



Purchasing Services

REQUEST FOR PROPOSAL (RFP)

TITLE: Commercial Institutional Review Board Services for UMDNJ

RFP NUMBER: P11-004

DATE ISSUED: July 6, 2010

DUE DATE: August 10, 2010

TIME: 2:00 P.M.

LOCATION: UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY
DEPARTMENT OF PURCHASING SERVICES
LIBERTY PLAZA
335 George Street, 2nd Floor
New Brunswick, New Jersey 08903

Important Note: Bidders should check Section 1.3 of this document to verify if attendance at a mandatory event (e.g., pre-bid conference, site visit, etc.) is required for this procurement. Failure to attend a mandatory event will result in the rejection of your proposal.

In accordance with the requirements of this proposal, the undersigned offers and agrees, if their proposal is accepted, to furnish any and all services for which the prices are submitted in accordance with the attached conditions as specified in this proposal.

BIDDER'S NAME
AND ADDRESS

SIGNATURE AND TITLE OF
AUTHORIZED INDIVIDUAL

Name (signature)

Name (print)

Title

1.0 BIDDERS

1.1 Purpose and Intent of the Procurement

1.1.1 Purpose

This Request for Proposal (RFP) is being issued by the University of Medicine and Dentistry of New Jersey (UMDNJ), Department of Purchasing Services on behalf of the UMDNJ, Office of Research for Human Subjects Protection Program.

The purpose of this RFP is to enter a contract for reviewing clinical studies involving human subjects that are both industry initiated and industry sponsored.

1.1.2 Intent

It is the University's intent to make an award to one Contractor to review clinical studies involving human subjects in accordance with state and federal regulations for clinical studies including both industry initiated and sponsored.

The University (or "Institution") and the entire UMDNJ research community are committed to safeguarding the rights and welfare of human subjects in research.

UMDNJ is seeking assistance for reviewing clinical studies involving human subjects that are both industry initiated and industry sponsored. Utilizing an independent commercial IRB reduces turnaround time and eliminates the need to commit additional University resources (staff positions, facilities, and faculty reviewer time).

1.2 Background

UMDNJ is the nation's largest health sciences University. We are New Jersey's state wide system of health sciences education, biomedical research and HealthCare. UMDNJ, a public entity was founded in 1970 to consolidate New Jersey's health professions education has become the very core of the state's health sciences system. With five campuses and a network of more than 200 affiliated healthcare and educational partners spanning the state. In the field of biomedical research, UMDNJ is ranked among the top 100 research institutions in the nation.

UMDNJ provides educational, research and service programs at campuses in Camden, New Brunswick/Piscataway, Newark, Scotch Plains and Stratford, in communities throughout the state, nationally and internationally. UMDNJ receives over \$300 million of external research funding annually from federal, state & local government agencies and private industry.

Additional information about the University, its multiple locations, schools and healthcare facilities including our annual report and financial summary, can be found on the UMDNJ web site located at: <http://www.UMDNJ.edu/homepage/index.html>.

1.3 Key Events

1.3.1 Questions and Inquiries

It is the policy of the UMDNJ, Purchasing Services to accept questions and inquiries from all potential bidders receiving this RFP.

Written questions should be mailed or faxed to the UMDNJ, Purchasing Services to the attention of the assigned buyer at the following address:

UMDNJ, DEPARTMENT OF PURCHASING SERVICES
335 GEORGE STREET, 2ND FLOOR
NEW BRUNSWICK, NEW JERSEY 08903
ATTN: Denise Council
Buyer's Phone Number: 732-235-9060
Buyer's Fax Number: 732-235-9024
E-mail: counciem@umdnj.edu

1.3.1.1 Cut-Off Date for Questions and Inquiries

Since no mandatory Pre-Bid Conference has been scheduled for this procurement, the cut-off date for questions and inquiries relating to this RFP is July 20, 2010.

1.3.1.2 Question Protocol

Questions should be submitted in writing to the attention of the assigned UMDNJ, Purchasing Services buyer. Written questions should be directly tied to the RFP by the writer. Questions should be asked in consecutive order, from beginning to end, following the organization of the RFP. Each question should begin by referencing the RFP page number and section number to which it relates.

Short procedural inquiries may be accepted by telephone by the buyer; however, oral explanations or instructions given over the telephone shall not be binding upon the University. Bidders shall not contact any person within the University directly, in person, or by telephone, other than the assigned buyer, concerning this RFP.

1.4 Additional Information for Bidders

1.4.1 Revisions to this RFP

In the event that it becomes necessary to clarify or revise this RFP, such clarification or revision will be by addendum. Any RFP addendum will be distributed as follows:

The cut-off date for questions and inquiries concerning the RFP is stated in Section 1.3.1.1. If any addendum is issued for this procurement, it will be distributed to all bidders who were sent the RFP.

1.4.2 Addendum as a Part of this RFP

Any addendum to this RFP shall become part of this RFP and part of any contract resulting from this RFP.

1.4.3 Issuing Office

This RFP is issued by the UMDNJ, Department of Purchasing Services. The buyer noted in Section 1.3.1 is the sole point of contact between the bidder and the UMDNJ for purposes of this RFP.

1.4.4 Bidder Responsibility

The bidder assumes sole responsibility for the complete effort required in this RFP. No special consideration shall be given after bids are opened because of a bidder's failure to be knowledgeable of all the requirements of this RFP.

By submitting a proposal in response to this RFP, the bidder represents that it has satisfied itself, from its own investigation, of all the requirements of this RFP.

1.4.5 Cost Liability

UMDNJ assumes no responsibility and bears no liability for costs incurred by bidders in the preparation and submittal of proposals in response to this RFP.

1.4.6 Contents of Bid Proposal

All information submitted by bidders in response to a bid solicitation is considered public information, except as may be exempted from disclosure by the Open Public Records Act, N.J.S.A. 47:1A-1 et seq., and the common law.

All bid proposals as public records, with the exception of information determined by the courts or UMDNJ to be proprietary, are available for public inspection after contract award.

A bidder may designate specific information as not subject to disclosure when the bidder has a good faith legal/factual basis for such assertion. UMDNJ reserves the right to make the determination and will advise the bidder accordingly. The location in the bid proposal of any such designation should be clearly stated in a cover letter.

UMDNJ will not honor any attempt by a bidder either to designate its entire bid proposal as proprietary and/or to claim copyright protection for its entire proposal. The bidder will be required to withdraw such designation before the bid proposal will be considered for contract award.

In the event of a challenge to the bidder's designation of confidentiality/proprietary materials, the bidder shall have be solely responsible for defending its designation and UMDNJ shall have no responsibility therefore.

1.4.7 Price Alterations

Bid prices must be typed or written in ink. Any price changes (including "white-outs") must be initialed. Failure to initial price changes may preclude an award being made to the bidder.

1.4.8 Joint Venture

If a joint venture is submitting a bid, the agreement between the parties relating to such joint venture should be submitted with the joint venture's proposal. Authorized signatories from each party comprising the joint venture must sign the bid proposal. A separate Ownership Disclosure Form, Affirmative Action Employee Information Report, MacBride Principles Certification and, if applicable, foreign (out of State) corporate registration must be supplied for each party to the joint venture.

1.4.9 HIPAA Compliance

As a State Agency, New Jersey State regulations require that we obtain documentation regarding our vendor "HIPAA Compliance" status. In order to be in compliance and conduct business with your company for the procurements of goods and/or services, it will be necessary for your company to complete a Business Associate Agreement. This agreement involves the access to protected health information that is considered protected pursuant to federal, state and/or local laws and regulations in accordance with the privacy requirements of the "HIPAA" – Health Insurance Portability and Accountability Act of 1996. The requirement is a precondition of entering into a valid and binding contract.

1.4.10 Business Registration Notice

All New Jersey and out of State business organizations must obtain a Business Registration Certificate (BRC) from the Department of the Treasury, Division of Revenue, prior to conducting business with the State of New Jersey.

Proof of valid business registration must be submitted by a bidder with its bid proposal. Failure to submit such valid business registration with a bid will render the bid materially non-responsive. The business registration form (Form NJ-REG) can be found online at: <http://www.state.nj.us/treasury/purchase/busreg.htm>

1.4.10.1 Definitions

For the purpose of the section, the following shall be defined as follows:

“Affiliate” means any entity that (1) directly, indirectly, or constructively controls another entity, (2) is directly, indirectly, or constructively controlled by another entity, or (3) is subject to the control of a common entity. An entity controls another entity if it owns, directly or individually, more than 50% of the ownership in that entity.

“Business organization” means an individual, partnership, association, joint stock company, trust, corporation, or other legal business entity or successor thereof.

“Business registration” means a business registration certificate issued by the Department of the Treasury or such other form or verification that a contractor or subcontractor is registered with the Department of Treasury.

“Contractor” means a business organization that seeks to enter, or has entered into, a contract to provide goods or services with a contracting agency.

“Contracting agency” means the principal departments in the Executive Branch of the State Government, and any division, board, bureau, office, commission or other instrumentality within or created by such department, or any independent State authority, commission, instrumentality or agency, or any State college or university, any county college, or any local unit.

“Subcontractor” means any business organization that is not a contractor that knowingly provides goods or performs services for a contractor or another subcontractor in the fulfillment of a contract.

1.4.10.2 Requirements Regarding Business Registration Form

A contractor shall submit a copy of its business registration at the time of submission of its bid proposal in response to this RFP.

A subcontractor shall provide a copy of its business registration to any contractor who shall forward it to the contracting agency. No contract with a subcontractor shall be entered into by any contractor unless the subcontractor first provides proof of valid business registrations.

The contractor shall provide written notice to all subcontractors that they are required to submit a copy of their business registration to the contractor. The contractor shall maintain a list of the names of any subcontractors and their current addresses, updated as necessary during the course of the contract performance. The contractor shall submit to the contracting agency a copy of the list of subcontractors, updated as necessary during the course of performance of the contract. The contractor shall submit a complete and accurate list of the subcontractors to the contracting agency before a request for final payment is made to the using agency.

The contractor and any subcontractor providing goods or performing services under the contract, and each of their affiliates, shall, during the term of the contract, collect and remit to the Vice President of the Division of Taxation in the Department of Treasury the use tax due pursuant to the "Sales and Use Tax Act, P.L. 1966, c. 30 (N.J.S.A. 54:32B-1 et seq.) on all their sales of tangible personal property delivered into the State.

1.4.11 Deficit Reduction Act

The University of Medicine and Dentistry (UMDNJ) is committed to the prevention and detection of any fraud, waste, and abuse within the University related to all health care programs, including Federal and State programs. To this end, UMDNJ maintains a vigorous compliance program geared in part to educating our community on the range of fraud and abuse laws, including the importance of submitting accurate claims and reports to the Federal and State governments. Our policies prohibit the knowing submission of a false claim for payment in relation to any health care program, including a Federal or State funded health care program. Such a submission is a violation of Federal and State law and can result in significant administrative and civil penalties under the Federal and State False Claims Acts.

