

04-021: Geography and Epidemiology of Health Data for the City of Camden: Creating a Neighborhood Health Indicator Database

Summary of Changes for Amendment

In general, the approved research protocol is adequate for the research to continue. The changes requested by the investigators should fall under expedited review because there is no change in risk.

The main changes are as follows:

1. Modify protocol for length of storage of unique identifiers. Because of the need to perform multiple ongoing queries, it is necessary to maintain unique identifiers in our research records for longer than the investigators originally anticipated. This change does not affect our strict procedures for data storage. All protected health information (PHI) is stored on one password-protected external hard drive in a locked cabinet and locked room in the E&R Building at UMDNJ, and will not leave the building.

2. Allow for comparison of hospital data with external datasets. In order to obtain a more complete picture of health conditions in Camden and to begin to address issues with ER utilization, the investigators would like to compare the hospital billing data with datasets provided by external sources, including primary care providers, Medicaid HMOs, vital statistics (death certificates), and others. All matching of data would take place in the same location that the hospital billing data is stored, and PHI in the billing data will not be shared with external entities not approved as part of the research protocol.

A more complete iteration of requested changes follows:

Page	Change	Rationale
1	Remove Ian Hoffman from Other Investigators; replace with Derek Ziegler as Study Coordinator	Ian has finished medical school and is now in residency in California and will no longer be participating in the research.
4	Change "Excel spreadsheet or SPSS database" to database	Because of the increasing complexity of the data, we may use tools such as Access or SQL Server instead of Excel for data management
4	Delete "No patient names or other unique identifiers will be maintained in this research record. Once data has been processed, all unique identifiers	See #1, above

	will be destroyed"	
5	Add external datasets	See #2, above
5	Change 1980-2003 to 2000-2008	We would like to obtain newer data than 2003 to allow for a more robust dataset for comparison purposes. Acquisition of the newer data will not affect our protocol for protecting PHI
6	Add building, housing development to Visualization of the Data	Our initial research has shown that some apartment towers in Camden appear to show very high concentrations of ER visits
7	Revise text under "Procedures to Maintain Privacy and Confidentiality"	See #1, above
8	Add charges, receipts, and primary care physician to "PHI To Be Obtained"	This additional data will allow us to do further research on the costs of treating certain conditions in a hospital setting
9	Revise text under "PHI Protection Protocol"	See #1, above