Protocol/Project Title:
Osteopathic Manipulative Treatment (OMT) for the Management of Feeding Dysfunction in Breastfed Newborns

Date:
Approved 4/12/2019

Version 3/12/2019
Amended previously on 9/6/2017 for assent of one parent, not two and contact info
Created 6/7/2017

Project/Protocol Review Form

SECTION 1: REVIEW TYPE REQUEST

Review Type (check one):

☐**Exempt Review -- ONLY COMPLETE BLUE SHADED SECTIONS.** *Research activities fall under one or more of the exemption categories specified by the federal regulations listed in* **Section 3.**

☐**Expedited Review – COMPLETE ALL SECTIONS OF THIS FORM EXCEPT SECTION 3.** *Research activities fall under one or more of the expedited categories specified by the federal regulations listed in* **Section 4.**

☒ **Full Board Review -- COMPLETE ALL SECTIONS OF THIS FORM EXCEPT SECTIONS 3 & 4.** *For Full Board Reviews, the Principal Investigator may present the protocol at the next convened IRB meeting. Please contact a member of the OHRO staff to set up a time at 309-680-8630.*

SECTION 2: INVESTIGATOR/PROJECT INFORMATION

Protocol/Project Title: Osteopathic Manipulative Treatment (OMT) for the Management of Feeding Dysfunction in Breastfed Newborns

FDA Phase Designation: ☒NA

☐I ☐II ☐III ☐IV

If Phase I, II, III and/or IV are checked, please ensure this research is registered at http://clinicaltrials.gov/ If NA, the research may still require registration with clinicaltrials.gov. Please click HERE for a helpful tool or contact the IRB at 309-680-8630 for assistance.

IND/IDE #: **Sponsor:** **Drug Name(s):**

Principal Investigator Name: Dominique Fons, MD **Department:** Department of Family and Community Medicine

Institution: University of Illinois College of Medicine at Peoria, UnityPoint Health Methodist, OSF St. Francis Medical Center

UICOM-P Affiliation (faculty or student employee sponsor): Faculty

Address: 815 Main Street, Suite B, Peoria, IL 616102 **Telephone:** (309) 672-4221

Fax: (309) 672-4790

Where will the research be taking place?

A performance site is a location at which the research is conducted, data is gathered from subjects, and/or records, and/or subjects are consented into the research.

☒OSF St. Francis Medical Center
☒Unity Point Methodist/Proctor
☐Illinois CancerCare
☐St. Jude Midwest Affiliate
☐UICOM-P
☐OSF Saint Joseph Medical Center--Bloomington
☐Patient Home
☐Other: *(If using multiple clinics, please list*

here)

SECTION 3: REQUEST FOR EXEMPTION

A. Eligibility for Exemption:

1. Will this research involve prisoners as subjects?
   ☒No – Answer must be **NO** for an IRB exemption.
   ☐Yes - **Skip to Section 5. Research involving prisoners is not eligible for an IRB exemption.**

2. Is this research FDA-regulated?
   ☒No
   ☐Yes, but eligible for **Exemption Category 6. FDA-regulated research is only eligible for exemption under Category 6.**

B. Eligibility as Minimal Risk Research:

Does this research pose minimal risk to subjects?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

☒No - **Skip to Section 5. Research that is greater than minimal risk is not eligible for an IRB exemption.**
☐Yes – Answer must be **YES** to be eligible for an IRB exemption.

C. Exemption Categories:

Please identify the exemption category or categories that apply to your research. If your research does **NOT** fit within any of the categories below, then please **STOP** and complete and submit an Initial IRB Review application.

☐**Category 1 – Check the statement(s) below which apply to this research:**
☐Research conducted in established or commonly accepted educational settings
☐Research involves normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

☐**Category 2 – Check the statement(s) below which apply to this research:**
☐Research does **NOT** involve children as subjects when procedures include interviews, surveys, or observations of public behavior and the investigators participate in the activities being observed.
☐Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) **AND/OR**
survey procedures **AND/OR** interview procedures **AND/OR** observations of public behavior.

