

UNIVERSITY OF MINNESOTA

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Bid Events	Auction Events	My Profile	
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Edit Bid Response - 10714.769997.JST

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Bid Number 10714.769997.JST (External Review of Clinical Research on Human Subjects)

Close Date & Time 3/7/2014 2:00:00 PM Central

Time Left 2 days 3 hours 12 minutes 42 seconds

Response Status **NOT SUBMITTED - To complete your response, you must click 'Submit Response' in the Response Submission tab.**

- [Event Details](#)
- [Activities](#)
- [Attachments](#)
- [Attributes](#)
- [Response Attachments](#)
- [Response Submission](#)

Bid Information

Bid Type RFP

Issue Date & Time 2/13/2014 10:00:01 AM Central

Close Date & Time 3/7/2014 2:00:00 PM Central

Bid Status Issued

Bid Notes The University is seeking a contractor to define and manage the process of an expert review of current policies, practices and oversight of clinical research on human subjects. RFP specifications will not be mailed or faxed. RFP specs must be viewed and responses submitted electronically through the MBid system. Suppliers must register or already be registered in MBid in order to view the full RFP and respond. If you are not already a registered supplier go to <http://purchasing.umn.edu/mbid/login.html> and click New Supplier Registration link to register. If already registered, log in at the above URL to view the RFP and respond.

Bid Contact Information

No Bid Contact Information

Ship to Information

No Ship to Information

Bill to Information

No Bill to Information

UNIVERSITY OF MINNESOTA

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Bid Number 10714.769997.JST (External Review of Clinical Research on Human Subjects)

Close Date & Time 3/7/2014 2:00:00 PM Central

Time Left 2 days 3 hours 12 minutes 14 seconds

Response Status **NOT SUBMITTED - To complete your response, you must click 'Submit Response' in the Response Submission tab.**

- [Event Details](#)
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- [Attributes](#)
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Event Activities

[View](#)

<input type="checkbox"/>	Date	Activity Name	Description
<input type="checkbox"/>	2/26/2014 10:30:00 AM CT	Pre-Proposal Conference Call	A Pre-Proposal conference call will be held to provide an overview of the project. Conference Call Phone in Number: 1-866-865-2157 Code: 9131070954 (press # after)
<input type="checkbox"/>	2/27/2014 2:00:00 PM CT	Deadline for Questions	Follow the instructions on the Questions Template in the Bid Attachment Section for submitting questions.

Items 1-2 shown of 2

1

Bid Events	Auction Events	My Profile	
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Edit Bid Response - 10714.769997.JST

[Return](#)
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Bid Number 10714.769997.JST (External Review of Clinical Research on Human Subjects)

Close Date & Time 3/7/2014 2:00:00 PM Central

Time Left 2 days 3 hours 11 minutes 51 seconds

Response Status **NOT SUBMITTED - To complete your response, you must click 'Submit Response' in the Response Submission tab.**

- Event Details
- Activities
- Attachments
- Attributes
- Response Attachments
- Response Submission

Bid Attributes

[Save](#)
[Go to Attribute](#)
[Save & Next](#)
[Error Check](#)

Attribute Response

1 **External Review of Clinical research on Human Subjects** * Read and Understood

On December 5, 2013 the Faculty Senate approved a resolution requesting an external review of clinical research on human subjects at the University of Minnesota. Specifically the Senate resolution stated:

BE IT RESOLVED that a panel external to and independent from the University of Minnesota be constituted for the purpose of conducting an inquiry examining current policies, practices, and oversight of clinical research on human subjects at the University, in particular clinical research involving adult participants with diminished functional abilities. The administration, in collaboration with appropriate faculty governance committees, shall initiate the constitution of such an independent panel and shall support its inquiry. The panel shall have authority to obtain any records it deems necessary for a thorough inquiry, to the extent consistent with applicable law. At the conclusion of the inquiry, the panel shall issue a report that will be made publicly available, within the limitations of regulations governing the protection and privacy of individuals, including research participants, and the results will be reported back to the Faculty Senate so that senators have an opportunity to ask questions and discuss the report.

