MASTER CLINICAL SERVICES AGREEMENT

Between

Fujirebio Diagnostics, Inc.

And

The Trustees of the University of Pennsylvania
CLINICAL TRIAL CLINICAL SERVICES MASTER AGREEMENT

This Master Clinical Services Agreement ("Master Agreement") is entered into by and between: THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation, owner and operator of the University of Pennsylvania Health System, through its Office of Research Services, P-221 Franklin Building, 3451 Walnut Street, Philadelphia, PA 19104-6205 hereinafter called "Institution," and Fujirebio Diagnostics, Inc., a corporation with its principal office and place of business at 201 Great Valley Parkway, Malvern, PA 19355, hereinafter called "Sponsor."

BACKGROUND

The clinical services contemplated by this Master Agreement are of mutual interest and benefit to the Institution and to the Sponsor, and will further the Institution's public mission as an academic healthcare center in a manner consistent with its status as a non-profit, tax-exempt corporation.

TERMS

The parties hereto, intending to be legally bound, agree as follows:

1. SCOPE OF WORK AND CLINICAL SERVICE SPECIFIC AGREEMENTS

   Sponsor and Institution intend for this Master Agreement to establish terms and conditions for contract the performance of clinical research which may include laboratory analysis, validation services, preclinical studies, diagnostic test methods clinical studies and assay development ("Clinical Service"). In the event that Sponsor and Institution agree that Institution will conduct a Clinical Service, the parties shall enter into a Clinical Service Specific Agreement under this Master Agreement prior to conducting the Clinical Service at Institution. An executed Clinical Service Specific Agreement, along with this Master Agreement, shall constitute the agreement of the parties with respect to that Clinical Service. A Clinical Service Specific Agreement form, which may be modified by mutual agreement of the parties for specific Clinical Services, is included as Exhibit A. Each Clinical Service Specific Agreement will incorporate by reference the terms of this Master Agreement and a detailed technical description of the planned Clinical Service ("Protocol"), but each Clinical Services Specific Agreement shall be a unique agreement and shall stand alone with respect to any other Clinical Service Specific Agreement. If any provisions of a Clinical Services Specific Agreement are in direct conflict with this Master Agreement so that the provisions of both cannot be given effect, the terms of the Master Agreement shall govern the specific issue.

2. PRINCIPAL INVESTIGATOR

   Institution's Principal Investigator, as designated in each Clinical Service Specific Agreement, will be responsible for the direction of the Clinical Service in accordance with the Protocol, applicable Institution policies, generally accepted standards of good clinical practice, all applicable local, state and federal laws and regulations governing the performance of clinical investigations. If for any reason, a Principal Investigator is unwilling or unable to continue to serve as Principal Investigator and a successor, acceptable to both the Institution and the Sponsor is not available, the Clinical Service Specific Agreement may be terminated as provided in Article 12 of the Master Agreement.

3. PERFORMANCE PERIOD

   The effective period of this Master Agreement will be from the date of execution of this Master Agreement and will continue until completion of the obligations established in this Master Agreement unless otherwise terminated in accordance with Article 12. The effective period may be extended by the mutual written consent of the parties hereto, as provided in Article 13. No Clinical Services may begin until approval is received from the Institutional Review Board.

CLINICAL SERVICES MASTER AGREEMENT JULY, 2005

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4. RECORDKEEPING

A. The Institution and the Principal Investigator shall prepare and maintain records, reports and data as provided in the Protocol, IRB requirements, and in accordance with all applicable local, state and federal laws and regulations.

B. Institution shall cooperate with any regulatory authority with appropriate jurisdiction and allow them reasonable access to relevant Clinical Service records and data.

C. All data from Clinical Services may be utilized by Sponsor for any reasonable purpose, including use of the test results and any other information provided hereunder for the evaluation, development, and commercial introduction of diagnostic test methods and FDA submissions. Sponsor understands that it bears sole responsibility for its use of such data and any other information provided by Institution and/or Principal Investigator hereunder.

D. Clinical Service records shall be maintained for a period of three (3) years following termination of the related Clinical Service Specific Agreement, or for a period defined in the protocol, whichever is longer, but shall not be destroyed without Sponsor's consent.

E. Institution shall notify Sponsor promptly upon receipt of a request for an inspection by FDA or other regulatory authority in relation to a Clinical Service. In the event that Institution or Principal Investigator receive an FD-483 or warning letter relating to the Clinical Service, a copy shall be promptly sent to Sponsor. A copy of the draft response to the FD-483 or warning letter shall be provided to Sponsor before the response is sent to FDA.

