

# Policy on Inventions, Patents, and Technology Transfer

*DRAFT*

## ***I. Preamble and Objectives***

Duke University (University) is dedicated to teaching, research, and the expansion of knowledge. The University has a mission of knowledge in the service of society, and in that context inventions sometimes result from the research and clinical activities carried out wholly or in part with University funds and facilities. It is the policy of the University to assure the utilization of such inventions for the common good and, where necessary, to pursue protection of intellectual property and licenses to encourage their development and marketing.

This policy applies to University employees who are defined for purposes of this policy as all faculty, staff, and other persons receiving compensation from the University and Duke University Health System, Inc. for services rendered, as well as students and graduate assistants, whether compensated or not, who work on any research project under University control. Duke University has established the following policies and procedures with respect to inventions, patents, and technology transfer in order to:

- (A) Promote the University's academic policy of encouraging scientific research and scholarship;
- (B) Serve the public interest by providing an organizational structure and procedures through which inventions that arise in the course of University research may be made readily available to the public through established channels of commerce;
- (C) Encourage, assist, and provide tangible reward to members of the University community who make inventions processed under this policy;
- (D) Establish principles and uniform procedures for determining the rights and obligations of the University, inventors, and sponsors, with respect to inventions arising during the inventor's and sponsor's association with the University;
- (E) Enable the University to enter into institutional agreements with federal research funding agencies;
- (F) Produce funds for further scientific investigation and research and for the overall needs of the University.

The Office of Licensing and Ventures shall operate in a manner that incentivizes decisions guided by the long view, including promotion of invention disclosures, prompt reviews of new disclosures, wide transition of Duke IP to the marketplace as measured by licensing transactions, faculty satisfaction, and revenue generation.

## ***II. Administrative Responsibility***

- (A) The President of the University shall be responsible for administrative matters relating to inventions, patents, and technology transfer and shall represent the University in all matters of policy affecting the University's relations with inventors, government, private research sponsors, industry, and the public. The President may designate another senior administrative officer to carry out these responsibilities in whole or in part.
- (B) *Director of the Office of Licensing and Ventures.* The Provost and Chancellor shall jointly appoint a director of the Office of Licensing and Ventures (OLV), with the appointment made in consultation with

the President of the University. The Director of OLV or her/his designee shall:

- (1) Establish liaison with appropriate faculties to monitor research and to assist in the identification of potentially patentable discoveries and in the reporting of such discoveries;
- (2) Establish liaison with federal and private sponsors of research and ensure compliance with any provisions in sponsored research agreements regarding inventions;
- (3) Receive all disclosures of invention submitted under this policy;
- (4) Determine the ownership of and equities involved in inventions, in accordance with Section V below;
- (5) Determine whether an invention in which the University has an equity is patentable or otherwise protectable;
- (6) In consultation with the inventor, evaluate potential commercial use and investigate possible courses of action for patenting and/or marketing inventions in which the University has an equity;
- (7) Negotiate patent licensing and technology transfer agreements;
- (8) Maintain complete records on all disclosures and other patent matters of interest to the Duke administration;
- (9) Prepare an annual report to the OLV Board;
- (10) Promote the cross-fertilization of ideas within the Duke scientific community consistent with the need for confidentiality of potentially patentable subject matter until patent applications have been filed.

(C) *OLV Board.* The OLV Board consists of seven members. Five Board members shall be selected from the faculty and two from the administration. Three of the faculty members shall be selected by the Chancellor of Health Affairs (Chancellor), in consultation with the Dean of the SOM; the Provost shall select two faculty from Campus Schools in consultation with the Deans of those Schools. One of the Campus representatives shall be a faculty member in the Pratt School of Engineering. The Chancellor shall select the SOM administrative representative, and the Provost will select the Campus administrative representative. The Board will be co-Chaired by the Campus and SOM administrative representatives. The director of OLV shall be a non-voting ex-officio member of the Board and the Board shall designate an ex-officio Secretary of the Board. A designated member of the Counsel's Office shall also be a non-voting ex-officio member of the Board. The director of OLV shall report jointly to the Provost and Chancellor, or their designees, who would be the administrative members of the Board. The Board shall:

- (1) Receive and review the annual report of the director of the OLV and consult with the director of the OLV when requested.
- (2) Report to the President or designee on the implementation of this policy, and recommend such new or different policies or guidelines as may be more suitable for the achievement of its objectives.
- (3) Sit as a tribunal for the resolution of specific disputes involving the ownership of and equities involved in inventions, on appeal from decisions of the director of the OLV.

