
MEMORANDUM

From: Shantel Kelly – Director, Quality Assurance

Subject: Exemption for Precision for Medicine IRB Approval under National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Study Contract HHSN275201600006C

Date: August 21, 2018

To Whom It May Concern:

The NIDDK Biorepository at Precision for Medicine (PFM) is exempt from both local and central Institutional Review Board (IRB) Approval for the receipt, storage, laboratory research, and distribution of biospecimen samples. The Biorepository does not receive, maintain or distribute Protected Health Information. Even though PFM serves as a subcontracted biorepository, NIDDK is still considered to maintain custodianship of stored biospecimens, in accordance with Good Clinical Practices, which were previously obtained under an IRB approved protocol with written consent from the study participant.

 21 Aug 2018

Signature/Date