SERVICES AGREEMENT

This Services Agreement ("Agreement") is made this _____ day of _____, 20____ by and between the Regents of the University of New Mexico ("UNM") and _____ ("Company"), each individually a "party" and collectively the "parties".

RECITALS

A. Company requires certain IRB services, as detailed below.

B. UNM has unique capabilities and is willing to provide such services.

The parties agree as follows:

I. RESPONSIBILITIES

UNM will perform the services ("Services") described in Exhibit A and assume responsibilities described in Exhibit B, attached hereto and incorporated herein by reference. UNM IRB reserves the right to not review projects for which it does not have the appropriate expertise to review. The Company will be notified promptly of this determination.

Company will assume responsibilities described in Exhibit B.

II. LIABILITY AND INSURANCE

A. **Liability.** IN NO EVENT SHALL UNM BE LIABLE FOR ANY DAMAGES WHATSOEVER INCLUDING, WITHOUT LIMITATION, DAMAGES ARISING OUT OF OR IN ANY WAY CONNECTED WITH UNM'S PERFORMANCE, OR COMPANY'S USE, OF THE SERVICES. The liability of UNM will be subject in all cases to the immunities and limitations of the New Mexico Tort Claims Act, Sections 41-4-1 *et seq.* NMSA 1978, as amended.

B. **Insurance.** UNM will maintain general and professional liability coverage with such coverages and in such amounts as set forth in the New Mexico Tort Claims Act. Company will procure and maintain, at its own expense, general and professional liability insurance with limits of at least $1,000,000 per occurrence and $3,000,000 in the aggregate covering the acts or omissions of its employees. Company will notify UNM immediately if Company's insurance coverage is modified or terminated.

III. COMPENSATION

Company will pay UNM for the Services provided under this Agreement in the amounts and at such times as are set forth in Exhibit A. Disputed invoices will be resolved in good faith by UNM and Company in a timely manner. In the event any such invoice is not paid within thirty (30) days of the date of such invoice, all past due amounts shall be subject to a late payment charges of 1-½% per month.

UNM will submit invoices to Company at the following address:

_____
_____
_____
Attn:_____

Company will pay UNM within thirty (30) days of the date of each such invoice at the following address:

University of New Mexico
MSC01 1260
1 University of New Mexico
Albuquerque, New Mexico 87131-0001

IV. TERM AND TERMINATION

This Agreement will continue in effect for five years from the date first set forth above, unless earlier terminated. Either party may terminate this Agreement at any time upon ten (10) days written notice.

UNM contact for termination:

Linda Petree
Director, Office of the IRB
MSC02 1665
1 University of New Mexico
Albuquerque, New Mexico 87131-0001

Company contact for termination:

_____
_____
_____
_____

V. COMPLIANCE WITH LAWS

In the performance of this Agreement, the parties shall comply with all applicable Federal, State and local laws, rules, regulations, and directives, including completion of the *Institutional Review Board Authorization Agreement* attached as Exhibit C. Company shall indemnify and hold harmless UNM from and against any and all liability, damages, costs, and expenses, including, but not limited to, defense costs and attorneys' fees, arising from or related to any violation on the part of Company or its employees, agents, or sub-contractors of any such laws, rules, regulations, or directives.

VI. MISCELLANEOUS

A. **Entire Agreement.** This Agreement represents the entire understanding between the parties and supersedes any prior agreements or understandings with respect to the subject matter of this Agreement.

B. **Waiver of Breach.** The waiver by either party of a breach or violation of any provision of this Agreement will not operate as or be construed as a waiver of any subsequent breach of this Agreement.

C. **Modifications.** No changes, amendments or alterations to this Agreement will be effective unless in writing and signed by both parties.

D. **Non-Assignability.** This Agreement will not be assigned by either party, nor will the duties imposed upon either party by this Agreement be delegated, subcontracted, or transferred by either party, in whole or in part, without the prior written consent of the other party.

E. **Governing Law.** This Agreement will be construed, interpreted, governed and enforced in accordance with the statutes, judicial decisions, and other laws of the State of New Mexico.

F. **Severability.** The invalidity or unenforceability of any term or provision of this Agreement will in no way affect the validity or enforceability of any other term or provision to the extent permitted by law.

G. **Headings.** Headings and captions used in this Agreement are for convenience and ease of reference only and will not be used to construe, interpret, expand or limit the terms, conditions, or other provisions of this Agreement.

I. **Relationship of Parties.** The parties and their respective employees are at all times acting as independent contractors. UNM and its employees will not be considered employees of Company for any purpose, including, but not limited to, workers' compensation, insurance, bonding or any other benefits afforded to employees of Company. Neither party has any express or implied authority to assume or create any obligation or responsibility on behalf of or in the name of the other party. Company may not use UNM's name in any manner not pre-approved in writing by UNM.

J. **Third Parties.** Nothing in this Agreement, express or implied, is intended to confer any rights, remedies, claims, or interests upon a person not a party to this Agreement.

