



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

March 27, 2025

Elizabeth Ailes, PhD
NCBDDD/DBDDD
Eha0@cdc.gov

RE: CDC IRB Approval of Changes to CDC Protocol 2087, "Centers for Birth Defects Research and Prevention (CBDRP)"
Amendment 126

Dear Dr. Ailes:

On March 24, 2025, the CDC Institutional Review Board (IRB) reviewed and approved changes to CDC Protocol 2087, "Centers for Birth Defects Research and Prevention (CBDRP)" in accordance with 45 C.F.R. §§46.110(b), categories 3, and 7. This approval is effective as of March 24, 2025.

The CDC IRB has approved **all proposed change(s) as follows:**

- We have updated our temporary break letters/scripts with more versatile language in case they are needed again in the future. Revisions remove old dates and include language tailored for stillbirth participants.
- Changes required by the United States Office of Personnel Management's January 29, 2025 memorandum, "Initial Guidance Regarding President Trump's Executive Order Defending Women."

The CDC IRB finds that the research study involves no more than minimal risk to subjects, consistent with its previous determination.

You are required to adhere to the protocol as approved on March 24, 2025, and implement the changes immediately in accordance with the approved amendment.

We appreciate your commitment to responsible conduct of research and your cooperation with the IRB review process. If you have any questions or concerns regarding the conduct of your study or the IRB review process, please do not hesitate to contact your Center Human Subjects Contact or Jerrell Little, IRB Administrator, at 04-639-3536, or via email at jiv4@cdc.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Chirila".

Robert Chirila, Lead
Human Research Protections Office