

A Randomized Phase III Study of Sublobar Resection (SR) versus Stereotactic Ablative Radiotherapy (SABR) in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

“Stablemates Trial”

## Frequently asked questions from subsites

**Question: Are all the procedures standard of care?**

Answer: It depends on the facility and the state. Every state has different laws and there may be slight variances in Medicare coverage. Per UT Southwestern coverage analysis, the treatments are standard of care.



Robert Timmerman

**Question: What information do you require for invoicing?**

Answer: Submit an invoice detailing each patient for which payment is being requested, including study ID, patient initials, date of registration, and date of treatment completion. All required case report forms must be completed prior to invoicing. Please refer to Exhibit B of the clinical trial subcontract for more information. UT Southwestern will review study data prior to processing.

**Question: What is the “prerandomization” process?**

Answer: Prior to the first visit, the coordinator screens the patient to see if they are eligible. It’s highly recommended that a waiver for prescreening is obtained so records can be reviewed prior to the first visit. Randomization should not occur until all work-up/staging/biopsy is completed confirming eligibility.

If eligible, patients are then randomized using REDCap software. After randomization, there is no blinding to the treatment team.

The randomization results and consent form are then presented to the patient. The intention is to give patients a choice in their own care.

Physicians have some leeway in choosing when to talk about the trial with the patient and when they divulge the pre-randomization assignment. At our center, it has been variable, both done at the visit where eligibility was confirmed and pre-randomization was obtained, and in other cases, physicians talked to the patient about the trial ear-

lier while still undergoing the work-up.

The timing of the discussion is not so important; the key is whether the patient accepts the assignment. Both treatment options should be presented fairly so patients can decide whether to accept the pre-randomization assignment or not.

**Subsite update**

**Active:**

- CHUM-Notre Dame Hospital
- Lifespan Oncology Clinical Research
- UT Southwestern Medical Center

**Completed contracts and IRB approval:**

- Anne Arundel Medical Center
- Henry Ford Health System
- Mount Nittany Medical Center
- Ochsner Medical Center
- Ohio State University
- Swedish Cancer Institute
- University of Tennessee

**Completed contracts:**

- Mayo Clinic Rochester
- University of Louisville Physicians

**Visit the Stablemates website**

[www.joltca.org](http://www.joltca.org)

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