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(If this statement has been checked, please submit surveys, questionnaires, interview or focus group scripts, observation plans, etc. that will be used in the research)

☐Subjects could **NOT** be identified directly or indirectly through their responses, codes, demographics, or linked to identifiers **OR** subjects could be identified directly or indirectly through their responses, demographics, or codes linked to identifiers **AND** any disclosure of their responses outside the research could **not** reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, reputation, or insurability.

☐**Category 3 – Check the statement(s) below which apply to this research:**

☐Research is **NOT** exempt under Category 2 above.

☐Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) **AND/OR** survey procedures **AND/OR** interview procedures **AND/OR** observations of public behavior. **(If this statement has been checked, please submit surveys, questionnaires, interview or focus group scripts, observation plans, etc. that will be used in the research.**

☐Subjects are elected or appointed public officials or candidates for public office **OR** federal statute(s)
require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐**Category 4 – Check the statement(s) below which apply to this research:**

☐Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

☐All material used to conduct the research exists at the time of IRB submission and no on-going **OR**
prospective collection of material will occur.

☐Sources of the data and/or material are publicly available **OR** information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Please submit data collection/extraction sheets and/or a list of variables or data elements that will be ACCESSED AND COLLECTED.

☐**Category 5 – Check the statement(s) below which apply to this research:**

☐The project is a research or demonstration project.

☐The project is conducted by or subject to the approval of department or agency heads.

☐The project is designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐The program(s) under study must deliver a public benefit (e.g., financial or medical benefits as provided
under the Social Security Act) or service (e.g. social, supportive, or nutritional services as provided under the Older Americans Act).

☐The project is conducted pursuant to specific federal statutory authority.

☐The project has no statutory requirements for IRB review.

☐The project does not involve significant physical invasions or intrusions upon the privacy interests of subjects.

☐This project has an authorization or concurrence from the funding agency (**Please attach a copy of the authorization or concurrence**).

☐**Category 6 – Check the statement(s) below which apply to this research:**

☐Research involves taste and food quality evaluation or is a consumer acceptance study.

☐Wholesome foods without additives are consumed **OR** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe **OR** a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

SECTION 4: CATEGORIES OF RESEARCH THAT MAY BE REVIEWED THROUGH EXPEDITED PROCEDURES

A. Eligibility for Expedited Review:

1. Will this research involve prisoners as subjects?

   ☐No – Answer must be **NO** to be eligible for expedited IRB review.

   ☐Yes - **Skip to Section 5. Research involving prisoners is not eligible for expedited review.**

2. Would identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing?

   ☐No

   ☐Yes - Describe protections that will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal:

3. Is this classified research involving human subjects?

   ☐No - Answer must be **NO** to be reviewed by PIRB.

   ☐Yes - **Skip to Section 5. Research involving classified research is not eligible for expedited IRB review.**

B. Eligibility as Minimal Risk Research:

Will this research be minimal risk?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

☒No - **Skip to Section 5. Research that is greater than minimal risk is not eligible for expedited review.**

☐Yes – Answer must be **YES** to be eligible for expedited IRB review.

C. Expedited Categories:

Please identify the expedited category or categories that apply to your research. If your research does **NOT** fit within any of the categories below, then please **STOP and Skip to Section 5.**

1. ☐Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). (b) Research on medical devices for which (i) an investigational device exemption application (21CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. ☐Collection of blood samples by finger stick, heel stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects,

the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. ☐Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not moreinvasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with acceptable prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. ☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. ☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as for medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Please submit data collection/extraction sheets and/or a list of variables or data elements that will be ACCESSED AND COLLECTED.

6. ☐ Collection of data from voice, video, digital, or image recording made for research purposes.

7. ☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some

research in this category may be exempt from the HHS regulations for the protection of human subjects 45CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

SECTION 5: AUTHORIZED STUDY PERSONNEL

List all AUTHORIZED STUDY PERSONNEL: Authorized study personnel are research personnel who are directly involved in conducting research with human subjects, or who are directly involved with the handling of identifiable private information related to those subjects, including protected health information, in the course of a research project. PLEASE NOTE: Authorized study personnel are required to complete CITI Human Subjects Protection Course, the CITI COI Mini-Course and provide a current CV or resume. The Peoria IRB recognizes CITI certifications to be valid for 3 years. To complete our education series, please refer to the CITI website at: https://www.citiprogram.org/

Name	**Degree**	**Role(s)**	**Date of CITI Training Completion**	**Date of CITI COI Mini-Course Completion**	**CV on File with IRB within 3 years? Y or N**	**Conflict of Interest Disclosure Form submitted with this study? Y or N**	**Will this person be involved in the consenting process? Y or N**
Example: John Doe	*MD*	*Principal Investigator*					Y
Dominique Fons	MD	Principal Investigator	June 5, 2017	6/5/2017	Y	Y	Y
Kari Beth Watts	DO	Investigator	07/12/2015	07/12/2015	Y	Y	Y
Shane Rainey	DO	Investigator	08/2014	08/2014	Y	Y	Y
Holly Kapraun	DO	Investigator	02/02/2016	02/02/2016	Y	Y	Y
Gary Knepp	DO	Investigator	01/29/2017	01/29/2017	Y	Y	Y
Jesse Ford	DO	Investigator	10/8/2017	10/8/2017	Y	Y	Y

SECTION 6: RESEARCH SUMMARY

Summary of Protocol: Please summarize your research protocol within 2-6 pages and submit into IRBNet. The research summary can be submitted as a separate document instead of within this form. Please submit the protocol in addition to your research summary. You must address all of the following points. YOUR PROPOSAL WILL BE RETURNED IF THE SUMMARY IS NOT ORGANIZED AS FOLLOWS:\

Please see Appendix A- Research Protocol for a summary of this information.

1. Objectives of this project. Also include a hypothesis to be tested.
2. Background. Provide the scientific background information with references that provide the rationale for the project or the device to be used.
3. Study Method. Include study design (controlled, open, etc.), treatments, procedures or measurement on human subjects, as well as statistical methods, if appropriate. If this is a questionnaire study, include the instrument to be used. If this study involves data collection, please include a data collection tool.
4. Inclusion/Exclusion Criteria for Subjects.
   Population and Sample:
   A. Estimated number of subjects:
   B. Age (inclusive)
   C. Sex (estimate M:F ratio)
   D. Describe the population from with which the sample will be drawn:
5. Include the procedure to recruit subjects and any advertising materials:
6. Theoretical risks and potential benefits to: (1) research subjects, (2) others:
7. Alternative treatments to patients (if applicable).
8. Describe subject compensation, including plans for prorating.

SECTION 7: USE OF DRUGS, BIOLOGICS (if research does not involve the use of drugs or biologics, **skip to Section 8**)

A. Use of Drugs or Biologics:

1. Does this research involve the following test articles:

☒None - **Skip to Section 8.**

☐FDA-approved drug(s)/biologic(s)

☐"Off-Label" use of an approved drug (using an FDA-approved drug for an unapproved use)

☐Investigational (Non-FDA approved) drug(s)/biologic(s)

2. Please indica**te the status of the drug or biologic being used in this study:**

☐Use of the drug in this study is exempt from the requirements for an Investigational New Drug (IND) application. (Please attach a copy of the FDA Determination Letter.)

☐I am seeking an exemption from the requirements for an IND. (Please complete Request for an

Exemption from the Requirement of an IND by answering the following questions. ***If your trial does not satisfy all of the five exemption requirements above, you must submit an IND to the FDA prior to beginning your study.***

The FDA has clearly stated that this determination should be made by the physician proposing the clinical investigation.

a. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug
   ☐True
   ☐False

b. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product
   ☐True
   ☐False

c. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product
   ☐True
   ☐False

d. The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR 56) and the requirements for informed consent (21 CFR 50)
   ☐True
   ☐False

e. The investigation is conducted in compliance with the requirements of 21 CFR 312.7 (Promotion and sale of investigational drugs)
   ☐True
   ☐False

☐Use of the drug in this study requires an Investigational New Drug (IND) application.
   a. Provide IND number:
   b. Attach one of the following to allow verification of the IND number:
      IND approval letter from the FDA, IND number printed on sponsor's protocol, OR a letter from the sponsor.

