

Grand Challenges in Global Health: Preventing Preterm Birth initiative

Global Access Strategy and Intellectual Property Management Policy

Purpose:

The Global Alliance to Prevent Prematurity and Stillbirth (“GAPPS”), an initiative of Seattle Children’s, requires that innovations, products, and information are owned and managed for the purpose of facilitating (i) the access to affordable health solutions for the benefit of people most in need within the developing world¹ (the “Charitable Objective”), and (ii) the broad availability of data and information to the scientific community. GAPPS refers to this concept as a “Global Access Strategy.”

While acknowledging that Intellectual Property (“IP”) protection may or may not be appropriate to best further global access in support of the Charitable Objective with respect to any particular item of technology or information, GAPPS requires (the “Grantee”) to prepare a strategy for how any invention coming out of the project (“Project”) may be made accessible to the developing world in order to address health needs. GAPPS requires each Grantee, in consultation with the Grantee’s collaborators if such exist, to prepare a Global Access Plan (the “Plan” or “Global Access Plan”) that includes mechanisms and approaches to (a) identify Key Background Technologies and ensure freedom to achieve the goals of the Project, (b) secure, if necessary, and manage and allocate IP rights to meet the Charitable Objective, (c) report inventions, (d) publish research results of the Project (including making available data and materials), (e) describe post-project development plans, and (f) develop strategies, to the extent possible, for the commercialization and sustainability of the Project’s anticipated health solution in keeping with GAPPS’ Charitable Objective and Global Access Strategy.

Upon GAPPS approval, the Grantee’s Global Access Plan shall become a part of the grant agreement and a term obligating compliance. The section of this document entitled “Global Access Plan” describes the provisions that shall be addressed by the Plan. Please use this format to provide the requested information. Preparation of the Global Access Plan is the shared responsibility of the PI and the Grantee institution (“Grantee”).

As part of an annual progress report, Grantee will be required to provide an update of the Global Access Plan, including any new information regarding Key Background Technologies and Grantee’s rights to use the Key Background Technologies, the status of any patent applications and licenses for inventions made with GAPPS funding, and any other arrangements affecting IP rights for inventions made with GAPPS funding.

¹ *The developing world includes those countries defined as low income or low middle income by the World Bank – www.worldbank.org/data/countryclass/classgroups.htm.*

Global Access Plan

The following provisions shall be addressed in Grantee's Global Access Plan

1. Background Technology and Freedom to Operate

Grantee must conduct appropriate and ongoing due diligence with respect to the relevant background technologies to be used by Grantee and Grantee's collaborators/subgrantees in the Project, including ownership of intellectual property rights.

Background Technology is defined as pre-existing technology (including materials, methods, etc.) that the Project may use.

Key Background Technologies are defined as pre-existing technologies on which a project invention is or will be dependent.

Potential Key Background Technologies are defined as those technologies that are likely to become Key Background Technology.

1.1 Current Background Technology

GAPPS requires Grantees to disclose any relevant background technologies they are aware of. Using the table below, provide a list of known Key Background Technology including whether the technology is subject to a third party's intellectual property rights or other restrictions.

For each technology identified by Grantee as a Key Background Technology, indicate in the table whether Grantee has the rights to use the Key Background Technology for research and/or commercial purposes or describe the steps Grantee has taken to obtain such rights.

If the Key Background Technology is one without which the Project cannot proceed, documentation that Grantee has freedom to operate for eventual implementation in the developing world will be required before an award is made.

Table 1. Current Key Background Technologies (Example)

Key Background Technology	Source and/or owner	Subject of third party restrictions						
		Third party owner					Grantee owns	Grantee doesn't know
		Nature of agreement- Indicate MTA, CDA, license, etc.	Permission for Research use only (Y/N)	Permission for research with potential for commercial use (Y/N)	Permission for commercial use (Y/N)	Steps taken to obtain commercial license if not yet available**	(Y/N) If yes, and prior agreements related to the technology exist, see section 5.	Describe steps being taken to determine who owns

1.2 Potential Key Background Technology

Describe how and when future Potential Background Technologies will be identified; how additional Key Background Technologies added to the Project will be analyzed for IP status; and, how reasonable steps will be taken to obtain the rights needed for commercial use of any current or future Key Background Technologies for the benefit of the developing world. Whenever specific new Key Background Technologies are identified, Grantee must notify GAPPS and describe the steps being taken to obtain the necessary intellectual property rights to use the new Key Background Technologies for the benefit of the developing world. Continued funding is at GAPPS' discretion and is dependent on Grantee obtaining the rights to use the Key Background Technologies for the benefit of the developing world.