To assist UMDNJ in meeting its legal and ethical obligations, any employee, contractor or agent who is aware of the preparation or submission of a false claim or report or reasonably suspects any other potential fraud, waste, or abuse in relation to a Federal or State funded health care program is required to report such information to his or her supervisor and UMDNJ's Office of Ethics and Compliance.

Any employee of UMDNJ who in good faith reports such information will be protected against retaliation for coming forward with such information both under UMDNJ's internal compliance policies and procedures and United States and New Jersey law.

As an organization, UMDNJ obligates itself to investigate any such information swiftly and thoroughly through its internal compliance programs and mechanisms. Nonetheless, if an employee, contractor or agent believes that the organization's response is deficient and unresponsive, the employee shall bring these concerns to UMDNJ's Office of Ethics and Compliance. If such follow-up still does not trigger an investigation, after a reasonable period of time, the employee, contractor or agent has the ability to bring his/her concerns to the appropriate government agency under the relevant Federal and/or State laws.

This information shall be provided to all UMDNJ employees and all contractors and agents of UMDNJ.

2.0 DEFINITIONS

The following definitions shall be part of any contract awarded or order placed as a result of this RFP:

“Addendum” – Written clarification or revision to this RFP issued by UMDNJ, Purchasing Services.

“Amendment” – A change in scope of work to be performed by the contractor. An amendment is not effective until it is signed by the Vice President for Finance and Treasurer.

“Bidder” – An individual or business entity submitting a bid in response to this RFP.

“CINJOG” – Cancer Institute of New Jersey Oncology Group.

“Contract” – This RFP, any addendum to this RFP, and the bidder’s proposal submitted in response to this RFP and UMDNJ’s Contract Term Sheet.

“Contractor” – The contractor is the bidder awarded a contract.

“DHHS” – Department of Health and Human Services, a branch of the Federal government.

“Evaluation Committee” – A committee established to review and evaluate bid proposals submitted in response to this RFP and to recommend a contract award to the Vice President of Supply Chain Management.

“HIPAA” – Health Insurance Portability and Accountability Act of 1996.

“IRB” – Institutional Review Board.

“May” – Denotes that which is permissible, not mandatory.

“Project” – The undertaking of services that are the subject of this RFP.

“Request for Proposal (RFP)” – This document, which establishes the bidding and contract requirements and solicits proposals to meet the purchase needs as identified herein.

“Shall” or “Must” or “Will” – Denotes that which is a mandatory requirement. Failure to meet a mandatory requirement will result in the rejection of a bid proposal as materially non-responsive.

“Should” – Denotes that which is recommended, not mandatory.

“Subtasks” – Detailed activities that comprise the actual performance of a task.

“Task” – A discrete unit of work to be performed.

“UMDNJ” – The University of Medicine and Dentistry of New Jersey, or otherwise referred to as the “University.”

“Vice President” – The Vice President of Supply Chain Management; the contracting officer for UMDNJ.

3.0 SCOPE OF WORK

3.1 General Requirements

3.1.1 New Research Studies:

The Contractor will assume Institutional Review Board (“IRB”) oversight responsibility and perform IRB functions in compliance with applicable federal and state regulations for new research studies involving human subject’s research to be conducted at the Institution as defined below. The Contractor’s services shall include, but not be limited to: review and approval or disapproval of new protocols; review and approval, disapproval or modification of consent forms; review and approval or disapproval of the investigator(s); monitoring of adverse event reports; and maintenance of required IRB records pursuant to 21 CFR § 56.115 and 45 CFR § 46.115. The Contractor shall conduct continuing review of new research studies appropriate to the degree of risk in such studies. The Contractor must conduct at least an annual review of each study.

3.1.2 Contractor’s Primary Duty:

As set forth in 21 CFR §§ 56.102(g) and 45 CFR §§ 46.102(g), 46.109 and 46.111, the Contractor’s primary duty is to protect the rights and welfare of “human subjects,” a term defined by 21 CFR § 56.102(e) and 45 CFR 56.102(f). Nothing in this contract will be construed to limit Contractor’s independence to take actions necessary to protect the rights and welfare of human subjects, or to alter Contractor’s primary duty to human subjects. Contractor shall report all concerns, violations and actions to the University.

3.1.3 Compliance with Applicable Laws and Regulations:

The Contractor shall perform the services hereunder in compliance with applicable federal and state laws and regulations governing IRB’s and research with human beings, including the United States Food and Drug Administration (“FDA”) Regulations 21 CFR Parts 50 and 56 and the United States Department of Health and Human Services (“DHHS”) Regulations 45 CFR Part 46. The Contractor will notify UMDNJ in the event that the Contractor has been cited by any federal or state agency for failure to comply with the aforementioned laws and regulations.

3.1.4 Compliance with Applicable Institutional Policies:

The Contractor shall apply all University Policies to the reviews conducted by the Contractor.

3.1.5 Notification Requirements:

The Contractor must notify the UMDNJ, Executive Director, Human Subjects Protection, Office of the Vice President for Research, as set forth in Section 4.1 of the RFP, of any of the following: The Contractor termination or suspension of a study; reports of unanticipated problems; instances of serious or continuing noncompliance with the federal regulations or the requirements and determinations of the Contractor; allegations of scientific misconduct, and any other matter that comes to the attention of the Contractor that adversely affects UMDNJ's compliance with applicable regulations and laws governing human subjects research. The Contractor shall also notify UMDNJ of receipt of submissions (as part of Contractor's routine operations practices), and its decisions to approve, disapprove, or recommend modification of UMDNJ's research studies. The Contractor will provide a copy of the pertinent section of the IRB meeting minutes regarding the IRB initial review for UMDNJ's records. The Contractor will coordinate with the UMDNJ to address issues that have the potential to adversely affect the regulatory compliance on human subject research of any active study.

3.1.6 Auditing:

UMDNJ has the right to attend Contractor IRB meetings, review all proceedings, documents and records, and audit the work done by the Contractor on behalf of UMDNJ, during working hours, with reasonable advance notice and in consultation with the Contractor's contact.

3.2 UMDNJ'S RESPONSIBILITIES

3.2.1 General:

UMDNJ agrees that the Contractor shall be one of its IRBs of record. UMDNJ agrees to facilitate Contractor access to UMDNJ expertise when needed for IRB review. In keeping with the requirements of 21 CFR § 56.112 and 45 CFR § 112, UMDNJ cannot approve any research study that has been disapproved by the Contractor. UMDNJ may, however, disapprove any study approved by the Contractor. UMDNJ agrees to abide by the decisions of the Contractor and shall use reasonable efforts to ensure that the clinical research performed by the UMDNJ shall be conducted in accordance with those decisions.

3.2.2 Criteria for Which Studies Will be Reviewed by Contractor:

UMDNJ and the Contractor agree that the following criteria shall be used to determine which new studies to be conducted at UMDNJ will be referred to the Contractor, and, if applicable, which active studies will be transferred to the Contractor for re-review:

UMDNJ may refer to the Contractor new industry-sponsored clinical studies (multi-site and single-site) to be conducted at UMDNJ performance sites. UMDNJ reserves the right to refer any study to its internal IRB(s), or any other IRB. New industry-sponsored clinical studies that are specific to CINJOG may be referred to another IRB. CINJOG is a cooperative group with a network of affiliates developed by the University's Cancer Institute of New Jersey of which the Institute is one of the affiliates.

In addition, UMDNJ will refer studies that it determines are exempt from review or that meet the requirements for expedited review to UMDNJ's internal IRB(s). UMDNJ may also refer certain non-industry sponsored studies (e.g., federally-funded and/or investigator-initiated) to the Contractor for conflict of interest reasons. It is not anticipated that UMDNJ will transfer active studies to the Contractor for re-review.

3.3 PROGRAM FOR KNOWLEDGE OF THE LOCAL RESEARCH CONTEXT

UMDNJ has established the following program to ensure that the Contractor has proper knowledge of the local research context in accordance with the OPRR August 27, 1998 [updated July 21, 2000]; memorandum entitled "IRB Knowledge of Local Research Context." The Contractor and UMDNJ agree to follow the program for knowledge of the Local Research Context to assure the Contractors' knowledge of the local research context through a systematic, reciprocal, and documented interchange between the UMDNJ and the Contractor.

3.3.1 Exchanges and Site Visits:

There will be exchanges between the Contractor and UMDNJ as appropriate that may consist of on-site visits, videoconference or teleconference meetings. In addition, the Contractor representatives will conduct site visits to UMDNJ's research sites pursuant to Contractor's site visit policy and in the course of such visits will gather information and report on the local conditions. UMDNJ representatives may make visits to the Contractor annually or as appropriate, or in lieu of such visit(s) may attend Contractor's annual Training Seminar. Visits by UMDNJ will include discussions with Contractor administration, and may include attendance at IRB meetings.

3.3.2 Consultations on Local Context:

In addition to the site visits as described above, UMDNJ staff will: provide notice to the Contractor of local concerns and conditions at UMDNJ through regular communications; provide consultations (written, electronic, and in-person) as needed; and arrange consultations with community representatives, UMDNJ faculty and/or administration as requested by Contractor. In exceptional individual cases, where it is considered that additional knowledge of the community is required, and upon mutual agreement of the Contractor and UMDNJ, representatives of the UMDNJ's community may participate in IRB reviews by teleconferencing.

3.3.3 UMDNJ Liaisons:

The UMDNJ has appointed the Executive Director, Human Subjects Protections, Office of the Vice President for Research as primary liaison for purposes of this contract and the Contractor will designate a primary contact. In addition, any staff member of UMDNJ's requesting department is designated as a contact for day-to-day matters. Additional Liaisons may be designated as needed.

3.3.4 UMDNJ Contact:

3.3.4.1 The overall goal of establishing a UMDNJ Contact is to increase the effectiveness and efficiency of Contractor's role as part of UMDNJ's human protections system. The UMDNJ Contact will aid in this goal by providing an on-site point of communication and problem resolution.

3.3.4.2 The UMDNJ Contact will serve as the conduit for communications between the Contractor and UMDNJ, and ensure that all relevant information is transmitted to the necessary UMDNJ parties and departments.

3.3.4.3 The UMDNJ Contact will help facilitate the Contractor's initial and continuing review of research at the UMDNJ in the following ways:

- a. The UMDNJ Contact will assist in gathering information required for the Contractor's initial and continuing review if the Contractor has difficulty in obtaining such information through normal procedures of contacting the investigator/study coordinator.
- b. The UMDNJ Contact will assist in obtaining the necessary documents required for the Contractor's initial and continuing review, if the Contractor has difficulty in obtaining them through normal procedures of contacting the investigator/study coordinator.