2 **Rationale for Requesting Services** * Read and Understood

The intent of this review is to ensure that the University's processes for clinical research on human subjects meet or surpass the established best practices and norms and to instill confidence among faculty and the public that the University of Minnesota research is beyond reproach. It is to be forward looking, productive, transparent and independent review of current practice by an external expert panel.

3 **Objectives** * Read and Understood

- Obtain an independent, external assessment of the current policies, practices and oversight of clinical research on human subjects at the University of Minnesota - in particular clinical research involving adult participants with diminished capacity to provide consent.

- Select an external contractor with widely recognized expertise and experience in clinical research on human subjects to manage the review process. External contractor selected will empanel an independent team of no less than three experts who will conduct a thorough, professional, independent and transparent review and issue a report that will be made publicly available.

- Seek recommendations for any changes, if needed, to policies, practices and oversight of clinical research to align with best practices nationally.

4 **Outcomes Needed**

* Read and Understood

We expect the contractor selected in response to this RFP to define and manage the process of an expert review of the current policies, practices and oversight of clinical research on human subjects at the University of Minnesota - in particular clinical research involving adult participants with diminished capacity to provide consent.

The expert review must include a review of relevant standard operating procedures and an assessment of compliance with regulations and other applicable law. A detailed report outlining the strengths and weaknesses of current policies, practices and oversight of clinical research involving adult participants with diminished capacity to provide consent is required. If any deficiencies in our current practices are found, the review should include recommendations for remedying them.

The contractor will select and empanel an independent team of no less than three experts to include an MD who will conduct a thorough, professional, independent and transparent review. The review must examine policies, practices and oversight of clinical research on human subjects at the University, in particular clinical research involving adult participants with diminished functional abilities. At least one member of the panel should be prepared to speak publicly to their process, findings and any recommendations for improvement.

The contractor will develop a plan for identifying the data needed, gathering the data and producing a final report that will be public.

The contractor will orchestrate site visits and acquisition of materials and data to conduct the review.

Key audiences for the results of the review include: University President, Board of Regents, University Faculty Senate, IRB and external stakeholders. The report will also be made publicly available.

5 University of Minnesota Obligation

The University of Minnesota will ensure that the panel has appropriate access to information, resources and individuals needed to meet their charge.

* Read and Understood

6 Timeline

The final report shall be delivered on or about July 1, 2014.

* Read and Understood

7 Evaluation Criteria

The selected Respondent will be the Respondent whose Proposal is the most advantageous to the University. The University is not bound to accept the lowest priced Proposal if the Proposal is not in the best interests of the University as determined by the University in its sole discretion. Proposals will be evaluated on the following criteria:

* Read and Understood

#	Evaluation Criteria	Percentage
1	Recognized expertise and experience with clinical trials research and nationally recognized accreditation processes (AAHRP)	20%
2	Extensive connections and networks with expertise required to perform this review.	10%
3	Experience with managing these types of reviews in a higher education system.	20%
4	Total Cost - Provide a Fixed Price for the work as outlined, that includes travel and expenses.	30%
5	Quality of the proposed project plan, which could include methods, accountability metrics and communication/dissemination plan.	20%
	TOTAL	100%

8 ** VENDOR INSTRUCTIONS **

This RFP contains multiple pages. You can move from page to page by clicking on the numbers or arrows that are located on the maroon bar that appears at the bottom of the Attributes section.

Respond with a thorough answer to each question in the space provided unless it is noted that a response may be provided in a separate attachment. Be as brief as possible while still providing pertinent information. If a response is lengthy (e.g. longer than 200 words), summarize your answer in the space provided and include a more detailed answer as an attachment.

All attachments should be labeled as 'vendorname_attachmentname'. DO NOT USE A "#" SIGN OR "&" SIGN IN YOUR ATTACHMENT NAME.

