

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Database Inquiry
Date: Wednesday, September 23, 2015 1:01:28 PM

Good afternoon –

This is not the correct office. We do not have access to a national database of pregnant women. You most likely will need to contact someone in the Center for Drugs (CDER) and the Division of Pediatric and Maternal Health. CDER's email address is druginfo@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Wednesday, September 23, 2015 12:18 PM
To: OC GCP Questions
Cc: 0YXUM/XQ
Subject: Database Inquiry

Good morning,

My name is [REDACTED] and I am a doctoral student at the [REDACTED]. My dissertation research is breastfeeding intention with first-time antepartum women. I was instructed by the The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC) to contact you for assistance in this matter. My case number is [REDACTED]. I wanted to know if you were willing to share a national database of pregnant women to conduct primary data collection. I am in the exemption process of IRB approval for the University of Toledo. If you have any questions, please feel free to contact me at [REDACTED].