- c. The UMDNJ Contact will assist in contacting investigators with noted problems (such as missing continuing review reports or the use of an unapproved consent form) if the Contractor has difficulty contacting the investigator through normal procedures. Significant concerns will be communicated to the Contractor's Contact.
- d. The UMDNJ Contact will assist in assuring the investigator and UMDNJ compliance with Contractor decisions.

3.3.4.4 The UMDNJ Contact may review UMDNJ studies prior to submission to the Contractor:

- a. An investigator, the UMDNJ Contact or the Contractor's contact may request prior review.
- b. When prior review occurs, it will address UMDNJ policies and submission packet completeness, not IRB Board issues. The UMDNJ Contact will notify the Contractor of outstanding issues noted during prior review.
- c. If the prior review reveals inadequate documentation, the Contractor Contact and the UMDNJ Contact will decide whether it needs to be corrected prior to submission to the Contractor or if it can be done in parallel with the Contractor's review.

3.3.5 Review of Contractor-approved consent forms:

The UMDNJ Contact may conduct a policy review of the Contractor-approved consent forms. Any problems identified during this review will be communicated to the Contractor's Contact for resolution.

3.3.6 Audiovisual Conferencing:

In addition to speakerphone facilities, audiovisual conferencing capabilities exist at UMDNJ and the Contractor so that, when warranted, representatives and IRB members at both sites can fully interact during convened meetings with appropriate representatives.

3.4 CONFIDENTIALITY

3.4.1 Definitions:

For purposes of this Agreement, the party that transmits Information shall be referred to as the “Discloser,” and the party to which Information is transmitted shall be referred to as the “Recipient.” The term “Confidential Information” shall mean any and all information disclosed by the Discloser to the Recipient, or to any of its agents, affiliates, officers, directors, employees and subcontractors either in oral, written or any tangible form. Confidential Information includes, but is not limited to, technical, scientific, financial, strategic, marketing or product information; practices and processes; business systems and techniques; billing practices; computer processes, programs and codes; forms; and production processes.

3.4.2 Non-Disclosure and Non-Use:

Recipient shall hold in confidence any and all Confidential Information revealed by the Discloser or with which it became acquainted within the framework of this Agreement, and shall not use or disclose Confidential Information to any person or entity, except (i) to such of its own employees, independent contractors and representatives in the course of providing services hereunder, (ii) to authorized agents of the federal government if required for audit or regulatory purposes, and (iii) to such other recipients as the Discloser may give prior written approval ; provided, however, that recipients of Confidential Information shall have first executed a confidentiality and non-use agreement with the Recipient. Each party further agrees that Confidential Information shall not be used except for the purpose of this Agreement as set forth herein.

3.4.3 Exceptions:

The obligations of this Section 4 will not apply to any Confidential Information which the Recipient is able to demonstrate:

- i. was in its possession prior to being received from the Discloser and was not acquired, directly or indirectly, from the Discloser, or
- ii. was in the public domain, at the moment of being received from the Discloser, or
- iii. became part of the public domain through no fault of the Recipient, after having been so communicated, or
- iv. was lawfully received by the Recipient from some third party having a right of further disclosure, or
- v. is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by Recipient.

4.0 SPECIAL CONTRACTUAL TERMS AND CONDITIONS

4.1 Contract Term and Extension Option

4.1.1 Contract Term

The contract will be awarded for three (3) years, commencing from the date of award. If delays in the bid process result in an adjustment of the anticipated contract effective date, the bidder agrees to accept a contract for the full term of the contract.

Notwithstanding the immediately preceding paragraph, the parties specifically recognize that 21 CFR § 56.109(f) requires that, “An IRB shall conduct continuing review of research . . . not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.” Therefore, termination of this Agreement shall not affect Contractor’s obligations of continuing review for studies approved hereunder until such studies are transferred to and re-reviewed by the responsible IRB.

Upon expiration or termination, Contractor will continue its oversight of active studies until closure, unless otherwise mutually agreed to by the parties. If UMDNJ requests that active studies be transferred to UMDNJ or other IRB, no additional fee may be charged by Contractor for the transfer, and the Contractor shall cooperate fully in providing all documentation regarding that study.

4.1.2 Contract Extension Option

This contract may be extended for two (2) additional one (1) year options. Any extension of this contract under this provision will be put into effect by mutual agreement between the University and the Contractor, with written notification being provided to the Contractor by the University. The original terms and conditions will remain in effect for any extension period.

4.2 Contract Transition

In the event services end by either contract expiration or termination, it shall be incumbent upon the Contractor to continue services, if requested by the Vice President, until new services can be completely operational. The Contractor acknowledges its responsibility to cooperate fully with the replacement Contractor and UMDNJ to ensure a smooth and timely transition to the replacement Contractor. Such transitional period shall not extend more than ninety (90) days beyond the expiration date of the contract, or any extension thereof. The Contractor will be reimbursed for services during the transitional period at the rate in effect when the transitional period clause is invoked by UMDNJ. However, Contractor shall not be paid any fee for the actual transition.

4.3 Precedence of the University's Standard Terms and Conditions

The contract resulting from this procurement shall consist of this RFP (including UMDNJ's Standard Terms and Conditions); any addendum to this RFP, the Contractor's bid proposal and UMDNJ's Contract Term Sheet.

In the event of a conflict between the provisions of this RFP, including any addendum to this RFP, and the bidder's proposal, the RFP and/or the addendum shall govern.

Unless specifically noted within this RFP, UMDNJ's Standard Terms and Conditions take precedence over the Special Terms and Conditions contained in this Section of the RFP. The Standard Terms and Conditions in effect for this procurement can be found at the following Internet address: www.umdj.edu/purchweb

The version of the Standard Terms and Conditions that apply to this procurement is as follows:

- 1) If a mandatory event is conducted as part of this procurement (e.g., mandatory pre-bid conference, mandatory site visit, etc.), the Standard Terms and Conditions that apply to this procurement are those that are posted on the Web site referenced above on the business day prior to the mandatory event; or,
- 2) If no mandatory event is conducted as part of this procurement, yet an addendum is issued (e.g., in response to questions from bidders), the Standard Terms and Conditions that apply to this procurement are those that are posted on the Web site referenced above on the business day prior to the date of issuance of the addendum; or,
- 3) If no mandatory event is conducted and no addendum is issued for this procurement, the Standard Terms and Conditions that apply to this procurement are those that are posted on the Web site referenced above on the business day prior to the bid opening date.

In the event of a conflict between the provisions of this RFP, including UMDNJ's Standard Terms and Conditions and the Special Terms and Conditions contained in this Section, and any addendum to the RFP, the addendum shall govern.

4.4 Departure From Bid Specifications or Terms and Conditions

Notwithstanding the forgoing, a bidder's proposal may be deemed **NON-COMPLIANT AND BE REJECTED** and/or be found **non-responsive** if the change is a material departure from the bid specifications or the terms and conditions of this RFP. A material departure occurs when the change increases the likelihood that the waiver from compliance with the RFP is capable of giving the appearance of corruption or favoritism, or encouraging excessive spending or is likely to affect the amount or price of the bid or to influence any potential bidder to refrain from bidding or is capable of affecting the ability of the University to make a bid comparison, or is unacceptable to the University. The determination of material departure shall be in the sole discretion of the University.

4.5 Insurance

The insurance to be provided by the Contractor shall be as follows:

- **Commercial General Liability Insurance** - including contractual liability endorsement, subject to primary limits of coverage of not less than \$1,000,000 per occurrence/\$1,000,000 annual aggregate. If applicable, XCU coverage may be required;
- **Automobile Liability Insurance** – covering owned, non-owned and hired vehicles with not less than \$1,000,000 for bodily injury and property damage;
- **Excess Liability Insurance** - subject to an additional limit of liability of not less than \$1,000,000 per occurrence/\$3,000,000 aggregate excess of the primary policy;
- **Workers' Compensation Insurance** - statutory coverage and including employers liability coverage of not less than \$1,000,000 per occurrence and \$1,000,000 annual aggregate;
- **Additional Insured** - UMDNJ to be named as additional insured ATIMA with respect to Commercial General, Automobile and Excess Liability Insurance provided by contractor pursuant to this proposal/contract;
- **Errors and Omissions Liability insurance** - with limits of \$1million/\$1million; UMDNJ to be named as additional insured ATIMA with respect to services provided by contractor pursuant to this proposal contract. If applicable, this insurance may be required.
- **Professional Liability Insurance** - coverage in an amount no less than \$5,000,000 each claim/\$5,000,000 annual aggregate and officer and director liability coverage in an amount no less than \$2,000,000 each claim/\$2,000,000 annual aggregate.

- **Professional Insurance** - maintain adequate staffing and to conduct all services in a timely and professional manner. The Contractor will maintain good standing with all federal and state regulatory agencies overseeing human subject research and will immediately correct any deficiencies.

The Contractor shall maintain full accreditation from the Association for the Accreditation of Human Research Protection Programs (“AAHRPP”) or an equivalent accreditation body.

- All insurers affording coverage are to be licensed to conduct the business of insurance within the State of New Jersey and to be rated not less than A- by Bests Insurance Rating Service.

-UMDNJ is to be named as certificate holder with respect to all afore-mentioned insurance coverages.

- All Insurance coverages shall remain in effect throughout the course of the contract. Contractor shall be responsible for any and all future claims, litigation, damages, liabilities, whatsoever, which may arise as a result of Contractor’s performance of services pursuant to this contractual agreement.

All required commercial general liability insurance and any required pollution liability insurance coverage shall be maintained throughout the course of the project. Failure to maintain said insurance coverage shall be deemed sufficient cause to immediately terminate the contract without having to show additional cause. Further, said liability insurance coverages shall be subject to an extended reporting period of not less than six years following the completion of the contract/project and, also, shall include completed operations coverage for a period of not less than six years following the completion of the project /contract.

4.6 Contract Amendment

Any changes or modifications to the terms of the contract shall only be valid when they have been reduced to writing and executed by the Contractor and the Vice President.

4.7 Contractor Responsibilities

The Contractor shall have sole responsibility for the complete effort specified in the contract. Payment will be made only to the Contractor. The Contractor shall have sole responsibility for all payments due any subcontractor.

The Contractor is responsible for the professional quality, technical accuracy and timely completion and submission of all deliverables, services or commodities required to be provided under the contract. The Contractor shall, without additional compensation, correct or revise any errors, omissions, or other deficiencies in its deliverables and other services.

The approval of deliverables furnished under this contract shall not in any way relieve the Contractor of responsibility for the technical adequacy of its work. The review, approval, acceptance or payment for any of the services shall not be construed as a waiver of any rights that UMDNJ may have arising out of the Contractor's performance of this contract.

4.8 Substitution of Staff

If it becomes necessary for the Contractor to substitute any management, supervisory or key personnel, the Contractor will identify the substitute personnel and the work to be performed.