If you wish to generate a copy of this RFP for review, click on Documents and choose the Invitation Document. A PDF extract of your response will be generated.

9 RFP Deadlines

It is important that you note the RFP Close date and time. The MBid system will not accept a late submission.

If you submit early and wish to change an answer, hit RETRACT, make your changes and then resubmit.

10 Questions and Answers

Questions regarding the RFP must be included on the QUESTIONS ATTACHMENT and submitted via email to the buyer responsible for the RFP by the time and date noted in the Bid Events section of the RFP.

* Read and Understood

Responses to questions which involve an interpretation or change to this RFP will be issued as an addendum by Purchasing Services and will be posted electronically in the MBID system. Vendors registered in the MBID system for the specific commodity will be notified via email that the Addendum has been issued. At that time you should review the RFP and any changes/additional information included.

Only additional information provided by formal written addenda shall be binding. Oral and other interpretations or clarifications, including those occurring at pre-Proposal meetings, site visits, tours, etc. are not binding unless otherwise stated.

11 Addendum

The University reserves the right to issue one or more addenda to the RFP at any time for any reason.

* Read and Understood**12 Withdrawing Proposals**

You may withdraw your Proposal at any time prior to the RFP Close Date and Time by viewing your Submitted response in the MBID system and then clicking on **RETRACT**. The Respondent may submit another Proposal at any time prior to the Close Date and Time. No Proposal may be withdrawn after the Close Date and Time without approval by the University. Such approval shall be based on Respondent's submittal, in writing, of a reason acceptable to the University in its sole discretion.

* Read and Understood**13 Proposal Submission**

All responses must be submitted electronically using the University's MBID system. All supplemental information should be uploaded into the **RESPONSE ATTACHMENTS** section in your bid response and should be clearly labeled with Respondent's name and content using this format - 'vendorname_attachmentname.'

* Read and Understood**14 Late Submissions**

The University will not accept Proposals received after the Close Date and Time. The MBID system will not allow for a late submittal and if Respondent has not submitted their proposal by Clicking on the **SUBMIT** button, their Response will not be available for review by the University. The Respondent assumes the risk of submitting their Response by the Close Date and Time.

* Read and Understood**15 Ownership of Proposal**

All materials submitted in response to this request become the property of the University and may become a part of any resulting contract. Award or rejection of a Proposal does not affect this right.

* Read and Understood**16 Release of Claims, Liability and Preparation Expenses**

Under no circumstances shall the University be responsible for any Proposal preparation expenses,

* Read and Understood

submission costs, or any other expenses, costs or damages, of whatever nature incurred as a result of Respondent's participation in this RFP process.

Respondent understands and agrees that it submits its Proposal at its own risk and expense and releases the University from any claim for damages or other liability arising out of the RFP and award process.

17 Duration of Respondent's Proposal

* Read and Understood

The Respondent certifies that its Proposal is a valid, firm and irrevocable offer which the University may accept within a minimum of **90** days from the Due Date of this RFP, and that its Proposal, if accepted, shall remain valid for the life of this contract.

18 Errors in Proposals

* Read and Understood

The University shall not be liable for any errors in Respondent's Proposal. Except during negotiations initiated by the University, no modifications to a Proposal shall be accepted after the Close Date and Time. You must ensure that all information, including pricing, is correct and complete.

You are responsible for all errors and omissions contained in your proposal; so the University may reject a Proposal based on its erroneous or omitted information, even if the correct or complete information was available to the University elsewhere. Similarly, the University may accept your Proposal based on the erroneous or omitted information, and you will be bound by the information as it appears in the Proposal, even if the correct or complete information was available to the University elsewhere.

19 Public Proposal Viewing

* Read and Understood

After the award has been made and upon finalizing a contract with the selected Respondent(s), the Proposal file may be viewed subject to the University's Record and Information Management policies and procedures.

