



NOT HUMAN SUBJECTS

December 13, 2023

Dear Jim Hughes:

On 12/13/2023 the University of Washington Human Subjects Division (HSD) reviewed the following application:

Type of Review:	Initial Study
Title of Study:	STEPPED-WEDGE CLUSTER RANDOMIZED TRIALS: PROTOCOL FOR DATASET COLLECTION AND ANALYSES
Investigator:	Jim Hughes
IRB ID:	STUDY00019267
Funding:	Name: National Institute of Allergy and Infectious Diseases (NIAID), Grant Office ID: FA224257, Funding Source ID: 5R37AI029168 Funding Title(s): "Statistical Issues in AIDS Research" Pass-through institution(s):
IND, IDE, or HDE:	None

HSD determined that the proposed activity does not involve human subjects, as defined by federal and state regulations. Therefore, review and approval by the University of Washington IRB is not required.

This determination applies only to the activities described in this application. **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data or specimens (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to conduct activities in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**

HSD does not make determinations on behalf of other institutions. If other institutions are involved in the research, they may need to make their own determination or they may decide to be guided by our determination.

If you need to make changes in the future that may affect this determination or are not sure, contact us or submit a new request for a determination. You can create a modification by clicking Create Modification within the study.

We wish you great success.

Sincerely,

Lindsey Westlake, Senior Administrator
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