



# REQUEST FOR PROPOSAL (RFP)

**TITLE: Clinical Ethicist for the Cancer Institute of New Jersey**

**RFP NUMBER: P10-013**

**DATE ISSUED: October 13, 2009**

**DUE DATE: November 17, 2009**

**TIME: 2:00 P.M.**

**LOCATION: UNIVERSITY OF MEDICINE AND DENTISTRY  
OF NEW JERSEY –  
DEPARTMENT OF PURCHASING SERVICES  
LIBERTY PLAZA  
335 George Street, 2<sup>nd</sup> 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 INFORMATION FOR 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 Cancer Institute of New Jersey.

The purpose of this RFP is to enter a contract for the services of an Ethics Consultant to ensure the ethical integrity of the Cancer Institute of New Jersey.

#### 1.1.2 Intent

It is the University's intent to award this contract to one firm who will be responsible for meeting the charge of the engagement as outlined in Section 3, Scope of Work, of this document.

### 1.2 Background

In 1993, The Cancer Institute of New Jersey (CINJ) opened its doors with a mission to put an end to the devastating effects of cancer. And every day, we are a step closer to our goal. Our efforts have led to our inclusion as one of only 40 National Cancer Institute (NCI)-designated Comprehensive Cancer Centers in the nation - the only one in New Jersey.

As part of this elite group of centers nationwide, CINJ is a leader in laboratory, clinical, prevention, and population research. CINJ delivers advanced comprehensive care to adults and children and conducts cutting edge cancer research. Laboratory research at CINJ is supported by more than \$90 million annually in cancer-related research grants.

It is well recognized that ethical considerations are critical in performing clinical research. Since the mission of CINJ is to find better methods to prevent, identify, and treat malignancy that occurs in patients, clinical research is an essential function for CINJ. Therefore, it is essential that expert ethics consultation is readily available to CINJ administration and investigators. This consultation must be available for both the development and monitoring of clinical research performed at CINJ.

CINJ receives approximately 49,070 patient visits a year, of which more than 6,700 are new patients.

### 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, 2<sup>ND</sup> FLOOR  
NEW BRUNSWICK, NEW JERSEY 08903  
ATTN: Jennifer L. Havens  
Buyer's Phone Number: 732-235-9886  
Buyer's Fax Number: 732-235-9024  
Buyer's Email: havensjl@umdnj.edu

#### 1.3.1.1 Cut-Off Date for Questions and Inquiries

A non-mandatory Pre-bid Conference has been scheduled for this procurement, therefore, the cut-off date for submission of questions will be the conclusion of the non-mandatory Pre-Bid Conference. While all questions will be entertained at the non-mandatory Pre-bid Conference, it is strongly urged that questions be submitted in writing prior to the non-mandatory Pre-bid Conference. Written questions must be delivered to the Department of Purchasing Services' Buyer. It is requested that bidders having long, complex or multiple part questions submit them in writing as far in advance of the non-mandatory Pre-bid Conference as possible. This request is made so that answers can be prepared prior to the non-mandatory Pre-bid Conference.

#### 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.

#### 1.3.2. Non-Mandatory Pre-Bid Conference

A non-mandatory Pre-bid Conference has been scheduled for this procurement. All bidders interested in submitting proposals are strongly encouraged to attend the non-mandatory Pre-bid Conference. The purpose of this conference is to provide a structured and formal opportunity for bidders to raise questions and clarify any of the proposal requirements. The date, time and location are provided as follows:

DATE: October 27, 2009

TIME: 10:00 a.m.

LOCATION: UMDNJ, DEPARTMENT OF PURCHASING SERVICES, LIBERTY PLAZA, 335 GEORGE STREET, Conference Room C 3<sup>rd</sup> FLOOR, NEW BRUNSWICK, NEW JERSEY

It is the responsibility of the bidder to identify and address any additional requirements or information needed to submit a proposal. No special consideration shall be given to any bidder, because of the bidder's failure to be knowledgeable of all the requirements of the proposal after the pre-bid conference date.