☐The study protocol involves the use of an Investigational New Drug (IND), but the IND will not be administered at this study site.

3. **Is the manufacturer of the drug sponsoring this trial?**
☐No
☐Yes

4. **Is the investigator the IND holder (sponsor)?**
☐No
☐Yes - Attach a copy of the FDA letter approving the IND application.

B. An investigator's brochure (IB) or FDA-approved product information (package insert) must be submitted with this application. Please indicate which document is being submitted:
☐Investigator's brochure (IB): required when the drug's status is investigational
☐FDA-approved product information (package insert)

C. Address how the study drug will be handled at each site:

☐Investigational drug service (IDS) will be responsible for the storage and handling of study drug.
☐The investigator will be responsible for the storage and handling of the study drug.

1. Describe how disposition of the study drug will be controlled, including procedures for storage, dispensing, limiting access to individuals listed as study personnel on the protocol and accountability.
2. Indicate where the drug will be stored.
3. Provide a contact person at the site who can verify the institution's approval of these procedures.

Drug accountability records along with storage and dispensing of study drug are subject to audit.

D. Does the sponsor of this research require compliance with the ICH-GCP guidelines?
☐No
☐Yes

SECTION 8: USE OF MEDICAL DEVICES (if research does not involve the use of medical devices, **skip to Section 9**)

A. Use of a Medical Device:

1. **Does this research involve any of the following Devices?**
☒None - **Skip to Section 9**.
☐FDA-approved medical device
☐"Off-Label" use of an approved medical device (using an FDA-approved medical device for an unapproved use)
☐The device is a Humanitarian Use Device (HUD)
☐The device is exempt from the requirements for an Investigational Device Exemption (IDE). (Please attach a copy of the FDA Determination Letter.)
☐I am seeking an exemption from the requirements for an IDE. (Please complete Request for an Exemption

from the Requirement of an IDE.

☐The device is a non-significant risk device. (Please attach a copy of the FDA determination letter.)

☐This is a significant risk device.

a. Provide IDE number:

b. Please attach the IDE approval letter or conditional approval from FDA to allow verification of the IDE number and the FDA's risk determination.

2. **Is the manufacturer of the device sponsoring this trial?**

☐No - Indicate the sponsor:

☐Yes

3. **Is the investigator the IDE holder (sponsor)?**

☐No

☐Yes - Attach a copy of the FDA letter approving the IDE application.

4. **A device manual and/or FDA-approved product labeling must be submitted with this application.**

☐Device Manual

☐FDA-approved product labeling

5. **Address how the study device will be handled at each site.**

☐The investigator is responsible for the storage and handling of the study device.

a. Describe how disposition of the study device will be controlled, including procedures for storage, dispensing, limiting access to individuals listed as study personnel on the protocol and accountability.

b. Indicate where the device will be stored.

c. Provide a contact person at the site who can verify the institution's approval of these procedures.

Device accountability records along with storage and dispensing of study device are subject to audit.

SECTION 9: SPONSOR DATA

Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(f) require that each application or proposal for HHS-supported human subject research be reviewed and approved by the Institutional Review Board (IRB).

The IRB's review should ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.

PLEASE NOTE: If grant funding is awarded AFTER IRB approval, the IRB must be informed of the change in funding status via Change in Research.

Please check one of the categories below to designate funding status:

☐The research specified in this protocol will not be funded.
☐The research specified in this protocol may be funded, but no research application/proposal has been submitted. **UICOMP Faculty: Proposal Approval Form (PAF) Number:**
☐The research specified in this protocol is funded by a pharmaceutical/device company.
☐The research specified in this protocol is funded through NIH
☐IL Cancer Care/CCOP Grant (include copy of front page of grant)
☒Other: This research is support by the Caterpillar Faculty Scholar Fellowship- part of which does supply some financial support. No further grants or funding will be used for this research.

