



## OPEN SCIENCE POLICY

### Background

Agora Open Science Trust (“Agora”) is a Canadian registered charity whose mission is to advance the public good by engaging in, supporting, and promoting open scientific research as a mechanism to:

- accelerate the discovery and development of new medicines affordable to all; and
- increase the efficiency, transparency, reproducibility, and socio-economic impact of medical and scientific research.

In implementing its mission, Agora seeks to enter research partnerships (i) with wholly-owned subsidiaries of Agora engaged in specific open science drug discovery initiatives or other open projects, as well as (ii) with a broad network of scientists and institutions across academia, government, philanthropy, and industry willing to collaborate in the open.

The objective of this Open Science Policy is to ensure that the outputs of Agora’s open partnerships – be they new knowledge, data, research tools, technologies, services, or breakthrough medical therapies – are made available, accessible, and affordable to the communities who may benefit from them.

### Guiding Principles

Agora’s Open Science Policy is grounded in the following core principles:

- Open and prompt sharing of scientific knowledge, data, and research tools improves research efficiency and accelerates discovery by facilitating broad collaboration, by avoiding duplication of effort, and by enabling the scientific community to more quickly apply past learnings to generate new hypotheses to address unsolved needs.
- The pursuit of patents to protect the outputs of scientific research can undermine the discovery of new knowledge and the development of new medical breakthroughs by diverting resources away from research, by necessitating the imposition of restrictive proprietary agreements that impede collaboration and delay scientific disclosure, by eroding norms in the scientific community around knowledge sharing, and by deterring others from taking up and employing new knowledge in follow-on research or in unanticipated applications.

- Transparency in scientific research builds public trust and furthers the public good by enabling independent verification of analyses and conclusions. Transparency in the development and approval of new medicines also builds public trust and furthers the public good by permitting independent scrutiny of assertions made in regulatory submissions and drug product marketing materials, by enabling independent secondary analyses and meta-analyses that may lead to better-tailored applications for new medicines, and by promoting better-informed use of new medicines by prescribers and their patients. At the same time, open sharing of the results of human subjects research, including clinical trials, must be done in a manner consistent with the informed consent and privacy interests of research participants.
- Dissemination of the fruits of scientific research, whether through commercialization or other means, should be pursued with the primary goal of improving health outcomes, including by making new medicines and other new technologies and services available, accessible, and affordable to those who need them.

### Policy Requirements

In furtherance of these principles, Agora will ensure adherence to the following requirements:

1. **Open Sharing of Scientific Outputs.** All scientific outputs – including research-related results (both positive and negative), data, models, methodologies, reagents, and other tools – arising from collaborative research projects in which Agora or its wholly-subsidiaries provide funding or participate must be made publicly available as promptly as possible for research use by others, including in accordance with the following:
  - a) *Open Access Publication.* For research that is either funded or carried out by Agora or its wholly-owned subsidiaries, results must be published in journals that enable immediate open access and online discoverability under a Creative Commons Attribution (CC BY) or equivalent license, and manuscripts must be deposited into suitable pre-print servers by the date of submission for publication. Agora will strive to encourage collaborators making independent contributions to joint research projects to publish on the same terms.
  - b) *Open Data Practices.* Subject to requirement 3, all data arising from research projects in which Agora or its wholly-owned subsidiaries provide funding or participate must be deposited into freely accessible digital repositories in accordance with FAIR data principles (findable, accessible, interoperable, and reusable). Data generated for regulatory submissions for new medicines may be deposited under terms that prohibit third party use in competing regulatory filings, but such terms must not impair access and subsequent research use by the scientific community.

- c) *Facilitating Access to Research Tools.* All reagents and other research tools generated in projects in which Agora or its wholly-owned subsidiaries provide funding or participate must be openly shared with the research community at a reasonable cost (i.e., on a cost recovery basis) and under terms that both preserve the tools as a public resource and permit recipients to share them with third parties on the same basis.
2. **Approach to Intellectual Property.** Agora will ensure that all scientific outputs arising from research projects in which Agora or its wholly-owned subsidiaries provide funding or participate can be used in follow-on research without restriction. To that effect, Agora must ensure that all collaborators on joint research projects agree (i) not to file or assist in filing patent applications claiming resulting scientific outputs and (ii) not to pursue or enforce other intellectual property rights or contractual provisions in respect of such outputs to restrict research use by others. Agora or its wholly-owned subsidiaries may seek to obtain exclusive rights to use data arising from collaborative drug development programs in regulatory submissions, so long as the data are otherwise made available for research use in accordance with requirement 1(b).
3. **Human Subjects Research.** In all clinical trials and other human subjects research in which Agora or its wholly-owned subsidiaries provide funding or participate, Agora will ensure that the privacy and informed consent of human research participants is safeguarded and that all applicable laws, regulations, and ethical review processes are respected, including in connection with the open sharing of results, data, and materials (e.g. human tissue samples). Agora and its collaborators may restrict access to certain data or materials to the extent reasonably connected to protecting these interests, so long as good faith efforts are made to employ the least restrictive means available.
4. **Availability, Accessibility, Affordability, and Proceeds.** Agora will ensure, to the best of its abilities, that new medicines and other new technologies and services arising from its open discovery and development programs are made available, accessible, and affordable to those that need them. In the case of new medicines, Agora's wholly-owned subsidiaries may seek to partner with pharmaceutical companies to complete clinical trials, register, market, or sell the new medicines, so long as such partnerships include terms that ensure availability, accessibility, and affordability for patients. To entice companies to partner on such terms, Agora's wholly-owned subsidiaries may pursue, obtain, and license, in a manner otherwise consistent with this Open Science Policy, the various forms of data and market exclusivities and other regulatory incentives available to sponsors of new medicines. Any proceeds to Agora's wholly-owned subsidiaries from the distribution of new medicines or other products or services will be donated or distributed to Agora for use in furtherance of Agora's charitable mission.