



To: **All Basic and Clinical Researchers not employed by UH**

From: **Grace A McComsey, MD, FIDSA**

Vice President of Research & Associate Chief Scientific Officer, UHHS  
Director, UH Clinical Research Center

Date: **November 19<sup>th</sup>, 2018**

Subject: **Deadline Extension – Requirement for UH Principal Investigator**

After consultation with Dean Pamela Davis, Vice Dean for Research Mark Chance and CTSC Principal Investigator (PI) Mike Konstan, we have elected to extend the deadline to designate a UH PI with the UH IRB for all studies using UH patients or their data. The new date is Dec 31, 2018.

During this time of transition, we are exploring multiple options that would take into consideration the risk and type of the specific study. We are thoughtfully balancing our mandate to protect UH patients and UH data while seeking to promote broad translational and clinical research participation by all faculty members. Drs. Simon, Jain, and I will be working closely with CWRU SOM leadership on these issues in the upcoming weeks.

Research compliance audits will continue to take place in order to help inform UH CRC of what additional training, tools and resources are required for investigators. Please note that both UH and CWRU SOM leadership view research compliance audits as mandatory for UH and non-UH investigators.

As a reminder, if you are sending or receiving patient information, you are required to use your UH email. Patient information should only be stored on a UH-encrypted device. Patient information should never be stored at home or off campus. Access to patient information is limited to only those persons listed on your IRB personnel table. Failure to follow these requirements may result in the suspension of research privileges.

As mentioned above, UH CRC will be creating additional training, tools and resources for all investigators. If you have any suggestions, please do not hesitate to reach out to the UH research concierge at the following link

<https://redcap.uhhospitals.org/redcap/surveys/?s=KHHXM3C9FL>. Questions about how to submit a change in PI should be directed toward the UH IRB Administration office at 216-844-1529.