Third party rights to background technologies that might impede further development of GAPPS-supported inventions for the benefit of the developing world should be considered as a factor in decisions regarding which of multiple promising approaches will be pursued in the Project.

2. Future Development and Commercialization

Describe, to the extent possible, the plan or pathway to marketing/implementation of GAPPS-supported inventions arising from the Project for the benefit of the developing world. This should include strategies for production and distribution, including commercialization and marketing, or identification of non-commercial partners (e.g. NGOs, government or international/multilateral organizations) able to pursue implementation.

3. Management of IP Arising from the Project

GAPPS primary concern is ensuring the Global Access Strategy addresses: (i) access to affordable health solutions for the benefit of people most in need in the developing world (the Charitable Objective) and (ii) the broad availability of data and information to the scientific community. In order to assure that the Charitable Objective is met, and data and information is available broadly to the scientific community, Grantees must develop mechanisms for management of technologies and knowledge arising from the Project that are consistent with GAPPS' patent and licensing policies described in *Appendix A*. If Grantee has established patent and licensing policies, GAPPS will defer to those policies provided they are consistent with the Global Access Strategy and the policies in *Appendix A*. Grantee shall include provisions in all agreements with third parties for collaboration on any aspect of the Project, binding the third parties to the provisions of GAPPS' Global Access Strategy, and its patent and licensing policies.

Please describe your patent and licensing policies and how they address the Global Access Strategy and the requirements set forth in *Appendix A*.

3.1 Collaboration (or Inter-Institutional) Agreement

If collaborators are or will be involved in any aspect of the Project, Grantee shall execute formal agreements with the collaborators ("Collaboration Agreements"). The Collaboration Agreements shall take the form of a signed contract or a memorandum-of-understanding and must bind the collaborators to the GAPPS Global Access Strategy and the patent and licensing policies set forth in *Appendix A*. The Collaboration Agreements shall describe (a) the manner in which work under the grant is to be managed among the collaborators, (b) the allocation of intellectual property rights among the collaborators and whether rights may be granted to or otherwise held by entities outside the collaboration, (c) the management and allocation of grant funds and any audit rights, and (d) the resolution of any disputes that may arise.

Describe the nature of the agreements Grantee plans to execute and the provisions Grantee plans to include.

Grantee shall notify GAPPS of any pre-existing collaborations that may affect IP rights in GAPPS-supported inventions and upon GAPPS' request, Grantee shall provide GAPPS with copies of the collaboration agreements for GAPPS review.

Grantee shall notify GAPPS of any collaborations to be formed that may affect IP rights in GAPPS-supported inventions and upon GAPPS' request, Grantee shall provide GAPPS with copies of the collaboration agreements, prior to the execution of those agreements, for GAPPS review. GAPPS will review the agreements for consistency with the Global Access Strategy and the patent and licensing policies set forth in *Appendix A*. GAPPS reserves the right to withhold continued funding of the Project until the agreements are reviewed and GAPPS at their discretion determines the agreements are consistent with the Global Access Strategy and GAPPS' patent and licensing policies.

3.2 Patenting/Publication Review and Disclosure

3.2.1 Project Management Committee

Grantee shall establish a "Project Management Committee", including collaborators/sub-Grantees if such exist, for the primary purposes of: (a) evaluating proposed publications arising out of the Project, (b) evaluating whether filing or not filing for intellectual property protection, and the allocation of resulting rights, would best further the Global Access Strategy, (c) considering potential IP impact of alternative activities within the scope of the Project, (d) evaluating potential research or commercialization partners, and (e) resolving IP disputes among the Grantee and the collaborators/subgrantees.

Preferably the Project Management Committee shall include multiple members and comprises at least one person who is independent from the Grantee and collaborators/subgrantees, as well as at least one person with expertise in IP or technology transfer. In determining the composition and mechanism of action of the committee, consideration should also be given to the need for timely decision-making.

Please describe how Grantee plans to constitute and charter the Project Management Committee, with particular emphasis on how GAPPS-supported research that is the subject of the collaboration, if such collaboration exists, will be managed during the term of the grant so as to ensure that the Global Access Strategy will be satisfied. Grantee shall establish the Project Management Committee within the first quarter of the award. If the Project Management Committee is not established by the second quarter of the award, GAPPS reserves the right to withhold continued funding of the Project until Grantee establishes the Project Management Committee.

3.2.2 Disclosure of Research Results to GAPPS

Grantee must notify GAPPS in writing of the Project Management Committee's decision to seek patent protection or to make the results public no later than 30 days after the decision is made and in all cases prior to submission of the research results for publication or presentation. Grantee shall provide GAPPS with a copy of the GAPPS-supported research results concurrently with the written notice of Grantee's Project Management Committee's decision. In the case that GAPPS disagrees with the Project Management Committee's decision, Grantee shall discuss with GAPPS their justification for the disposition of GAPPS-supported research results.