F. Institution and Sponsor each represents and warrant to the other that it will comply with all applicable laws, rules or regulations that relate to the conduct of any Clinical Service and the performance by the parties of their respective obligations under this Master Agreement ("Applicable Laws"). Applicable Laws include the federal Medicare/Medicaid Anti-kickback Law and regulations promulgated thereunder (the "Federal Anti-kickback Law") and the HIPAA Privacy Regulations. Failure by either party to comply with any Applicable Law shall be considered a material breach of this Master Agreement. Each party shall adopt, implement, and maintain throughout the term of this Master Agreement appropriate and adequate security policies, procedures, and practices, physical and technological safeguards, and security mechanisms to protect patients' Individually Identifiable Health Information ("IIHI") against unauthorized use, disclosure, alteration, or destruction ("Safeguards"). Sponsor shall require its subcontractors or agents to adopt Safeguards that are equally appropriate and adequate. In the event the Sponsor shall come into contact or otherwise have access to Clinical Service subject's medical records, the Sponsor shall hold in confidence the identity of the subject and shall comply with all applicable law(s) regarding the confidentiality of such records. Sponsor will review and approve of the Informed Consent document and any Authorization document. Sponsor agrees that, should Sponsor gain access to any IIHI of Clinical Service subjects, Sponsor will treat such IIHI in accordance with the Informed Consent document, any Authorization document, and all applicable laws and regulations. If Sponsor gains access to any protected health information that is not covered by the Informed Consent or Authorization, Sponsor shall hold such information in the strictest confidence, shall not remove records containing such information from the Institution and, if inadvertently removed, shall immediately return any records containing such information to the Institution.
5. COST AND PAYMENT

A. As consideration for performance under the terms of any Clinical Service Specific Agreement, Sponsor shall pay the Institution a total in accordance with the Compensation section of the Clinical Service Specific Agreement. All costs outlined on the budget shall remain firm for the duration of the Clinical Service, unless otherwise agreed in writing by the Institution and Sponsor. If not budgeted, a one-time clinical trial review and monitoring fee will be invoiced.

B. Checks will be made payable to: "The Trustees of the University of Pennsylvania." Checks or accompanying letter will reference the Clinical Service and the Principal Investigator's name and will be sent to:

Office of Research Services
University of Pennsylvania
P-221 Franklin Building
3451 Walnut Street
Philadelphia, PA 19104-6205
ATTENTION: EXECUTIVE DIRECTOR

23-1352685
Institution Tax Identification Number

6. CONFIDENTIAL INFORMATION

Institution shall use reasonable care not disclose to any third party or use for purposes other than the performance of this Clinical Service trade secrets, privileged records or other proprietary information designated by Sponsor as confidential ("Confidential Information") disclosed to the Institution pursuant to this Master Agreement. Sponsor shall only disclose Confidential Information to Institution necessary for the conduct of the Clinical Service. The Institution’s obligations of confidentiality will exist during the performance of this Master Agreement and for five (5) years following termination or expiration of this Master Agreement, unless disclosure is required by law or regulation. Excluded from the definition of Confidential Information is information (i) which is known by the Institution without restriction prior to disclosure under this Master Agreement; (ii) is disclosed to the Institution by a third party without an obligation of confidentiality; (iii) is generally available to the public through no fault of the Institution; (iv) is independently developed by Institution without knowledge or use of Confidential Information disclosed by Sponsor under this Master Agreement; (v) is required to be disclosed in accordance with Federal, State or Local law or regulation; or (vi) is published, presented or disclosed in accordance with the terms of this Master Agreement.

7. REPORTS AND PUBLICATIONS

Institution shall cooperate with Sponsor in making records, reports and data developed under this Master Agreement available to the Sponsor upon reasonable notice during Institution’s normal business hours. Principal Investigator shall provide to Sponsor such written Reports on the results of the Clinical Services as are agreed to in the Protocol. Such Reports shall be the property of Sponsor. Principal Investigator shall have the right to publish new scientific results and data resulting from the Clinical Services. Principal Investigator shall use reasonable efforts not to disclose Sponsor’s Confidential Information. Prior to submission for publication or presentation, the Institution will provide the Sponsor thirty (30) days for review of a manuscript. Sponsor shall have the right to request reasonable alterations in the proposed publication. In the event that the proposed manuscript or publication contains patentable subject matter, Institution shall refrain from making such publication or presentation or other disclosure for a maximum of sixty (60) days in order for patent application(s) directed to the patentable subject matter contained in the proposed publication or presentation to be
filed with the United States Patent and Trademark Office and/or foreign patent office(s). Expedited reviews for abstracts, poster presentations or other materials will be arranged by the Sponsor and the Institution and Principal Investigator

8. PATENTS AND INVENTIONS

A. "Sponsor's Inventions" shall mean any invention or discovery conceived or reduced to practice during and as part of the Clinical Services performed pursuant to this Master Agreement which are based entirely on Sponsor's Protocol. Sponsor's Inventions shall be disclosed promptly to Sponsor and shall be the property of Sponsor.

