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I have made substantial contributions to the intellectual content of the paper as described below.

1. (check at least 1 of the 3 below)

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Some research projects involve very extensive teams with many people who do not meet the criteria for authorship but who have contributed importantly to the work. The box below is designed to acknowledge other types of contributions. As appropriate, use this box to name other people who have made important contributions to the work reported in this manuscript. Please also name people who have played a significant role in preparing the manuscript but who are not listed as authors. NOTE: If you wish to acknowledge any of these contributors in print, please include their names and roles in the joint acknowledgment section below.

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- all authors have approved the Joint Acknowledgement/Disclosure Statement intended for publication and the author matrix.

I, the corresponding author, certify that the above statements are true.

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UM-KECC

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August 21, 2018

S. Jack Hu, PhD
Office of VP for Research
4080 Fleming Building 1340

RE: Request for Approval of Publication Restrictions – Supplemental Proposal Approval Form (PAF-R)

Departmental Endorsement of the PAF-R related to 18-PAF05910

Dear Dr. Hu,

This letter is sent to provide strong support and to encourage the University of Michigan to accept the contract proposal from the Center for Medicare and Medicaid Services (CMS) described in 18-PAF 05910. This proposed contract award allows the University of Michigan, through UM-KECC, to participate in the CMS MIDS Contract Umbrella, a CMS program that awards contracts for various aspects of quality measure development and evaluation for CMS clinical programs. The University of Michigan is currently a participant in the soon to expire MIDS contracting mechanism that this award will replace. UM-KECC led UM's application five years ago, and again over the last several months, to participate in this contracting mechanism in order to be eligible to compete for award of the ESRD Measures Task Order, a MIDS contract.

The ESRD Measures contract under the MIDS umbrella was first awarded to UM-KECC five years ago. The contract's tasks include support of public reporting of outcomes for the 7000+ US Medicare dialysis facilities and, importantly, quality measure development activities for Medicare's ESRD chronic dialysis program. The national recognition inherent in performance of these tasks is significant. In addition, in order to complete these tasks, we are required to develop and maintain a comprehensive database of all US ESRD patients spanning the last several decades. This very large database is available as a resource for investigators working on the project, allowing UM-KECC's affiliated faculty and graduate students to develop research analyses informing future policy direction for this important national program. This contract is a unique source of funding and access to these Medicare data for development of this database and the research opportunities it affords.

In the course of completing the current contract, we have successfully collaborated with faculty and graduate students from several UM schools to produce numerous publications in peer reviewed journals and presentations at national academic meetings. In addition, the contract

affords UM faculty, students and staff the opportunity to participate in and facilitate national technical expert panels and forums related to ESRD quality measure development and revision.

Section G.10 of Solicitation 75FCMC18D0041 outlines the rules regulating the dissemination, publication, and distribution of information related to the contract award. In recognition of the combined administrative and research features of the type of project, CMS requires such language in the contracts that involve the analysis of such data. This language has been included as a restriction in multiple previous contracts awarded to UM-KECC. Historically, our ability to fulfill our responsibilities as academic investigators, including publication of research results has been unimpeded by CMS under previous contracts with similar restrictions. UM-KECC has presented at conferences and published many important research papers in prominent journals related to projects such as this one, which were based upon confidential data and which required the approval of the contacting officer.

Graduate student(s) have been allocated for effort on this contract for research experience. This effort is not part of their academic requirement. The students' effort on this project is not tied in any way with their curriculum or academic requirements. If a graduate student were to propose a research project related to data or research scenarios linked to this contract, the Principal Investigator would inform the CMS contract officer of the proposed graduate student's research project during the project development phase. The CMS project officer's concerns would be vetted at an appropriate early point in the project, with the expectation that the graduate student and mentor would be aware of any concerns about potential inappropriate information release during the planning stage. The CMS project officer would also approve the final product prior to publication release.

In summary, the constraints upon publication rights in this project relate to two important considerations. First, CMS has an important responsibility to protect individual protected health information. Their approval process evaluates whether information requested for publication includes potentially identifiable patient information related to data structure or reporting of small cell size issues. Second, CMS has statutory requirements to avoid publication during specific time periods while active rule-making is in progress. In our extensive history working on similar contracts over the last two decades, CMS has imposed no constraints upon our academic freedom to publish research results outside the scope of these minimal contract requirements. The University of Michigan can be assured that the academic freedom to publish research results will be respected and our academic productivity significantly enhanced by participation in this contract, despite the potential limitations inherent in the language of the contract.

Sincerely,



Joseph M. Messana, MD

Richard D. Swartz Collegiate Professor of Nephrology,
Professor of Internal Medicine,
University of Michigan Medical School

Research Professor,
Department of Health Management and Policy,
University of Michigan School of Public Health

G.10 DISSEMINATION, PUBLICATION AND DISTRIBUTION OF INFORMATION

- a. Data and information either provided to the Contractor, or to any subcontractor or generated by activities under this contract or derived from research or studies supported by this contract, shall be used only for the purposes of the contract. It shall not be duplicated, used or disclosed for any purpose other than the fulfillment of the requirements set forth in this contract. This restriction does not limit the contractor's right to use data or information obtained from a non-restrictive source. Any questions concerning "privileged information" shall be referred to the CO.
- b. Some data or information may require special consideration with regard to the timing of its disclosure so that preliminary findings which could create erroneous conclusions are not stimulated. Also, some data or information, which relate to policy matters under consideration by the Government, may also require special consideration with regard to the timing of its disclosure so that the open and vigorous debate, within the government, of possible policy options is not damaged.
- c. Any questions about use or release of the data or information or handling of material under this contract shall be referred to the CO who must render a written determination. The CO's determinations will reflect the results of internal coordination with appropriate program and legal officials.
- d. Written advance notice of at least forty-five (45) days shall be provided to the CO of the Contractor's desire to release findings of studies or research or data or information described above. If the Contractor disagrees with the CO's determination, and if this disagreement cannot be settled by the Contractor and the CO in a mutually satisfactory manner, then the issue will be settled pursuant to the "Disputes" clause.
- e. Any presentation of any report, statistical or analytical material based on information obtained from this contract shall be subject to review by the COR and higher level approval, when required, before dissemination, publication, or distribution. Presentation includes, but is not limited to, papers, articles, professional publications, speeches, testimony or interviews with public print or broadcast media. This does not apply to information that would be available under the Federal Freedom of Information Act.
- f. The COR review shall cover accuracy, content, manner of presentation of the information, and also the protection of the privacy of individuals. If the review finds that the Privacy Act is or may be violated, the release/use of the presentation shall be denied until the offending material is removed or until the CO makes a formal determination, in writing, that the privacy of individuals is not being violated.
- g. If the review shows that the accuracy, content, or manner of presentation is not correct or is inappropriate in the light of the purpose of the project,

the COR shall immediately inform the Contractor, in writing, of the nature of the problem. If the Contractor disagrees, the COR may insist that the presentation contain, in a manner of equal importance, materials which show the government's problem with the presentation.

- h. The Contractor agrees to acknowledge support by CMS whenever reports of projects funding, in whole or in part, by this contract are published in any medium. The Contractor shall include in any publication resulting from work under this contract, an acknowledgement substantially, as follows:

"The analyses upon which this publication is based were performed under Contract Number [], entitled, "[]," sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services."

Any deviation from the above legend shall be approved, in writing, by the CO.