20 Award Process

* Read and Understood

1. After completion of the RFP review process, an award may be made on the basis of the Proposals submitted, without discussion, clarification or modification, or on the basis of negotiation with any or all of the Respondents.
2. Issuance of this RFP does not require the University to award or contract. The University reserves the right to reject any or all Proposals, wholly or in part; to waive any technicalities, informalities, or irregularities in any Proposal at its sole option and discretion. The University reserves the right to request clarification or additional information. The University reserves the right to award a contract in whole or in part, to award multiple contracts to multiple Respondents, to re-solicit for Proposals or to temporarily or permanently abandon the procurement. If the University awards a contract, it will award the contract to the Respondent or Respondents whose Proposal(s) is(are) the most advantageous to the University as determined by the University in the exercise of its sole discretion.

3. If the University awards a contract as a result of this RFP process, the resulting contract shall consist of:
- The terms, conditions, specifications and requirements of this RFP and its attachments.
 - Any addenda issued by the University pursuant to this RFP.
 - All representations (including but not limited to, representations as to price, specifications, performance and financial terms) made by the Respondent in its Proposal and during any presentations (videotaped or otherwise) or demonstrations for the benefit of the University.
 - Any mutually agreed upon written modifications to the terms, conditions, specifications, and requirements to this RFP or to the Proposal.

21 Responses Subject to Public Disclosure

* Read and Understood

The University considers all information, documentation and other materials (collectively "Materials" or "items") submitted in response to this RFP to be non-confidential and/or non-proprietary, and subject to public disclosure after a contract is awarded. By submitting a Proposal, Respondent agrees to release the University from any liability resulting from University's disclosure of such information.

If submitting information that you believe to be trade secret materials, as defined by the Minnesota Government Data Practices Act, Minnesota Statute 13.37, subd. 1(b) (MBDPA), you must follow these instructions exactly for information to be considered for confidentiality review:

1. Confidential Information should be limited to that which is truly confidential under the MGDPA.
NOTE: The Department of Administration has opined in several decisions based on Minn Stat. 13.37, Subd, 1(b) that pricing information may not be considered trade secret information. Financial statements can be considered as a trade secret.
2. Include all Materials that are to be considered "Confidential" in a separate word document which is clearly and conspicuously marked "CONFIDENTIAL." This document must also include the RFP #, the Subject of the RFP and the name of your company.
3. Include an opinion indicating the legal basis for regarding the Material as a trade secret under the MGDPA. Include the name of the person who has written the opinion.
4. Upload the document containing BOTH the legal basis for confidentiality **and** the Confidential Information to the **RESPONSE ATTACHMENTS** section of the RFP.

5. **NOTE:** Confidential Information will be provided electronically to the RFP review committee to be used during the RFP review process.
6. Prior to release of the files for public viewing, the Office of Records Management will review the Confidential Information to ensure it meets the MGDPA standards.

22 Confidential Information Submission

* [Please Select] 

Respondent acknowledges that if they are submitting confidential information that they have carefully read the above section, Responses Subject to Public Disclosure in the RFP Process and General Instructions Document. Respondent further acknowledges that they have followed the instructions exactly as outlined in that Section and that the confidential information provided is limited to that which is truly confidential and considered a trade secret under the Minnesota Government Data Practices Act.

23 Oral Presentations/Site Visits

* Read and Understood

One or more Respondents may be required to do an oral presentation and/or allow the University to visit the Respondent's site. Each Respondent should be prepared to discuss and substantiate any area of its Proposal, its own qualifications for the Goods/and or Work, and any other area of interest relative to its Proposal.

24 Testing and Samples

* Read and Understood

The University reserves the right to request a demonstration of, or to test, any or all Goods and/or Work proposed in response to this RFP. If Respondent fails to provide such demonstration or fails to provide such Goods and/or Work for testing, the Respondent's Proposal may be rejected by the University in its sole discretion.

