



May 20, 2024

Jacqueline Miller, MD
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RE: CDC IRB Approval of Continuation of CDC Protocol 1976, "Collection and Analysis of Minimum Data Elements Data Set from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)" Continuation 26

Dear Dr. Jacqueline Miller:

On May 20, 2024, the CDC Institutional Review Board (IRB) reviewed and approved your continuation for CDC Protocol 1976, "Collection and Analysis of Minimum Data Elements Data Set from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)". This approval is effective from May 21, 2024 to May 17, 2025.

Please comply with the previously approved protocol, as well as any subsequent modifications approved by the CDC IRB in accordance with CDC policies and procedures. Additionally, please be attentive to the following requirements:

- Continuation of Research: The continuation of your research study requires investigators to adhere to the research study design, methodology, and subject eligibility criteria, as outlined in the protocol approved by the CDC IRB. Any changes to the research study design, methodology, or subject eligibility criteria must be submitted to the CDC IRB for review and approval before implementation.
- Subjects Recruitment: You must continue to recruit subjects in accordance with the recruitment methods and procedures approved by the CDC IRB. Any changes to the recruitment methods or procedures must be submitted to the CDC IRB for review and approval before implementation.
- Informed Consent: You must continue to obtain informed consent from subjects in accordance with the approved consent form and procedure. Any changes to the consent form or procedure must be submitted to the CDC IRB for review and approval before implementation.
- Data Collection and Analysis: You must continue to collect and analyze data in accordance with the approved methods and procedures. Any changes to the data collection or analysis methods or procedures must be submitted to the CDC IRB for review and approval before implementation.

- Reporting of Incidents: Any unanticipated problems or noncompliance of a serious or continuing nature, as defined by CDC policies and procedures should be promptly reported to the CDC's Human Research Protections Office.

Please note that failure to comply with the above requirements may result in suspension or termination of your research.

Thank you for your attention to these matters. The CDC IRB appreciates 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 Felecia Peterson, IRB Administrator, at 404-639-4961, or via email at fdp1@cdc.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Felecia Peterson', written in a cursive style.

For Robert Chirila, Lead
Human Research Protections Office