University Hospitals

To: **All Clinical Researchers**

From: **Grace A McComsey, MD, FIDSA**
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Director, UH Clinical Research Center

Date: **October 25, 2018**

Subject: Requirement for UH Principal Investigator

Due to a recent series of events, the UH CRC is issuing and enforcing the below requirements for studies involving UH data or UH patients.

Any study that uses UH patients or accesses UH data, will be required to have a UH Principal Investigator (PI) in the SpartaIRB electronic submission system. This requirement is applicable to both newly submitted research and currently approved studies. All currently approved studies must submit an amendment identifying a UH PI and revising applicable study documents by November 25, 2018.

The designation of a UH PI is intended to ensure that UH personnel are primarily responsible for research using UH patients or data. It is not intended to dictate authorships or diminish acknowledgment of non-UH investigators.

As a reminder, the UH Research Credentialing process was put in place to expand UH research to non-employees while continuing to protect our UH data and patients. The UH PI identified for these studies should be responsible for sponsoring the UH Research Credentialing of the non-UH investigators. It is important that the UH PI understands the serious responsibility involved in sponsoring and overseeing the sharing of UH data and access to patients with non-UH employees.

University Hospitals takes the privacy and confidentiality of its patients and their data seriously. The measures outlined above are designed to help protect our valued patients.