October 1, 2020

Re: Transfer of IRB oversight from UCHealth IRB to COMIRB

To: UCHealth Principal Investigators and research sponsors

On October 1, 2020, COMIRB assumed IRB oversight for human subjects research at UCHealth formerly under the oversight of the UCHealth IRB. This letter is for general notification to you and your sponsors of this change. Study-specific letters will be sent to you after specific studies are fully transferred to COMIRB’s electronic record system. A detailed FAQ on the IRB transition is published at UCHealth on The Source.

The UCHealth Federalwide Assurance (FWA00023003) identifies COMIRB as an IRB of record. COMIRB has full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Our federal IRB registration number is IORG0000433. See the About COMIRB webpage for additional details, including a general compliance letter for sponsors.

Please notify sponsors of your research about this change. If you maintain FDA Form 1572 for your research, please update the form to identify COMIRB as the reviewing IRB with the address listed above, unless you are transferring oversight to a private IRB. Keep the updated form in your records. You need not submit the form to COMIRB. Researchers transferring IRB oversight to private IRBs should review the FAQ linked above.

COMIRB is working in close collaboration with UCHealth Research Administration, such that we do not require you to take any other specific action until you otherwise need IRB review (e.g., submitting and amendment, continuing review, or unanticipated problem). Similarly, COMIRB and UCHealth do not require re-consent or re-authorization from currently enrolled subjects solely for this administrative transition of IRB oversight.

If you have any questions, do not hesitate to contact COMIRB or UCHealth Research Administration. Points of Contact are identified on the UCHealth page of our website.

I welcome this opportunity to serve UCHealth researchers,

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