



PRIZE AND AWARD 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 goals of the Foundation in granting prizes and awards are to recognize past achievement in independent medical, agricultural and scientific research that has advanced smoking cessation and the field of tobacco harm reduction and that addressed the impact of the reduced world-wide demand for tobacco (collectively, “Achievements” and individually, an “Achievement”), free from the influence of any commercial entity that may be affected by the scientific research outcome. The Foundation will recognize one or more Achievements by selecting deserving Achievements to receive a prize or award pursuant to these policies and procedures.

No prize and award made by the Foundation recognizing an Achievement is intended to be a grant for travel, study or other similar purposes.¹ As such, no prize or award made by the Foundation pursuant to these policies and procedures is intended to finance any future activity of a recipient. Moreover, there is no requirement that a recipient perform any further research or other activity and no conditions or restrictions are imposed on the manner in which a prize or award may be expended by a recipient.

In furtherance, the Foundation will:

- Select appropriately qualified individuals, organizations and institutions to receive a prize or award recognizing outstanding past Achievements 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;

¹ Such grants are described in section 4945(d)(3) of the Internal Revenue Code of 1986, as amended and in effect (the “Code”). Specifically, no prize or award of the Foundation is intended to be a grant for travel, study or other similar purposes by an individual within the meaning of Code section 4945(d)(3) and the Treasury Regulations promulgated thereunder.

- 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.
- Select, as appropriate, projects to receive a prize or award that 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 prizes and awards 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) 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 prizes and awards is conducted in a transparent manner and includes explicit and clear guidelines for applicants. The selection process for prizes and awards 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 prizes and awards that ensures that the 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 prize and award recipients and prize and award 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 prize and award recipients or prize and award 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 prize and award recipients have the freedom to publish their findings, studies and results in the form submitted to the Foundation. To the extent legally possible, the Foundation requests that prize and award recipients make their raw research data available for secondary analyses and review on an open-access platform.

An overview of the Foundation's prize and award policies and procedures is presented below.

Additional information about the Foundation can be found at www.smokefreeworld.org.



PRIZE AND AWARD POLICIES AND PROCEDURES

This section provides an overview of the policies and procedures that guide the Foundation's prize and award activities from submission through implementation.

PRIZE AND AWARD SOLICITATION, REVIEW AND APPROVAL PROCESS

Prize and Award Solicitation and Application

- The Foundation directly grants prizes and awards to individuals and organizations known to have performed independent scientific research consistent with the mission and programs of the Foundation.
- The Foundation also coordinates prize and award solicitations by issuing periodic calls for applications for a prize or award, which shall specify the purpose of the prize or award, the amount(s) of prize(s) and award(s), eligibility and how recipients will be selected.
- The Foundation does not accept unsolicited applications for a prize or award.
- Applications for prizes and awards are submitted through the Foundation's online prize and award submission system, which provides explicit and clear guidelines to applicants.
- Prize and award applicants are required to provide the following information on prescribed templates:
 - Applicant Information (including individual or 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 organization Applicants (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 organization Applicants (including copy of exemption ruling)

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

- Detailed information regarding the research to be recognized by the receipt of a prize or award from the Foundation, including the background or *curriculum vitae* of the individual or key personnel who participated in and were directly responsible for the research.
- The Foundation maintains separate files for each prize and award applicant in which all correspondence and other information are retained.

Prize and Award Application Review and Approval

- All prize and award applications are evaluated by either the Foundation’s Health, Science, and Technology Grant Committee or the Foundation’s Agriculture and Livelihood Grant Committee.
- 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.
- Prize and award applicants selected for further consideration will be contacted by the Foundation.
- All prize and award applicants are advised of the outcome of their applications on the date and timelines announced with the call for applications.
- The terms and conditions of all prizes and awards made under this process are memorialized in a formal prize or award agreement, which shall recognize the outstanding research of the recipient and shall not impose any future conditions or restrictions on the prize or award recipient.

PRIZE OR AWARD AGREEMENT

General Terms

- Each prize or award is made generally pursuant to a written prize or award agreement which specifies, among other terms:
 - The past achievement of the recipient being recognized;
 - The amount of the prize or award;
 - That the prize or award is not intended to finance any future activity of the recipient; and

- No conditions or restrictions are imposed on the manner in which a prize or award may be expended.

Intellectual Property

- The prize or award agreement requests, to the extent legally possible, that the prize or award recipient will make his, her or its raw research data available for secondary analyses and review on an open access platform.
- If the prize or award recipient has ownership of the intellectual property that is the subject of a prize or award agreement, the Foundation will be provided a non-exclusive, royalty-free, worldwide, perpetual license to all of recipient'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 the recipient as part of the prize or award.

Publicity

- The prize or award recipient specifically authorizes the Foundation to publish his, her or its name, address, the achievement recognized and the amount of the prize or award.

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 prize or award recipient must take all reasonable steps necessary to ensure that none of the prize or award 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 recipient shall include, but not be limited to, taking all reasonable steps necessary to ensure that none of the prize or award 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 prize or award recipient is required to certify in the prize or award agreement compliance with the requirements of the Foundation's Anti-Corruption Policy.

DISCLOSURE OF POTENTIAL CONFLICTS, ETHICAL GUIDELINES IN BIOMEDICAL RESEARCH AND ETHICAL STANDARDS

Issues related to disclosure of potential conflicts, ethical guidelines in biomedical research and ethical standards are set out in the attachment to these policies and procedures.



PRIZE AND AWARD POLICIES AND PROCEDURES

ATTACHMENT

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). As part of the prize and award 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 (i) the scientific research conducted or funded by the Foundation or (ii) any prize or award made by the Foundation.

ETHICAL GUIDELINES IN BIOMEDICAL RESEARCH

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 Prize and Award 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.

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
 - Recipients of a prize or award must have obtained 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.