

NATIONAL INSTITUTES OF HEALTH (NIH) APPLICATION FOR LICENSE

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 Licensing and Patenting Manager.

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. Please be sure to accurately identify the Licensing and Patenting Manager so that your license application will be properly routed.

In order to apply for a license, please email a signed PDF of the completed license application to the appropriate Licensing and Patenting Manager whose name and email address can be found toward the bottom of the technology abstract at <https://www.techtransfer.nih.gov/search>.

- I. **IDENTIFICATION OF INVENTIONS(S) FOR WHICH LICENSE IS SOUGHT (Complete all relevant sections)**
 - A. NIH Reference Numbers (E# for a new license, or L#, 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 (**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. Name & Address of Applicant (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:

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; copies cannot be provided):

D. Name, title, address, phone, fax and email for Applicant's representative who should receive invoices for any agreement (only one contact is permitted; copies cannot be provided):

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)

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)
- _____ Amendment to Exclusive or Non-exclusive Patent License (Please Indicate L#: L-XXX-XXXX-X)
- _____ Exclusive Start-up License* (for evaluation and/or 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 and not all NIH ICs may offer this type of license.

B. Non-Patented Inventions:

_____ Non-exclusive Biological Materials License for Commercial Use (for commercial manufacture and sale of materials and/or services)

_____ Non-exclusive Biological Materials License for Internal Use (for internal use; no right to sell or distribute materials or services)

_____ Non-exclusive Commercial Evaluation Biological Materials License (for internal use; no right to sell or distribute materials or services)

_____ Amendment to Non-exclusive Biological Materials License (Please Indicate L#: L-XXX-XXXX-X)

IV. PROPOSED FIELD(S) OF USE:

V. DESCRIPTION OF APPLICANT

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

- 1) A statement as to the number of full-time employees, with a statement about those 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.

The use of a separate sheet to provide this information is encouraged.

VI. OTHER LICENSES TO NIH/IC INVENTIONS

Identify any licenses previously granted to the Applicant for federally owned inventions.

VII. PROPOSED LICENSE TERMS

Model Agreements can be found here: <http://www.techtransfer.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. DEVELOPMENT PLAN (RESEARCH & DEVELOPMENT, MARKETING, AND ACCESS)

Insufficient detail and/or scope may result in the application being returned or refused as incomplete. The use of a separate sheet to provide this information is encouraged, as well as providing this in an editable format for inclusion in any executed agreement.

A. R&D AND MARKETING PLAN

Provide a detailed and specific plan for the development of the invention across the full scope of the Proposed Field(s) 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.

B. ACCESS PLAN

(only required for applications seeking to license certain NIH patented inventions, see below)

Are you applying for a patent license to commercialize a drug, biologic (including vaccine), or device for the prevention, diagnosis, or treatment of human disease?

_____ Yes _____ No

If yes, continue to the paragraph below. If no, continue to section IX.

An “access plan” is required to be submitted as part of your application if it falls within the NIH IRP Access Planning Policy (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-136.html>) (the policy is applicable where the license would grant rights under patent(s) wholly owned by the United States of America at the time of your application). In a separate subsection of your development plan, describe how you will support broad access to the product(s) that would be within the scope of the patent rights and field of use identified in this application. This shall include a brief description of:

- The product(s) that would be covered by the patent rights of interest;
- The anticipated patient population(s) who would use the product(s);
- Other products, tools, facilities, or unique resources that would be necessary for the use of the product(s);
- Strategies to promote patient access to the product(s) across criteria of affordability, availability, acceptability, and sustainability, to the extent such access can be advanced on terms that are commercially reasonable; and
- A description of how you will monitor the efficacy and implementation of the proposed access plan over the term of the license.

You may cross-reference relevant information from other parts of this application. More information about policy scope, FAQs, and how to prepare an access plan, can be found here: <https://www.techtransfer.nih.gov/policy/access-policy>.

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 OR PARTIALLY EXCLUSIVE LICENSES ONLY

Provided 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;
- 4) The exclusive licensing of this invention will not tend substantially to lessen competition or result in undue market concentration; and
- 5) If this invention is covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

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.