



Enrollment of Uninsured Patients in Clinical Research

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Case: Post-COVID Syndrome

BreatheBetter8 (BB8) is a new compound meant to treat impaired lung function among those suffering from post-COVID syndrome (PCS). Investigators are proposing, multi-site randomized, double-blinded, placebo-controlled study among patients discharged from the hospital but with lingering pulmonary symptoms.

Case: Post-COVID Syndrome

Patients will be randomized to receive BB8 or a placebo for twelve weeks with a one year follow up. All patients will receive the same background current standard of care.

Case: Post-COVID Syndrome

The trial is a collaboration between the National Institutes of Health (NIH) and Dameron Biologics, a private company. As the COVID pandemic has slowed the study team is concerned about their ability to meet their targeted enrollment goals.

Case: Post-COVID Syndrome

The trial is currently underway at sites in four states. One of the sites in State X has indicated that they plan to exclude otherwise medically eligible subjects who are currently uninsured.

The health system of which they are a part bills standard-of-care expenses to participants insurers. The health system has notified the PI that it will not cover these expenses for participants who do not have health insurance.

Considerations

Is it OK for State X site to limit enrollment in this way?

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Fair Participant Selection

Participants should be chosen based primarily on a trial's scientific objectives

Participants should be chosen in a way that reduces risks and enhances potential benefits to both individuals and society

Risks, burdens, and potential benefits of research participation should be distributed fairly across individuals and societal groups

Undue Inducement?

It is unlikely that the additional, modest ancillary benefit of covering certain standard-of-care procedures for length of enrollment would induce otherwise resistant patients to enroll.

Categorically excluding uninsured patients from the trial would be a disproportionate response to undue inducement concerns, and would likely violate the principle of fair participant selection (as discussed above).

Fairness Concerns

Who should cover the cost?

Covering cost fair to other participants?

Covering cost at one site fair to other sites, States?