# NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
# CLINICAL TRIALS AGREEMENT
# FOR STUDIES DONE WITH THE DIR

**Based on**

**Protocol _____**

**(TITLE)**

**In Collaboration With**

**(Pharmaceutical Sponsor)**

**(Date)**

This Agreement, effective as of _____, is made between _____, The National Institutes of Health ("Study Center"), and _____ ("Sponsor"), (collectively the "Parties") for the purpose of conducting clinical research. Citations to the Code of Federal Regulations ("C.F.R.") in this agreement are citations to regulations governing investigations of new drugs.

## 1.0 DEFINITIONS

For the purposes of this Agreement:

1.1 "**Company**" means the Party with which NIAID will work in this scientific undertaking.

1.2 "**Investigational New Drug**," as that term is defined in 21 C.F.R. 312.3(b), is _____.

1.3 "**Investigator**," as that term is defined in 21 C.F.R. 312.3(b), is _____, who agrees to direct the administration of the Investigational New Drug in accordance with the Protocol.

1.4 "**Protocol**" means the protocol, number _____, which is entitled "_____," and which is attached as Exhibit A. Exhibit A is made a part of this Agreement as though fully set forth. Any statement in the Protocol which is inconsistent with this Agreement is superseded by the Agreement.

1.5 The "**Sponsor**," as that term is defined in 21 C.F.R. 312.3(b), is _____.

1.6 "**Study**" or "**Clinical Investigation**" means the work performed by the Investigator and any Sub-investigators in connection with the Protocol.

1.7 "**Sub-investigator**" as that term is defined in 21 C.F.R. 312.3(b), is any individual designated by the Investigator in the event the clinical investigation is conducted by a team.

1.8 "**Subject**," as that term is defined in 21 C.F.R. 312.3(b), is a human being who participates in the Study.

1.9 "**Confidential/Proprietary Information**," means confidential scientific, business, or financial information provided that such information:

is not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;

has not been made available by its owners to others without a confidentiality obligation;

is not already known by or available to the receiving Party without a confidentiality obligation; or

does not relate to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan of this Agreement.

## 2.0 THE STUDY

2.1 The Study shall be conducted in accordance with the Protocol and no changes in the Protocol will be made unless agreed upon in advance by Sponsor or unless necessary to protect the safety, rights, or welfare of the Subjects.

2.2 Enrollment for the Study will begin on or about _____. The planned enrollment is ____ Subjects. The Study is to be completed by _____, unless the Parties mutually agree to a different date.

## 3.0 INVESTIGATIONAL NEW DRUG

Company shall provide, without charge, appropriate quantities of the Investigational New Drug and placebo, if applicable, to be used in the Study. Such drug shall be shipped to Study Center in appropriately marked containers in accordance with 21 C.F.R. 312.6.

When NIAID holds the IND, the NIAID shall be responsible for the submission of an IND covering Protocol _____. The IND shall satisfy all of the requirements of the United States Food and Drug Administration (U.S. FDA). A letter granting cross reference to **(Pharmaceutical Sponsor)**'s FDA files which pertain to **(Drug)** shall be supplied by **(Pharmaceutical Sponsor)**, and, in return, the NIAID will also supply a letter, if requested, granting cross reference to the NIAID'S IND to **(Pharmaceutical Sponsor)**.

When the Company holds the IND, the Company shall be responsible for the submission of an IND covering Protocol _____. The IND shall satisfy all of the requirements of the United States Food and Drug Administration (U.S. FDA). A letter granting cross reference to NIAID's FDA files which pertain to **(Drug)** shall be supplied by NIAID, and, in return, the Company will also supply a letter, if requested, granting cross reference to the Sponsor's IND to NIAID.

## 4.0. FDA MEETINGS

With respect to any discussions with FDA involving data obtained from this trial, IND holder shall take the initiative in arranging meetings with the FDA. Formal meetings with the FDA concerning the trial data shall be discussed and agreed upon by **(Pharmaceutical Sponsor)** and the DIR, NIAID in advance.

## 5.0 HUMAN SUBJECTS

Informed consent of the Subjects participating in the Study shall be obtained in accordance with 21 C.F.R. Part 50 and Institutional Review Board ("IRB") review and approval of the Protocol, including the Informed Consent form, shall be obtained in accordance with 21 C.F.R. Part 56. Study Center agrees to supply Company with evidence of IRB approval, a copy of the informed Consent form which is IRB-approved, and a copy of any modified Informed Consent form later approved by the IRB and used.

## 6.0 RECORD KEEPING AND ACCESS TO RECORDS

6.1 Study Center agrees to maintain adequate and accurate records as required under 21 C.F.R. 312.62 relating to the disposition of the Investigational New Drug and the treatment of Subjects of the Study.

6.2 Study Center agrees to maintain the records required by 21 C.F.R. 312.62 for a minimum of two years following the date a marketing application is approved for the drug for the indication which is being investigated, or until two years after Sponsor has provided written notice to the Investigator that the investigation has been discontinued.

6.3 Study Center further agrees to permit Sponsor access to the records, except blinded records, maintained pursuant to paragraph 6.1 upon request at reasonable times.