- The Respondent warrants that if awarded a contract, the Goods and/or Work delivered under such contract shall meet or exceed the quality of the Goods and/or Work demonstrated or tested.
- Samples of the quoted products, when requested, must be furnished free of charge and in a timely manner.
- If not destroyed by testing and if practical, samples may be returned at the Respondent's request and expense following contract award.
- Respondent should not submit unsolicited samples.
- If samples are requested in the RFP, Respondent must follow the instructions provided for submitting the samples.

25 Subcontracting

* Read and Understood

Unless otherwise agreed to in writing by the University, the selected Respondent is responsible for performance of any subcontractors. Use of subcontractors in the performance of the contract is subject to University consent. The selected Respondent must ensure that any subcontractors abide by all terms and conditions of the contract.

26 Office of Business and Community Economic Development

The Office of Business and Community Economic Development ("BCED") is available to assist Small Business as part of the University's goal of fostering economic growth in urban communities. Businesses owned by women, people of color, people with disabilities, and other historically and

currently underrepresented groups are especially encouraged to take advantage of the BCED's services. For inquiries regarding these services, contact BCED at 612-624-0530.

27 University Travel Policy Acknowledgment * Acknowledged

Respondent acknowledges that they have read and understood the University Travel Policy as provided in the Bid Attachments section of the RFP.

28 **RESPONDENT PROPOSAL CERTIFICATIONS**

By agreeing to the certifications listed below, Respondent certifies that they have carefully examined all instructions, requirements, specifications, terms and conditions of this RFP; and hereby offers to furnish the Work and/or Goods, as applicable, at the prices quoted in Respondent's Proposal, and in accordance with the requirements, specifications, terms and conditions of this RFP.

29 Certifications

1. RESPONSIBLE RESPONDENTS.

- Respondent certifies that it has the necessary experience, knowledge, abilities, skills, capacity and resources to satisfactorily perform the requirements, specifications, terms and conditions of this RFP.
- The University reserves the right to award contracts only to responsible Respondents, defined as companies that demonstrate the financial ability, resources, skills, capability, willingness and business integrity necessary to perform under the contract. The University's determination of whether a Respondent is a responsible Respondent is at the University's sole discretion.

2. Respondent certifies that it is aware of, is fully informed about, and is in full compliance with all applicable federal, state and local laws, rules, regulations and ordinances and it is not currently debarred or suspended from doing business with the Federal government, the state of Minnesota, any other state in the United States, or any of their respective agencies.

3. Respondent certifies that all statements, information and representations prepared and submitted in response to this RFP are current, complete, true and accurate. The Respondent acknowledges that the University will rely on such statements, information and representations in selecting the successful Proposal.

4. Respondent acknowledges that submission of a Proposal indicates the Respondent's acceptance of the evaluation process described in the RFP and the Respondent's recognition that some subjective judgments may be made by the University as part of the evaluation in its sole discretion.

5. CONFIDENTIALITY.

- Respondent certifies that it understands and agrees that the University will not treat any information, document, or materials submitted by Respondent as confidential unless the Respondent strictly adheres to the procedures set forth in the RFP Process and General Instructions.
- Respondent agrees that the University may disregard confidentiality notices on headers/footers as well as copyright designations that accompany or are contained on material or documents submitted as part of Respondent's Proposal.
- It is further understood and agreed that all material and documents not conforming to the procedures set forth in the RFP Process and General Instructions will be made available for immediate public inspection and copying upon completion of the RFP process.
- Respondent agrees to defend any action seeking release of the Materials believed to be trade secret, and indemnify and hold harmless the University, its regents, agents and employees ("Releases"), from any judgments or damages awarded against the Releases in favor of the party requesting the materials and any and all costs connected with that defense.

30 Electronic Signatures * Read and Understood

IMPORTANT LEGAL NOTICE Subject to state and federal law, the University of Minnesota accepts electronic signatures with the same force and effect as original, physically written signatures. By placing the name of a person on the required signature lines in your response, you are certifying that the person has authority to bind your company and that your company

is bound by the statement, representation, or contractual promise.

Items 1-30 shown of 53 Page 1 of 2 shown

1 2 >>

