**[Insert Network Name] Bill of Rights and Responsibilities for Tuberculosis Research**

This document provides a short list of the rights and responsibilities you have while you participate in a [Insert Network Name] clinical trial. The purpose of this Bill of Rights and Responsibilities is to help research participants act on their behalf and in partnership with study staff to ensure they have all the information needed for their protection during study participation. See the study informed consent form for more information. Your dedicated time and active participation in clinical research studies are invaluable and deeply appreciated.

**Participant Rights**

As a participant in a [Insert Network Name] Tuberculosis-related research study, you have the right to:

* **Receive knowledge and information about TB, clinical research, services, and resources** which you can use to reduce the likelihood that you and people close to you might experience TB disease.
* **Have all questions answered.**
* **Have all known information, including potential risks and benefits of study participation, presented to you in a way you can understand.** You will be told about any new information learned during the study.
* **Refuse to join the study or decide to leave the study at any time.** You can also refuse to join any follow-up studies. You will not lose any of the rights referred to in this document if you refuse to join the study or leave the study.
* **A discrimination-free study environment.** Your age, race/ethnicity, gender identity, sexual orientation, personal choices, values, beliefs, and cultural context will be respected by the people running the stud**y.**
* **Assistance resolving study-related social problems and/or discrimination.** With your permission, we can talk to the people you ask us to contact to explain more about your participation in the study.
* **Maintain your legal and human rights.** As a trial participant, you are not waiving any of your rights.
* **[Customize for Network/Site] Referral to available counseling, support, medical, and treatment services for illnesses you suffer during the study.**
	+ Right to referral to medical services for illnesses or health conditions that arise during the study that are not related to TB.
	+ Right to treatment and care for TB, or referral to treatment and care services if not provided by the study team, if you are diagnosed with TB at any point during the study.
* **[Customize for Network/Site] Treatment for physical injuries, should they occur, for any injury more likely to be related to study products or procedures than to any other cause, to the extent described in the study consent form.** There are funds to pay for treatment of these injuries. A group that reviews safety issues for the study makes the determination of relatedness. You can have the decision reviewed if you disagree. In some cases, the funds may not be enough to cover full treatment. The groups involved in the study will seek more funds if needed but cannot guarantee them. Your study staff will provide more information on this issue and will answer any questions you may have or put you in touch with the person most qualified to answer your questions.
* **Assistance in meeting study commitments.** The study site will provide you with a list of available resources, e.g., call reminders, and transportation to study visits at the site.
* **Confidentiality.** Communications and records about you and your participation in the study will be shared only as needed to conduct the study, or as required by law. See your study site’s informed consent form for more information.
* **[Customize for Network/Site] Be offered a study identification card that shows that you are in the study.** This optional card will include the phone number and/or address of a person who can provide additional information and the study visit schedule.
* **Be informed whether you received a placebo or an active study product when the study ends, or when medically necessary.**
* **Be updated about progression of studies, told when study results may be available, and study staff will share and explain study results.**
* **Right to know if there are costs associated with participation and whether you will receive compensation for your participation.**

**Participant Responsibilities**

As a participant in a [Insert Network Name] TB-related research study, you have the responsibility to:

* **Review and demonstrate an understanding of all the materials given to you, including the informed consent documents.** Ask for explanation about any information you do not understand before you agree to participate in the study. You can also ask questions anytime during the study.
* **Make an informed decision about whether to participate in this study after weighing the risks and benefits.** It is important to know what the study is about. The staff will assist you in this. If it helps you decide, talk to people you trust and respect about whether joining the study is right for you.
* **Tell study staff as soon as possible if you experience discrimination and/or social harm that you think may be related to your trial participation.**
* **Depending on study requirements, if you are able to get pregnant, avoid pregnancy during the study by using effective contraception methods.** The staff will review effective contraception methods with you.
* **Keep your study appointments.** Tell study staff as soon as possible if you need to reschedule an appointment.
* **Treat study staff with respect.**
* **Keep confidential the participation of others in the study.**
* **Give the study staff complete and accurate study-related information.** Tell the study staff about any changes in your contact information or health information.
* **Follow the instructions of the study staff to the best of your ability.** Work together with the study staff to maintain your health and safety during the trial.
* **Tell study staff as soon as possible if you are unable to continue or if you decide to stop your study participation.**
* **Do not participate in other clinical trials while in this study except with the permission of the study team.**

**Study Staff Responsibilities**

The [Insert Network Name] study staff, including the Principal Investigator (PI) have the responsibility to:

* **Consult the local community on research related issues and ensure the fair representation of participants in the clinical trial.**
* **Be answerable to and receive direction from a research-governing body, such as an Institutional Review Board (IRB) or similar research ethical review committee.**
* **Obtain informed consent from participants for all-research related activities or interventions.** If there are significant study changes, consent from current participants will be obtained again.
* **Conduct the study in an ethical manner, including protecting the rights, confidentiality, and well-being of participants in the research study.** At the end of the study, the study staff has the responsibility to inform participants which product they were receiving as well as share research study results with participants and the community.
* **[Customize for Network/Site] Provide appropriate referral for counseling and TB prevention services and/or referral for TB treatment services and/or psychosocial services if needed during the study.**
* **Respond to all questions and concerns of study participants in a timely manner.**
* **Treat study participants with respect.**

**Additional Resources:**

For additional resources and information, visit https://www.hanc.info/resources/sops-guidelines-resources/community.html#tb-community

[Institution Name]

[Department]

[Address 1]

[Address 2]

[Contact phone #]

[url]