K. **Exclusion from Participation in Government Programs.** Each party represents that neither it, nor any of its management or any other employees or independent contractors who will have any involvement in the services or products supplied under this Agreement, have been excluded from participation in any government healthcare program, debarred from or under any other federal program (including but not limited to debarment under the Generic Drug Enforcement Act), or convicted of any offense defined in 42 U.S.C. § 1320a-7, and that it, its employees, and independent contractors are not otherwise ineligible for participation in federal healthcare programs. Further, each party represents that it is not aware of any such pending action(s) (including criminal actions) against it or its employees or independent contractors. Each party shall notify the other party immediately upon becoming aware of any pending or final action in any of these areas.

L. **Binding Effect.** This Agreement is binding upon, and inures to the benefit of, the parties to this Agreement and their respective successors and assigns.

M. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which constitute one and the same instrument.

COMPANY

By:_____

Printed Name:_____

Title:_____

Date:_____

REGENTS OF THE UNIVERSITY OF NEW MEXICO

By:_____

Printed Name:_____

Title:_____

Date:_____

EXHIBIT A

Services and Payment Schedule

Services:

• Perform all of the functions required under 45 CFR 46, 21 CFR 56, 45 CFR 160 &164, where applicable, and UNM IRB policies and procedures.
• Perform consultations with and provide training for researchers involved in the conduct of human research.
• Provide access to IRBNet© software for submission to IRB.
• Provide access to CITI Program UNM affiliation for human research protections training.
• Maintain all documents related to IRB review as required by federal regulations and make records available upon written request from appropriate officials.
• Maintain IRB records for three years (or as applicable) following project closure.

Company contact for this Agreement: _____

Fee schedule:

New Projects	$1500
Continuations	$500
Amendments	$500
Human Subject Research Determinations	$500
Just in Time or 118 Determinations	$500

No fees for:

Reporting events and unanticipated problems
Review of modifications requested by IRB
Project closures
Administrative reviews

EXHIBIT B

Duties and Responsibilities of UNM IRB and Relying Institutions

THE UNM IRB WILL:

1. Perform all of the functions required under 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56 and 45 CFR Parts 46.160 & 164 HIPAA Privacy Rule, and the human subjects protection requirements of a Department of Health and Human Services (HHS) federalwide assurance (FWA) for the review and continuing oversight of human subjects research conducted under the auspices of the IRB approved protocol, where applicable.
2. Communicate IRB determinations to the Principal Investigator and others, as applicable.
3. Maintain current IRB registration with OHRP in compliance with the Federal Policy and applicable FDA regulations.
4. Retain the authority to suspend or terminate the research for failure to comply with conditions of approval or regulatory requirements.
5. Notify relying institution of any unanticipated problems, termination or suspension of research.
6. Establish, maintain and make accessible online written procedures for:
    i. IRB membership, quorum and review procedures.
    ii. Requirements for full board, expedited, exempt and minimal risk review of research.
    iii. Requirements for obtainment and documentation of informed consent/assent.
    iv. Requirements for reporting the IRB findings and actions to the Principal Investigator and officials at the deferring institution.
    v. Determining how often projects require continuing review.
    vi. Determining which projects need verification from sources other than the researchers that no material changes have occurred since the previous IRB review.
    vii. Ensuring concordance between any applicable federal grant and the IRB protocol.
    viii. Ensuring prompt reporting to the IRB of proposed changes in a research activity.
    ix. Ensuring that changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant.
    x. Ensuring prompt reporting of any unanticipated problems involving risks to participants or others.
    xi. Reviewing unanticipated problems and allegations of noncompliance including complaints, protocol deviations and audit reports.
    xii. Ensuring prompt reporting of any serious or continuing noncompliance.
    xiii. Conducting post approval monitoring including observation of the consent process and conduct of the research by an IRB designee.
    xiv. Obtaining additional approvals from DHHS when necessary (e.g. prisoner certification).
7. The UNM IRB or its authorized representatives, including HHS to the extent allowed by law, will be permitted to conduct the following:
    i. Examine and inspect facilities used for the performance of the studies.
    ii. Observe the conduct of the studies.
    iii. Inspect and copy all documents relating to the studies, including research records, informed consent documents, and other study specific data.
8. Interview, as necessary, all essential researchers involved in the conduct of human research.
9. Consider applicable conflicts of interest (COI) as identified and determined by the deferring institution's COI policies and procedures including review of any COI management plans.
10. Maintain all documents reviewed in connection with the IRB review of the research, including any relevant communication with researchers. The UNM IRB will make its records available upon written request from appropriate officials at the relying institution for studies approved under this agreement. The UNM IRB will maintain electronic IRB records indefinitely in IRBNet.
11. Cooperate fully with relying institution and make appropriate records available to regulatory and accrediting entities at such time as the Human Research Protection Program (HRPP) of the relying institution is under review, to include making appropriate records available to the reviewers.
12. Ensure that in the event of termination of this agreement, the UNM IRB will remain responsible for continued oversight of related activities until closure or transfer of oversight.

