

APPROVAL OF SUBMISSION

February 12, 2019

Dear Bobak Ghaheri, MD:

On 1/22/2019, the IRB reviewed the following protocol:

Type of Review:	Full Board Initial Study
Title of Study:	The Impact of Lingual Frenotomy on Bottle Feeding Mechanics: A Randomized, Controlled Trial
Investigator:	Bobak Ghaheri, MD
IRB ID:	STUDY2018000616
Sponsor:	None
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none"> <li>• Protocol Version 1, dated 31DEC2018</li> <li>• Visual Analog Scale, undated</li> <li>• Analytics – Objective Metrics, Revision B, undated</li> <li>• Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF), undated</li> <li>• Infant Gastroesophageal Reflux Questionnaire (I-GERQ-R), dated 2004</li> <li>• Consent Form</li> </ul>
IRB of Record:	Providence Health and Services (Oregon)

The IRB approved the study from 1/22/2019 to 1/21/2020 inclusive. Before 1/21/2020 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 1/21/2020, approval of this study expires on that date.

The following determination was made:

Per 45 CFR §46.404, the IRB finds that minors may participate in the research as the procedures do not involve more than minimal risk.



Attached are stamped approved consent documents. Use copies of these documents to document consent. In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,

Heather Murchison  
Administrative Assistant, PH&S IRB