STeP ETHICS AND SAFETY GUIDE

The Sanitation Technology Platform

CONTENTS

GLOSSARY

Acronyms and Abbreviations

CP	Commercial Partner
the Foundation	Bill & Melinda Gates Foundation
IEC	Information, Education, and Communication
IRB	Institutional Review Board
NIH	National Institutes of Health
PMI	Project Management Institute
STeP	Sanitation and Technology Platform
TP	Technology Partner
WHO	World Health Organization
WSH	Water, Sanitation, and Hygiene

Introduction

The Sanitation and Technology Platform (STeP) project is committed to providing Bill & Melinda Gates Foundation (the Gates Foundation) partners tips, tools, and best practices to successfully manage field testing for new sanitation technologies. In partnership with the Gates Foundation, STeP has developed this manual as one of several guidance and training resources. The structure of the manual follows what STeP considers the key areas of focus for ethics and safety. As such, the manual is organized into the following chapters:

1. Institutional Review Board (IRB)
2. Informed Consent
3. Regulations and Permissions
4. Standards
5. Field Testing Safety

Purpose of This Manual

Whether testing technologies in the field or collecting information about and with users, Partners will confront a number of ethical and safety issues. Adhering to the highest ethical standards, and ensuring compliance with local rules and regulations is essential. Accordingly, STeP is committed to supporting Partners as they navigate the requirements and rules, ensure ethical conduct, adhere to local and national regulations, and comply with the rules and guidance of implementing and partner organizations.

Regulations and standards that apply to field testing activities can cross national, subnational, and organizational boundaries. By following regulations, standards, and good ethical practices, we protect people, property, and information; appropriately manage risks; acquire consent; and respect customs and cultures. We also ensure that we meet contractual and legal obligations of our respective organizations. Careful and diligent management of safety and ethics will also support trust with field partners, preserve reputations, and strengthen relationships, further increasing the probability of project success and longer term market viability of innovations.

In light of this, the purpose of this manual is to share STeP learnings with Partners of the Gates Foundation to support them as they manage field-testing activities of their own, drive collaboration and alignment among teams, and promote good ethical practices. We hope this manual will be distributed widely, and used to support any individuals and organizations

conducting field-testing of new sanitation technologies. We welcome any and all feedback and input from partners so that we may build on our collective experiences.

Overview of STeP

The Sanitation Technology Platform (*STeP*) helps transformative technologies reach the 2.5 billion people worldwide who don't have access to safe, affordable sanitation. STeP provides a full range of services including field testing, market intelligence and user insights to help inventors and industry develop products and services that address market and consumer needs. STeP is a collaboration of global experts and organizations that removes risk and streamlines the path to market, fostering greater success for its partners. STeP support STeP offers a holistic approach that addresses technical, market, and non-market factors in parallel. While testing technologies in the field, STeP incorporates user insights and market intelligence to inform design and business planning. In short, STeP ensures that its partners have the resources and data they need to develop and launch products.

STeP not only supports individual partners, but functions as a platform for the broader sanitation community, converting knowledge and insights gained through doing into resources, tools, and tips that can be used by others invested in testing and commercializing technologies.

For more information on STeP, please visit www.stepsforsanitation.org.

1. IRB

Prior to implementing any new research activity involving human subjects, STeP recommends that project teams submit their research plans for review and approval to a certified Institutioanl Review Board, "IRB" within their organization or in their home country (i.e., domestic-based), and any other relevant, international bodies. The IRB may elect to review and consider the study or deem the study not relevant (not human subject research). Project teams should work with all stakeholders to rectify any concerns or answer any questions that the IRB may present in its review. Once the project teams receive approval or are deemed not relevant, they may then engage one or more local IRBs. In some cases, the STeP project team may help identify through consultation with local partners. Project teams should not move forward with human subject research plans until after they receive domestic and local IRB approval. Throughout the process of drafting and implementing human subject research plans, the project teams must ensure compliance with all required IRB regulations.

1.1 Key Principles for IRBs

All organizations that conduct research involving human subjects must use IRBs. If your organization or collaborating organization does not have an internal IRB, feel free to contact STeP, and we will help you consider options. Options may include forming an IRB or identifying a collaborating partner with a pre-existing IRB, in your country and/or in or nearby testing locations. In some cases, STeP may be able to offer direct support.

IRBs use the set of basic principles outlined in the *Belmont Report*, issued in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, to guide their review of proposed research protocols. The *Belmont Report* outlines three basic principles:

- **Respect for Persons.** Potential research subjects should be treated as autonomous agents who have the capacity to consider alternatives, make choices, and act without undue influence or interference from others.
- **Beneficence.** The two basic principles of beneficence are (1) do no harm and (2) protect from harm by maximizing possible benefits and minimizing possible harm.
- **Justice.** This ethical principle requires fairness in the distribution of the burdens and benefits of research.

1.2 Necessity of an IRB Review

For IRB to be applicable, it should meet two key criteria: (1) research is conducted, and (2) the research should pertain specifically to human subjects.

