University Hospitals

To: **All Clinical Researchers**

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Date: **December 19, 2018**

Subject: UH Principal Investigator Progress Update

The UH Clinical Research Center has been working closely with CWRU to resolve concerns related to the new UH requirement to include a UH Principal Investigator on studies that involve use of UH patient data and/or biological materials. Both CWRU and UH agree that the primary purpose of this new policy is to support and promote research activities of CWRU primary faculty accessing hospital based material or data for research purposes in a secure manner.

With the cooperation of many Investigators from both CWRU and UH, we have already resolved the issues related to the majority of open studies. A new set of Standard Operating Procedures will be issued once finalized; however, some of the basic principles are below.

- UH and CWRU encourage and support multi-investigator and multi-site research.
- Institutions need to establish guidelines for research authenticity, privacy, and accountability.

In general, the initiator of the research will be identified as the Research PI and the hospital based PI will be identified as the Site PI.

The Research PI will remain the PI of record with the sponsoring agency and will be the overall responsible PI for budgetary and authorship consideration. The Research PI will also share responsibility, with the Site PI, over compliance related to security, privacy, confidentiality and hospital based reporting

of the hospital material or data used in the research project. Both the Research and Site PI must follow any hospital based policies related to the security of hospital material or data.

The Site PI will keep the Research PI informed on all hospital based compliance matters and the Research PI will include the Site PI in research activities and review, as negotiated among the partners. The Site PI will be required to be named in any protocol or proposal submitted to the UH IRB. The overall role of the Site PI in the research project will be negotiated by the partners and articulated in the UH IRB submission. If CWRU researchers are unsure who an appropriate Site PI is for a study that will involve hospital material or data, they are encouraged to reach out to Dr. McComsey (Grace.McComsey@UHhospitals.org) or Beth Hagesfeld (beth.hagesfeld@uhhospitals.org) for assistance.

Finally, currently approved UH IRB studies that are no longer collecting data or interacting with patients may be eligible for an exemption. The exemption will be subject to completion of a research compliance audit with no material findings. If you believe you qualify for an exemption, please contact Dr. McComsey (Grace.McComsey@UHhospitals.org) and Beth Hagesfeld (beth.hagesfeld@uhhospitals.org).

Please contact the UH IRB administration office with questions about process: 216-844-1529.

We thank you for your collaboration as we strive to provide exceptional protection to our UH patients.