NON-HUMAN SUBJECT RESEARCH DETERMINATION

DATE: 8 Mar 2024

TO: Ronald Weigel, MD

PROJECT: American College of Surgeons, 5.8 Lung NODES (Pro00077842)

DOCUMENTATION REVIEWED:

Protocol Version(s):
- Protocol (Not Dated)

Recruitment Material:
- Standard 5.8 Lung NODES, Informational Webinar (Dated December 7, 2023)

Other Material:
- Internet, Standard 5.8 Lung NODES Quality Improvement Project (January 29, 2024)
- Appendix C FAQ (Not Dated)
- Questionnaire, Initial Data Collection Form (Not Dated)
- Ongoing Data Collection Form (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.

Please be advised that as Advarra IRB is not overseeing the conduct of the study, study materials, documents and reports should not state that the study is "approved" by an IRB. Also, if your study includes subject-facing materials such as consent forms, recruitment materials, and other materials used by subjects in the study, the IRB company name and contact information should not be referenced. Study materials, documents and reports may include a general statement that the study was reviewed by an IRB, such as, "This study has been reviewed by an institutional review board (IRB), which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner."

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.

Compliance Statement/REB Attestation (Applicable for research conducted in Canada):

The IRB attests that this submission has been approved by an IRB whose membership complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56, and HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21 CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

Advarra IRB is registered with OHRP and FDA under IRB#00000971.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to review your project.

Sincerely,

Luke Gelinas, PhD
Executive Board Chair