#### 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

The entire content of every bid proposal will be publicly opened and becomes a public record. This is the case notwithstanding any statement to the contrary made by a bidder in its bid proposal.

All bid proposals, as public records, are available for public inspection after contract award. Interested parties can make an appointment to inspect bid proposals received in response to this RFP with the buyer.

#### 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.

#### 1.4.11 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.

#### 1.4.12 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>

#### 1.4.12.1 Definitions

“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.

#### 1.4.12.2 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.

#### 1.4.13 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.

“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.

“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.

“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

The Contractor must have experience in clinical ethics, clinical trials, and research protocols involving human subjects. The Contractor will serve as the primary ethics consultant for CINJ, and will assist in clinical trial and research project development, as indicated below. The Contractor must have a doctoral degree in ethics, and must have published work relating to the ethics of clinical research.

The Contractor shall have experience in working with oncologists and other cancer researchers in the development and monitoring of clinical trials with regard to ethical issues.

#### 3.1 Membership on the CINJ Scientific Review Board (SRB)

3.1.1 The Contractor must be a full-time member of the SRB and must attend each meeting. This effort will include review of clinical trial protocols and informed consent documents submitted to the SRB.

3.1.2 The Contractor must review protocols and consent documents before the meeting. The Contractor must also lead the ethical discussions regarding these protocols.

#### 3.2 Attendance at Phase I Clinical Trials Group

3.2.1 The Contractor must attend the Phase I Clinical Trials Group meetings, as needed as agreed upon with the Associate Director of Clinical Sciences, to address ethical issues arising as part of clinical trial development, research grant applications, and patient management.

3.3 The Contractor will attend other Tumor Study Group Meetings as agreed upon with the Associate Director of Clinical Sciences.

3.4 The Contractor may be asked to attend other committees relevant to Human Subjects and ethics, such as the Human Investigations Executive Committee as agreed upon by the Contractor and Associate Director of Clinical Sciences.

#### 3.5 Availability for Individual Faculty and Other Consultations

The Contractor shall assist faculty investigators in the ethical development of clinical trials. For example, this may include negotiations with sponsors regarding ethical issues in trial design. The scope of this work shall be overseen by the Associate Director of Clinical Sciences.

#### 3.6 Reports

The Contractor must report to the Associate Director of Clinical Sciences at CINJ in writing on a quarterly basis.

## 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.

#### 4.1.2 Contract Extension Option

This contract may be extended for two, one-year renewal periods. 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. Unless otherwise noted in this RFP (or any Addendum thereto), pricing for each optional year is to remain the same as the final year of the original contract term.

### 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.

### 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](http://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/\$1,000,000 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.

- 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 monthly with supporting documentation evidencing that work for which payment is sought has been satisfactorily provided. Invoices must reference the purchase order number and must be in strict accordance with the hourly rate as indicated on the RFP pricing sheet. All invoices must be approved by UMDNJ before payment will be authorized.

Invoices must also be submitted for any special projects, additional work or other items properly authorized and satisfactorily completed under the contract. Invoices shall be submitted according to the payment schedule agreed upon when the work was authorized and approved. Payment can only be made for work when it has received all required written approvals and has been satisfactorily completed.

#### 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 compete 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](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](http://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 four (4) full, complete and exact copies of the original. 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>

### 5.5.6 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.umdnj.edu/purchweb/employees/employ36\\_forms\\_policies.htm](http://www.umdnj.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.

The bidder should identify the contract scheduling and control methodology to be used and should provide the rationale for choosing such methodology.

### 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 Budget

The bidder should submit the budget it has developed for providing the services required by this RFP. *This information will be used for evaluation purposes only*, and is intended to provide the University with an additional perspective on how the bidder will allocate financial resources in undertaking the work required by this RFP.

