NATIONAL INSTITUTES OF HEALTH (NIH) APPLICATION FOR LICENSE TO

INVENTIONS from the NIH or the Food and Drug Administration OR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Thank you for your interest in the technology transfer activities of the NIH, FDA, and CDC. Your answers to the following questions will provide the foundation for licensing decisions.

**If you would like 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 are found toward the bottom of the technology “Abstract” or if you have spoken to him/her, the correct email address may be found here:** [**http://www.ott.nih.gov/staff**](http://www.ott.nih.gov/staff)

Identification of Inventions(s) For Which License is Sought (Complete all relevant sections)

NIH Reference Numbers (E#):

U.S. Patent Application(s) Serial Number(s), Filing Date(s), and Patent Number(s) (if issued):

Title of Patent Application(s):

Biological Material(s) Requested (please be specific in quantity):

Inventor(s):

Source from which you learned of availability of a license to the present invention(s):

Information About Applicant

1. Name & Address of Applicant:

2. Name, title, address, phone, fax and email, of Applicant's licensing representative:

3. Name, title, address, phone, fax and email for Applicant's representative who should receive official notices for any agreement:

4. Name, title, address, phone, fax and email for Applicant's representative who should receive invoices for any agreement:

1. Name, title, address, phone, fax and email for Applicant's representative who should receive any materials; please include shipping carrier and account number:
2. Is Applicant a U.S. Corporation? \_\_\_\_\_ yes \_\_\_\_\_ no

State of incorporation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If non-US, state country of origin: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If an individual, citizenship: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. Is Applicant a Small Business Firm? \_\_\_\_\_ yes \_\_\_\_\_ no

1. Is Applicant a Start-up Company? \_\_\_\_\_ yes \_\_\_\_\_ no

9. Applicant Tax ID # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Type of License Sought

|  |  |
| --- | --- |
| **Patented Inventions** | **Unpatented Inventions** |
| \_\_\_\_\_ **Exclusive** Patent License\* | \_\_\_\_\_ **Nonexclusive** Biological Materials License\* |
| \_\_\_\_\_ **Co-exclusive** Patent License\* | \_\_\_\_\_ **Nonexclusive** Biological Materials License – Internal Use\*\* |
| \_\_\_\_\_ **Nonexclusive** Patent License\* | \_\_\_\_\_ **Nonexclusive** Commercial Evaluation Biological Materials License -- Internal Use\*\*\* |
| \_\_\_\_\_ **Nonexclusive** Patent License – Internal Use\*\* |  |
| \_\_\_\_\_ **Nonexclusive** Commercial Evaluation Patent License-- Internal Use\*\*\* |  |

\_\_\_\_\_ **Start-Up Exclusive License Agreements**\*\*\*\*

\_\_\_\_\_Start-up Exclusive Option Agreement

\_\_\_\_\_Start-up Exclusive Patent License Agreement

\* for commercial sale

\*\* for internal use only: no right to sell or distribute materials

\*\*\* for internal use only: no right to sell or distribute materials and **for a limited-term evaluation**

\*\*\*\* Applications accepted from Oct. 1, 2013-Sept. 30, 2014. Specific information may

be found here: <http://www.ott.nih.gov/startup/>.

**Will applicant accept PDF execution copy of the agreement? \_\_\_\_\_\_ Yes \_\_\_\_\_\_ No**

Proposed Field(s) of Use (please provide a desired Licensed Field of Use):

ON *SEPARATE ATTACHMENTS* TO THIS APPLICATION, PLEASE PROVIDE THE FOLLOWING INFORMATION:

1. Description of Applicant

Include nature and type of applicant's business; number of employees; corporate/divisional commitment to R&D, production, sales & marketing; financial resources; products or services successfully commercialized and any unique capabilities of your company relative to the licensed technology. (If a prior license application has been submitted to the Office of Technology Transfer within the past year, you may reference that application for the company description.)

* 1. If this license application is for a start-up agreement, the following conditions must be met by the applicant company:
     1. start-up companies less than 5 years old;
     2. less than $5M in capital raised; and
     3. company has fewer than 50 employees.

II. Other Licenses and Use of the Invention

Identify any licenses previously granted to the Applicant under federally owned inventions. Also, identify, to the best of Applicant's knowledge, the extent to which the invention for which a license is sought is being practiced by private industry or Government, or is otherwise available commercially.

III. Proposed License Terms

Include definitions of licensed products, processes or methods; geographic territories; duration of license; claims (if known) of patent/patent application under which the proposed licensed technology would fall; and other terms for which you wish to make a proposal at this time.

IV. Research, Development and Marketing Plan

Include description of product(s) or method(s) to be developed with the licensed technology and, for each product or method to be developed, a description of expected product research and development programs, including (where relevant) major preclinical, clinical, regulatory, manufacturing and marketing stages; monetary and personnel commitments for each development stage; and the projected time to accomplish each stage of commercial development. *If you will be using the licensed technology in house but will not be directly commercializing the licensed technology or providing a service based on the technology, you need only describe the research program in which the licensed technology will be utilized.*

V. Market Analysis

Include relevant market segment(s) the licensed technology will serve when commercialized; market size and projected growth of relevant markets during the duration of the license; estimated market share once product is introduced; and sales projections based on market share analysis. *(THIS INFORMATION NEED NOT BE PROVIDED IN APPLICATIONS FOR COMMERCIAL EVALUATION LICENSES OR NONEXCLUSIVE COMMERCIAL RESEARCH LICENSES.)*

VI. Other Information Which You Believe Will Support a Determination to Grant the Requested License

VII. For Applicants for Exclusive or Partially Exclusive Licenses ONLY

A detailed statement as to *1)* why Federal and public interests will be best served by exclusive licensing of this invention; *2)* why expeditious practical application of the invention is unlikely to occur under a nonexclusive license; *3)* why the exclusive licensing of this invention is a reasonable and necessary incentive to attract investments of risk capital; *4)* why the exclusive licensing of this invention will not tend substantially to lessen competition or result in undue market concentration; and *5)* why the proposed license terms and scope of exclusivity are not greater than reasonably necessary.

**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. Additionally, if applicant is applying for a “Start-Up Exclusive Option Agreement,” the signature below affirms that the applicant’s company meets the stated requirements in Section I(a)(i-iii) of this NIH License application.**

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Signature of Applicant or Authorized Representative Date

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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(a)***](http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=RETRIEVE&FILE=$$xa$$busc35.wais&start=560691&SIZE=6621&TYPE=TEXT)***; and, to the extent permitted by law, will not be accessible under the Freedom of Information Act.***