University of Michigan Medical School
and Peking University Health Science Center
Intellectual Collaboration, Authorship, and Data Sharing Policy

I. **Purpose**

In addition to the Memorandum of Understanding (signed on June 10, 2010) and Appendix C Agreement (signed on October 12, 2010) between the University of Michigan Health System (UMHS) and Peking University Health Science Center (PUHSC), this policy establishes a set of principles to guide UMHS and PUHSC Joint Institute for Translational and Clinical Research (JI) members in intellectual collaboration about authorship and data sharing, to support and promote equitable participation by JI members in presentations and publications.

II. **Policy**

A. Each of the primary investigators for JI projects shall follow the policy and principles, and shall develop an agreement for the project about the writing and authorship of manuscripts to ensure that the tasks of writing and recognition of authorship are distributed fairly among study investigators and not dominated by any one investigator.

C. Disagreements within JI projects needing arbitration will be brought before the Co-Chairs of the JI Executive Committee, and the JI Executive Committee shall have the ultimate authority to make the final decision.

D. These policies remain in effect even after formal conduct of research and funding from JI are complete.

E. Data, as defined below, shall be controlled by the JI and this policy, and not any individual investigator or collaborating investigator.

F. This policy applies to the following types of Publications:

1. Papers that represent reports of the main outcomes of the JI funded studies based on analysis of both PUHSC and UMMS data.

2. Secondary manuscripts that address issues more peripheral to the main study outcome but that are based on data collected as part of the main study.

3. Papers that represent reports of data collected as part of a JI initiative from either PUHSC or UMHS, but which reports contain data only collected at one site.

4. Methodology/Validation papers.

5. Abstracts, meeting proceedings, extended abstracts, oral and poster presentations.
6. Letters to the Editor.
7. Invited manuscripts.

G. This policy applies to the following types of "data" or "samples": those data and samples generated directly through the direct use of JI funds and does not include those materials generated from subsequent studies using non-JI funding. If any investigator in a project intends to use third party funding in conjunction with a JI project, the PI is advised to define such external funding in writing in the plan referenced herein, for JI Executive Committee approval. Data may include any of the following: raw data, analytical data (data obtained from processing samples, such as the genomic data generated from samples), collected materials, specimens, and samples. For clarity, data does not include inventions, journal publications, manuscripts, abstracts, posters, software (unless otherwise including data), or other "scholarly works" as defined under the policy at the University of Michigan or the Peking University Health Science Center.

H. This policy shall be interpreted in accordance with local law, which shall take precedence over the policy if there is any conflicting provision.

III. Procedures

A. Authors should participate in the writing, reviewing and revision of the paper, in accordance with recommendations from the International Committee of Medical Journal Editors (published in April 2010). Those who participated in conception and design, study implementation, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript relating to important intellectual content, and final approval of the manuscript should be included as authors. According to the Memorandum of Understanding and Appendix C Agreement between the University of Michigan Health System (UMHS) and Peking University Health Science Center (PUHSC), the number of first authors and corresponding authors in the publications from each side should reflect the principle of "equal contribution and equal benefit".

B. For each main paper or joint publications, the Co-Primary Investigators (PIs) of JI projects are responsible to designate one or two responsible (i.e. lead) authors and an appropriate team to prepare the manuscript.

C. For publications that will not be published jointly from both institutions, the publishing party shall provide publications for review to the other party at least

thirty (30) days prior to the submission of such a publication. The Party who is not part of the submission shall identify any confidential information, potentially patentable information, or subject matter owned in whole or in part by such non-publishing Party and provide comments to the publishing Party within 21 days of receipt of the manuscript. However, there will be a fast track on special occasions that requires approval from Co-Chairs of the JI Executive Committee.

D.   Authors who plan to write a paper on any topic using JI study data or JI samples must submit a concept proposal and for review and approval by the Co-PI(s) of the JI project before proceeding. In cases where the PI's do not agree on the terms above or have questions to be resolved, the situation can be brought before the Co-Chairs of the JI Executive Committee, and the JI Executive Committee shall have the ultimate authority to make the final decision.

