

**Charter of the Nantucket Steering Committee
for the management of
the Genetic Mice Project on Nantucket**

Approved by the Nantucket Board of Health January 16, 2020

This document provides guidelines for the operation of the Nantucket Steering Committee which oversees the Genetic Mice Project¹ on Nantucket.

INTRODUCTION

The Genetic Mice / Mice Against Ticks project aims to fight tick-borne disease on islands like Nantucket and Martha's Vineyard by reducing the number of infected ticks. Since most ticks become infected when they bite infected mice, the project aims to break the disease transmission cycle and reduce the number of infected ticks by releasing tick-borne disease resistant white-footed mice derived from the local population. The Mice Against Ticks Research Team plans to produce Lyme-resistant mice first followed by mice that either resist multiple tick-borne diseases and/or ticks.

The concept of the project was proposed by Dr. Kevin Esvelt and the research for the project is being conducted at the Media Lab at the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, the Dana-Farber Cancer Institute and Tufts University under the direction of Dr. Esvelt.

The Nantucket Steering Committee was established to ensure that project research would be guided by the community members who stand to be most affected by Mice Against Ticks. The Nantucket Steering Committee is made up of community representatives elected by the Nantucket Board of Health. The Board of Health have entrusted their representatives with overseeing the Mice Against Ticks project on Nantucket. Steering Committee members are expected to foster responsive, responsible, transparent and inclusive project guidance through regular public meetings and the oversight powers and responsibilities established in this document.

The Steering Committee reflects the skills and perspectives of its members and their knowledge of community values and interests as Nantucket residents and non-resident homeowners. The Steering Committee will work to channel the voice of the larger community as representatives and by facilitating communication between the Mice Against Ticks Research Team, the Board of Health, other government bodies, other geographic locations involved in the project and the

¹ "Genetic Mice Project" is the title of the project used on Nantucket. "Mice Against Ticks" is the title of the project adopted by the scientific research team. Mice Against Ticks will be used in this document for consistency with the scientific team, the press and other geographic locations involved in the project (at this time, Martha's Vineyard).

Nantucket community. However, the Steering Committee itself will not speak on behalf of all or any particular community member.

MEMBERSHIP

The Nantucket Steering Committee will be composed of six to twelve multi-background individuals chosen by the Board of Health. One member of the Steering Committee shall be a member of the Nantucket Select Board.

ROLE & FUNCTION OF THE STEERING COMMITTEE

The specific functions and responsibilities of the Steering Committee are detailed below:

- 1) **Facilitating Community Input.** The primary function of the Steering Committee will be to facilitate community involvement in project guidance in the following ways:
 - a) **Public Events.** The Steering Committee will facilitate public meetings with the MAT Research Team.
 - b) **Coordination with other Nantucket Boards and Commissions.** In addition to the Board of Health, the Steering Committee will be available for consultation to the Select Board, the Conservation Commission or any governmental or non-profit island entity regarding the project.
- 2) **Research & Development.** The Steering Committee will advise the MAT Research Team in order to help facilitate the incorporation of local values, perspectives and needs into project development. More specifically, the Steering Committee will help customize MAT biotechnology for Nantucket by voting on research options, such as mouse designs and release strategies to be used on Nantucket.
- 3) **Oversight & Monitoring.** The Steering Committee will review the Research Team's results and plans at regularly scheduled Steering Committee meetings in order to:
 - i) Provide general project supervision
 - ii) Review study designs for mouse testing and field trials
 To perform these duties, the Steering Committee may ask the research team for additional information at any time and consult outside experts.
- 4) **Go/no go approval.** Following the successful completion of regulatory review, the Steering Committee will vote to determine if the committee recommends that the Board of Health (or an appropriate Board/Committee) propose a Warrant for approval at a Town Meeting.

Additionally, the Steering Committee will provide input on any "stopping rules" for the Mice Against Ticks project in collaboration with the Martha's Vineyard Steering

Committee and the Data Safety Monitoring Board (see below). These rules may pause or resume any or all aspects of the project that would affect Nantucket or other geographic areas within the purview of the Data Safety Monitoring Board and following a vote by the Steering Committee.

RELATIONSHIPS & EXPECTATIONS

Board of Health

The Steering Committee will function as an advisory board to the Board of Health. The Committee will present a project update to the Board of Health at least once-a-year or as requested by the Board.

MAT Research Team

The purpose of the relationship between the Steering Committee and the MAT Research Team is to ensure the provision and incorporation of community perspectives into project decision-making. To foster communication and enable project oversight, the Research Team agrees to the following requirements:

- 1) A senior member of the Research Team will provide a project update at all regularly scheduled Steering Committee meetings.
- 2) At any time, the Steering Committee may request scientific information from the Research Team, which must be supplied in a reasonable time frame. While the Research Team does not anticipate noncompliance due to confidentiality, the Research Team agrees to make any confidential information available to the Steering Committee through a Non-disclosure Agreement.
- 3) When the Research Team initiates federal and state regulatory review, the Steering Committee will revisit the Research Team's expectations and likely impose reporting requirements, such as detailed reports on the regulatory review process and its findings.

Martha's Vineyard Steering Committee

Where possible, the Nantucket Steering Committee will work with the Martha's Vineyard Committee to ensure consistency between the two committees and their approach to project management.

Data Safety Monitoring Board

The Data and Safety Monitoring Board (DSMB) is a committee *independent* of the Nantucket and Martha's Vineyard Steering Committees, the MAT Research Team or funding agencies with the authority to recommend termination of the project. A single DSMB will have oversight responsibility for both Nantucket and Martha's Vineyard.

The Nantucket and Martha's Vineyard Steering Committees will collaborate with the MAT Research Team to appoint the DSMB's Chair. The Chair will then appoint the other members. DSMB members may be compensated for their time.

Duties of the Data Safety Monitoring Board include:

- 1) Preventing harm to the environment, animals and humans
- 2) Defining the “stopping rules” in collaboration with the Nantucket and Martha’s Vineyard Steering Committees
- 3) Reviewing all study designs and providing feedback to the Steering Committees at regular intervals
- 4) Recommending discontinuing or altering the design of the project at pre-determined times or at any time in the interest of safety
- 5) Reviewing project compliance and progress at specified intervals and ad hoc if requested by either Steering Committee about any issue or potential issue
- 6) Recommending to the Steering Committees if the project should proceed on the islands of Nantucket and Martha’s Vineyard once the field trial has been completed
- 7) All reports issued by the DSMB will be made public

POLICIES & PROCEDURES

The Nantucket Steering Committee shall function under all regulations specified in Nantucket Town Rules, Massachusetts Open Meeting Laws and Conflict of Interest Laws.

PROJECT DECISION POINTS

Laboratory phase – production of immune mice	Evaluation 1	Introduction to uninhabited island(s)	Evaluation 2	Introduction to Nantucket
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Evaluations below represent the view of the Nantucket Steering Committee. The criteria for other communities may be different.

Evaluation 1

Project go/ no go recommendation by DSMB

If go, project continues if:

- Regulatory approval obtained for the next phase
- Approval for the use of a private island is obtained from the landowner/local government involved
- Nantucket Board of Health continues to express interest in the project

Evaluation 2

Project go/ no go recommendation by DSMB

If go, project continues if:

- Regulatory approval obtained for the next phase
- Nantucket Steering Committee votes to recommend that the Board of Health (or an appropriate Board/Committee) propose a Warrant for approval at a Town Meeting
- Town Meeting approves the project