The following two subsections provide details on what constitutes "research" and "human subjects."

1.3 Research

Research is defined by U.S. regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." A systematic investigation is an activity that involves a prospective study plan that incorporates data collection, either qualitative or quantitative, and data analysis to answer study questions. This may include research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

Investigations that develop or contribute to generalizable knowledge are those designed to draw general conclusions. Knowledge gained from these investigations can be applied to populations or groups other than the population or group that was involved in the investigation itself. Results of these investigations can also be used to inform policy.

1.4 Human Subjects

A human subject is defined by U.S. regulations as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable (either directly or indirectly through coding systems) private information."

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) for its use to constitute research involving human subjects.

The specification that the data be "about whom" is an important distinction when researchers are interacting directly with individuals to collect data. If the data being collected are not about those individuals (about whom) but rather are about something that the individual happens to

have knowledge about (about what), then those individuals providing the data may not be human subjects. For example, asking a school principal to provide information on the average number of days that students attend school and to answer factual questions about the school policies on student absenteeism would not be "about whom"—these activities would be "about what." On the other hand, asking the principal what she thinks influences absenteeism and what changes she thinks should be made to improve school attendance or to refine school policies on absenteeism would be "about whom."

1.5 IRB Applicability and Approval

Project teams must engage IRBs to determine if a project involves research with human subjects, project teams cannot make this determination on their own because doing so can be quite complicated and nuanced.

The general rule of thumb is that any project that involves interacting with people, collecting information from people, or working with secondary data collected from people requires the project team to consult with an IRB to discuss the details of the planned project and obtain a formal determination of whether it involves research with human subjects.

If the IRB makes a determination that a project does not involve research with human subjects as defined by U.S. human subjects regulations (for U.S. organizations), then the IRB provides the project with a memorandum documenting this determination, and further IRB oversight of the project is no longer required.

If the IRB determines that the project is carrying out research with human subjects, then the IRB determines which of three possible levels of IRB review is required:

- **Exempt.** The project does not require ongoing IRB review after an IRB representative verifies the exemption status.
- **Expedited Review.** An IRB or chair member—rather than the full IRB committee—can review the project.
- **Full Review.** The full IRB committee must review the project.

1.6 Exempt Research

Certain types of research may be exempt from IRB review. This means that the IRB reviews the project to determine exempt status; it does not mean that no IRB review is required. Only the IRB—not the project team—can declare an exempt status.

1.7 Expedited Review

If the proposed research qualifies under U.S. regulations, an IRB or chair member—rather than the full IRB committee—expedites a review. Only the IRB—not the project team—can determine an expedited status. For an expedited review, the project leader typically will provide the needed information to the IRB, which will then determine whether the protocol can be approved or requires modification.

1.8 Full IRB Review

Any study that involves human subjects and does not qualify for exemption or expedited review must go through a full IRB review. Full IRB review involves the full IRB committee evaluating a research protocol at a convened meeting. The frequency of the convening can influence timelines, as some organizations review "as needed", while others review submissions on a regular and perhaps infrequent schedule (i.e., once a quarter).

During these meetings, the project leader has an opportunity to describe the research and answer questions from the IRB members. The board then votes to approve, approve contingent on required modifications, defer approval upon receipt of further information, or disapprove the study (or amendment). After the meeting, the project team receives a signed copy of the minutes with the committee's decision. If the study is deferred, the project or amendment must be resubmitted to another convened meeting of the IRB committee. If the project was approved contingent on required changes, the IRB will send the project team instructions on how to submit the revisions. After the committee has approved the study, and all required changes have been submitted and accepted, the IRB will issue a signed approval notice to the project leader. The project team may contact the human subjects or receive specimens/information only after they receive the approval notice from the IRB.

2. INFORMED CONSENT

Informed consent is a person's voluntary agreement, based on adequate knowledge and understanding of relevant information, to participate in a project activity related to implementation, research, monitoring, or evaluation. When testing technologies in the field and, particularly with vulnerable populations, Partners may find it tempting to assume consent, given that the tested technology may provide a better option than existing solutions. However, we consider gaining informed consent a mandatory requirement for all field-testing activities irrespective of the type of technology being tested or associated conditions.

Prior to commencement, field testing plans, system design and configuration, and the expected impact of testing should be communicated to the potential participants. When preparing the communication, project teams should incorporate the key principles of informed consent into their presentation and/or materials. The project teams are responsible for communicating these principles effectively to participants. The three primary principles are the following:

- **Information.** Provide adequate information about the study, including purpose, procedures, risks, and benefits.
- **Comprehension.** Present the information in a way that is understandable to the person.
- **Voluntariness.** Convey that participation in any activity is always a free choice.

STeP has found a town hall meeting with potential participants to be an excellent method of communication, especially if in a particular apartment block or neighborhood. Both the meeting and the informed consent forms should be in the vernacular language so participants accurately comprehend both the letter and spirit of the informed consent process. The result of the meeting should be signed informed consent forms from willing participants. In settings where participants are not comfortable with providing signatures, an authorized project team member should obtain oral consent from participants and record that consent was orally obtained. Please note, the communication leading to informed consent will most often accompany, not displace, wider information, education and communication (IEC) activities.

