

NATIONAL INSTITUTES OF HEALTH (NIH) PATENT LICENSE APPLICATION

Thank you for your interest in technology transfer activities at the NIH. A completed application is required before any action can be taken towards negotiating a license. Your answers to the following questions will provide the sole foundation for licensing decisions, so provide complete and thorough responses. Failure to complete all sections of the license application in a satisfactory manner may result in delays in processing your application, the refusal of your application as being incomplete, or the failure of your application to survive an objection to the grant of a license. If you have questions about the completion of the application, contact the appropriate Technology Transfer Manager (TTM).

Please be aware that NIH patenting and licensing functions are no longer handled in a centralized manner by the Office of Technology Transfer. The efforts have been decentralized to nine NIH Institutes and Centers (ICs), the FDA and the CDC.

To apply for a license, please email a signed PDF of the completed license application to the appropriate TTM whose name and email address can be found toward the bottom of the technology “Abstract,” or if the information was received from another source, please email the signed application to ncitechtransfer@mail.nih.gov.

I. IDENTIFICATION OF INVENTIONS(S) FOR WHICH LICENSE IS SOUGHT (Complete all relevant sections)

- A. NIH Reference Numbers (E#: E-XXX-XXXX-X for a new license, or L#: L-XXX-XXXX-X, if amending a license):
- B. U.S. Patent Application(s) Serial Number(s), Filing Date(s), and/or Patent Number(s) (if issued):
- C. Title of Patent Application(s) (if the same name is listed on multiple patents, it only needs to be listed once):
- D. Biological Material(s) Requested, if any (**PLEASE BE SPECIFIC IN NAME AND QUANTITY**):
- E. Inventor(s):
- F. Source from which you learned of availability of a license to the present invention(s):

II. BASIC INFORMATION ABOUT APPLICANT

- A. “Company Name and Address” (Must be the organization with Signatory Authority for any Agreement resulting from this application):
- B. Name, title, address, phone, fax and email, of Applicant's licensing representative (only one

contact is permitted):

- C. Name, title, address, phone, fax and email for Applicant's representative who should receive official notices for any agreement (only one contact is permitted):
- D. Name, title, address, phone, fax and email for Applicant's representative who should receive invoices for any agreement (only one contact is permitted):
- E. Name, title, address, phone, fax and email for Applicant's representative who should receive any materials; please **include shipping carrier and account number** (only one contact is permitted):
- F. Is Applicant a U.S. Corporation? _____ Yes _____ No
- 1) State of incorporation:
- 2) If non-US, state country of origin:
- G. If the applicant is an individual, provide his/her citizenship:
- H. Is Applicant a Small Business Firm? _____ Yes _____ No
- I. Is Applicant a Start-up Company? _____ Yes _____ No
- J. Will applicant accept PDF execution copy of the agreement? _____ Yes _____ No
- K. Will applicant accept a Digital Signature in the execution copy of the agreement?
_____ Yes _____ No
- L. Does applicant have an SBIR/STTR grant? _____ Yes _____ No
- M. Applicant Tax ID # _____ (must provide before license is executed)
- N. **Description of the Applicant (a few sentences).** Please address the following questions:
- 1) How many individuals are employed by Applicant?
- 2) What is the Applicant's overall company structure?
- 3) If Applicant is a large company with many subsidiaries, what arm and research facility of the company will be using the licensed invention?

III. TYPE OF LICENSE SOUGHT

A. Patented Inventions:

- _____ Exclusive Patent License (for commercial manufacture and sale of materials and/or services)
- _____ Co-exclusive Patent License (for commercial manufacture and sale of materials and/or services)
- _____ Non-exclusive Patent License for Commercial Use (for commercial manufacture and sale of materials and/or services)
- _____ Non-exclusive Patent License for Internal Use (for internal use; no right to sell or distribute materials or services)
- _____ Non-exclusive Commercial Evaluation License (short term license for internal use/evaluation; no right to sell or distribute materials or services; term is typically up to 1 year)
- _____ Amendment to Exclusive or Non-exclusive Patent License (Please Indicate L#: L-XXX-XXXX-X)
- _____ Exclusive Start-up License* (for evaluation and commercialization)

* start-up licenses are considered on a case-by-case basis, pending review of applicant's qualifications; some technologies are not available for start-up licenses.