The Contractor must provide detailed justification documenting the necessity for the substitution. Résumés must be submitted evidencing that the individual(s) proposed as substitution(s) have qualifications and experience equal to or better than the individual(s) originally proposed or currently assigned.

The Contractor shall forward a request to substitute staff to the Vice President, through the University's Project Manager, for consideration and approval. No substitute personnel are authorized to begin work until the Contractor has received written approval to proceed from the Vice President, through the University's Project Manager.

4.9 Substitution or Addition of Subcontractor(s)

If it becomes necessary for the Contractor to substitute and/or add a subcontractor, the Contractor will identify the proposed new subcontractor and the work to be performed. The Contractor must provide detailed justification documenting the necessity for the substitution or addition.

The Contractor must provide detailed résumés of the proposed subcontractor's management, supervisory and other key personnel that demonstrate knowledge ability and experience relevant to that part of the work, which the subcontractor is to undertake.

In the event a subcontractor is proposed as a substitution, the proposed subcontractor must equal or exceed the qualifications and experience of the subcontractor being replaced. In the event the subcontractor is proposed as an addition, the proposed subcontractor's qualifications and experience must equal or exceed that of a similar subcontractor proposed by the Contractor in its bid proposal.

The Contractor shall forward a request to substitute/add a subcontractor to the Vice President, through the University's Project Manager, for consideration and approval. No substitution or addition of a subcontractor is authorized until the Contractor has received written approval to proceed from the Vice President, through the University's Project Manager.

4.10 Ownership of Material

All data, technical information, materials gathered, oriented, developed, prepared, used or obtained in the performance of the contract, including, but not limited to, all reports, surveys, plans, charts, literature, brochures, mailings, recordings (video and/or audio), pictures, drawings, analyses, graphic representations, software computer programs and accompanying documentation and print-outs, notes and memoranda, written procedures and documents, regardless of the state of completion, which are prepared for or are a result of the services required under this contract shall be and remain the property of UMDNJ and shall be delivered to UMDNJ upon 30 days notice by UMDNJ.

With respect to software computer programs and/or source codes developed for UMDNJ, the work shall be considered “work for hire,” i.e., UMDNJ, not the Contractor or subcontractor, shall have full and complete ownership of all software computer programs and/or source codes developed.

4.11 Data Confidentiality

All financial, statistical, personnel and/or technical data supplied by UMDNJ to the Contractor are confidential. The Contractor is required to use reasonable care to protect the confidentiality of such data. Any use, sale or offering of this data in any form by the Contractor, or any individual or entity in the Contractor’s charge or employ, will be considered a violation of this contract and may result in contract termination and the Contractor’s suspension or debarment from UMDNJ contracting. In addition, such conduct may be reported to the State Attorney General for possible criminal prosecution.

4.12 News Releases

The Contractor is not permitted to issue news releases pertaining to any aspect of the services being provided under this contract without prior written consent of the Vice President.

4.13 Advertising

The Contractor shall not use UMDNJ’s name, logos, images, or any data or results arising from this contract as a part of any commercial advertising without first obtaining the prior written consent of the Vice President.

4.14 License and Permits

The Contractor shall obtain and maintain in full force and effect all required licenses, permits, and authorizations necessary to perform this contract. The Contractor shall supply UMDNJ with evidence of all such licenses, permits and authorizations.

This evidence shall be submitted subsequent to the contract award. All costs associated with any such licenses, permits and authorizations shall have been included by the Contractor in its bid proposal.

4.15 Claim and Remedies

4.15.1 Claims

The following shall govern claims made by the Contractor regarding contract award rescission, contract interpretation, Contractor performance and/or suspension or termination.

Final decisions concerning all disputes relating to contract award rescission, contract interpretation Contractor performance and/or reduction, suspension or termination are to be made in a manner consistent with N.J.A.C. 17:12-1.1, et seq. The Vice President's final decision shall be deemed a final agency action reviewable by the Superior Court of New Jersey, Appellate Division.

All claims asserted against UMDNJ by the Contractor shall be subject to the New Jersey Tort Claims Act, N.J.S.A. 59:1-1, et seq., and/or the New Jersey Contractual Liability Act, N.J.S.A. 59:13-1, et seq.

However, any claim against UMDNJ relating to a final decision by the Vice President regarding contract award rescission, contract interpretation, Contractor performance and/or contract reduction, suspension or termination shall not accrue, and the time period for performing any act required by N.J.S.A. 59:8-8 or 59:13-5 shall not commence, until a decision is rendered by the Superior Court of New Jersey, Appellate Division (or by the Supreme Court of New Jersey, if appealed) that such final decision by the Vice President was improper.

4.15.2 Remedies

Nothing in the contract shall be construed to be a waiver by UMDNJ of any warranty, expressed or implied, or any remedy at law or equity, except as specifically and expressly stated in writing executed by the Vice President.

4.16 Form of Compensation and Payment

UMDNJ's payment terms are Net 45 days.

The Contractor must submit invoices to UMDNJ with supporting documentation evidencing that work for which payment is sought has been satisfactorily completed. Invoices must reference the purchase order number and must be in strict accordance with the prices submitted for on the RFP pricing sheet. The Contractor agrees to bill either the sponsor or the investigator as directed by UMDNJ. UMDNJ is not responsible for non-payment by a research sponsor.

The Contractor shall bill for services rendered and expenses incurred at the end of each month and shall be paid for services performed and expenses documented to the satisfaction of the University. UMDNJ does not agree to pay for “Late Fee” charges. All invoices must be approved by UMDNJ before payment will be authorized.

4.17 Additional Work and/or Special Projects

In the event that the need for additional work and/or a special project arises, UMDNJ will submit such a request to the Contractor in writing. The Contractor must present a written proposal to perform the additional work/special project to UMDNJ. The proposal should provide justification for the necessity of the additional work/special project. The relationship between the additional work/special project being requested and the work required by the Contractor under the base contract must be clearly established by the Contractor in its proposal for performing the additional work/special project. The Contractor’s written proposal must provide a detailed description of the work to be performed, broken down by task and subtask. The proposal should contain details on the level of effort, including hours, labor categories, etc., necessary to complete the additional work.

The written proposal must detail the cost necessary to complete the additional work in a manner consistent with the contract. The written cost proposal must be based upon the hourly rates, unit costs or other cost elements submitted by the Contractor in the Contractor’s original bid proposal submitted in response to this RFP. Whenever possible, the cost proposal should be a firm, fixed cost to perform the required work. The firm fixed price should specifically reference and be tied directly to costs submitted by the Contractor in its original bid proposal. A payment schedule, tied to successful completion of tasks and subtasks, must be included.

Upon receipt of the Contractor’s written proposal, it shall be forwarded to the Vice President for written approval. Complete documentation from the using agency, confirming the need for the additional work/special project, must be submitted.

No additional work and/or special project may commence without the Vice President’s written approval. In the event the Contractor proceeds with additional work and/or special projects without the written approval of the Vice President, it shall be at the Contractor’s sole risk. UMDNJ shall be under no obligation to pay for work done without the Vice President’s written approval.

4.18 Option to Reduce Scope of Work

UMDNJ has the option, in its sole discretion, to reduce the scope of work for any task or subtask called for under this contract. In such an event, the Vice President shall provide advanced, written notice to the Contractor.

Upon receipt of such written notice, the Contractor will submit, within five (5) working days to the Vice President, an itemization of the work effort already completed by task or subtasks. The Contractor shall be compensated for such work effort according to the applicable portions of its cost proposal.

4.19 Suspension of Work

The Vice President may, for valid reason, issue a stop order directing the Contractor to suspend work under the contract for a specific time. The Contractor shall be paid until the effective date of the stop order. The Contractor shall resume work upon the date specified in the stop order or upon such other date as the Vice President may thereafter direct in writing. The period of suspension shall be deemed added to the Contractor's approved schedule of performance. The Vice President and the Contractor shall negotiate an equitable adjustment, if any, to the contract price.

4.20 Change in Law

Whenever an unforeseen change in applicable law or regulation affects the services that are the subject of this contract, the Contractor shall advise the Vice President in writing and include in such written transmittal any estimated increase or decrease in the cost of its performance of the services as a result of such change in law or regulation. The Vice President and the Contractor shall negotiate an equitable adjustment, if any, to the contract price.

4.21 Requirements of PL 2005, Chapter 51/ Executive Order 117 Vendor Certification and Disclosure of Political Contributions

In order to safeguard the integrity of State government procurement by imposing restrictions to insulate the award of State contracts from political contributions that pose the risk of improper influence, purchase of access, or the appearance thereof, Public Law 2005, c.51, was signed into law on March 22, 2005. On September 24, 2008, Governor Corzine issued Executive Order 117, which is designed to enhance New Jersey's efforts to protect the integrity of procurement decisions and increase the public's confidence in procurement. The Executive Order builds upon the provisions of Chapter 51. Pursuant to the requirements of Public Law 2005, c.51, and Executive Order 117, all bidders must submit the Two-Year Chapter 51/Executive Order 177 Vendor Certification and Disclosure of Political Contributions with their bid proposal. See Section 9 of this RFP for the certification form. The form and instructions for completion of the form may be found at http://.umdnj.edu/purchweb/employees/employ36_forms_policies.htm .

4.21.1 State Treasurer Review

The State Treasurer or his designee shall review the Disclosures submitted pursuant to this section, as well as any other pertinent information concerning the contributions or reports thereof by the intended awardee, prior to award, or during the term of the contract, by the Contractor. If the State Treasurer determines that any contribution or action by the Contractor constitutes a breach of contract that poses a conflict of interest in the awarding of the contract under this solicitation the State Treasurer shall disqualify the Business Entity from award of such contract.

4.22 New Jersey Election Law Enforcement Commission Requirement

The Contractor is advised of its responsibility to file an annual disclosure statement on political contributions with the New Jersey Election Law Enforcement Commission (ELEC), pursuant to N.J.S.A. 19:44A-20.13 (P.L. 2005, c.271, section 3) if the Contractor receives in excess of \$50,000 from a public entity in a calendar year. It is the Contractor's responsibility to determine if filing is necessary. Failure to so file can result in the imposition of financial penalties by ELEC. Additional information about this requirement is available from ELEC at 888-313-3532 or at www.elec.state.nj.us.

4.23 Federal and State Laws and Regulations Regarding Healthcare

The University is committed to compliance with all federal and state regulations regarding healthcare, including but not limited to licensing, Stark and anti-kickback laws, Medicare and Medicaid regulations. All services provided under this bid and the contract award under this bid must comply with all applicable laws.

In addition, if a violation comes to the attention of either party, or any changes in the laws or regulations occurs which make the bid or contract entered into between the parties as a result of the bid, to be in violation of any applicable law, then the agreement shall be amended to address the violation or to comply with the change, or terminated if amending will not resolve the violation. The University shall have the option to amend the contract resulting from the RFP in order to comply with all applicable local, State and Federal laws, rules and regulations.

