**Agreement for Submitting Products to the Division of Microbiology and Infectious Diseases, NIAID, NIH for Antiviral Screening**

The Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (DMID, NIAID), an institute of the National Institutes of Health, which is a component of the U.S. Public Health Service, an agency of the U.S. Government, offers antiviral screening services, through contract testing laboratories, to for-profit and non-profit organizations to help facilitate the rapid development and commercialization of products for the treatment of viral diseases other than AIDS. The COMPANY would like to submit its product(s) for antiviral screening. Therefore, the COMPANY and DMID, NIAID agree as follows:

1. **Restricted Use of COMPANY Product(s).** COMPANY may submit product(s), patented or unpatented, to DMID, NIAID for the purpose of being evaluated for antiviral activity in *in vitro* systems by one or more testing laboratories under contract with the DMID, NIAID (hereinafter "contractor(s)"). DMID, NIAID agrees that the product(s) will be evaluated only in accordance with known testing protocol(s) by its contractor(s), as approved by COMPANY, as agents with potential for the treatment or prevention of infectious diseases and for no other purpose. The product(s) will not be transferred to any party other than the approved contractor(s). In addition, the product(s) will not be chemically modified, replicated, derivatized or reverse engineered unless required by the approved testing protocol or otherwise approved in writing by COMPANY.

2. **Confidentiality.** Information, data and records will be handled as follows:

   a. COMPANY shall forward to the Virology Branch (VB) or Enteric and Hepatic Diseases Branch (EHDB) of the DMID, NIAID or, as directed by either the VB or the EHDB, to the contractor(s) the data sheet(s) on the product(s) to be evaluated, marked "confidential". COMPANY shall provide duplicate copies of the data sheet(s) for each product, which shall include all pertinent available data as to chemical composition, solubility, toxicity, etc. and any precautions that should be followed in handling, storing and shipping the product. For those products in which COMPANY has a proprietary interest but does not yet have adequate patent protection, COMPANY may, in rare cases and with approval by DMID, NIAID, submit a product(s) under code number(s) only. In these cases, COMPANY agrees to reveal to DMID, NIAID and its contractor(s) the structures or identities of the coded product(s), marked "confidential", which subsequently turn out to be positive in any one of the test systems. The structures or identities of such product(s) will remain confidential in accordance with Section 2b below.

   b. COMPANY may provide to DMID, NIAID and/or its contractor(s) any scientific, business or financial information relevant to the product(s) that COMPANY deems to be its proprietary and confidential information. COMPANY must identify such information as confidential. To the extent permitted by law, this information will remain confidential for five (5) years from the date of disclosure unless:

      (1) the information is known by the public or becomes known by the public through no fault of DMID, NIAID or its contractor(s);

      (2) the information was obtained by DMID, NIAID or its contractor(s) from a third party having no confidentiality obligation to COMPANY;

(3) the information was made available to DMID, NIAID or its contractor(s) by COMPANY without a confidentiality obligation;

(4) the information has been independently developed by DMID, NIAID or its contractor(s) without reference to COMPANY's information; or

(5) the information is required to be disclosed by law, regulation or court order provided that COMPANY has been notified and DMID, NIAID and/or its contractor(s) have taken reasonable efforts to minimize the extent of the required disclosure.

c. DMID, NIAID agrees that information or data about the product(s), including the evaluation results, will be kept in restricted-access files by DMID, NIAID and the contractor(s). Only employees of DMID, NIAID or its contractor(s) will have access to the files containing information about the product(s) including the evaluation results. COMPANY acknowledges that the evaluation results are not its confidential information and may be disclosed by DMID, NIAID and/or its contractor(s) *only* in accordance with Section 3b below.

d. The contracts between DMID, NIAID and the testing laboratories require the contractor(s) to abide by the terms of this Agreement.

e. DMID, NIAID will use its best efforts to assure rapid ongoing communication of the evaluation results to COMPANY and, in turn, COMPANY will use its best efforts to keep DMID, NIAID up-to-date on COMPANY's own ongoing concomitant studies.

3. **Intellectual Property and Publications.** COMPANY recognizes that the exchange of biological data and other information is generally desirable in the field of antiviral treatment, and DMID, NIAID recognizes that COMPANY, is entitled to protection for its research and development work on the product(s) and its related technical information. Therefore:

a. Intellectual Property. DMID, NIAID agrees that all right, title and interest in and to all products and information provided by COMPANY to DMID, NIAID under this Agreement will remain with COMPANY. DMID, NIAID acknowledges that this Agreement may not be construed as a grant by COMPANY of a license or any other right or interest beyond those expressly set forth herein. The contracts between DMID, NIAID and its testing laboratories require the contractor(s) to assign to COMPANY all right, title and interest in and to any invention made during the evaluation that directly relates to COMPANY's product(s). For purposes of this Agreement the phrase "directly relates to" means "contains, in whole or in part, COMPANY's product(s)" and/or any new use of COMPANY's product(s).

b. Publications. COMPANY and DMID, NIAID agree that the publication of biological data on COMPANY's product(s) evaluated under this Agreement is worthwhile and to be encouraged. Therefore:

(1) COMPANY agrees that DMID, NIAID and/or its contractor(s) may publish or otherwise publicly disclose the evaluation results after a period of six (6) months from the date the evaluation results are reported to COMPANY. Publication of data within the six (6) month period will require COMPANY'S prior consent, which shall not be unreasonably withheld. DMID, NIAID and/or its contractor(s) shall not publish

information identifying COMPANY as the source of the product(s) without COMPANY's prior written approval.

(2) As soon as the evaluation(s) is/are completed and reported by the contractor(s) to the VB or EHDB of DMID, NIAID, COMPANY will receive a full report of the evaluation(s). COMPANY agrees to consult the VB or EHDB of DMID, NIAID whenever COMPANY desires to include the evaluation results in any publication or other public disclosure such as a press release, and shall give appropriate credit to the U.S. Public Health Service and the DMID, NIAID's contractor(s) that performed the evaluation(s). COMPANY shall not construe the involvement of DMID, NIAID or its contractor(s) in the evaluation(s) as an endorsement of the product(s) by the U.S. Government or any of its agencies or employees.

4. **Liability and Indemnification.** Each Party shall be liable for any loss, claim, damage, or liability that it incurs as a result of its activities under this Agreement except that the NIAID, as an agency of the U.S. Government, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Ch. 171. No indemnification is provided by either Party under this Agreement. The NIAID is prohibited under statute, the Anti-Deficiency Act, 31 U.S.C. § 1341, from indemnifying any party, absent other specific statutory authorization.

If COMPANY agrees to the terms above, please have an authorized representative countersign below and return one fully-signed original to the Division of Microbiology and Infectious Diseases, NIAID.

**National Institute of Allergy and Infectious Diseases**

_____
Carole Heilman, Ph.D.
Director, Division of Microbiology & Infectious Diseases
NIAID, NIH

_____
Date

**COMPANY**

_____
Signature of Authorized Representative

_____
Printed/Typed Name

_____
Name of Company

_____
Address of Company

_____
Date