- (4) Receive requests for interpretations of this policy and, after deliberation, recommend to the President such interpretations as it considers appropriate.
- (5) Receive, review and recommend to the Chancellor and Provost the OLV budget as annually submitted by the Director of OLV.

*(D) Duke Innovation & Entrepreneurship Initiative*

- (1) The Office of Licensing and Ventures will work with the Duke Innovation & Entrepreneurship (I&E) Initiative and other areas focusing on innovation, to help meet the need for entrepreneurial education. The OLV, Duke I&E and their Boards will work with Deans and Department Chairs to promote a culture of translation across the institution.
- (2) Duke strongly welcomes innovation amongst the members of its community that result in patentable inventions. While OLV's resources are targeted towards finalizing patents and ventures, it will also, together with the OLV Board and in conjunction with I&E and other units involved in translation, help define expectations, and provide guidance on ways faculty and students can make their innovations patentable and more attractive to the marketplace.

***III. Invention Management***

- (A) Within three months from submission of a new invention disclosure, OLV will respond to the prospective inventor(s), notifying them of one of the following:
  - (1) The submission is not a valid new invention. The individual(s) who submitted the disclosure may be directed to I&E or to other areas focused on innovation, for help in refining and improving the invention; the prospective inventor(s) will be made aware of what is required of a proper invention.
  - (2) The submission is of potential value, but it is recommended that it be improved and strengthened, before filing a provisional patent. OLV will work with the inventor(s) to help strengthen the disclosure, and define its proper place in the marketplace, and in so doing better quantify its value. Under this circumstance the inventor(s), OLV and I&E or other entities responsible for translation (upon mutual consent) will work together to strengthen and position the potential invention, for a subsequent provisional patent. This process may take an extended period that respects the needs of all parties, including the requirements of students to publish their work in a timely manner. The OLV Board may be consulted by the inventor, if desired, to achieve the proper balance between strengthening the invention and the need to publish.
  - (3) If either of the above two options do not apply, OLV will make a statement about whether it is interested in pursuing a provisional patent or not and the timing of the filing or refiling of a provisional to maximize the chances for translational success. If OLV elects not to protect, the invention will be assigned back to the inventor(s), who have the opportunity to pursue the patent(s) as they wish.
- (B) After OLV files a provisional patent, it will have an additional six months to inform the inventor if OLV will file additional protection. If OLV chooses not to protect the invention, the invention will be assigned back to the inventor. If the patent is unusually complex, requiring more time for the assign-back decision, such an extension of the above time period must be approved by a majority vote of the OLV Board.
- (C) For disclosures or provisional patents that OLV assigns back to the inventor(s), if the inventor(s) chooses to file a patent on their own, that patent must contain claims that are substantially similar with the original invention disclosure and/or the previously filed provisional patent. The OLV Board or its

designee will review the consistency between the inventor's patent application and the original disclosure and any provisional patent application. If the inventor's subsequent patent is found to substantially differ from the original disclosure, then the University's assignment shall be null and void and ownership of the invention will revert to the University.

- (D) If a license negotiation between OLV and a company proceeds for six months without resolution, unless both sides ask for more time, the OLV Board will intervene, and recommend terms for an equitable outcome, which may include an option to continue to negotiate.

At the regular meetings with the OLV Board, the OLV Director will provide updates on the broad status of inventions as they run through the system, and demonstrate that the desired timelines are being met.

#### ***IV. Report of Inventions***

University employees who during their associations with the University invent a device, product, service, business model or method, whether or not on University time or with University facilities, shall cooperate with the University in defining the rights to such inventions by promptly reporting to the director of OLV on the University's Invention Disclosure Form.

