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Executive Director

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To Whom It May Concern:

Northwestern University's Office for the Protection of Research Subjects has begun to implement a new electronic (web-based) submission process and tracking database that will facilitate the electronic submission, review, approval and warehousing of all IRB-related documentation. In order to successfully implement this new approach to managing the IRB review process, the University has entered into a license agreement with Click Commerce™.

For our research community to use this system, they will be required to provide all regulatory documents in an electronic format. While paper documents may be scanned and attached to our servers, we would encourage all sponsors to provide the research staff with electronic documents (especially documents like the protocol or investigators brochure) in a format like "pdf" files so as to minimize the possibility of inadvertent changes from the original documentation. We also wish to assure all sponsors that reasonable security precautions have been taken by Northwestern University to ensure the ongoing confidentiality of all proprietary information.

This new system implementation means a number of changes from prior practices. Rather than receiving "stamped" consent documents with IRB approval information, we will now provide an electronic "stamp" in the footer of the consent document which will be applied by the eIRB system when the version of the consent is approved by the IRB. While our paper documents have been the official source documents for the institution, the source documents for new studies that are initiated through eIRB will be the electronic version that is available online. This may require modification of some procedures for our research community in order to ensure that the current approved version of the consent document is being used, and this may require some modification of the monitoring procedures for our study Sponsors and CROs. Please feel free to contact me or OPRS in the event you need additional assistance in resolving issues related to implementation of eIRB.

Thank you in advance for your support and cooperation as we seek to provide enhanced service to our research community.

Sincerely,

A handwritten signature in blue ink that reads "Don E. Workman, PhD".

Don E. Workman, Ph.D.