5.0 PROPOSAL PREPARATION AND SUBMISSION INSTRUCTIONS

5.1 General

The bidder must follow instructions contained in this RFP and in the bid cover sheet in preparing and submitting its bid proposal. The bidder is advised to read thoroughly and to follow all instructions.

The information required to be submitted in response to this RFP has been determined to be essential in the bid evaluation and contract award process. Any qualifying statements made by the bidder to the RFP's requirements could result in a determination that the bidder's proposal is materially non-responsive. Each bidder is given wide latitude in the degree of detail it elects to offer or the extent to which plans, designs, systems, processes and procedures are revealed. Each bidder is cautioned, however, that insufficient detail may result in a determination that the bid proposal is materially non-responsive or, in the alternative, may result in a low technical score being given to the bid proposal.

The bidder is instructed to clearly identify any requirement of this RFP that the bidder cannot satisfy.

5.2 Proposal Delivery and Identification

In order to be considered a bid proposal must arrive at the Department of Purchasing Services in accordance with the instructions on the RFP cover sheet. Bidders submitting proposals are cautioned to allow adequate delivery time to ensure timely delivery of proposals. UMDNJ regulations mandate that late proposals are ineligible for consideration. The exterior of all bid proposal packages must be labeled with the Request for Proposal identification number, final bid opening date and the buyer's name.

5.3 Number of Bid Proposal Copies

Each bidder must submit one (1) complete original bid proposal, clearly marked as the "ORIGINAL" bid proposal. Each bidder should also submit five (5) full, complete and exact copies of the original. A copy must also be provided on Compact Disk (CD). The copies required are necessary in the evaluation of the bid. It is suggested that the bidder make and retain a complete copy of its bid proposal.

5.4 Proposal Form and Content

The proposal should follow the format indicated in the following Sections of this RFP. The bidder should limit their response to one volume, if at all possible, with that volume divided into four (4) sections as indicated below.

5.5 Section 1 – Forms

5.5.1 Ownership Disclosure Form

The bidder must complete the attached Ownership Disclosure Form. A complete Ownership Disclosure Form must be received prior to, or accompanying, the bid. Failure to do so will preclude the award of a contract.

5.5.2 MacBride Principles Certification

The bidder must complete the attached MacBride Principles Certification evidencing compliance with the MacBride Principles. Failure to do so may result in the award of the contract to another bidder.

5.5.3 Affirmative Action

The bidder should complete the attached Affirmative Action Employees Information Report, or, in the alternative, supply either a New Jersey Affirmative Action Certificate, or evidence that the bidder is operating under a Federally approved or sanctioned affirmative action program. The requirement is a precondition of entering into a valid and binding contract.

5.5.4 Business Associate Agreement

The bidder should complete the attached Business Associate Agreement, involving the access to protected health information that is considered protected pursuant to federal, state and/or local laws and regulations in accordance with the privacy requirements of the “HIPAA” – Health Insurance Portability and Accountability Act of 1996. The requirement is a precondition of entering into a valid and binding contract.

5.5.5 Business Registration Notice

All New Jersey and out of State business organizations must obtain a Business Registration Certificate (BRC) from the Department of the Treasury, Division of Revenue, prior to conducting business with the State of New Jersey. Proof of valid business registration must be submitted by a bidder with its bid proposal. Failure to submit such valid business registration with a bid will render the bid materially non-responsive. The business registration form (Form NJ-REG) can be found online at:

<http://www.state.nj.us/treasury/revenue/gettingregistered.htm#busentity>

5.5.8 Requirements of PL 2005, Chapter 51/ Executive Order 117 Vendor Certification and Disclosure of Political Contributions

Pursuant to the requirements of Public Law 2005, c.51, and Executive Order 117, all bidders must submit the Two-Year Chapter 51/Executive Order 177 Vendor Certification and Disclosure of Political Contributions with their bid proposal. See Section 9 of this RFP for the certification form. Instructions for completion of the form may be found at http://www.umdny.edu/purchweb/employees/employ36_forms_policies.htm .

5.6 Section 2 – Technical Proposal

In this Section, the bidder shall describe its approach and plans for accomplishing the work outlined in the Scope of Work Section, i.e., Section 3.0. The bidder must set forth its understanding of the requirements of this RFP and its ability to successfully complete the contract. This section of the proposal should contain at least the following information:

5.6.1 Management Overview

The bidder shall set forth its overall technical approach and plans to meet the requirements of the RFP in a narrative format. This narrative should convince UMDNJ that the bidder understands the objectives that the contract is intended to meet, the nature of the required work and the level of effort necessary to successfully complete the contract. The narrative should convince UMDNJ that the bidder's general approach and plans to undertake and complete the contract are appropriate to the tasks and subtasks involved.

Mere reiterations of RFP tasks and subtasks are strongly discouraged, as they do not provide insight into the bidder's ability to complete the contract. The bidder's response to this Section should be designed to convince UMDNJ that the bidder's detailed plans and approach proposed to complete the Scope of Work are realistic, attainable and appropriate and that the bidder's proposal will lead to successful contract completion.

5.6.2 Contract Management

The bidder should describe its specific plans to manage, control and supervise the contract to ensure satisfactory contract completion according to the required schedule. The plan should include the bidder's approach to communicate with UMDNJ, including, but not limited to, status meetings, status reports, etc.

5.6.3 Contract Schedule

The bidder should include a contract schedule. If key dates are a part of this RFP, the bidder's schedule should incorporate such key dates and should identify the completion date for each task and sub-task required by the Scope of Work. Such schedule should also identify the associated deliverable items(s) to be submitted as evidence of completion of each task and/or subtask.

5.6.4 Implementation Plan

It is essential that UMDNJ move forward quickly to have the contract in place. Therefore, the bidder must include as part of its proposal an implementation plan, beginning with the date of notification of contract award. Such implementation plan should include the following elements:

5.6.4.1 A detailed timetable for the implementation period. The timetable should be designed to demonstrate how the bidder will have all services available within the time frame indicated in the RFP.

5.6.4.2 The bidder's plan for the deployment and use of management, supervisory or other key personnel during the implementation period. The plan should show all management, supervisory and key personnel that will be assigned to manage, supervise and monitor the bidder's implementation of the contract within the period specified.

NOTE: The bidder should clearly identify management, supervisory or other key staff that will be assigned only during the implementation period.

5.6.4.3 The bidder's plan for recruitment of staff required to provide all services required by the RFP on the contract start date at the end of the implementation period. The bidder should submit a plan for the purchase and distribution of equipment, inventory, supplies, materials, etc., that will be required to fully implement the contract required start date.

5.6.4.4 The bidder should submit plan for the use of subcontractor(s), if any, on this contract. Emphasis should be on how any subcontractor identified will be involved in the implementation plan.

5.6.5 Potential Problems

The bidder should set forth a summary of any and all problems that the bidder anticipates during the term of the contract. For each problem identified, the bidder should provide its proposed solution.

5.7 Section 3 – Organizational Support and Experience

The bidder should include information relating to its organization, personnel, and experience, including, but not limited to, references, together with contact names and telephone numbers, evidencing the bidder's qualifications and capabilities to perform the services required by this RFP.

5.7.1 Location

The bidder should include the location of the bidder's office that will be responsible for managing the contract. The bidder should include the telephone number, e-mail and name of the individual to contact.

5.7.2 Organizational Chart (Contract Specific)

The bidder should include a contract organizational chart, with names showing management, supervisory and other key personnel (including subcontractor's management, supervisory or other key personnel) to be assigned to the contract. The chart should include the labor category and title of each such individual.

5.7.3 Résumés

Detailed résumés should be submitted for all management, supervisory and key personnel to be assigned to the contract. Résumés should be structured to emphasize relevant qualifications and experience of these individuals in successfully completing contracts of a similar size and scope to those required by this RFP. Résumés should clearly identify previous experience in completing similar contracts. Beginning and ending dates should be given for each similar contract. A description of the contracts should be given and should demonstrate how the individual's work on the completed contract related to the individual's ability to contribute to the successfully providing the services required by this RFP. With respect to each similar contract, the bidder should include the name and address of each reference together with a person to contact for a reference check and telephone number.

5.7.4 Backup Staff

The bidder should include a list of backup staff that may be called upon to assist or replace primary individuals assigned. Backup staff must clearly be identified in the proposal as backup staff.

5.7.5 Organization Chart (Entire Firm)

The bidder should include an organizational chart showing the bidder's entire organizational structure. This chart should show the relationship of the individuals assigned the contract to the bidder's overall organizational structure.

5.7.6 Experience of Bidder on Contracts of Similar Size and Scope

The bidder should provide a comprehensive listing of contracts of similar size and scope that it has successfully completed, as evidence of the bidder's ability to successfully complete the services required by this RFP. Emphasis should be placed on contracts that are similar in size and scope to those required by this RFP.

A description of all such contracts should include and should show how such contracts relate to the ability of the firm to complete the services required by this RFP. For each such contract, the bidder should provide the name and telephone number of a contact person for the other contract party. Beginning and ending dates should also be given for each contract.

5.7.7 Financial Capability of the Bidder

The bidder should provide proof of its financial capabilities to undertake and successfully complete the contract. A certified financial statement for the most recent fiscal year and current bank reference(s) are acceptable. If a bidder chooses not to include this information with its bid, this information may be requested from the bidder during the evaluation process. If the bidder is requested to submit this information during the evaluation process, the bidder will be required to submit it, and failure to do so will be cause for finding the bid non-responsive.

5.7.8 Subcontractor(s)

5.7.8.1 Should the bidder propose to utilize a subcontractor(s) to fulfill any of its obligations, the bidder shall be responsible for the subcontractor's(s): (a) performance; (b) compliance with all of the terms and conditions of the contract; and, (c) compliance with the requirements of all applicable laws.

5.7.8.2 The bidder should provide detailed description of services to be provided by each subcontractor, referencing the applicable Section or subsection of this RFP.

5.7.8.3 The bidder should provide detailed résumés for each subcontractor's management supervisory and other key personnel that demonstrate knowledge, ability and experience relevant to that part of the work, which the subcontractor is designated to perform.

5.7.8.4 The bidder should provide documented experience demonstrating that each subcontractor has successfully performed work on contracts of a similar size and scope to the work that the subcontractor is designated to perform in the bidder's proposal.

5.8 Section 4 – Cost Proposal

Bidders must submit their cost proposal in accordance with the Price Sheet(s) included in this RFP as Section 8.0.

Failure to submit all information required will result in your bid being considered non-responsive. Each bidder is requested to hold its prices firm for a minimum of one hundred twenty (120) days so that an award can be made.

Each bidder may also submit any additional price or cost information that the bidder feels may be required to perform any additional work and/or special projects required by this RFP.