#### ***V. Ownership of Inventions and Supportive Technology***

- (A) Inventions resulting from research, clinical, or other work conducted by University employees wholly on their own time and without use of University funds or facilities shall be considered the property of the inventor and may be patented and/or commercialized by the individual at the individual's expense. It is recognized that when the invention is within the specific subject area of the inventor's current and ongoing University research or clinical activities, disputes may develop concerning whether the work was conducted by University employees wholly on their own time and without use of University funds or facilities. In order to reduce the possibility of such disputes, it shall be the responsibility of the employee to provide notice to the respective departmental chair (or, as appropriate, dean, director or chief) of engagement in research or clinical activities independently within the subject area of her or his current University activities, and describe in such notice the focus of these independent research activities, with a copy to the Provost or Chancellor. In questionable cases, it shall be the responsibility of the inventor to demonstrate that the above criteria and administrative approvals are present to exercise this option.
- (B) Inventions resulting from research, clinical, or other work conducted by University employees wholly on their own time, but involving some but not significant use of the University funds or facilities, shall be considered the property of the individual and may be patented and/or commercialized by the individual at the individual's expense. The University will not construe the payment of salary from unrestricted funds or the provision of office or library facilities as constituting significant use of University funds or facilities. In questionable cases, it shall be the responsibility of the inventor to demonstrate that the criteria and administrative approvals are present to exercise this option.
- (C) Inventions resulting from research, clinical, or other work conducted by University employees in whole or in part on University time or with significant use of University funds or facilities shall be considered the property of the University. Employees shall upon request assign to the University all rights and title to such inventions and shall make known and available to the University all supportive technology related to the same. Supportive technology is intended to include any non-patentable invention which would assist the University in achieving the goals of this policy. If the University decides not to request assignment of all rights and title to such an invention, and if there are no restrictions by any outside sponsor of the research, the University may release ("assign back") its proprietary interest to the inventor.
- (D) Inventions arising from research financed by the U.S. Government are controlled by the terms of the

applicable grant or contract and Federal laws. The University is obligated to report to the appropriate government agency all such inventions or discoveries for definition of the government's rights and interests. In cases where the government claims no patent rights or waives its rights, University patent policies will control, subject to such limitations as the government may impose.

- (E) Inventions resulting from research, clinical, or other work sponsored by nongovernmental entities are controlled by the terms of the research agreement, if applicable, and if not, by University patent policies.
- (F) Where mutually agreeable between inventors and the University, and on terms and conditions acceptable to both, the University will accept by assignment, bequest, or other appropriate instrument, title to inventions falling in sections A and B above.
- (G) Any dispute between the Director of OLV and the inventor as to the determination of equities in an invention shall be resolved by the OLV Board. The decision of the OLV Board may be further appealed to the President or, upon the President's referral, to the Board of Trustees.
- (H) Any use of the University's name in connection with the commercialization of an invention by an individual shall require approval in advance by the University.

#### ***VI. Division of Income***

- (A) All income derived from inventions falling within Article V, Section A and Section B above shall belong to the inventor.
- (B) If inventions that are assigned back by OLV to the inventor shall be patented and/or commercialized by the inventor, then the University and inventor shall enter into an agreement, which shall provide for the inventor to reimburse the University its direct expenses incurred in connection with the patenting and commercialization of the invention.
- (C) All income derived from inventions falling within Article V, Section C shall be distributed in accordance with the following formulas:
  1. The University will first deduct any direct expenses incurred by it in connection with the patenting and commercialization of the invention. Any such expenses incurred by the inventor with the prior approval of the director of OLV will also be deducted and paid to the inventor.
  2. The University will then pay and distribute the cumulative income remaining after payment of direct expenses in the following manner:
    - (a) income from \$0 up to \$500,000:
      - (1) fifty percent (50%) thereof to the inventor;
      - (2) ten percent (10%) thereof to the inventor's laboratory or program until, in the discretion of the President after consultation with the Chancellor or the Provost, this distribution equals the maximum amount which can reasonably be expended in that laboratory, after which any excess shall be added to and distributed as a part of the share in accordance with VI.C.2.a.(2) above;
      - (3) ten percent (10%) thereof to the inventor's department/organizational unit
      - (4) thirty percent (30%) thereof to be directed to the school of the inventor's primary appointment.