B. "Institution's Inventions" shall mean any invention or discovery conceived or reduced to practice during and as part of the Clinical Services performed pursuant to this Master Agreement which are not based on Sponsor's Protocol. Institution's Inventions shall be the property of Institution.

C. Institution shall provide to Sponsor a complete written disclosure of any Institution's Inventions reasonably considered patentable. For Institution's Inventions, Sponsor shall reimburse Institution upon receipt of invoice for all documented expenses incurred in connection with the filing and prosecution of the patent applications and maintenance of the patents that Sponsor has requested Institution to file and prosecute. If Sponsor does not request Institution to file and prosecute such patent applications, Institution may proceed with such preparation and prosecution at its own cost and expense, without any further obligation to Sponsor. Institution grants Sponsor a first option to negotiate to acquire a royalty-bearing license to practice Institution's Inventions. If Sponsor and Institution fail to execute a license agreement within six (6) months after disclosure of Institution's Inventions, or if Sponsor fails to make payment for intellectual property expenses as provided for in Paragraph C, Institution shall be free to license Institution's Inventions to any party upon such terms as Institution deems appropriate, without any further obligation to Sponsor.

E. Any license granted to Sponsor pursuant this section hereof shall be subject, if applicable, to the rights of the United States government reserved under Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, and any regulations issued thereunder.

F. It is agreed that neither the Sponsor nor the Institution transfers to the other by operation of this Master Agreement any patent right, copyright right, or other proprietary right of either party, except as specifically set forth herein.

9. USE OF THE INSTITUTION'S OR SPONSOR'S NAME (ADVERTISING)

A. The Institution and the Sponsor will obtain prior written permission from each other before using the name, symbols and/or marks of the other in any form of publicity in connection with the Clinical Services. This shall not include legally required disclosure by the Institution or Sponsor that identifies the existence of the Master Agreement or Clinical Service Specific Agreement. Further, Sponsor's use of the name, symbols and/or marks of Institution, or names of Institution's employees, shall be limited to identification of Institution as the Clinical Services site and the Clinical Services staff as participants in the Clinical Services.

B. The Sponsor will not use, nor authorize others to use, the name, symbols, or marks of the Institution in any advertising or publicity material or make any form of representation or statement in relation to the Clinical Service which would constitute an expressed or implied endorsement by the Institution of any commercial product or service without prior written approval from the Institution.

10. NOTICE
Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail or overnight courier, postage prepaid, return receipt requested and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

To Sponsor:

W. Jeffrey Allard, Ph.D.
Vice President and Chief Scientific Officer
Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

To Institution:

EXECUTIVE DIRECTOR
OFFICE OF RESEARCH SERVICES
UNIVERSITY OF PENNSYLVANIA
P-221 FRANKLIN BUILDING
3451 WALNUT STREET
PHILADELPHIA, PA 19104-6205

11. **INDEMNIFICATION**

A. Sponsor shall defend, indemnify and hold harmless the Institution, the Principal Investigator and faculty, students, trustees, officers, agents and employees of Institution from any and all liabilities, claims, actions or suits arising out of or in connection with the performance of the Clinical Service. The obligation to indemnify shall not apply to:

   (1) the extent the loss is due to Institution’s failure to conduct the Clinical Service in accordance with the Protocol; or

   (2) to the extent it has been ultimately determined that, on a comparative basis between Institution and Sponsor, such loss arises out of the negligence or willful misconduct of any Indemnitee. Deviations from the terms of the Protocol that may arise out of necessity or for health or safety issues do not per se constitute negligence or willful misconduct, provided that Institution shall promptly notify Sponsor of any such deviations.

B. The Institution and the Principal Investigator shall reasonably cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Master Agreement or Clinical Service Specific Agreement. In the event a claim or action is or may be asserted, the Institution shall have the right to select and to obtain representation by separate legal counsel. If the Institution exercises such right, all costs and expenses incurred by Institution for such separate counsel shall be borne by Institution and Sponsor shall reasonably cooperate with Institution and its legal representatives in the investigation and defense of any such claim or action.

