Yale

Human Research Protection Program
Institutional Review Boards
FWA00002571
25 Science Park – 3rd Fl., 150 Munson St.
New Haven CT 06520-8327

Telephone: 203-785-4688
http://www.yale.edu/hrpp

August 19, 2019

EXEMPTION DETERMINATION

Determination Date: 8/19/2019

Investigator:	Andres Martin
Type of Review:	Initial Study
Title of Study:	Flipped (Co-constructive) Patient Simulation in Child and Adolescent Psychiatry
IRB Protocol ID:	2000026241
Submission ID:	2000026241
Documents:	• Consent Form, Category: Consent Form; • Flipped Simulation , Category: IRB Protocol;

- This research was deemed exempt under 45CFR46.104 (2)(ii)
-
- The protocol does not require annual IRB review.

See the next page for important reminders.

Yale

Human Research Protection Program
Institutional Review Boards
FWA00002571
25 Science Park – 3rd Fl., 150 Munson St.
New Haven CT 06520-8327

Telephone: 203-785-4688
http://www.yale.edu/hrpp

IMPORTANT REMINDERS:

- Exempt research does not require additional IRB oversight except in cases where the study is to be modified in a way that would change the applicability of the exempt status.

- Should you wish to modify the study in way that affects the applicability of the exemption determination, a new protocol must be submitted for the IRB review. See IRB Guidance document 100 GD 9: Guidance on Exemption from IRB Review for examples.

- Information that requires prompt reporting to the IRB must be done so within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events). This includes potential serious noncompliance, continuing noncompliance, and unanticipated problems to subjects or others.

- In conducting this activity, you should refer to and follow the Investigator Manual (HRP-103) as applicable, which can be found in the IRB Library within the IRB system.

Please keep this letter with your copy of the protocol documents.