6.4 Sponsor shall not at any time disclose the name of any Subject or any information which identifies a Subject to a third party unless specifically required to do so by law or the Food and Drug Administration.

## 7.0 CONFIDENTIALITY

7.1 Study Center agrees that all written information marked "Confidential" and received from Sponsor, and received by and agreed to by NIAID, including but not limited to the Investigator's Brochure and the Protocol, is "Confidential Information" which is the sole and exclusive property of Sponsor during the period of this Agreement and subsequent thereto. Likewise, all information which is disclosed visually or orally and subsequently confirmed as Confidential Information in writing within ten (10) working days after first disclosure will be held as Confidential Information.

7.2 Study Center agrees not to disclose Company's Confidential Information to any person, except the Investigator, Sub-investigators, members of the Institutional Review Board or, as required, to the Food and Drug Administration, without the prior written consent of Company and further agrees to take all reasonable

precautions to prevent the disclosure by the Investigator, Sub-investigators, and the IRB of Sponsor's Confidential Information to a third party.

7.3 The Investigator agrees to use Company's Confidential Information only in the conduct of the Study and evaluation of its results, and not for its own purposes.

## 8.0 PUBLICATION

The Investigator agrees to provide the Company copies of any presentations or publications thirty (30) days prior to disclosure for review so that any Confidential Information can be identified and to allow the Sponsor to provide comments on the presentation or publication.

## 9.0 REPORTING

Adverse experience reports shall be collected by the IND holder according to the procedures outlined in the Protocol. The Sponsor shall assume total responsibility for the reporting of such adverse events to the FDA with a copy to Sponsor.

The Sponsor shall report all serious and life threatening adverse events observed in this clinical trial to Sponsor on a timely basis consistent with Federal Regulations 21 CFR 312.32. All other adverse experiences shall be reported by IND holder to Sponsor on a timely basis consistent with Federal Regulations 21 CFR 312.33 for the Annual Report. Specific provisions for reporting adverse experiences to agencies outside the U.S. shall be provided for as required.

Company shall, in a timely manner and during the term of this trial, provide the IND holder with any information it now has or may obtain in the future regarding the safety and/or the toxicity of **(Drug)**.

**Mandatory Article/Modifiable (depends on who holds IND)**

## 10.0 MONITORING

The Sponsor shall be responsible for clinical site monitoring and the quality assurance of all data. Monitoring shall be done in compliance with U.S. FDA Good Clinical Practices Guidelines.

**Mandatory Article/Modifiable (depends on who holds IND)**

## 11.0 INVENTIONS

Company does not grant to NIAID or any other person or entity any right or license to any patent, confidential information, or other intellectual property rights owned by Sponsor. Accordingly, any invention, discovery, or other patentable subject matter created or discovered in the course of this Agreement shall be the property of the entity

whose employees were the inventors of the creation or discovery. Where employees of both parties are co-inventors of such invention or discovery, such invention or discovery shall be joint property of both parties. NIAID will seriously consider Sponsor's patent and/or licensing position with respect to _____in the licensing of government-owned intellectual property rights, if any, arising from the study described herein. All licensing of government-owned intellectual property will be negotiated consistent with Federal Statute(s) and NIH Policy on Intellectual Property and Licensing.

## 12.0 COMPLIANCE WITH STATUTES

Study Center and the Investigator and Company agree to conduct the Study in accordance with the applicable portions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.. 301 et seq., and its implementing regulations and other applicable federal and state statutes and regulations.

## 13.0 TERMINATION

13.1 Company and the Investigator, by mutual written agreement, may amend or terminate the Study and this Agreement at any time.

13.2 Company has the right to terminate this Agreement upon written notice to the Investigator for good cause and with reasonable notice. Good cause shall include unsatisfactory clinical results, non-compliance with any Food and Drug Administration or other applicable regulatory requirements, or material breach by the Study Center of any of its obligations under this Agreement. Investigator also has the right to terminate this Agreement upon written notice to Sponsor for good cause and with reasonable notice. Good cause shall include the circumstance in which the Investigator becomes unable to direct the work and the Study Center is unable to propose a substitute agreeable to Sponsor.

13.3 Section 7.0 will remain in full force and effect without regard to whether the Parties have fully performed their obligations under this Agreement and as long as Study Center or the Investigator are in possession of Sponsor's "Confidential Information."

## 14.0 CHANGES, GOVERNING LAW, AND NOTICE

14.1 This Agreement constitutes the entire understanding of Company and Study Center. No changes, amendments, or alterations shall be effective unless in writing and signed by the Parties.

14.2 The construction, validity, performance, and effect of this CTA shall be governed by Federal Law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

14.3 Any notice required to be given under this Agreement shall be sent to the other Party by certified mail, return receipt requested, and shall be deemed given 3 days after the date of postmark. Notice shall be given to each Party at the address set forth at the beginning of this Agreement unless otherwise mutually agreed upon in writing.

The persons executing this Agreement represent and warrant that they have the full power and authority to enter into this Agreement on behalf of the persons or entities they are signing on behalf of.

**Study Center:**

By: _____

Name: _____

Title: _____

Date: _____

**Sponsor:**

By: _____

Name: _____

Title: _____

Date: _____

**Investigator:**

By: _____

Name: _____

Title: _____

Date: _____