Author's response to reviews

Title: Geographic variation in cesarean delivery in the United States

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Version: 2 Date: 14 February 2014

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The database used in this study is the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID). As noted in the Data Use Agreement signed by all the investigators (see http://www.hcup-us.ahrq.gov/team/StateDUA.jsp ), "... AHRQ omits from the data set all direct identifiers that are required to be excluded from limited data sets as consistent with the HIPAA Privacy Rule ..." According to the U.S. Department of Health and Human Services (see http://www.hhs.gov/ohrp/policy/cdebiol.html ), "... HHS regulations define human subject at 45 CFR 46.102(f) as follows: Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information ..." Because these two conditions do not pertain to HCUP data, HCUP data does not involve human subjects as defined by HHS. Consequently, because Institutional Review Boards (IRBs) are responsible for oversight of human subject research and because HCUP does not involve human subjects, IRB approval is not required.