

Pathway to Stop Diabetes Intellectual Property Policy

PURPOSE

The American Diabetes Association (“Association”) is committed to being good stewards of the funds entrusted to us by donors in support of our mission to find a cure for diabetes and improve the lives of all people affected by diabetes. A critical part of our stewardship is to ensure that we fund meaningful research that will lead to discoveries and inventions and adopt policies and practices that enhance the likelihood that beneficial discoveries and inventions will be exploited to benefit the diabetes community, researchers and humanity. Therefore, we strive to ensure that these discoveries and inventions are administered, patented and licensed in such a way that they are brought into public use at the earliest possible time.

Accordingly, the Association has adopted the following intellectual property policy that is binding on all Grantees (hereinafter “Grantee”). Acceptance of a grant from the Association constitutes acceptance of the terms and conditions of this policy.

For the purposes of this Policy, these definitions are provided:

“Invention” is any discovery, composition of matter, method, process, product, program, software or know-how, whether or not patented or patentable or copyrighted or copyrightable, that is conceived or reduced to practice in the performance of an Association award and has an application of value such that its use, licensing, lease or sale can generate revenue.

“Grant” is the Association’s funding mechanism and accompanying financial support given to a specific institution to support the research, work and/or training of a specific Investigator.

“Grantee Institution” is the named entity (e.g. university, medical center, hospital, research institute or any other organization) in the Grant application where the work and/or training supported by Association funding will be conducted or where Principle Investigator receiving the Grant conducts the research.

“Grantee” (and “Co-Investigator(s)” if applicable) is (are) the individual(s) receiving the award and responsible for the conduct of the research supported by an Association Grant.

“Collaborating Investigator” is an individual who contributes in a substantive way to the scientific development or execution of the project.

“Inventor(s)” is the Principal Investigator, Co-Investigator(s) and/or Collaborating Investigator(s) (if applicable) who made or contributed to the creation of an Invention.

"Public Disclosure" shall mean any publication, presentation, offer for sale or any activity that would affect the patentability of the invention under 35 USC. § 102 or 103.

"Net Income" shall mean gross income received by Institution in respect of an Invention less distributions in accordance with Institution's policy, including payments to Inventor(s) of the Invention, and unreimbursed directly assignable out-of-pocket expenses resulting from patenting and licensing for the Invention.

TITLE TO INVENTION – Title resides with Grantee Institution

- 1) Unless otherwise indicated or requested by the Grantee or Grantee Institution, title to any Invention made with the support of the Association Grant, in whole or in part, shall reside in the Grantee's Institution.

EFFECTIVE ADMINISTRATION – Grantee must exercise effective administration of Invention.

- 2) The Grantee Institution or other titleholder, when it licenses an Invention to another party for commercialization, shall include provisions in the license obligating the licensee to commercialize the Invention in a diligent manner and meet appropriate diligence requirements and concrete development milestones to avoid the license terminating, and the Institution or other titleholder shall monitor performance of the licensee relative to these requirements and milestones. The Institution or other titleholder, or its designee or licensee shall take commercially reasonable steps to bring the invention to practical or commercial application in a reasonable time period (based on type of Invention) after issuance of a patent or other clear determination of commercial value.

INVENTION REPORTING – Grantee must Inform Association within 60 days of Invention discovery, notice(s) and Public Disclosure

- 3) All inventions made with the support, in whole or in part, of Association Grant funds must be reported to the Association within i) a reasonable period after creation of the Invention, ii) within sixty (60) days after any and all notices of the Invention to Institution is received by Institution and iii) within a reasonable period prior to any Public Disclosure.

The report to the Association shall include a brief description of the Invention, possible commercial use, a list of all inventors, and the Grantee's plan for protecting the invention (i.e. filing of a patent application, trademark or copyright application) and any plans for commercializing the invention, including a list of any potential licensees – if known at the time of the report.

