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Joint Standard Operating Procedures (SOP's) for Review of Joint Institute Protocols

This document aims to specify and clarify the procedures regarding the submission, the review, the communication of decisions, as well as post-approval management of protocols funded by the UMHS-PUHSC Joint Institute (JI) for Translational and Clinical Research. This document specifies requirements for IRB review of JI protocols. Protocols must also follow institutional policies and procedures when under the jurisdiction of the IRBMED, University of Michigan and/or the Peking University Institutional Review Board (PKU IRB).

1. Requirements for Application Submission of JI Protocols

For JI protocols, it is expected that the IRB application at both sites will describe in sufficient detail the human subject research activities that will take place at both the University of Michigan and PKU (Peking University). This includes submitting the consent form(s) to be used at each site (if applicable). In some JI research, it is understood that investigators from the University of Michigan and Peking University may not follow the same protocol, or may have different roles, research procedures and interventions/interactions, etc. To ensure that both IRBMED and PKU IRB can provide a thorough and comprehensive review, a full-version JI protocol is required, describing the research activities at both UM and PKU, in addition to other essential application materials.

Should human subjects research activities at Michigan Medicine not require IRB review because the activities are not regulated, JI projects at Michigan Medicine should still submit a not regulated application to the IRB and have the IRBMED acknowledge that the activities are not regulated. All JI projects at PKU should contact the PKU IRB for consultation and further actions. If JI staff or investigators have questions regarding whether IRB review is needed, they should contact one of the co-leads at their site or their respective IRB office for a determination.

Principal investigators from PKU and UMHS are responsible for the oversight, preparation, and submission of the full-version protocol along with other required materials to complete the application process for ethical review at both IRBs. The full version protocol can be the same document submitted to the JI for funding, provided that the human subjects research activities at both sites are adequately described. This full protocol should identify and specify the research procedures at both sites, responsible personnel, and any other related issues (such as a communication plan) that the principal investigator believes requires additional clarification beyond that provided by the basic questions within the application. Submission of the full protocol in both English and Chinese to each IRB is strongly encouraged. However, if this is not feasible, JI investigators can submit the full protocol to IRBMED in English and to the

PKU IRB the English proposal and Chinese protocol.

2. Review Decision Communication between UM IRBMED and PKU IRB

After completion of the application process, the protocol review will follow the existing policies and procedures at each IRB. Both IRBMED and PKU IRB will conduct the review independently and communicate review decisions and/or suggestions as needed. If human subjects research is only being done at one site, that site's IRB will be responsible for the review, and no communication will be needed between the IRBs. Both IRBs can share review materials, meeting minutes and any other information related to a project under review at either site.

Investigators should be aware that there might be some delay in approval decisions as the two IRBs have different meeting frequencies; further, there may be disagreements in terms of the review decisions, requiring adjudication. The IRB chairs are responsible for exchanging such decisions, concerns or suggestions by emails or scheduled videoconferences. If necessary, disagreements may require further review of the protocol at each site. Each IRB has the responsibility to communicate review decisions and/or suggestions to the investigators at their site. Each IRB will issue an approval letter once they approve the study. Investigators must not start their research at a particular site until they receive approval from the IRB at that site.

3. Post-Approval Management of JI Protocols

Generally, the post-approval management of JI protocols at each site will follow the requirements of related policies and procedures involving human subject protection at the respective university.

Principal investigators have the responsibility to exchange information with collaborators at all engaged sites regarding safety issues, unanticipated problems, internal or external auditing reports, and any other information that may affect the rights and welfare of human subjects, the integrity of research, and /or the sustainability of the research. Principal investigators are also obliged to report such issues to each IRB in a timely manner.

The IRB chairs and their designees from both IRBMED and PKU IRB will set up quarterly videoconferences to exchange information regarding approval concerns, the post-approval management of JI protocols and any other concerns that they consider need communication.

The IRBMED, University of Michigan and Peking University Institutional Review Board (PKU IRB) who issue this SOP jointly, share equal responsibility for these SOPs and jointly reserve the right for further interpretation and modifications to this document. If you have any questions or concerns, please contact:

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