Grantee shall continue reporting to GAPPS on IP matters related to the Project, including decisions to seek IP protection and negotiations to license or otherwise transfer IP rights, for a period of 5 years after the Project is concluded, in order to permit GAPPS to continue evaluating Grantee's compliance with the Global Access Strategy. Where the IP matters relate to an issued patent or pending patent application for a GAPPS-supported invention, the reporting period shall be 5 years after the award is concluded or for the life of the patent, whichever is longer.

Please describe how you will adhere to these requirements.

4. Publication of Research Results

Grantee shall seek to publish the results of GAPPS-supported research as expeditiously as is consistent with the need to seek patent protection. Data and materials produced with GAPPS funding shall be made available through trade publications, public databases or repositories where suitable ones are available or, where these are not available, through other appropriate means of sharing. Costs of making data and materials available are allowable expenses to the grant.

5. Prior Arrangements Affecting IP Rights

Grantee shall notify GAPPS of any existing licenses, agreements or other arrangements that might affect Grantee's freedom to operate or objectivity with respect to any invention made with GAPPS funds. Grantee shall provide copies of licenses or other agreements to GAPPS upon their request for review to insure that the agreements are consistent with the Global Access Strategy of GAPPS and the patent and licensing policies recited in *Appendix A*.

5.1 Grantee – Third Party

Describe any licenses or agreements between Grantee and another organization (not-for-profit or for profit) that would affect patent rights, trade secrets or copyrights for GAPPS-supported inventions or discoveries arising in whole or in part from the research supported under this grant. Such agreements include, but are not limited to, pre-existing agreements relating to Key Background Technologies described in Table 1 above.

5.2 Principal Investigator/Essential Personnel – Third Party

Describe any ownership interest (including employment), on the part of the Principal Investigator/Essential Personnel or other key investigators, in a business that could benefit from the research. Grantee shall notify GAPPS in the event of any new agreement between such investigators and a third party for dealing with the patent rights, trade secrets, copyrights or licenses for GAPPS-supported inventions.

Appendix A

GAPPS Policy for Management of Intellectual Property Arising from GCGH Projects

Patent Policy

- Any patent applications and patents directed toward GAPPS-supported inventions, if subsequently granted, for GAPPS-supported inventions shall not be sold or assigned without prior written approval of GAPPS.
- Patents or patent applications directed toward GAPPS-supported inventions shall not be abandoned without first notifying GAPPS and permitting GAPPS to elect to take title and pursue the application at its own expense. At the election of GAPPS, Grantee shall assign title of any GAPPS-supported inventions to GAPPS at no additional charge.
- The results of GAPPS-supported research shall be submitted for publication within a reasonable time, consistent with the need to protect intellectual property when indicated.
- Prosecution of patent applications directed toward GAPPS-supported inventions and payment of all costs involved with seeking patent protection are the responsibility of the Grantee. Government filing and prosecution fees for GAPPS-supported inventions may be charged to the grant.
- Grantee must notify GAPPS in writing when a secondary patent is being considered. GAPPS will conduct appropriate due diligence to determine whether the secondary patent impedes the Charitable Objective. This will often be conducted in conjunction with the Grantee and will include input from the Executive Committee if necessary. Grantee shall prohibit licensees from applying for secondary patents in the developing world that would impede the Charitable Objective.

Licensing Policy

- Grantee must include provisions in all licenses and other revenue generating agreements for GAPPS-supported inventions with third parties that bind the third parties to provisions of this agreement relating to the Global Access Strategy of GAPPS for the benefit of the developing world.
- Grantee may not enter into any license or other revenue generating agreement with a third party for the development and or exploitation, in any way, of a GAPPS-supported invention without first providing written notice to, and consulting with, GAPPS.
- Grantee shall not exclusively license GAPPS-supported inventions to a third party except as necessary in order to provide development and marketing incentive for new products to be used in the developing world.
- Grantee grants GAPPS a transferable, irrevocable, perpetual, non-exclusive, royalty free license for GAPPS-supported inventions with the right to sublicense, to use, manufacture, make, have made, produce, reproduce, copy, distribute, offer to sell, and sell the invention for the benefit of the developing world. Exercise of the license is at GAPPS' sole discretion, which GAPPS does not intend to undertake unless GAPPS determines that the Grantee or licensee(s) has taken inadequate steps toward making the invention available to the developing world within a reasonable time at a reasonable cost.