- 4) The Grantee Institution will have the first right to pursue patent protection consistent with its policy for any Inventions created or derived from any Association Grant funded research, whether such funding is provided directly or indirectly, by the Association.

NO GRANTEE INSTITUTION POLICY – Association determines Invention disposition

- 5) The American Diabetes Association shall have the right to determine the disposition of Invention rights where a Grantee Institution does not have an established patent policy or procedure for administering Inventions.

INVENTION STATUS REPORTING – Within 60 days of filing and issuance

- 6) The Grantee (or Grantee Institution) must promptly notify the Association in writing of the filing and/or issuance or grant of any application for a patent or other statutory rights for any funded invention, and provide the Association with reasonable notice and information concerning the status and progress of all such applications and inventions. The time period for such notification(s) to the Association shall not exceed sixty (60) days.

MARCH IN RIGHTS – After intent to abandon; Institution failure to manage Invention; or 5 years after patent issued & no commercialization

- 7) Grantee must provide the Association at least sixty (60) days prior notice of Grantee's intent to abandon the Invention or the patent for the Invention. The Grantee and Grantee Institution shall agree that the Association has the right to, as permitted by law, assume assignment of the patent, cancel any existing licenses, and grant new licenses in connection with any Association supported or funded Inventions where the Grantee, Grantee Institution or its licensee have not i) managed the Invention's right as provided in section 1 above, ii) made a proactive attempt or taken effective steps, within five (5) years after a U.S. patent issues, to bring that Invention to the point of practical application, or (iii) has not made such Invention available for licensing.

INCOME SHARING – Association share is 5% Net Income capped at ten times (10x) the amount of the funds provided by the Association.

- 8) Income generated from commercially licensing the Invention derived from Association funding shall be shared with the Association. The Association's royalty share shall be five (5%) of the Net Income derived from the Invention ("Royalty"). The Association's Royalty shall be capped at an amount equal to ten times (10x) the amount of the funding the Association provided to the research that resulted in the Invention. The methods and timing for such payments shall be mutually agreed upon in writing by the American Diabetes Association and the Grantee or Grantee Institution, but such payments to the American Diabetes Association shall be made not less often than annually.
- 9) In the event there are multiple funders of the research, section 7 shall apply unless a revision to the Association's share is mutually agreed upon by and between the Grantee, third party funder's (if necessary), and the Association and is subsequently memorialized in fully executed agreement.

- 10) If any Invention is created or derived from research where there are multiple funders, it is expected that all organizations will defer to the policies of the Grantee Institution. Royalty distribution shall be in accordance with the provision of this policy, with shares distributed to sponsoring agencies in proportion to their initial contribution. Should an exception be taken to this provision, the Grantee, Grantee Institution, the American Diabetes Association, and other sponsoring agencies will confer to arrive at a mutually satisfactory disposition of invention rights.
- 11) Federal funders. Notwithstanding any other provisions of this policy, if an Invention is conceived or reduced to practice from the performance of research funded by the joint support of the ADA and an agency or department of the United States Government, the ADA may defer to the patent, intellectual property or technology transfer policy of the United States Government.

CREDIT

- 12) Grantee and Grantee Institution agree to provide credit to the Association in any and all publication and marketing materials concerning the Invention, including without limitation any Public Disclosure, scientific or journal articles, abstracts, poster or similar materials. Grantee and Grantee Institution must acknowledge the Association's support by including the following language in the acknowledgement section of the publication(s):

“Supported by American Diabetes Association Pathway to Stop Diabetes Grant XX-XX-XXX-XXX”

NOTICE OF INFRINGEMENT – MUTUAL

- 13) Grantee, Grantee Institution and the Association agree to promptly notify the other parties in writing after receipt of any notice or information concerning the infringement of the Invention(s).

AUDIT RIGHTS

- 14) The Association retains right to audit the financial and research records of the Grantee and Grantee Institution concerning the Grant and the Invention(s) annually.
- 15) **All inquiries concerning this Policy must be made in writing.**