### 5.6.6 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 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 provided, as evidence of the bidder's ability to successfully provide 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 provide 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.

5.7.6.1 The bidder must provide documented experience in clinical ethics, clinical trials, and research protocols involving human subjects.

5.7.6.2 The bidder must provide a copy of its doctoral degree in ethics.

5.7.6.3 The bidder must provide documented experience in working with oncologists and other cancer researchers in the development and monitoring of clinical trials with regard to ethical issues.

5.7.6.4 The bidder must provide documented experience in state, national, and international regulations related to the ethics of clinical research.

5.7.6.5 The bidder must provide documented experience demonstrating membership on an institutional review board for clinical trials.

#### 5.7.7 Publications

5.7.7.1 The bidder must submit a complete list of all published work relating to the ethics of clinical research.

5.7.7.2 The bidder must submit a sample of its published work relating to the ethics of clinical research with the original and each copy of the RFP response.

## 5.7.8 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.

## 5.7.9 Subcontractor(s)

5.7.9.1 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.

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

5.7.9.3 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.

5.7.9.4 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

5.8.1 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.

5.8.2 Each bidder should also provide a comprehensive listing of all labor categories that may be used to perform additional work and/or special projects or according to the additional work and/or special project clause(s) of this RFP. Loaded hourly rates are to be submitted for all labor categories that the bidder anticipates may be required to perform additional work and/or special projects.

Failure to include a labor category along with a loaded hourly rate will exclude that category from eligibility to perform additional work and/or special projects under the contract resulting from this RFP. Each bidder may submit labor categories for additional work that are not included in the base proposal to perform the Scope of Work required by this RFP.

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 credentials and published body of work relating to the ethics of clinical research.

- 6.3.2 The bidder's documented experience in working with oncologists and other cancer researchers in the development and monitoring of clinical trials with regard to ethical issues.
- 6.3.3 The bidder's documented experience in state, national, and international regulations related to the ethics of clinical research.
- 6.3.4 The bidder's documented experience as a member of an institutional review board for clinical trials.
- 6.3.5 The overall ability of the bidder to mobilize, undertake and successfully meet the requirements as listed in Section 3.0, Scope of Work.
- 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 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.

## 6.6 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

**UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY**

**CLINICAL ETHICIST**

**BID/RFP# P10-013**

TOTAL COMPREHENSIVE HOURLY RATE (INCLUSIVE OF TRAVEL AND ALL OTHER EXPENSES) TO PROVIDE ALL THE SERVICES REQUIRED BY THIS RFP:

\$\_\_\_\_\_per hour

## 9.0 REQUIRED FORMS

- Ownership Disclosure Form
- MacBride Principle Certification
- Affirmative Action Employee Information
- Business Associate Agreement
- Business Registration Certificate
- Two Year PL 51/Executive Order 117 Vendor Certification Form

**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 connection 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 \_\_\_\_\_

**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 Vice President of the Division of Purchase and Property, pursuant to N.J.S.A. 52:34-12, or the Vice President 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 Vice Presidents 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 Vice Presidents 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

**Business Associate Agreement  
Involving the Access to Protected Health Information**

The following provisions (Amendment) are added and incorporated into the attached Request for Proposal : Clinical Ethicist for CINJ; Proposal# P10-013 (“Agreement”) entered in between UMDNJ-University-wide (“Covered Entity”) and

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Name of Contracting Party

(Business Associate) herein collectively referred to as the “Parties”. Any conflict in the terms of the Agreement and this Amendment shall be governed by the terms of this Amendment.