ONLY price and costing information provided by the bidder in its original bid proposal submitted in response to this RFP may later be used for additional work and/or special projects to be paid against the contract resulting from this RFP.

6.0 PROPOSAL EVALUATION AND CONTRACT AWARD

6.1 Proposal Evaluation Committee

Proposals may be evaluated by an Evaluation Committee composed of members of affected departments together with representative(s) from the Department of Purchasing Services. Representatives from other governmental agencies may also serve on the Evaluation Committee. On occasion, the Evaluation Committee may choose to make use of the expertise of an outside consultant in an advisory role.

6.2 Oral Presentation and/or Clarification of Bids

A bidder may be required to give an oral presentation to the Evaluation Committee concerning its bid proposal. The Evaluation Committee may also require a bidder to submit written responses to questions regarding its bid.

The purpose of such communication with a bidder, either through an oral presentation or a letter of clarification, is to provide an opportunity for the bidder to clarify or elaborate on its bid. The original bid, as submitted, however, cannot be supplemented, changed, or corrected in any way during the evaluation process. No comments regarding other bids are permitted. Bidders may not attend presentations made by their competitors.

It is within the Evaluation Committee's discretion whether to require a bidder to give an oral presentation or require a bidder to submit written responses to questions regarding its bid. Action by the Evaluation Committee in this regard should not be construed to imply acceptance or rejection of a bid. The Purchasing Services' buyer is the sole point of contact regarding any request for an oral presentation or written clarification.

6.3 Evaluation Criteria

The following evaluation criteria categories, not necessarily listed in order of significance, will be used to evaluate bid proposals received in response to this RFP. The evaluation criteria categories may be used to develop more detailed evaluation criteria to be used in the evaluation process.

- 6.3.1 The bidder's general approach and plans to meet the requirements of this RFP.
- 6.3.2 The bidder's detailed approach and plans to perform the commercial IRB services required by the Scope of Work Section of this RFP.
- 6.3.3 The bidder's documented experience in successfully providing commercial IRB services for contracts of a similar size and scope of those required by this RFP.
- 6.3.4 The qualifications and experience of the bidder's management, supervisory or other key personnel assigned to the contract, with emphasis on documented experience in successfully providing commercial IRB work on contracts of similar size and scope to those required by this RFP.
- 6.3.5 The overall ability of the bidder to mobilize, undertake and successfully provide the services required under the contract. This judgment will include, but not be limited to, the following factors: the number and qualifications of management, supervisory and other staff proposed by the bidder to complete the contract, the availability and commitment to the contract of the bidder's management, supervisory and other staff proposed and the bidder's contract management plan, including the bidder's contract organizational chart.
- 6.3.6 The bidder's cost proposal.

6.4 University's Right to Consider Additional Information

- 6.4.1 The Vice President may obtain any information determined to be appropriate regarding the ability of the bidder to supply and/or render the service required by this RFP.
- 6.4.2 The Vice President may consider such other factors that, in the opinion of the Vice President, are important in evaluating the bidder's proposal and awarding contracts as determined to be in the best interest of the University.

6.4.3. The University reserves the right to request all bidders to explain the method used to arrive at any or all cost or pricing figures.

6.4.4 When making the contract award decision, the University may consider evidence of formal or other complaints against any bidder(s) by the University for contracts held in the past or present by the bidder.

6.4.5 The University reserves the right to check the bidder's financial capacity and ability to successfully undertake and provide the services required by this RFP by any means deemed appropriate.

6.4.6 The University reserves the right to conduct site inspections of any facility(s) serviced by the bidder(s) to assist in judging the bidder's ability to provide the services required by this RFP. This applies to all facilities services by the bidder or any sub-contractor to the bidder. This right extends to all facilities of which the University is aware, or about which it becomes aware, that the bidder is servicing, whether or not the facility is listed in the bidder's proposal.

6.5 NEGOTIATION AND BEST AND FINAL OFFER (BAFO)

After evaluating bid proposals, the evaluation committee may enter into negotiations with each bidder in the competitive range, unless there are too many highly rated proposals to evaluate efficiently. In this situation, UMDNJ may limit the competitive range to the number of proposals that will permit efficient competition among the most highly rated proposals.

The primary purpose of negotiations is to maximize UMDNJ's ability to get the best value, based on the requirements and evaluation criteria set forth in the RFP. Negotiations may involve the identification of significant proposal weaknesses, ambiguities and other deficiencies that could limit a bidder's award potential, including payments. More rounds of negotiations may be held with one bidder in the competitive range than with another. Negotiations will be structured to safeguard information and ensure that all bidders in the competitive range are treated fairly. When the evaluation committee determines to conclude negotiations, all bidders in the competitive range will be so notified and advised of the time and place for submission of best and final offers. The best and final offer can modify any aspect of the bid proposal, provided mandatory RFP requirements are satisfied and further provided that the revised payment proposal is not higher than the original payment proposal. Any revised payment proposal that is not equal to or higher in payment than the original payment proposal will be rejected as non-responsive.

Evaluation of the best and final offers will be on the basis of payment and the evaluation criteria set forth in the RFP. If, after review of the best and final offers, clarification is required, it may be sought from the bidders. If further negotiation is desired after evaluation of the revised proposals, it will be followed by another BAFO opportunity. UMDNJ reserves the right to reassess the competitive range before proceeding with a subsequent round of negotiations and BAFO submissions and to remove from the competitive range any proposal that is no longer considered to be a leading contender for award.

After evaluation of the final BAFO submissions, the evaluation committee will recommend to the Vice President for award the responsible bidder(s) whose bid proposal(s), conforming to the RFP, is most advantageous to the State, payment and other factors considered. The Vice President may accept, reject or modify the recommendation of the Evaluation Committee. The Vice President may negotiate further increases in payment with the selected bidder.

Negotiations will only be conducted in those circumstances where they are deemed by UMDNJ to be in UMDNJ's best interests and to maximize the UMDNJ's ability to get the best value. Therefore, bidders are advised to submit their best technical and payment proposals in response to this RFP, because the UMDNJ may, after evaluation, make a contract award based on the content of these initial submissions, without further negotiation with any bidder.

All contacts, records of initial evaluations, any correspondence with bidders related to any request for clarification, negotiation or BAFO, any revised technical and/or payment proposals, the Evaluation Committee Report and the Award Recommendation, will remain confidential until a Notice of Intent to Award a contract is issued.

6.6 Contract Award

The contract shall be awarded with reasonable promptness by written notice to that responsible bidder whose bid, conforming to the invitation for bids, will be most advantageous to UMDNJ, price and other factors considered. Any or all bids may be rejected when the Vice President determines that it is in the public interest to do so.

6.7 Bidder's Right to Challenge a Contract Award

Except in cases of emergency, bidders have the right to protest a proposed contract award.

A bidder's protest must be submitted to the buyer of record with a copy to the Vice President of Supply Chain Management ("Vice President") within ten (10) days of receipt of notice to the bidder that it did not receive a contract award for its submitted bid proposal or notice that an award had been made to another bidder. The protest period may be shortened by the Vice President of Supply Chain Management. If the protest period is shortened or a protest period is not authorized due to emergency, all bidders will receive notice of the shortened protest period or emergency in the notice sent to bidder on the award of the contract.

Notices of contract award under this section may be faxed, e-mailed, sent by regular mail or by any other means, excluding telephonic communication, conducive to transmitting the notice. If notice is sent by regular mail, the recipient is deemed to have received the notice three (3) days after mailing.

If a bidder files a protest to a contract award under this section, the bidder must set forth in writing with specificity the basis of the protest. At the time of the protest filing, the bidder must also submit all documentation supporting the basis of the protest. Failure to comply with these requirements may lead to rejection of the protest and UMDNJ award of the contract.

The protest will be reviewed and addressed with reasonable promptness. If deemed necessary by Vice President, a hearing may be held on the merits of the protest. In all cases, the Vice President will notify the bidder of the final determination on the protest.

7.0 BIDDER'S DATA SHEETS (FORMS TO BE COMPLETED BY BIDDER)

Not applicable to this procurement.

8.0 PRICE SHEET AND SUPPORTING DETAIL

PROVIDE COMERCIAL IRB SERVICES FOR UMDNJ

PROPOSAL #P11-004

PLEASE COMPLETE AND SUBMIT THIS FORM AS YOUR COST PROPOSAL. RATE TO INCLUDE TOTAL, ALL-INCLUSIVE HOURLY COST FOR THE COMPLETE REVIEW, INCLUDING TRAVEL COSTS AND RELATED EXPENSES:

	Year #1	Year #2	Year #3
8.1 Initial Review			
Initial Review of Protocol and investigation	\$ _____	\$ _____	\$ _____
Additional Investigation, Multi-Center studies	\$ _____	\$ _____	\$ _____
Additional Consent Forms (each)	\$ _____	\$ _____	\$ _____
8.2 Continuing Review:			
Continuing Review, Study Renewal Review	\$ _____	\$ _____	\$ _____
Annual Review of Generic or Non-Protocol Related Material	\$ _____	\$ _____	\$ _____

8.3 Changes in Research:

Changes to Research Involving
Consent Form Review \$_____ \$_____ \$_____

Changes to Research not Involving
Consent form Review \$_____ \$_____ \$_____

Same Change, Each Additional
site in Same Submission \$_____ \$_____ \$_____

Co-Principal Investigator or
Change in Investigator \$_____ \$_____ \$_____

8.4 Other Services:

Videoconference \$_____ \$_____ \$_____

Teleconference \$_____ \$_____ \$_____

Generic or Non-Protocol
Related Material \$_____ \$_____ \$_____

Translation Services \$_____ \$_____ \$_____

Written Consent Form \$_____/Hr. \$_____/Hr. \$_____/Hr.

8.5 Consulting Services

Year 1 - \$_____/Hour

Year 2 - \$_____/Hour

Year 3 - \$_____/Hour

8.6 Optional Year's Percentage Increase: Fourth Year_____% Fifth Year_____%

9.0 REQUIRED FORMS

- Ownership Disclosure Form - attached
- MacBride Principle Certification - attached
- Business Associate Agreement – attached
- Affirmative Action Employee Information can be found online at:
http://www.umdnj.edu/purchweb/words_download/Form%20AA%20_302%20.pdf
http://www.umdnj.edu/purchweb/words_download/AA302_instructions.pdf
- Two Year PL 51/Executive Order 117 Vendor Certification Form
<http://www.umdnj.edu/purchweb/vendors/index.htm>
- The business registration form (Form NJ-REG) can be found online at:
<http://www.state.nj.us/treasury/purchase/busreg.htm>

OWNERSHIP DISCLOSURE FORM

Name of Firm: _____

INSTRUCTIONS: Provide below the names, home addresses, dates of birth, offices held and any ownership interest of all officers of the firm named above. If additional space is necessary, provide on an attached sheet.