C. Sponsor will maintain during the performance of this Master Agreement a policy or policies of comprehensive general liability Insurance including broad form and contractual liability and product liability, in a minimum amount of $1,000,000 combined single limit per occurrence and in the aggregate with respect to personal injury, bodily injury and property damage. Such insurance shall be issued by an insurance carrier with an A.M Best rating of “A” or better. Sponsor will
provide institution with a certificate of insurance evidencing such coverage upon signing of this Master Agreement. Such certificate to be forwarded to:

Executive Director  
Office of Research Services  
University of Pennsylvania  
P-221 Franklin Building  
3451 Walnut Street  
Philadelphia, PA 19104-6205

Sponsor shall provide institution with thirty (30) days advance written notice of cancellation or of material change in the policy or policies of insurance required.

12. TERMINATION

A. This Master Agreement or Clinical Service Specific Agreement may be terminated by either party for any reason upon thirty (30) days prior written notice.

B. Upon the effective date of expiration or termination of a Clinical Service Specific Agreement, there shall be an accounting conducted by the Institution. Within thirty (30) days after receipt of the final accounting for a Clinical Service, Sponsor will make payment to the Institution for:

(1) All services rendered and monies expended by the Institution until the date of termination not yet paid for; and

(2) Non-cancelable obligations incurred for the Clinical Services by the Institution prior to the effective date of termination.

C. Termination of this Master Agreement or Clinical Service Specific Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Articles 5, 6, 7, 8, 9, 10, and 11 survive the termination or expiration of this Master Agreement.

D. Upon any termination of this Master Agreement or completion of the Clinical Service, whichever is earlier, any instrumentation, reagents, reagent kits, and any unused material, including all written or descriptive matter, such as descriptions, or other papers or documents which contain any such confidential information described under Section 6, hereof provided by Sponsor, shall be returned to Sponsor at Sponsor's expense.

13. Miscellaneous

A. This Master Agreement and Clinical Service Specific Agreement shall be governed by the laws of the Commonwealth of Pennsylvania without regard to its principles of conflict of law.

B. This Master Agreement and the Clinical Service Specific Agreement may only be extended, renewed or otherwise amended by the mutual written consent of the parties hereto. This Master Agreement and any Clinical Service Specific Agreement including the Exhibits represents the entire understanding of the parties with respect to the subject matter hereof. The invalidity or unenforceability of any term or provision of this Master Agreement shall not affect the validity or enforceability of any other term or provision hereof.

C. Neither party hereto may assign, cede or transfer any of its rights or obligations under this Master Agreement or Clinical Service Specific Agreement without the written consent of the other party, which consent may not be unreasonably withheld; provided, however, without such consent either
party may assign this Master Agreement in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another company. Either party may assign this Master Agreement in whole or in part to any corporate affiliate without consent of the other party. This Master Agreement shall inure to the benefit of and be binding upon each party signatory hereto, its successors and permitted assigns. No assignment shall relieve either party of the performance of any accrued obligation(s) which such party may then have under this Master Agreement.

D. The headings and captions used in this Master Agreement are for convenience of reference only and shall not affect its construction or interpretation. No waiver of any term, provision or condition of this Master Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Master Agreement.

E. In the performances of all services hereunder, the Institution shall be deemed to be and shall be an independent contractor and, as such, shall not be entitled to any benefits applicable to employees of the Sponsor.

F. Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty or representation as to any matter. Neither party shall be bound by the acts or conduct of the other.

G. Institution and Sponsor shall not unlawfully discriminate against any employee or applicant for employment because of race, color, gender, sexual preference, marital status, age, religion, national or ethnic origin, disability or status as a veteran.

H. Neither party shall be liable for any failure to perform as required by this Master Agreement to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, labor disturbances or labor disputes of any kind, accident, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrence.

I. This Master Agreement represents the entire Master Agreement between the parties and supersedes any and all prior Master Agreements, whether written or oral, concerning the clinical trial which is the subject of this Master Agreement and any and all prior Master Agreements between Sponsor and Principal Investigator.

J. Principal investigator agrees to complete Financial Disclosure Forms as required by FDA, and to provide copies to Sponsor.

K. Institution and the Principal Investigator accept responsibility for assuring that any and all necessary informed consents, releases, or other legal requirements have been obtained from each subject participating in the Clinical Service, including consent to collect clinical specimens. Further, specimen collection shall be conducted in compliance with accepted hospital and clinical practices and standards, all governmental requirements including without limitation those imposed by the U.S. Food and Drug Administration, and any specific provisions set forth in the Protocol. FDI may utilize patient specimens obtained by Institution for any purpose not inconsistent with law.