E.   Selection of first authors: the responsible authors will be the first authors unless he/she delegates otherwise.

F.   Order of Authorship:

1.   The Co-PIs shall nominate the authors and recommend the order of the authorship. For some manuscripts, the contribution of PIs may be equivalent between UMHS and PUHSC and 'co first authors' would be most appropriate. For others, especially secondary manuscripts, the level of input will be considered in the order of authorship.

2.   Failure to complete assignment

If the responsible authors do not complete their work on a manuscript or fail to meet timeline milestones, the Co-PIs may reassign the roles of first author and/or select new responsible authors. This exigency will be exercised if no draft is produced within 4 months of the availability of a clean data set for the manuscript. The study statistician shall determine that the clean data set is available.

G.   Co-PIs who have left JI

Over the course of the JI research projects, Co-PIs may leave their institution and terminate their roles in the JI projects. The JI Executive Committee shall approve replacement for such investigators. If the new investigator is agreed by both the remaining co-PI and the JI Executive Committee, the new investigator will assume Co-PI role for the JI project. At a minimum, the original investigators will typically be acknowledged in an appendix. If a Co-PI leaving his/her institution is able to continue the JI-sponsored research in their new institution, the PI will have the option of submitting a research proposal to the JI. After JI

review process and approval, the PI will have the access to the data and samples generated before their departure. The departing Co-PI will have authorship on projects already underway at the time of departure. Authorship on future endeavors involving data and samples obtained from the work of the investigator will be commensurate with the intellectual contribution to the new project and if there is none, as determined by the Co-PIs at the time, no authorship needs to be granted.

H. Data in publications

If co-PI's are all authors of a publication under the procedures stated herein, then publications may include data.

I. Data sharing with JI Investigators outside the immediate study

The data collected by the JI projects shall be controlled by the JI and shall not be shared with non-study JI investigators without the mutual, documented consent of the study Co-PIs from PUHSC and UM and the JI Executive Committee. It will be helpful for new proposals to discuss a plan for both data sharing and possible use of third party funding that have been approved by involved Co-PIs.

J. Data sharing with Non-JI Investigators

The data are controlled by the JI and shall not be shared with non-JI investigators or third parties without the mutual, documented consent of the study Co-PIs from PUHSC and UM and the JI Executive Committee. The parties wishing to share the data must submit a proposal justifying the sharing the data and detailing how the data is to be used. Some JI studies may wish to invite outside experts to participate as scientific collaborators. Such addition of investigators shall be discussed and agreed upon by the Co-PIs from PUHSC and UM prior to presentation to the JI Executive Committee for approval. Ordinarily, manuscript authorship would be limited to JI investigators. If, however, such an outside expert has played a primary or very strategic role in the study, the Co-PIs may elect to recognize the important contribution of the outside investigator by including him/her as an author. Such a request, with supporting documentation, should be discussed and agreed by the Co-PIs and consequently be presented to the JI Executive Committee for approval.

K. All JI manuscripts, abstracts, posters, etc. should include an acknowledgement of JI funding.

L. When appropriate, other-institute support should be acknowledged.

IV. **References**

1. UMMS Appropriate Authorship Attribution (Ghostwriting, Guest Authorship) Policy
   http://www.med.umich.edu/medschool-regulatory/policies/ghostwriting_policy.pdf

2. UMMS Guidelines for Responsible Conduct of Research (Guidelines for Authorship section starting on page 12)
   http://www.med.umich.edu/medschool-regulatory/policies/rcr-guidelines.pdf

3. ICMJE requirements for Authorship and Contributorship
   http://www.icmje.org/ethical_lauthor.html

V. **Approval**

Signature: /Joseph C. Kolars/Joseph C. Kolars

Title: Senior Associate Dean for Education & Global Initiatives at UMMS

Date: September 27, 2013

Signature: /Weigang Fang/Weigang Fang

Title: Vice President, PUHSC

Date: September 27, 2013

I acknowledge and agree to the above policy:

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