



6100 Merriweather Dr., Suite 600
Columbia, MD 21044
410-884-2900

NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE: 22 Feb 2023

TO: Heidi Nelson, MD

PROJECT: American College of Surgeons, Beyond ASK: Towards Advising and Assisting Newly Diagnosed Cancer Patients on Smoking Cessation (Pro00069660)

DOCUMENTATION REVIEWED:

- Protocol Version:**
- Protocol (Not Dated)
- Other Material:**
- Direct Mailing, "Beyond ASK: Advising and Assisting Newly Diagnosed Patients with Smoking Cessation" (Dated January 19, 2022)
 - Direct Mailing, "Frequently Asked Questions" (Dated April 8, 2023)
 - Direct Mailing, "Baseline Questionnaire" (Updated 1.2)
 - Direct Mailing, Appendix B Newsletter Promo: "Register Today for Beyond ASK Informational Webinar" (Not Dated)
 - Instructions for Use, "Beyond ASK: Towards Advising and Assisting Newly Diagnosed Cancer Patients on Smoking Cessation" Informational Webinar (Dated January 20, 2023)

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.