THE RELYING INSTITUTION WILL:

1. Assume ultimate responsibility for the conduct of all research covered under the IRB Authorization Agreement (IAA).
2. Provide local context information to the UNM IRB regarding state laws and institutional requirements that pertain to the review of the deferred study.
3. Perform and document a review of the project to determine scientific validity prior to submission to the UNM IRB.
4. Accept the UNM IRB decisions and requirements and ensure the PI will not initiate any research or implement changes to approved research without first receiving approval from the UNM IRB.
5. Assume responsibility for maintaining an institutional process to monitor, evaluate, and continually improve the protection of human research participants, dedicating resources sufficient to do so, exercising oversight of research protection, educating researchers about their ethical responsibility to protect research participants, and, when appropriate, providing a mechanism to intervene in research and to respond directly to concerns of research participants. The relying institution will also monitor compliance with the terms and conditions of the IRB's approval.
6. Assure that the researchers disclose potential COI with regard to the research according to the relying institutions policies and procedures and provide relevant information to the UNM IRB.
7. Manage any organizational COI that may arise related to the proposed research.
8. Assure and warrant that all researchers conducting human research under the IAA remain members of the institution's staff in good standing and are credentialed and privileged to perform the procedures outlined in the IRB approved protocol and notify the UNM IRB should changes occur.
9. Ensure that an institutional mechanism exists by which complaints about the research can be made by local research participants or others to a local contact.
10. Notify, within five (5) business days, the UNM IRB of the termination, suspension, or modification of any research privileges of its Principal Investigators responsible for the oversight of the studies under the purview of the UNM IRB.
11. Notify, within five (5) business days, the UNM IRB of any events including: 1) unanticipated problems involving risks to subjects or others; or 2) any serious or continuing noncompliance with the federal regulations or the requirements or determinations of the UNM IRB.
12. Notify, within five (5) business days, the UNM IRB of the termination or suspension by the institution of any research under the purview of the UNM IRB.
13. Inform the UNM IRB of any contact by HHS, or any other persons or entities regarding any of the research under the IAA within five (5) business days of contact. The institution will also notify the UNM IRB within five (5) business days, in the event that a governmental agency issues the institution any Notice of Inspectional Observations, Warning Letters, or other communications citing improper or inadequate research practices with respect to the research.
14. Maintain the IAA as part of the institution's records.
15. Assume responsibility for ensuring compliance with the terms of its HHS approved FWA, if applicable.
16. Ensure researchers comply with the UNM IRB's required training(s) and other human research related policies.

REPORTING RESPONSIBILITIES:

1. The UNM IRB will report to the company the following:
    i. Serious or continuing noncompliance;
    ii. Unanticipated problems involving risks to participants or others;
    iii. Suspensions or terminations of IRB approval;
    iv. Action initiated by any oversight agency or other organization (including audits, compliance monitoring, and reporting).
    v. Any modification to the FWA or changes to the status of the Assurance documents.
2. The relying institution will promptly report to the UNM IRB the following:
    i. Serious or continuing noncompliance;
    ii. Unanticipated problems involving risks to participants or others;
    iii. Suspension or termination of the institution's approval of the research;
    iv. Allegations of scientific misconduct involving human research;
    v. Disclosure of significant COI by the deferring institution's researchers engaged in research;

vi. Any agency or organization that initiates any action (including audits, compliance monitoring, and reporting) with regard to the research under UNM IRB oversight;
vii. Any modification to the FWA or changes to the status of the Assurance documents;
viii. Changes in the IRB Point of Contact information.

3. The UNM IRB will promptly report (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance, and (iii) suspensions or terminations of previously approved research related to the deferring institution's FWA to the institution and/or OHRP as appropriate.

EXHIBIT C

Institutional Review Board Authorization Agreement

Name of Institution Providing IRB Review*:* The University of New Mexico (UNM)

UNM IRB Registration #: 00000431

UNM IRB Federal Wide Assurance (FWA) #: 00004690

Name of Institution Relying on the Designated IRB (Company): _____

FWA # (if applicable): _____

(check one):

☐ Company does not have an FWA.

☐ Company requires all human research to be conducted under the Institution's FWA.

☐ Company requires only federally funded research to be conducted under the Institution's FWA.

The Officials signing below agree that the Company may rely on the UNM IRB for review and continuing oversight of its human subjects research described below:

(*check one*):

☐ This agreement applies to all human subjects research conducted by Company.

☐ This agreement is limited to the following specific protocol(s):

Name of Research Project: _____
Protocol Number: _____
Name of Principal Investigator: _____
Sponsor or Funding Agency: _____

☐ Other (*describe*): _____

The review performed by UNM IRB will meet the human subject protection requirements of the Company's OHRP-approved FWA. UNM IRB will follow written procedures for reporting their findings and actions to appropriate officials at the Company. Relevant minutes of IRB meetings will be made available to the Company upon request. The Company remains responsible for ensuring compliance with the UNM IRB's determinations and with the terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (UNM):

_____ Date: _____

Print Full Name: Linda Petree Institutional Title: Director, Office of the IRB

Signature of Signatory Official (Company):

_____ Date: _____

Print Full Name: _____ Institutional Title: _____