Name	Home Address	Date of Birth	Office Held	Ownership Interest
_____	_____	_____	_____	_____

INSTRUCTIONS: Provide below the names, home addresses, dates of birth, and ownership interest of all individuals not listed above, and any partnerships, corporations and any other owner having a 10% or greater interest in the firm named above. If a listed owner is a corporation or partnership, provide below the same information for the holders of 10% or more interest in that corporation or partnership. If additional space is necessary, provide that information on any attached sheet. If there are no owners with 10% or more interest in your firm, enter "None" below. Complete the certification at the bottom of this form. If this form has previously been submitted to the UMDNJ, Purchasing Department in explanation with another bid, indicate changes, if any, where appropriate, and complete the certification below.

Name	Home Address	Date of Birth	Office Held	Ownership Interest
_____	_____	_____	_____	_____

COMPLETE ALL QUESTIONS BELOW

Within the past five years has another company or corporation had a 10% or greater interest in the firm identified above? (If yes complete and attach a separate disclosure form reflecting previous ownership interests.) Yes _____ No _____

Has any person listed in this form or its attachments ever been arrested, charged, indicted, plead guilty or been convicted in a criminal or disorderly persons matter by the State of New Jersey, any other Political subdivision state or the U.S. Government? (If yes, attach a detailed explanation for each instance.) Yes _____ No _____

Has any person or entity listed in this form or its attachments ever been excluded suspended, debarred or otherwise declared ineligible by any agency of government from bidding or Contracting to provide services, labor, material or supplies? (If yes, attach a detailed explanation for each instance.) Yes _____ No _____

Are there now any criminal matters, suspension or debarment proceedings pending in which the firm and/or its officers and/or managers are involved? (If yes, attach a detailed explanation for each instance.) Yes _____ No _____

Has any federal, state or local license, permit or other similar authorization, necessary to perform the work applied for herein and held or applied for by any person or entity listed in this form, been suspended or revoked, or been the subject of any pending proceedings specifically seeking or litigating the issue of suspension or revocation? (If yes to any part of this question, attach a detailed explanation for each instance.) Yes _____ No _____

CERTIFICATION: I, being duly sworn upon my oath, hereby represent and state that the foregoing information and any attachments thereto to the best of my knowledge are true and complete. I acknowledge that the State of New Jersey is relying on the information contained herein and thereby acknowledge that I am under a continuing obligation from the date of this certification through the completion of any contracts with the State to notify the State in writing or any changes to the answers or information contained herein. I acknowledge that I am aware that it is a criminal offense to make a false statement or misrepresentation, and if I do so, I recognize that I am subject to criminal prosecution under the law and that it will also constitute a material breach of my agreement(s) with the State of New Jersey and that the State at its option, may declare any contract(s) resulting from this certification void and unenforceable.

I, being duly authorized, certify that the information supplied above, including all attached pages, is complete and correct to the best of my knowledge. I certify that all of the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment. (Print or Type)

Date: _____ Signature _____
Name _____
Title _____

FEIN # _____

NOTICE TO ALL BIDDERS
REQUIREMENT TO PROVIDE A CERTIFICATION
IN COMPLIANCE WITH MACBRIDE PRINCIPLES
AND NORTHERN IRELAND ACT OF 1989

Pursuant to Public Law 1995, c.134, a responsible bidder selected, after public bidding, by the Director of the Division of Purchase and Property, pursuant to N.J.S.A. 52:34-12, or the Director of the Division of Building and Construction, pursuant to N.J.S.A. 52:32-2, must complete the certification below by checking one of the two representations listed and signing where indicated. If a bidder who would otherwise be awarded a purchase, contract or agreement does not complete the certification, then the Directors may determine, in accordance with applicable law and rules, that it is in the best interest of the State to award the purchase, contract or agreement to another bidder who has completed the certification and has submitted a bid within five (5) percent of the most advantageous bid. If the Directors find contractors to be in violation of the principles which are the subject of this law, they shall take such action as may be appropriate and provided for by law, rule or contract, including, but not limited to, imposing sanctions, seeking compliance, recovering damages, declaring the party in default and seeking debarment or suspension of the party.

I certify, pursuant to N.J.S.A. 52:34-12-2, that the entity for which I am authorized to bid:

_____ has not ongoing business activities in Northern Ireland and does not maintain a physical presence therein through the operation of offices, plants, factories or similar facilities, either directly or indirectly through intermediaries, subsidiaries or affiliated companies over which it maintains effective control; or

_____ will take lawful steps in good faith to conduct any business operations it has in Northern Ireland in accordance with the MacBride principles of nondiscrimination in employment as set forth in N.J.S.A. 52:18A-89.8 and in conformance with the United Kingdom's Fair Employment (Northern Ireland) Act of 1989, and permit independent monitoring of their compliance with those principles.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Signature of Bidder

Dated: _____

Print or Type Name

Title

PBMACB 12/95

—

This Business Associate Agreement
Is Related To and a Part of the Following
Underlying Agreement: RFP #P11-004 –
Commercial IRB Services for UMDNJ
Effective Date of Underlying Agreement: _____
School/Unit: _____
Vendor: _____

Business Associate Agreement

This Business Associate Agreement (“BAA”) is entered into between The University of Medicine and Dentistry of New Jersey - Office of Research for Human Subjects Protection Program (“UMDNJ”), a body corporate and politic of the State of New Jersey having its principal administrative offices at 65 Bergen Street, Newark, New Jersey 07107 (hereinafter referred to as “**Covered Entity**”) and

[Name and Address of Contracting Party] (hereinafter referred to as “**Business Associate**”) (the “**Covered Entity**” and “**Business Associate**” hereinafter collectively referred to as the “**Parties**”). Any conflict between the terms of this BAA and the Underlying Agreement between the Parties shall be governed by the terms of this BAA.

WHEREAS, in connection with the Underlying Agreement the Business Associate provides services to Covered Entity and Covered Entity discloses to Business Associate certain Protected Health Information that is subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”), the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) (the “**HITECH Act**”), and regulations promulgated by the U.S. Department of Health and Human Services (the “**HHS**”) (hereinafter the “**HIPAA Regulations**” and the “**HITECH Regulations**,” respectively) and/or applicable state and/or local laws and regulations; and

WHEREAS, for good and lawful consideration and with acknowledgment of the mutual promises, set forth in the Underlying Agreement and herein, the Parties, intending to be legally bound, hereby agree as follows:

I. Definitions¹

A. **Breach** means the unauthorized acquisition, access, use, or disclosure of protected health information (“PHI”) which compromises the security or privacy of such information in violation of HIPAA, the HITECH Act, the HIPAA Regulations, and/or the HITECH Regulations, except where a good faith belief exists that unauthorized persons to

¹ An expanded definition of the following terms as well as the definition of other relevant terms are available on UMDNJ’s website at <http://www.umdny.edu/purchweb/vendors/index.htm>. Terms used in this Business Associate Agreement but not otherwise defined shall have the meaning ascribed to those terms in HIPAA, the HITECH Act, and any current and future regulations promulgated under HIPAA and/or the HITECH Act. See 45 C.F.R. 160.103, 164.402 and 164.501.

whom such information is disclosed would not reasonably have been able to retain such information. The term “**Breach**” does not include:

1. Any unintentional acquisition, access, or use of PHI by an employee or person acting under the authority of a Covered Entity or Business Associate if:
 - a. Such acquisition, access, or use was made in good faith and within the course and scope of the employment or other professional relationship of such employee or person, respectively, with the Covered Entity or Business Associate; and
 - b. Does not result in further unauthorized use or disclosure; or
2. Any inadvertent disclosure by a person who is otherwise authorized to access PHI at a Covered Entity or Business Associate to another, similarly authorized person at the same Covered Entity, Business Associate or organized health care arrangement in which the Covered Entity participates and such information received as a result of such disclosure is not further used or disclosed in an impermissible manner.

B. **Business Associate** means a service provider that receives PHI from, or creates or maintains PHI on behalf of, a Covered Entity including, but not limited to, claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefits management, practice management, reprising, transcription, legal, actuarial, accounting, consulting, data aggregation, administrative, accreditation or financial services, and vendors that offer personal health records to patients as part of a Covered Entity’s electronic health record, where the service or function involves the use or disclosure of individually identifiable health information from the Covered Entity or from another Business Associate of the Covered Entity. A Business Associate excludes, among others, employees of Covered Entities.

C. **Covered Entities** include (i) health care providers that transmit patient health information electronically in connection with a covered transaction, (ii) health plans (including employer-sponsored employee welfare benefit plans and self-insured employer-offered health plans), and (iii) health care clearinghouses.

D. **Data Aggregation** means, with respect to PHI created or received by a Business Associate, the combining of PHI received by a Business Associate in its capacity as a Business Associate for more than one Covered Entity to permit data analyses that relate to the health care operations of the respective Covered Entities.

E. **Designated Record Set** means any grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a Covered Entity that is (i) medical records and billing records about individuals, and/or (ii) enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, used, in whole or in part, by or for the Covered Entity, to make decisions about individuals.

F. **Electronic Protected Health Information (“Electronic PHI”)** means PHI that is transmitted by or maintained in electronic media.

G. **Individual** means the person who is the subject of PHI and includes a person who qualifies as a personal representative (45 C.F.R. 164.502(g)).

H. **Protected Health Information (“PHI”)** means physical and/or mental health and demographic information collected from an individual and created or received by a Covered Entity and/or Business Associate that identifies or could reasonably identify an individual (*i.e.*, is “individually identifiable”) and is held or transmitted in any form including electronic media. PHI excludes educational records and employment records held by a Covered Entity as an employer (45 C.F.R. 164.501).

I. **Required By Law** means that Covered Entities may use and disclose PHI without individual authorization as required by law (including by statute, regulation, or court orders) in accordance with the requirements in 45 C.F.R. 164.512(c), (e) or (f).

J. **Unsecured PHI** means PHI not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of technology or methodology specified by the Secretary of HHS.

II. **Permitted Uses and Disclosures of PHI by Business Associate**

A. Except as otherwise limited in this BAA, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement, provided that such uses and/or further disclosures (i) do not violate the requirements of HIPAA’s Business Associate contract standard at 45 C.F.R. 164.504(e)(1) and/or the HITECH Act, if done by the Covered Entity, (ii) are the minimum necessary PHI to accomplish the intended purpose, or (iii) are Required By Law.

B. Except as otherwise limited in this BAA, Business Associate may use or disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of Business Associate, provided, however, that any such uses or disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that (i) the PHI will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and (ii) the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been Breached.

C. Except as otherwise limited in this BAA, Business Associate may use PHI to provide Data Aggregation services to Covered Entity (42 C.F.R. 164.504(e)(2)(i)(B)).

D. Business Associate may use PHI to report violations of law to appropriate federal and state authorities as permitted under HIPAA and/or other federal and state laws. (45 C.F.R. 164.502(j) (1)).

