

Patent, Intellectual Property and Technology Licensing Policy of the American Heart Association, Inc.

Effective Date: Oct. 27, 2011

Though the primary purpose of the AMERICAN HEART ASSOCIATION INC. (hereinafter designated AHA) in funding scientifically meritorious research is to advance its mission, the AHA recognizes that inventions having public health, scientific, business or commercial application or value may be made in the course of research supported by the AHA. It is the desire of the AHA that such inventions be administered in a manner that they are brought into public use at the earliest possible time. The AHA recognizes that this may be best accomplished through patenting, copyrighting, and/or licensing of such inventions.

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 AHA award and has an application of value such that its use, licensing, lease or sale can generate revenue.

"Award" is the American Heart Association funding mechanism and accompanying financial support given to a specific institution to support the work and/or training of a specific Investigator and any Co-Investigators.

"Institution" is the entity (university, medical center, hospital, research institute or any other organization) in which the work and/or training supported by AHA funding will be conducted.

"Principal Investigator" (and "Co-Investigator(s)" if applicable) is the individual(s) receiving the award and responsible for the conduct of the research supported by an AHA Award.

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

"Inventor(s)" is the Investigator, Co-Investigator(s) and/or Collaborating Investigator(s) (if applicable) who made an Invention.

1. Inventions are subject to AHA's Patent, Intellectual Property, and Technology Licensing Policy as set forth below:
2. All Inventions shall be reported in writing to the AHA within 60 days of the date when the Invention is disclosed to the Institution where the work was done, and prior to any public disclosure. The report to AHA should be the initial copy of the Institution's Invention disclosure form and any subsequent versions that have substantive changes or additional information.
3. If the institution receiving or disbursing the AHA funds that support the Invention has an established and applicable patent, intellectual property or technology transfer policy and procedure for administering Inventions, the AHA will defer to that policy

with the following exceptions and requirements which shall control in the event of a conflict:

- a. Title to any Invention shall reside in the Institution; and title may be permitted to reside in the Inventor(s) or any other person or institution with the prior written approval of the AHA, upon advice of the AHA's Legal Counsel and science advisors, except that no AHA approval is required for title to reside in the United States Government.
- b. Institution and Investigator(s), if appropriate, shall promptly determine whether they desire to seek patent or other statutory protection for an Invention and shall notify the AHA in writing within 60 days of the decision to seek (or not seek) such protection. The AHA also will be notified in writing within 60 days of a patent application being filed, and any patent subsequently being issued, and/or of a license, lease, sale or revenue generating agreement concerning the Invention prior to their execution. No patent or patent application shall be abandoned without prior notification by the Institution or Inventor(s) to the AHA and offering to assign to AHA all right, title and interest to the Invention to the extent permitted by law.
- c. Notwithstanding any other provision of this policy, the AHA shall participate in the income derived from the Invention. The AHA's participation shall be determined, within one year or a reasonable period of time after reporting of the Invention to the AHA, by mutual agreement between the Institution or other titleholder and the AHA, with the AHA's rights hereunder not being affected if such determination is not made within said time period. The amount of the AHA's participation shall be guided by the principle that the AHA's sharing of income shall be in proportion to the AHA's portion of support for the work or research giving rise to the Invention. The AHA waives receipt of income until the cumulative net income (i.e., net of any direct out-of-pocket patenting costs) from an Invention conceived or reduced to practice from the performance of an AHA Award exceeds \$500,000.
- d. The 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. If the Institution or other titleholder, or its designee or licensee, has not taken commercially reasonable steps and cannot show reasonable cause why it should retain title to and all rights in the administration of the Invention for a further period of time, then, if no other parties have superior legal rights, the Institution or other titleholder and the AHA shall determine a course of action including but not limited to

- i. the Institution or other titleholder's renegotiation of milestones with the current licensee or termination of the current license and licensing of the Invention to another licensee;
 - ii. a non-exclusive right to the Institution or other titleholder to practice the Invention for any non-commercial purpose;
 - iii. a global, exclusive or non-exclusive, non-revertible, royalty-free license to the AHA;
 - iv. the provision to the AHA of any additional materials necessary for regulatory filing and the technology's enablement that might be in the possession or control of the Institution or other titleholder, except for intellectual property that was not generated as a result of the AHA's assistance; or
 - v. any other action appropriate in the circumstances.
4. If the Institution has no established and applicable patent, intellectual property or technology transfer policy or procedure for administering Inventions, title to any invention shall reside in the Institution or Inventor(s) as agreed by them and the Institution and Inventor(s) shall comply with all requirements in Sections 3b and 3d and the AHA shall have all rights set out in Sections 3c and 3d.
5. Situations with multiple funders in addition to the AHA. The right of the AHA to participate in revenue derived from an Invention pursuant to section 3.c is not waived in these situations.
 - a. Multiple funders. If any Invention is conceived or reduced to practice from the performance of research funded by the AHA and by independent funding from another health agency or funding organization, not an agency or department of the United States Government, the Inventors and the Institution will work with the AHA to negotiate with the other agency/organization in good faith for a mutually satisfactory determination of rights to administer the Invention and determination of the fair share of the royalty or other income to be paid to the Institution, Inventor(s), AHA and other parties who independently funded such research.
 - b. 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 AHA and an agency or department of the United States Government, the AHA may defer to the patent, intellectual property or technology transfer policy of the United States Government.