each party hereto.
- 7.11 No waiver of any of the provisions of this Agreement shall be effective unless it is in writing and signed by the party waiving its right. Any waiver authorized on one occasion is effective only in that instance and only for the purpose stated, and does not operate as a waiver on any future occasion. No failure to exercise, or delay in exercising, any right, remedy, power, or privilege arising from this Agreement shall constitute a waiver thereof; nor shall any single or partial exercise of any right,

remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

- 7.12 This Agreement shall be governed by and construed in accordance with the laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction).
- 7.13 This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

FORM OF GRANT AGREEMENT

**Exhibit A**

Application

FORM OF GRANT AGREEMENT

**Exhibit B**

Budget

FORM OF GRANT AGREEMENT

**Exhibit C**

Work Plan

FORM OF GRANT AGREEMENT

**Exhibit D**

Anti-Corruption Policy and Certification

FORM OF GRANT AGREEMENT