

Roadmap for the Intellectual Property Working Group of GP-Write

Mission Statement: To promote and facilitate fair, transparent, and easy access and sharing of the technology, materials, data and innovation coming into and out of GP-Write. In this mission, we seek to create a level playing field for a wide variety of participants within the GP-Write community (academic and nonprofit institutions, for-profit companies, and citizen scientists) to collaborate on scientific discovery and technology development, while also providing appropriate incentives for industry to engage and invest in desirable, downstream commercial development of products and services based on the outputs of GP-Write.

The following Roadmap addresses immediate, mid-term, and longer-term objectives.

Immediate Objectives:

1. **Broad Statement of Principles:** Develop a statement of principles and policies that all GP-Write scientists, institutions, and companies can adopt.

Principles and policies related to intellectual property may address the following topics, among others:

- Creation and maintenance of a “safe harbor” for research within GP-Write
 - E.g., through a self-enforcing IP-nonassertion commitment
- The role of intellectual property within GP-Write (patent, copyright, trademark and trade secrets)
- Expectations and requirements for data and material exchange
- Areas where “open access” is required or desirable
- Ethical and social implications of intellectual property within GP-Write

2. **Develop an Intellectual Property Framework for the Initial GP-Write Project on Virus-Free Genomes**

Working with the scientific executive committee, other GP-Write Working Groups, and the institutions and other entities that will be involved in the Initial Project, we propose to develop an IP Framework geared specifically to the Initial GP-Write Project, with the understanding and expectation that aspects of this Framework may find applicability to subsequent GP-Write Projects

The Framework will provide the structure for addressing the following issues:

- **Background Intellectual Property**

- IP held by the institutions involved in the Initial Project and pre-dating the Initial Project
- Forms of Background IP: patents, trade secrets, know-how, data and databases, materials, reagents, research tools, models, expertise
- Ownership and Control of Background IP
 - Retained by the originator; or
 - Transfer ownership or control to a separate entity such as a repository/trust, nonprofit foundation, etc.
- Access, Use, and Sharing Strategies
 - Who can obtain access to the Background IP and under what conditions (i.e., user rights)
 - The extremes being:
 - Private access/Conditional
 - Access to project or consortium members only
 - Use conditions based on need for certain tasks, or to develop certain deliverables or products
 - Public domain/Unconditional
 - Access within and beyond GP-Write
 - Unconditional use (including outside of GP-Write)
 - Between these two extremes, customized hybrids and blends are possible and may be needed to create the proper set of incentives if both academic/nonprofit institutions and industry players will participate in the Initial Project
- **Foreground Intellectual Property**
 - IP created in the course of the Initial Project, including but not limited to future improvements and modifications to the Background and Foreground IP

- Brainstorm foreseeable outputs from the project and their potential applications
 - New research materials, technology platforms, research tools, models?
 - Downstream development of commercial products and therapies?
- Ownership and Control
 - Considerations and options are as outlined above for Background IP
 - How to handle joint origination/invention
- Role for Intellectual Property Protection?
 - Patents, Copyrights, and Trade Secrets
- Role for Open Source?
- Role for nonassertion pledge, defensive patent licensing, etc.?
- Access, Use and Sharing Strategies
 - Same basic concepts as outlined above under Background IP
 - Many options are available; here is a small set of examples:
 - Open access to research results; use limited by predefined boundaries
 - Sharing organized by an open-entry license model specifying the community's level of access and freedom to operate
 - Research results can be improved, modified and used for commercial and noncommercial purposes, but improvements and modifications must be provided back to the consortium
- **Management** of Background and Foreground IP
- **Legal instruments and agreements** – determine whether new agreements will be needed for the Initial Project

3. **White Paper**: Preparation of a white paper on intellectual property management models and regimes (e.g., patent pools, clearinghouses, open source, non-assertion pledges, etc.), particularly as applied to large scale, international scientific consortia and collaborations.

The paper will be used to inform the GP-Write community of the universe of alternatives so that suitable strategies may be employed as needed in the context of GP-Write scientific projects.

We will also aim to publish the white paper, or a distillation of it, as an example of intellectual property leadership within GP-Write, as many of our colleagues in the other working groups have expressed the desire that GP-Write be “out front” and forward-thinking with respect to removing barriers to the sharing of technology, materials, data and innovation.

Mid-term Objectives:

4. **Transfer of Knowledge and Materials**: Develop a streamlined, fair and “friction free” operating environment for the rapid transfer of both public and proprietary knowledge, data and materials within GP-Write.

We propose to start by addressing the transfer needs associated with the GP-Write Initial Project on Virus-Free Genomes; operating on the assumption that what we develop for this project will have applicability to subsequent GP-Write projects.

This objective may include the following elements, among others:

- Guidelines on what is expected to be exchanged and how it is to be done
- In conjunction with the Standards Working Group, develop a kit of tiered licensing/protection levels (e.g., public domain, BSD, GPL and proprietary) so that by a single stamp, a prospective user can quickly tell if an item can be used, what requirements/restrictions attach, and what type of authorization/documentation/permit is required.
- Model legal instruments and agreements (e.g., MTAs, licenses, export controls), ideally approved by the relevant academic institutions and companies, for the purpose of expediting transfer and achieving a level playing field across universities, nonprofit institutions, and companies, and across countries
- An automated process/system for complying with technical and legal requirements for exchange

- Seamless interfacing with data and material repositories.
5. **Coordination and Synergy with Other GP-Write Working Groups**: Continue to speak on a regular basis with the other GP-Write Working Groups and with individual GP-Write members to discuss intellectual property-related issues, solve immediate problems, and support their specific needs.

For example, we may be active in the following areas, among others:

- Working with the Public Communications Group on how to communicate intellectual property-related issues and concepts in GP-Write publications
- Supporting the needs of consortium members when difficulties arise in aligning the principles and guidelines of GP-Write with intellectual property-related requirements and contracts originating from their institutions or companies
- Development of consent procedures and language relating to the use of human samples

Longer Term Objectives:

6. **Tool Kit**: Develop a comprehensive “tool kit” of IP-related guidelines and model agreements tailored specifically to the needs of the GP-Write community, including, e.g., sponsored research and project funding, joint development, licensing for various types of use, how to manage publications, support for technology standards development, etc.