IV. PROPOSED FIELD(S) OF USE (please provide a desired Licensed Field of Use):

V. DESCRIPTION OF APPLICANT

Describe the nature and type of applicant's business, including:

- 1) A statement about employees with relevant technical expertise for the development of technologies within the "Proposed Field of Use" for this license application;
- 2) A statement regarding key managerial employees and board members, including their relevant technical experience and capabilities regarding the development of technologies within the "Proposed Field of Use" for this license application;
- 3) A statement regarding research and development facilities and capabilities, with supporting evidence for the statement;
- 4) A statement regarding manufacturing capabilities, including infrastructure and/or working relationships with contractors, with supporting evidence for the statement;
- 5) A statement regarding 37 CFR 404.5(a)(2), concerning the requirement that the manufacture of Licensed Products must occur substantially in the United States;

- 6) A statement regarding financial resources and capabilities, with supporting evidence for the statement;
- 7) A statement regarding sales and marketing capabilities and resources, with supporting evidence for the statement.

If necessary, please use additional sheets of paper to provide this information.

VI. OTHER LICENSES TO NIH/IC INVENTIONS

Identify any licenses previously granted to the Applicant under federally owned inventions (L-XXX-XXXX-X):

VII. PROPOSED LICENSE TERMS

Model Agreements can be found here: <http://www.ott.nih.gov/forms-model-agreements#MLA>

- 1) Please provide requests for specific changes to any definitions, terms or conditions as presented in the model agreements. Requested changes cannot be guaranteed, but will be considered during the initial evaluation of the license application and again prior to drafting an agreement.
- 2) Please provide suggested developmental benchmarks. Requested developmental benchmarks cannot be guaranteed, but will be considered during the initial evaluation of the license application and again prior to drafting an agreement.
- 3) Please provide suggested financial terms. Requested financial terms are not guaranteed, but will be considered during the initial evaluation of the license application and again prior to drafting an agreement.
- 4) Provide a list of territories in which the license should be effective.

VIII. RESEARCH, DEVELOPMENT AND MARKETING PLAN

Provide a detailed and specific plan for the development of the invention across the full scope of the “Proposed Field of Use” as indicated in this license application. List all relevant research and development plans to be employed (including all relevant preclinical, clinical, regulatory, manufacturing and marketing stages), and propose deadlines for starting and completing each stage (Gantt Charts are highly recommended). Indicate financial requirements and technical/personnel needs at each stage, including proposed partnering events. Insufficient detail and/or scope may result in the application being returned or refused as incomplete.

The use of separate sheets to provide this information is encouraged, as well as providing it in an editable format for inclusion in any executed agreement.

IX. MARKET ANALYSIS

Describe the relevant market segment(s) the licensed technology will serve when commercialized. Include an estimated market size (estimated patient population to be treated or diagnosed) and projected growth/reduction of relevant markets during the duration of the license. Provide an estimated market share once the product is introduced, and provide sales projections based on market share analysis.

X. OTHER INFORMATION WHICH YOU BELIEVE WILL SUPPORT A DETERMINATION TO GRANT THE REQUESTED LICENSE

Include relevant intellectual property, working agreements, access to technical expertise, or other arrangements that may provide the applicant with the best opportunity to bring the technology to practical application for the benefit of public health.

XI. FOR APPLICANTS FOR EXCLUSIVE, PARTIALLY EXCLUSIVE OR START-UP LICENSES ONLY

Provide a detailed statement as to how:

- 1) Federal and public interests will be best served by exclusive licensing of this invention;
- 2) The exclusive licensing of this invention is a reasonable and necessary incentive to attract investments of risk capital;
- 3) The proposed license terms and scope of exclusivity are not greater than reasonably necessary; and
- 4) The exclusive licensing of this invention will not tend substantially to lessen competition or result in undue market concentration.

I certify, to the best of my knowledge, that all of the information provided on this application and on attachments to this application is true and accurate.

Signature of Applicant or Authorized Representative

Date

Print Name

Title

The commercial and financial responses in this application will be treated as privileged and confidential information as provided in [35 U.S.C. 209\(f\)](#); and, to the extent permitted by law, will not be accessible under the Freedom of Information Act.