Cincinnati Children's Hospital Institutional Review Board Federalwide Assurance #00002988

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NOTIFICATION OF EXEMPT DETERMINATION

December 21, 2020

Maria Britto Anderson Ctr Health Sys Excell Dear Maria Britto:

On 12/21/2020, the Cincinnati Children's Hospital Institutional Review Board (IRB) reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Preventable Harm from Pediatric Outpatient
	Medication Errors: Measure Development
Investigator:	Maria Britto
IRB ID:	<u>2020-0968</u>
Review Level:	Exempt
Special Requirements:	There is no special language recorded.

The research activities described in the above submission have been determined to be EXEMPT from IRB review in accordance with applicable regulations and institutional policy. Ongoing IRB oversight is not required.

Any changes/updates to this research will require a new submission to the IRB as submission of modifications to research determined to be Exempt are not allowed.

Sincerely, Cincinnati Children's Hospital IRB Federalwide Assurance #00002988

The Office of Research Compliance and Regulatory Affairs (ORCRA) would like your feedback on your interactions with the Cincinnati Children's Hospital Human Research Protection Program and IRB. Click the following link to complete our anonymous feedback survey: https://survey.sogosurvey.com/r/chkrne

Statement regarding International Conference on Harmonization and Good clinical Practices. The Cincinnati Children's Hospital Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.