



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

## NON-HUMAN SUBJECT RESEARCH DETERMINATION

**DATE:** 28 Mar 2022

**TO:** Heidi Nelson, MD

**PROJECT:** American College of Surgeons -, Smoking in New Cancer Patients PDSA  
Quality Improvement Project and Clinical Study: Just ASK (Pro00057608)

---

### DOCUMENTATION REVIEWED:

**Protocol Version:** • Protocol (Not Dated)

Using the Department of Health and Human Services 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 46.102, you will resubmit 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.