

June 28, 2021

Waiver of Documentation of Informed Consent and IRB Approval

This is a waiver of Documentation of Informed Consent and IRB Approval for our study titled “Takotsubo Cardiomyopathy in Orthotopic Liver Transplant Recipients: A Cohort Study Using Multi-center Pooled Electronic Health Record Data”

This study is based on a multicenter analytics and research platform developed by IBM Watson Health (Explorys Inc, Cleveland, OH, USA).(1) At present, Explorys database is rich, integrated, and growing living clinical data set that is HIPAA-enabled, including more than 70 million unique patients across all 50 states in the United States, and thus provides a broad regional and climatic distribution of source population. Ethical review and informed consent were waived, since there are no identifiers associated with any of the patient data. The Explorys rounds cell counts to the nearest 10 and treats all cell counts between zero and 10 as equivalent in order to further protect the identities of patients. In other words, the identities of subjects is completely anonymous and there is no risk involved in the study. Additionally, the research presents no risk of harm to subjects and involves no procedures for which written consent is normally required outside the consent.

1. Solution Brief The IBM Explorys Platform Liberate your healthcare data [Internet].
[cited 2021 Jun 26]. Available from:
<https://www.ibm.com/downloads/cas/4P0QB9JN>.