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

November 5, 2020

EXEMPTION DETERMINATION

Determination Date: 11/5/2020

Investigator:	Anil Nagar
Type of Review:	Initial Study
Title of Study:	Impact of epinephrine volume on hemostasis in ulcer-related upper gastrointestinal bleeding in the combination therapy era
IRB Protocol ID:	2000029322
Submission ID:	2000029322
Documents:	• GI bleeding epinephrine project HRP-503C Medical Record Protocol.pdf, Category: IRB Protocol;

- This protocol has been determined to be exempt under federal regulation 45 CFR 46.104(d)(4)(iii).
- 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.