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 ("IP Policy") that is binding on all Grantees (hereinafter "Grantee") and their Grantee Institutions. Acceptance of a Grant, as defined below, from the Association constitutes acceptance of the terms and conditions of this IP Policy.

DEFINITIONS

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

   “Collaborating Investigator” is an individual who contributes in a substantive way to the scientific development or execution of research, work, and/or training supported by Association Grant Funds.

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

   “Grant Funds” are the funds provided by the Association to a Grantee Institution pursuant to the Grant to support the research, work and/or training of a Principal Investigator or Co-Investigator.

   “Grantee” is the individual receiving the award and responsible for the conduct of the research supported by the Grant.

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

   "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 created, conceived or reduced to practice in the performance of research, work and/or training supported in whole or part with Association Grant Funds.
“Inventor(s)” is any person who makes an intellectual contribution to the conception or creation of an Invention.

"Net Income" shall mean gross income received by an entity or individual having a right, title and interest in and to an Invention from the sale, distribution, licensing, or assignment of the Invention, including royalties, license issue fees, milestone payments, and the like, less the entity’s or individual’s unreimbursed directly assignable out-of-pocket expenses resulting from patenting and licensing the Invention (collectively “Distributions”) provided such Distributions are supported by contemporaneous written documentation.

“Principal Investigator” and “Co-Investigator(s)” (if applicable) are each an individual having responsibility for the conduct of the research supported in whole or part by the Association’s Grant Funds.

"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.

**TITLE TO INVENTION – Title resides with Grantee Institution**

2) Title to all Inventions shall reside in the Grantee Institution, subject to the Grantee Institution’s written policies. Grantee and Grantee Institution shall not assign its rights, title and interest in and to an Invention to a third party without the prior written approval of Association.

**EFFECTIVE ADMINISTRATION – Grantee must exercise effective administration of Invention.**

3) For each Invention, Grantee Institution and Grantee having an ownership interest in and to the Invention shall (i) include in each license permitting commercialization of the Invention provisions 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 (ii) monitor performance of the licensee relative to these requirements and milestones. The Grantee Institution and Grantee having an ownership interest in and to the Invention, and their licensee(s)(if any) 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 for the Invention or other clear determination of the Invention’s commercial value.

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

4) Grantee or Grantee Institution shall report all Inventions to the Association within i) a reasonable period after creation or conception of the Invention, ii) within sixty (60) days after any and all notices of the Invention are received by Grantee 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 and Grantee Institution’s plan for protecting the invention (i.e. filing of a patent, 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.

5) The Grantee Institution will have the first right to pursue patent protection for all Inventions subject to Grantee Institution’s policy.

NO GRANTEE INSTITUTION POLICY – Association determines Invention disposition

6) The 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

7) 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 each Invention. The time period for such notification(s) to the Association shall not exceed sixty (60) days after filing the application or issuance/grant of a patent. Grantee and Grantee Institution shall, upon Association request, provide the Association with reasonable notice and information concerning the status and progress of all such applications and Inventions.

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

8) For each Invention, Grantee and Grantee Institution must provide the Association at least sixty (60) days prior notice of Grantee or Grantee Institution’s intent to abandon a pending application or granted/issued patent for the Invention. The Grantee and Grantee Institution 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 the Invention where (i) the Grantee, and Grantee Institution, (a) have not managed title to the Invention as provided in Section 2 above, or (b) have not made such invention available for licensing, or (ii) the Grantee, Grantee Institution or licensee(s) (if any) have not made a proactive attempt or taken effective steps, within five (5) years after a U.S. patent to the Invention issues, to bring the Invention to the point of practical application.

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

9) For each Invention, Grantee Institution and Grantee having an ownership interest in and to an Invention shall share their Net Income, as defined herein, generated from the Invention with the Association in accordance with this IP Policy, and as permitted by law. Each of such Grantee Institution and Grantee shall pay to the Association five (5%) of its Net Income derived from the Invention (“Royalty”). For the purposes of this paragraph, payments to Inventor(s) of the Invention pursuant to Grantee Institution’s written policies shall be excluded from Grantee or Grantee Institution’s Net Income, provided such payments are supported by contemporaneous written
documentation. The Royalty shall be capped at an amount equal to ten times (10x) the amount of the Grant Funds. The methods and timing for such Royalty payments shall be mutually agreed upon in writing by the Association and the Grantee Institution and Grantee having an ownership interest in and to the Invention. Notwithstanding the foregoing, such Royalty payments to the Association shall be made not less often than annually.

In the event one or more third parties provide funds for the research supported by the Grant Funds, Section 9 shall apply to the Royalty due to Association, unless a revision to the Association’s Royalty is mutually agreed upon in writing by and between the Grantee Institution and Grantee having an ownership interest in and to an Invention, the third party funder(s) (if necessary), and the Association and is subsequently memorialized in a fully executed agreement.

10) Federal funders. Notwithstanding any other provisions of this IP Policy, if an Invention is conceived or reduced to practice from the performance of research funded by the joint support of the Association and an agency or department of the United States Government, the Association may defer to the patent, intellectual property or technology transfer policy of the United States Government.

CREDIT

11) Grantee and Grantee Institution shall provide acknowledgement of the Association’s funding in any and all publication and marketing materials concerning the Invention, including without limitation all Public Disclosures, 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

12) Grantee, Grantee Institution and the Association agree to promptly notify each other in writing after receipt of any notice or information concerning the infringement of copyright or any claim in an issued/granted patent for the Invention(s).

AUDIT RIGHTS

13) The Association retains right to review and audit the financial and research books and records of the Grantee and Grantee Institution relating to the Grant, use of the Grant Funds, and the Invention(s) annually. Grantee shall promptly make such books and records available to the Association upon request for review and audit.

SURVIVAL

14) The provisions of this IP Policy shall survive termination of the Grant.
INQUIRIES

15) All inquiries concerning this IP Policy must be made to the Association in writing.