(b) income from \$500,000 up to \$2,000,000:

- (1) thirty-three percent (33%) thereof to the inventor;
- (2) fifteen percent (15%) thereof to the inventor's laboratory or program until, in the discretion of the President after consultation with the Chancellor or the Provost, this distribution equals the maximum amount which can reasonably be expended in that laboratory, after which any excess shall be added to and distributed as a part of VI.C.2.b.(2) above;
- (3) fifteen percent (15%) thereof to the inventor's department/organizational unit
- (4) thirty-seven percent (37%) thereof to the inventor's school.

(c) income of \$2,000,000 and higher:

- (1) twenty-five percent (25%) thereof to the inventor;
- (2) fifteen percent (15%) thereof to the inventor's laboratory or program until, in the discretion of the President after consultation with the Chancellor or the Provost, this distribution equals the maximum amount which can reasonably be expended in that laboratory, after which any excess shall be added to and distributed as a part of VI.C.2.c.(2) above;
- (3) fifteen percent (15%) thereof to the inventor's department/organizational unit
- (4) thirty-five percent (35%) thereof to the inventor's school;
- (5) ten percent (10%) thereof to a quasi-endowment fund established by the university to provide direct support for graduate and post-doctoral research, as the president of the University shall direct.

3.

- (a) If for any reason the inventor ceases to be a University employee or, if not an employee is no longer studying or working in research at the University, then the disposition of the share to which that inventor's laboratory would have been entitled shall be determined by the School.
- (b) For purposes of this Article VI.C., the word "inventor" shall include co-inventors as a group and related words such as "laboratory" shall include not only the singular but also the plural form of the word, as may be appropriate.
- (c) For purposes of this Article VI.C., the dollar ranges in paragraphs VI.C.2.a. (0 to \$500,000), VI.C.2.b. (\$500,000 to \$2,000,000), and VI.C.2.b. (\$2,000,000 and higher) above, may be adjusted by the OLV Board as of July 1 of each year to reflect the change, if any, in the cost-of-living, such adjustment to be effective for the fiscal year from that July 1 through the following June 30. The cost-of-living adjustment to be made each year shall be the cost-of-

living adjustment calculated by the Department of Human Resources of the university for use by that department in determining wage and salary levels for the fiscal year for which the adjustment of dollar ranges under this Article VI.C. will be effective (whether or not such wage and salary adjustments are implemented).

- (d) For purposes of this Article VI.C., the net income referred to in paragraphs VI.C.2.a. (0 to \$500,000), VI.C.2.b. (\$500,000 to \$2,000,000), and VI.C.2.c. (\$2,000,000 and higher) above, as the same shall be adjusted from time to time, shall mean the cumulative net income earned from inventions.
4. Income from inventions falling within Article V, Section D, where the government claims no patent rights or waives such rights, shall be distributed in accordance with Article VI, Section C above, unless the waiver or other agreement between the University and the government provides for a different distribution.
  5. In the case of inventions falling within Article V, section E, any royalties received by the University shall be distributed in accordance with Article VI, section C above, unless the contract between the University and the sponsor provides for a different distribution.
  6. Income from inventions falling within Article V, section F, shall be distributed in accordance with the agreement between the inventor and the University.

### ***VII. Publication***

Inventors should be aware that publication prior to the filing of a U.S. patent application is a bar to the grant of certain foreign patents and can bar the grant of a U.S. patent if it occurred a year earlier than the filing date.

### ***VIII. Interpretation***

Questions of interpretation concerning this policy shall be submitted to the OLV Board and resolved, after consideration of the OLV Board's recommendations, by the President or designee, or upon the President's referral, by the Board of Trustees.

### ***IX. Termination or Revision of Policy***

This policy may be changed or discontinued at any time by action of the Board of Trustees upon recommendation by the OLV Board. Such changes or discontinuance shall not affect rights accrued prior to the date of such action.

### ***X. Agreements***

The policy as amended from time to time shall be deemed to be a condition of initial or continuing employment of every University employee and a condition of enrollment and attendance of every student who works on any research project under University control. All such employees and students will be expected to sign agreements incorporating the terms of this policy; but failure to sign shall not affect the applicability of the policy nor relieve any employee or student from the obligations imposed by it. Any use of University funds or facilities after the effective date of this policy shall be subject to this policy.

### ***Y. Effective Date***

This revision of the policy on Inventions, Patents, and Technology Transfer shall be effective \_\_\_\_\_.