WHEREAS Covered Entity is the state university of health sciences in New Jersey which maintains and operates UMDNJ;

WHEREAS Business Associate performs \_\_\_\_\_ work which requires it to have access to confidential health information that is considered protected pursuant to federal, state and/or local laws and regulations;

WHEREAS Covered Entity desires to protect the confidentiality and integrity of the information noted above, prevent inappropriate disclosure of such information and comply with all applicable federal, state and/or local laws and regulations governing the use and disclosure of such information;

NOW therefore, the parties agree as follows:

1. Confidentiality and Disclosure of Patient Information.

- A. The Parties to this Agreement agree that Business Associate, its agents and employees may have access to confidential protected health information (“PHI”), including but not limited to demographic information. As used herein, PHI shall mean individually identifiable health information, as defined in 45 CFR § 164.501 which includes health information that (i) identifies an individual (or can be used to form a reasonable basis upon which to identify an individual), (ii) is created or received by a health care provider, health plan, employer, or health care clearinghouse; (iii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past present, or future payment for the provision of health care to an individual; and (iv) is shared, transmitted or otherwise communicated between Covered Entity and Business Associate (including subcontractors or agents of such parties) in connection with this Agreement.
- B. The Parties to this Agreement agree that Business Associate:
  - a. will not use or further disclose PHI other than as permitted by this Agreement;
  - b. will ensure that all transmissions of PHI are authorized and in accordance with the privacy requirements of the Health Insurance Portability and Accountability Act of 1999, as amended from time to time (“HIPAA”) and will not use or disclose PHI in a manner that violates or would violate HIPAA;

- c. will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the Electronic Protected Health Information that it creates, receives, maintains or transmits on behalf of the Covered Entity.
- d. will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;
- e. will (i) promptly report to Covered Entity any use or disclosure of PHI not provided for by this Agreement, including but not limited to systems compromises, immediately upon becoming aware of such unauthorized use or disclosure; (ii) will take all necessary steps to prevent and limit any further improper or unauthorized disclosure and misuse of such information; and (iii) indemnify and hold Covered Entity, its Vice Presidents, officers, agents, and employees harmless from all liabilities, costs and damages arising out of, or in any manner connected with, the disclosure by Business Associate, its employees, agents, or independent contractors; and (iii) permit Covered Entity to investigate any such report and to examine Business Associate's premises, records and premises;
- f. will promptly report to the Covered Entity any security incident of which the Business Associate becomes aware; a security incident is defined as the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
- g. will ensure that to the extent that the Business Associate it uses one or more agents, including subcontractors, to provide services under this Agreement, such subcontractors or agents who receive or have access to PHI that is received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, will comply with the same restrictions and conditions to which Business Associate is bound by entering into a separate written agreement between Business Associate and its subcontractors to that effect;
- h. will ensure that any agent, including a subcontractor, to whom the Business Associate provides electronic protected health information, agrees to implement reasonable and appropriate safeguard to protect the electronic protected health information.
- i. will, at the request of, and in the time and manner designated by the Covered Entity, provide access to the PHI to the Covered Entity or the individual to whom such PHI relates or his or her authorized representative in order to meet a request by such individual under promptly notify Covered Entity as required by 45 CFR §164.524;
- j. will, at the request of, and in the time and manner designated by the Covered Entity, incorporate any and all amendments or corrections to PHI when notified by Covered Entity that such information is inaccurate or incomplete in accordance with 45 CFR § 164.526;
- k. will, at the request of, and in the time and manner designated by the Covered Entity, provide to the Covered Entity such information as is requested by the Covered Entity, including but not limited to current policies and procedures, operational manuals and/or instructions, and/or employment and/or third party agreements, to permit Covered Entity

to respond to a request by an individual for an accounting of the disclosures of the individual's PHI in accordance with 45 CFR 528;