III. Duties and Obligations of Business Associate Related to PHI

A. Business Associate shall not use or disclose PHI other than as permitted or required by the Underlying Agreement, this BAA, and/or as Required By Law. Business Associate shall immediately notify Covered Entity of any use or disclosure of PHI in violation of this BAA.

B. Business Associate shall use and implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of PHI and/or Electronic PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity.

C. Business Associate shall notify, in writing, the Covered Entity when the Business Associate discovers a Breach of Unsecured PHI. A Breach is deemed to have been discovered by a Business Associate as of the first day on which Business Associate (by its employee, officer, or other agent) knows or would have known of such Breach by exercising reasonable diligence. Business Associate's notification to Covered Entity (i.e., UMDNJ) shall:

1. Be made to the Covered Entity without unreasonable delay and in no event later than ten (10) days following the discovery of a breach, except in the case of a Business Associate that is an agent of the Covered Entity, in which case the Business Associate must provide the Covered Entity with immediate notification of the breach, except where law enforcement officials determine that a notification would impede a criminal investigation or cause damage to national security. Unless the language in the underlying agreement between the parties indicates that a Business Associate is an independent contractor, then the Business Associate shall be considered an agent of UMDNJ for purposes of breach notification.

2. To the extent possible, provide the identity of each Individual whose Unsecured PHI was, or is reasonably believed to have been, Breached, and any other information that the Covered Entity is required to include in the notice to affected Individuals under 45 C.F.R. 164.404(c), either at the time of notice of Breach to the Covered Entity or as promptly thereafter as information becomes available. Include information in substantially the same form as the "Notification To the Covered Entity About A Breach of Unsecured Protected Health Information" available to Business Associates at UMDNJ's website at:

http://www.umdj.edu/hipaaweb/BN/NOTICATION_TO_THE_COVERED_ENTITY.pdf .

D. Business Associate is subject to the same legal requirements to cure, terminate or report violations to the Secretary of HHS under the same duty and in the same manner as Covered Entity.

E. Business Associate shall mitigate, to the extent practicable, any harmful effect known to it resulting from an unauthorized use or disclosure of PHI or Breach of Unsecured PHI.

F. Business Associate shall ensure that any agent, including a subcontractor, to whom it provides PHI (i) received from, or (ii) created or received by Business Associate on behalf of, a Covered Entity agrees, in writing, to the same restrictions and conditions that apply through this BAA to Business Associate with respect to such PHI.

G. Business Associate (i) shall provide Covered Entity access to its premises for a review and demonstration of its internal practices and procedures for safeguarding PHI and, (ii) to the extent applicable, shall provide access for inspection and copying of PHI in a Designated Record Set at reasonable times at the request of Covered Entity or, as directed by Covered Entity, to an Individual (45 C.F.R. 164.524). If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act. (42 U.S.C. §17935(e)).

H. Business Associate shall, upon request with reasonable notice, provide Covered Entity with an accounting of uses and disclosures of PHI provided to it by Covered Entity.

I. Business Associate agrees to use, disclose and request (i) only the minimum necessary PHI, as defined by law, and (ii) to the extent practicable, only the limited data set of PHI excluding direct identifiers, as defined in 45 C.F.R. 164.514(e)(2).

J. Business Associate shall document such disclosures of PHI and information related to such disclosures as would be required for a Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI (45 C.F.R. 164.528). Should a Covered Entity or an Individual request an accounting of disclosures of PHI pursuant to 45 C.F.R. 164.528, Business Associate agrees to promptly provide Covered Entity with information in a format and manner sufficient to respond no later than sixty (60) days after receipt of such request, subject to specific statutory exceptions.

K. Business Associate shall make its internal practices, books and records, including policies and procedures, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, available to Covered Entity at the request of Covered Entity, or the Secretary of HHS, for purposes of the Secretary determining Covered Entity's compliance with HIPAA and/or the HITECH Act in the time, manner and place designated by the Covered Entity and/or the Secretary.

L. To the extent applicable, Business Associate shall make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to, no later than sixty (60) days after receipt of such request from a Covered Entity or Individual.

M. Business Associate agrees to abide by the limitations on marketing communications to Individuals regarding the purchase and use of products or services set forth in the HITECH Act and the HITECH Regulations.

N. Business Associate agrees and acknowledges that the administrative rules governing, and the civil and criminal penalties for violating, HIPAA, the HITECH Act, the HIPAA Regulations and the HITECH Regulations, apply to it in the same manner as they apply to Covered Entity, as more fully set forth at UMDNJ's website at <http://www.umdj.edu/complweb/policies/index.htm>.

IV. **Term and Termination**

A. Term. The term of this BAA shall be effective as of the effective date of the Underlying Agreement and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions of this Section IV.

B. Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

1. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this BAA and the Underlying Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;

2. Immediately terminate this BAA and/or the Underlying Agreement if Business Associate has breached a material term of this BAA and cure is not possible; or

3. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary of HHS.

C. Effect of Termination.

1. (a) Except as provided in paragraph C.2 of this Section, upon termination of this BAA, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of PHI.

- (b) Except as provided in paragraph C.2 of this Section, if Covered Entity, in its sole discretion, requires that Business Associate destroy any or all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, either due to the termination of this BAA or otherwise, Business Associate shall certify, in writing, to Covered Entity that the PHI has been destroyed and rendered indecipherable, pursuant to HIPAA and the HITECH Act. This provision also shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

2. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity written notification of the conditions that make return or destruction infeasible within thirty (30) calendar days of such request. In such case, Business Associate shall extend the protections of this BAA to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI. This provision also shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

3. Should the Business Associate make a disclosure of PHI in violation of this BAA, Covered Entity shall have the right to immediately terminate any contract, other than this BAA, then in force between the Parties, including the Underlying Agreement.

4. The provisions of this Section IV.C, shall survive the termination of this BAA and the Underlying Agreement for any reason.

V. Remedies In Event of Breach

A. Business Associate agrees and acknowledges that irreparable harm will result to Covered Entity, and to its business, in the event of breach by Business Associate of any covenants, duties, obligations and assurances in this BAA and further agrees that remedy at law for any such breach shall be inadequate and that damages resulting there from are not susceptible to being measured in monetary terms.

In the event of any such breach or threatened breach by Business Associate, Covered Entity shall be entitled to (i) immediately enjoin and restrain Business Associate from any continuing violations and (ii) reimbursement for reasonable attorneys' fees, costs and expenses incurred as a proximate result of the breach. The remedies in this Section V shall be in addition to any action for damages and/or other remedy available to Covered Entity for such breach.

B. Business Associate shall indemnify and hold Covered Entity, its directors, officers, employees and agents harmless from any and all liabilities, damages, reasonable attorneys' fees, costs and expenses incurred by Covered Entity as a result of a breach of this BAA caused by Business Associate's actions or inactions and/or those of its employees and agents.

C. Business Associate agrees and acknowledges that the provisions of this BAA shall be strictly construed.

VI. Miscellaneous

A. Independent Contractor. None of the provisions of this BAA and/or the Underlying Agreement are intended to create nor shall be deemed or construed to have created any relationship between the Parties other than that of independent entities contracting with each other unless otherwise explicitly stated in this BAA or the Underlying Agreement.

B. **Detrimental Reliance By Covered Entity.** Business Associate agrees and acknowledges that its covenants, duties, obligations and assurances herein shall be detrimentally relied upon by Covered Entity in choosing to commence or continue a business relationship with Business Associate. Covered Entity shall not be liable to Business Associate for any claim, loss, or damage relating to Business Associate's use or disclosure of any information received from Covered Entity or from any other source.

C. **Regulatory References.** Any reference herein to law means the law as in effect or as amended.

D. **Construction.** The BAA shall be construed broadly and any ambiguity shall be resolved in favor of a meaning that complies and is consistent with applicable law.

E. **Severability.** In the event that any provision of this BAA violates any applicable statute, ordinance or rule of law in any jurisdiction that governs this BAA, such provision shall be ineffective to the extent of such violation without invalidating any other provision of this BAA.

F. **Authority.** The signatories below have the right and authority to execute this BAA for their respective entities and no further approvals are necessary to create a binding agreement.

G. **Covered Entity's Notices To Business Associate.** Covered Entity's Notices to Business Associate are available on UMDNJ's website at:
http://www.umdj.edu/hipaaweb/privacy/privacy_NPPUMDNJ03.htm.

Such Notices include, but are not limited to, (i) any limitations in the Covered Entity's Notices of Privacy Practices that may affect the Business Associate, (ii) any changes in, or revocation of, permission by an Individual to use or disclose PHI, or (iii) any restriction in the use or disclosure of PHI that Covered Entity has agreed to.

H. **Compliance With State Law.** Business Associate agrees and acknowledges that as the holder of individually identifiable health information it is subject to New Jersey law. In the event of any conflict between federal health care laws and New Jersey law, the Business Associate shall comply with the more restrictive provision.

I. **Conflict Among Contracts.** Should there be conflict between the terms of this BAA and any other contract between the Parties (either previous or subsequent to the date of this BAA), the terms of this BAA shall control unless the Parties, in a subsequent writing, specifically otherwise provide.

J. **Modification.** This BAA may only be modified by a writing signed by the Parties. The Parties agree to take such action subsequent to this BAA as necessary to amend the BAA from time to time as necessary for the Parties to comply with the requirements of any applicable law.

K. Notices to Parties. Any notice required under this BAA to be given shall be made in writing to:

To The Covered Entity:

Office of Research for Human
Subjects Protection Program
Address: 65 Bergen Street
Newark, New Jersey 07017
Telephone:
E-Mail:

To The Business Associate:

Name/Title: _____

Address:
Telephone:
E-Mail:

IN WITNESS WHEREOF, the parties have executed this Business Associate Agreement the day and year first written below.

**By: UNIVERSITY OF MEDICINE
AND DENTISTRY OF NEW JERSEY
[COVERED ENTITY]**

By: [BUSINESS ASSOCIATE]

Approved: _____

Approved: _____

Title: Denise Mulkern
Senior Vice President for Finance

Title: _____

Date: _____

Date: _____

*Version 1
2009-2010*

AFFIRMATIVE ACTION DOCUMENTATION

Dear Vendor:

As a State Agency, New Jersey State Regulations N.J.A.C. 17:27 requires us to obtain documentation regarding our vendors' "Affirmative Action" status. In order for us to be in compliance and do business with your company for the procurement of goods and services, it will be necessary for you to provide only one of the following documents with your bid/proposal response.

1. A State of New Jersey "Certificate of Employee Information Report Approval," or
2. A Form AA/302 Affirmative Action Employee Information Report, or
3. A Federal letter of approval from the Department of Labor.

Please understand the importance of this request. Although you may have already submitted this information, our files must be updated annually with current employment statistics. Your noncompliance of this request may result in suspension of any future business with your company.

Sincerely,

Purchasing Services