

**MODEL LICENSE AGREEMENT FOR USE BY NON-PROFITS:
Providing Rights to NIH Technologies for Distribution and Sale of Products
for Neglected Tropical Diseases, HIV, TB and Malaria**

LICENSEE QUALIFICATIONS: Not-for-profit institutions such as Product Development Partnerships (PDP) and Non-Government Organizations (NGOs) with a demonstrated commitment to diligence in providing broad global access to technologies, products and services consistent with an acceptable Development Plans.

FIELD: Vaccines, drugs, therapeutics and diagnostics (or enabling technologies to produce such products) to prevent, diagnose or treat Neglected Tropical Diseases (NTDs see http://www.who.int/neglected_diseases/en/), HIV, TB and malaria in humans or animals. Other technologies will be considered on a case-by-case basis.

LICENSE TERM: Commercial license in a specified Field of use for the term of the patent(s) or 20 years for biological materials.

TERRITORY: Defined by specific countries within the World Bank categories of low and lower middle income countries (<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519>) as of the effective date of the license agreement.

DEVELOPMENT PLAN: The NGO/PDP's development plan will detail with time and financial commitments how the product will be brought to final application, distribution or sale and may include, but is not limited to: hiring of management personnel, completion of prototype or proof of concept, raising specific amounts of funds for R&D, manufacturing timelines, first sublicense, initiation of clinical trials (all phases), initiation of regulatory filings, first sale or distribution, etc.

DEGREE OF EXCLUSIVITY: By law and policy, NIH favors non-exclusive licenses. Licenses to platform technologies, including in the field of diagnostics, will be available on a nonexclusive basis or in some cases under an exclusive license with very narrow product specific limitations. Consistent with applicable laws, regulations and policies, exclusive licenses will be considered for potential drug (small molecular entities and biologics) and vaccine components and will be limited to defined indications and territories. Nonexclusive licenses will be available for technologies to the extent defined indications and territories are not already licensed exclusively or subject to an exclusive license option under a Cooperative Research and Development Agreement (CRADA).

TERMINATION OR "PULL BACK" TERMS: License terms will include mandatory sublicensing or surrender of rights in countries where diligence is not pursued consistent with the Development Plan. Exclusive licenses will include "pull back" terms for new or unmet needs that the licensee elects not to pursue or cannot commit to pursue. An exclusive licensee may be required to sublicense, reduce the license to non-exclusivity, or to relinquish rights to sell or distribute product in a particular territory or for a particular indication when the Development Plan milestones are not met, and the Licensee does not provide an adequate plan to remedy the lack of diligence. Alternatively, NIH may terminate the license in its entirety as necessary to ensure successful development and commercialization in the Field.

SCOPE: (1) Licenses to pending or issued US and/or foreign equivalent patents, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents, owned by the US Government and managed by the National Institutes of Health (NIH) Office of Technology Transfer, i.e. inventions made by NIH and FDA intramural scientists or co-invented with other institutions when OTT has the licensing lead; (2) licenses to unpatented biological materials developed by NIH or FDA intramural scientists and used in the production or sale of a product or service. Licenses are subject to statutory rights reserved by the U.S. Government.

FINANCIAL TERMS:

Patent Expenses: Exclusive Licensees will reimburse NIH for up to 50% of patent expenses and annuities for licensed territories incurred after the Effective Date of the Exclusive Commercialization License depending on the potential market and scope of license. Non-exclusive licensees of a patent or patent family will divide equally the reimbursement to NIH for up to 50% of patent expenses and annuities for licensed territories incurred after the Effective Date of the Non-Exclusive Commercialization License depending on the potential market and scope of license.

License Fee: \$2,000 up front fee. For biological materials, upfront costs may include the cost of providing the materials.

Royalty: 1.5 % (Exclusive) or 0.75% (Nonexclusive) of Licensee's Net Direct Sales of Licensed Product(s) or Process(es) excluding sales to public sector institutions or to institutions using public-sector funds (such as PEPFAR or Global Fund)

Sublicense:

Exclusive: 15% (which NIH can attribute first to patent expenses) if NIH has provided in vivo model data

10% (which NIH can attribute first to patent expenses) if NIH had not provided in vivo model data

Nonexclusive: Half these amounts

Milestone Payments: None. Enforceable performance (diligence) milestones are required based on the specific elements of the Development Plan.

Minimum Annual Royalty: None.

Stacking Royalty Clause: If Licensee is required to pay royalties to one or more third parties in order to make, use or sell the Licensed Product, then Licensee may deduct 50% of all such royalties paid to such third party from the royalties due to PHS [NIH]. In no event will the royalty payable to NIH be reduced by more than 50%.

Additional license terms will be based on NIH model agreements found at <https://www.ott.nih.gov/resources>.

RELATIONSHIP TO WIPO Re:Search: For technologies NIH has made available through WIPO Re:Search, any commitments to licensing terms under that program will supersede the terms above to the extent there is overlap. See <http://www.wipo.int/research/en/>.

CONTACT: For a specific technology, the Licensing Manager listed as the contact on the Technology Abstract, see <https://www.ott.nih.gov/opportunities>.