- l. will make its internal practices, books and records relating to the use and disclosure of PHI available to the Secretary of Health and Human Services governmental officers and agencies and Covered Entity for purposes of determining compliance with 45 CFR §§ 164.500-534; and
  - m. will adhere to the Covered Entity's HIPAA policies and procedures.
- C. **Termination for violation of disclosure restrictions.** Notwithstanding any other provision of this Agreement, Covered Entity may terminate this Agreement and any related agreements, without penalty if Covered Entity determines that Business Associate has violated a material term of this Agreement's restrictions, safeguards or requirements relating to the proper use and disclosure of PHI. Alternatively, Covered Entity may choose to: (i) provide Business Associate with written notice of the existence of a breach of the terms of this Agreement relating to PHI; and (ii) afford Business Associate an opportunity to cure such breach upon mutually agreeable terms. In the event that mutually agreeable terms cannot be achieved within 10 business days, Business Associate must cure said breach to the satisfaction of the Covered Entity within 10 business days. Covered Entity may immediately terminate this Agreement for Business Associate's failure to cure in the manner set forth in this section.
- D. **Return/Destruction of PHI.** Business Associate agrees that, upon termination of this Agreement for any reason, it will if feasible, return or destroy all PHI maintained in any form (including ensuring the return or destruction of all PHI in the possession of its subcontractors or agents) received from, or created or received by it on behalf of Covered Entity and retain no copies of such information.  
An authorized representative of Business Associate shall certify in writing to covered Entity, within five (5) days from the date of termination or other expiration of this Agreement, that all PHI has been returned or disposed of as provided above, (including all PHI in the possession of its subcontractors or agents) and that neither Business Associate nor its subcontractors or agents retains any such PHI in any form.
- E. **No Feasible Return/Destruction of PHI.** To the extent that the return or destruction of PHI as provided for in *Section 4* above is not feasible, Business Associate shall extend the precautions of this Agreement to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible. Notwithstanding any other provision of this Agreement to the contrary, Business Associate shall remain bound and shall ensure that the provisions of this Agreement, similarly bind its subcontractors and agents even after termination of this Agreement, until such time as all PHI has been returned or otherwise destroyed as provided in accordance with this section.
- F. **Disclaimer.** Covered Entity makes no warranty or representation that compliance by Business Associate with this Agreement or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in the possession of Business Associate or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure, nor shall Covered Entity be liable to Business Associate for any claim, loss or damage relating to the unauthorized use or disclosure of any information received by Business Associate from Covered Entity or from any other source.

Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

- G. **Legal Action.** Business Associate agrees that unauthorized disclosure of PHI may give rise to irreparable injury to the patient or to the owner of such information and accordingly the patient or owner of such information may seek legal remedies against Business Associate. Business Associate further agrees that the remedy at law for any breach by it of the terms of this Agreement shall be inadequate and that the damages resulting from such breach and are not be susceptible to being measured in monetary terms. Accordingly, in the event of a breach or threatened breach by Business Associate of the terms of this Agreement, covered Entity shall be entitled to immediate injunctive relief and may obtain a temporary order restraining any threatened or further breach. Nothing herein shall be construed as prohibiting Covered Entity from pursuing any other remedies available to Covered Entity for such breach or threatened breach, including recovery of damages from Business Associate. Business Associate further represents that it understands and agrees that the provisions of this agreement shall be strictly enforced and construed against it.
- H. **Construction.** This Agreement shall be construed as broadly as necessary to implement and comply with HIPAA. The parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with HIPAA.
- I. **Severability.** In the event that any provision of this Agreement violates any applicable statute, ordinance or rule of law in any jurisdiction that governs this Agreement, such provision shall be ineffective to the extent of such violation without invalidating any other provision of this Agreement.
- J. **Authority.** The persons signing below have the right and authority to execute this Agreement for their respective entities and no further approvals are necessary to create a binding agreement.
- K. **Governing Law.** This Agreement shall be governed by the laws of the State of New Jersey and shall be construed in accordance therewith.
- L. **Reference:** Code of Federal Regulations, Title 45, Part 160 et seq.

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

<b>Covered Entity</b>	<b>Business Associate</b>
By: _____	By: _____
Title: Francis X. Colford Vice President for Finance and Treasurer	Title: _____
Date: _____	Date: _____

Revised 2/21/07

## **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