L. Institution will not use in any capacity the services of any individual, corporation, partnership or association which:
(1) has been debarred under 21 U.S.C. 335a

(2) disqualified as a clinical investigator under the provision of 21 C.F.R. 312.70.

In the event that Institution becomes aware of the debarment or disqualification of any such individual, corporation, partnership or association providing services under this Master Agreement, Institution shall notify Sponsor.
IN WITNESS WHEREOF, the parties hereto have executed this Master Agreement in duplicate by proper persons thereunto duly authorized.

**SPONSOR:**

_**Fujirebio Diagnostics, Inc.**_

**BY:**  W. D. Allred  
(SIGNATURE)

_**Jeff Allred**  
(PRINT OR TYPE NAME)

**TITLE:**  _VP & CSO_  

**DATE:**  7-15-05

**INSTITUTION:**

_The Trustees of the University of Pennsylvania_

**BY:**  Donald T. Dayc, Esq.  
(Director, Corporate Contracts  
Office of Research Services  
University of Pennsylvania  
P221 Franklin Building  
3451 Walnut Street  
Philadelphia, PA 19104-6205)

**TITLE:**  

**DATE:**  7/13/05
EXHIBIT A – CLINICAL SERVICE SPECIFIC AGREEMENT FORM

This CLINICAL SERVICE SPECIFIC AGREEMENT ("Clinical Service Specific Agreement") is effective as of the date given below, is entered into by and between: THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation, owner and operator of the University of Pennsylvania Health System, through its Office of Research Services, P-221 Franklin Building, 3451 Walnut Street, Philadelphia, PA 19104-6205 hereinafter called "Institution," and Fujirebio Diagnostics, Inc., a corporation with its principal office and place of business at 201 Great Valley Parkway, Malvern, PA 19355, hereinafter called "Sponsor."

BACKGROUND. Sponsor and Institution are parties (or are Affiliates of the parties) to a Master Clinical Services Agreement effective __________ ("Master Agreement"). Under the Master Agreement, Sponsor and Institution are executing this Clinical Service Specific Agreement to contract for the following Clinical Service.

1. **THE CLINICAL SERVICE.** Institution agrees to perform the Clinical Service described below.

   **PROTOCOL TITLE:** ___________________________________________
   **PRINCIPAL INVESTIGATOR’S NAME:** ____________________________
   **ENROLLMENT MAXIMUM INITIALLY SET FOR INSTITUTION:** __________ subjects.
   **TOTAL ENROLLMENT TARGET AT ALL CLINICAL SERVICE SITES:** __________ subjects.
   **INSTITUTION’S TAX ID NUMBER:** ______________________________
   **CLINICAL SERVICES SPECIFIC AGREEMENT EFFECTIVE DATE:** ________________

2. **COMPENSATION.** In consideration for conducting the Clinical Service, Sponsor shall pay Institution as described below. The parties agree that such terms are consistent with the principles of fair market value payments for the performance of Clinical Service-related activities. Sponsor shall have no obligation to pay for activities or costs for which Sponsor has not agreed to pay under this Clinical Service Specific Agreement, that are associated with Protocol violations, or that are associated with Clinical Service subjects reasonably determined by Sponsor to be not evaluable.

3. **TERM; TERMINATION.** This Clinical Service Specific Agreement shall continue until the Clinical Service is completed or until terminated as provided in the Master Agreement.

4. **INCORPORATION BY REFERENCE.** The terms and conditions of the Master Agreement and the Protocol, as approved by Sponsor, Principal Investigator, and the responsible Institutional Review Board (along with any subsequently approved amendments to the Protocol), are hereby incorporated by reference into and made a part of this Clinical Service Specific Agreement. All defined terms in the Master Agreement shall have the same meaning when used in this Clinical Service Specific Agreement.

5. **NOTICE.** Notices applicable to this Clinical Service Specific Agreement shall be sent according to the terms of the Master Agreement. Notice to the Principal Investigator shall be sent to:

6. **ENTIRE AGREEMENT.** This Clinical Service Specific Agreement represents the entire and integrated agreement between Institution and Sponsor and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the Clinical Service.
SPONSOR

By: ______________________
Name:
Title:
Date: ________________

TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA

By: ______________________
Name:
Title:
Date: ________________

By my signature I indicate that Institution has made the Master Agreement available to me and that I am aware of its terms and also indicate my agreement to fulfill the role and obligations of Investigator under this Clinical Service Specific Agreement and Master Agreement.

INVESTIGATOR'S NAME

By: ______________________
   Investigator
Date: ________________