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NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE: 23 Feb 2023
TO: Heidi Nelson, MD
PROJECT: American College of Surgeons, Breaking Barriers Quality Improvement Collaborative (Pro00069749)

DOCUMENTATION REVIEWED:

- Protocol Version:**
- Protocol (Not Dated)
- Other Material:**
- Instructions for Use, "Breaking Barriers: An ACS Cancer Programs National Quality Improvement Project" Informational Webinar (Dated January 13, 2023)
 - Direct Mailing, Appendix B Newsletter Promo: "Register for January 13 Breaking Barriers Informational Webinar" (Not Dated)
 - Direct Mailing, "Year 1 Project At A Glance" (Dated January 11 2023)
 - Direct Mailing, "Frequently Asked Questions" (Dated January 20, 2023)
 - Direct Mailing, Appendix E Pre.PostSurvey (Not Dated)
 - Direct Mailing, Appendix F Pre.PostSurvey (Not Dated)
 - Direct Mailing, "Data Metrics" (Not Dated)

Using the Department of Health and Human Services (DHHS) regulations at 45 CFR 46, the IRB determined that your research project does not meet the DHHS definition of human subjects research under 45 CFR 46 and, therefore, does not require IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

The IRB granted this non-human subject research determination with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.
2. Should the nature of the research project, or any aspect of the study, change such that the nature of the study no longer meets the criteria found in 45 CFR 46, you will submit revised materials for IRB review.

This project is not subject to requirements for continuing review.



If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Thank you for selecting Advarra IRB to review your research project.