



Principal Investigator Notification:

From: Mayo Clinic IRB

To: Konstantinos Leventakos

CC: Sandra Algarin Parneth
Emma Behnken
Megan Branda
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Konstantinos Leventakos
Madeline O'Grady
Kaushal Parikh
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Christine Sagen
Angela Sivly

Re: IRB Application # [23-003089](#)

Application Title: Shared Decision-Making Encounter Tool for Adjuvant Treatment of Lung Cancer: Randomized Control Trial

Please note that all correspondence (modifications, continuing reviews, reportable events) related to this application must be submitted electronically in the IRBe system.

The following is an excerpt from the minutes of the Mayo Clinic Institutional Review Boards (IRB-C) meeting dated 9/15/2023:

DECISION: The Committee received the Deferral Response Form dated August 14, 2023, for the above referenced application. The investigator submitted: 1) Revised protocol, consent forms and contact/recruitment materials, aligned for clinical and patient participants; 2) Updated the Post Survey for Clinicians, to version 0.02 in Contact Materials; 3) Uploaded Word Document "NSCLC Tool Training Information" in the Contact Materials to reflect the tool and any training that will occur after the clinical team has signed consent; 4) Revised the External Parties (Landmark Transcription Services) to receive information including direct identifiers which may be disclosed in transcription; 5) Clarified that the intervention is just one encounter, therefore there will not be a subsequent encounter where a cross-over could occur; 6) Added waiver of documentation of consent (oral consent) for any guests attending the appointment; and 7) Updated the consent procedures clarifying who both groups will be approached for consent. The Committee determined that the concerns identified at the Committee meeting of July 21, 2023, were adequately addressed.

The Committee reviewed and approved the above referenced application and noted that all requirements for approval of research (45CFR46.111) were met. The Committee determined that the research involves greater than minimal risk. This approval is valid for one year unless during that time the IRB determines that it is appropriate to halt or suspend the study earlier. IRB approval will expire on September 14, 2024.

The Committee approved the accrual of 100 adult subjects. The Committee approved the following sites to conduct the study activities as specified in the application: Mayo Clinic in Rochester, Minnesota.

REVIEW: The Committee noted receipt of the protocol version 1.0, dated December 6, 2022. The Committee reviewed the Conflict of Interest (COI) Review Board determination related to Irbaz Riaz. The Committee accepted the COI Review Board determination of no conflict of interest. Funding for the study is provided by Emerson Collective, LLC.

CONTACT MATERIALS: The Committee approved the phone scripts, email scripts, surveys, instructions and shared decision-making tool as submitted.

CONSENT: The Committee approved the consent forms (00 and 01) with minor edits. The Committee updated the clinician consent (01) to inform clinician participants that year of birth and gender would be collected in the dataset. The final approved consent forms will be provided under the Documents tab of the main study workspace in IRBe. The Committee noted that the consent process includes the use of on-site and remote electronic consent.

The Committee noted that oral consent is appropriate for guest(s) of the subject to be video and/or audio recorded along with the subject in this study. The oral consent script was reviewed and approved as written. As protected health information is not being requested from guests, HIPAA authorization is not required in accordance with 45 CFR 160.103. The Committee approved waiver of the requirement for the Investigator to obtain a signed consent form in accordance with 45 CFR 46.117 as justified by the Investigator.

REMINDERS: The Committee:

- Reminds the investigator to submit a continuing review report prior to the expiration date (reminder will be sent prior to expiration).

Attachments (if applicable):

Name	version	dateCreated	dateModified
There are no items to display			

Meissner, Irene M.D., Chair
Julie Ray, Correspondent
Mayo Clinic Institutional Review Boards

IRB-C