When preparing an informed consent form for participant signature, project teams should ensure that the following elements are included in the form:

- Sponsor and purpose of the study
- Approximate number of participants
- Procedures to be followed
- Expected duration of participation
- Any planned re-contacts
- Acknowledgment that participation is completely voluntary

- Acknowledgment that participants are free to withdraw at any time or refuse to answer any question without a need for any justification
- Acknowledgment that a decision about participation will not affect the usual benefits received (if applicable)
- Expected risks and benefits
- Any compensation to be received, if applicable (this is not a "benefit" as mentioned above)
- How privacy will be maintained
- How the confidentiality of participants' data will be protected
- Who will have access to data (or biospecimens, if applicable)
- Who will answer questions; there must be two contacts, as applicable
    - A study/project contact, to answer study- or project-related questions
    - An IRB contact, to answer questions about the person's rights as a research participant

Project teams should note that in giving informed consent, persons do not waive any right or release those conducting the project activities from liability for negligence. They should also note that informed consent is an ongoing process, and not simply a signed piece of paper. As testing plans evolve, project teams are responsible for ensuring that participants are informed and agree to continue participating in the testing. Lastly, it is important to note that the above information consists of general guidelines and best practices for informed consent. As applicable, the IRBs the project engages with may provide more specific guidance for informed consent on a particular study or research activity.

For additional questions on informed consent, or if you are interested in seeing an example of an informed consent form, please contact STeP by navigating to the Contact Us section of www.stepsforsanitation.org.

3. REGULATIONS AND PERMISSIONS

Regardless of the country in which testing will take place, a number of municipal, state, and central government regulations will apply. Project teams must understand and comply with all rules and regulations during the course of field-testing. Project teams should work with stakeholders to proactively identify all applicable regulations, understand them, and develop strategies for compliance. This should be one of the first initiatives a project team undertakes when establishing a field-testing program. Project teams should work closely with applicable home office teams and with the Gates Foundation to appropriately address any real or potential regulatory concerns, in close collaboration with government stakeholders.

Project teams should be diligent in ensuring that permissions are received and compliance with applicable rules and regulations is achieved. This requires project teams to maintain a robust oversight function at the field level, and to thoroughly document actions against plans. Project teams should also develop risk assessment plans and matrices to manage risks associated with permission acquisition and regulatory compliance. If additional information on risk management is needed, STeP encourages project teams to review the excellent resources available on the Project Management Institute's (PMI) webpage, www.pmi.org.

4. STANDARDS

Project teams should seek to identify, understand, and apply standards to its planning and project operations. STeP has developed a number of standards to support its partners' field-testing efforts, to include, among others:

- ***Global Testing Parameters and Protocols for Sanitation Technologies:*** This best practices guide is for testing sanitation technologies in the field. It was created to provide scientifically rigorous testing protocols for partners who will be testing new sanitation technologies in the field.
- ***Field Operations Manual: Tips, tools and best practices for testing sanitation technologies in the field.*** This manual was created to provide detailed instructions and general requirements necessary for key stakeholders to successfully navigate all phases of the field-testing life cycle.
- ***Technology User Studies: Starting survey instrument.*** This document was created to provide partners with adaptable survey instruments designed to systematically capture the perceptions, attitudes, and behaviors of key stakeholders throughout the field-testing process.

Based on needs, STeP will continue to develop specific standards and guides for partners over time. All such resources will be posted on www.stepsforsanitation.org. In the absence of specific, STeP-created resources, we encourage partners to draw on standards and best practices developed by relevant, respected institutions such as the National Institutes of Health (NIH), the World Health Organization (WHO), and the World Bank.

5. FIELD TESTING SAFETY

As partners are aware, there are a substantial number of physical and biological risks associated with field-testing sanitation technologies. Project teams engaged in field-testing are responsible for ensuring a safe environment for both staff and participants. Safety must be at the forefront of the mind of the project team, and active measures should be in place to ensure the safe operation of the technology. Project teams should also ensure that their organization has sufficient insurance in the appropriate geography prior to field testing commencement.

Given the number and complexity of safety concerns, project teams and users may encounter in the field associated with testing of advanced systems and managing human waste, STeP is creating a comprehensive Field Testing Safety checklist that will serve as a living document. Needs and requirements will vary by Partner, technology, and testing plan. If you would like to review/receive the checklist, please contact Dr. Sonia Grego at sgrego@rti.org.

STeP encourages partners to review the G*lobal Testing Parameters and Protocols for Sanitation Technologies* and the *Field Operations Manual*, mentioned above. The former provides detailed guidance on the liquid, solid, air, sound, energy, and operational testing that should occur. The *Field Operations Manual* provides broad guidance on the operational procedures needed to ensure a safe environment for field-testing. If you have specific questions related to field testing safety that are not covered in the aforementioned guides, please contact STeP by navigating to the *Contact Us* section of http://www.stepsforsanitation.org/.