SECTION 10: SUBJECT POPULATIONS

PRIMARY SUBJECT POPULATION(S): (Check all that apply)

A. General Populations: Your research summary should justify inclusion of any 'vulnerable' populations. Required supplements will ask for details regarding additional protections or consent processes that would be implemented to address the rights and welfare of vulnerable groups:

☒Healthy Volunteers
☒In-Patient Population
☒Out-Patient Population
☐Employees
☐Students - Specify School: UICOMP
☐Residents/Fellows
☐Cognitively Impaired
☐Non-English Speakers
☐Other:

DHHS-Regulated Vulnerable Populations
☐None **STOP - Skip to Section 11.**
☒Children (Subjects under 18 yrs. of age)
☐Children who are "youth in care" (formerly wards of the state)
☐Prisoners **Prisoner's Vulnerable Population (VP) Supplement must be completed**
☒Pregnant Women, Fetuses, or Neonates **Pregnant Women's Vulnerable Population (VP) Supplement must be completed.**

B. Children Subject Population:

1. **Age Range (check all that apply):**

☒Newborn to 2 years of age **A request for a waiver of assent is expected for the age range of newborn to 6 years of age (*Request in Section 11*).**

☐3-6 Years

☐7-13 Years **Verbal assent is expected for this age range unless a waiver of assent is requested in Section 11. The research should be explained to the minor in age-appropriate terms.**

If the minor verbally assents, the verbal agreement must be documented in the patient notes by the consenting individual.

☐14-17 Years **Written documentation of assent is expected for this age range unless a waiver of assent is requested in Section 11. The research should be explained to the minor in age-appropriate terms and the consent/assent form should be provided or read to the minor. If the minor assents, the agreement must be documented by written documentation on the consent/assent form. The consenting/assenting process must be documented in the patient notes by the consenting individual.**

2. **Please identify which federally-defined category applies to this research and provide the appropriate rationale for the inclusion of children in the chosen research category.**

☒**45 CFR 46.404** (FDA 21 CFR 50.51)

- Research involves no greater than minimal risk to children AND
- Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian

a. Please explain why the research involves no more than minimal risk.
   - OMT is extremely safe and non-invasive, as observed in a RCT by Cerritelli et al. However, as with any medical procedure, OMT carries some risk. Risks associated with the treatments to be used in this study include fatigue, headache, stiffness, tenderness, redness or mild swelling to the area after treatment. If treatment does not work, while patients do not appreciate any benefit, they also do not usually show side effects. Patients who respond to treatment often begin feeling better within a day and then noticing improvement of their original symptoms (in this case, improved feeding).
   - The benefits of OMT can be numerous. Common benefits include reduction of pain, improved range of motion and use of a joint(s), improved flow of body fluids such as blood and lymph, decreased swelling, and improved balance between the sympathetic (fight or flight) and parasympathetic (rest and digest) nervous systems. Benefits can occur immediately after treatment and/or over several days to weeks after treatment. Potential benefits of treatment are improved feeding which includes improved latch of the baby, improved swallow, and reduced pain related to feeding for both mom and baby.

b. Please explain how assent of the child and permission of the parent/guardian will be obtained, and provide justification if the signature of only one parent/guardian will be solicited:
   - Parents will receive information about our study from the lactation specialist caring for them and their child in the way of our OMT Brochure entitled "Osteopathic Manipulative Treatment and Your Baby," which has been included in this IRB submission
   - This brochure will be given to all newborn babies who appear on the lactation rounding list and meet criteria for admission into our study.
   - The nurse or lactation specialist will page a member of the research team who will then consent the parents.
   - Once enrolled in the study, each newborn will be single blinded (to lactation) and randomized to either the treatment or the control group.
   - Signature from one parent will be obtained unless they have waived her parental rights. If the parent is not physically available she/he will be verbally consented.

☐**45 CFR 46.405** (FDA 21 CFR 50.52)

- Research involves greater than minimal risk to children BUT
- Presents the prospect of direct benefit to the individual child AND
- Anticipated benefit justifies the risk AND
- Anticipated benefit versus the risk is at least as favorable as that of alternative approaches AND
- Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian

a. Please explain why the risk is justified by the anticipated benefit to the child:

b. Please explain why the anticipated benefit versus the risk is at least as favorable as that of available alternative approaches:

c. Please explain how assent of the child and permission of the parent/guardian will be obtained, and provide justification if the signature of only one parent/guardian will be solicited:

☐**45 CFR 46.406** (FDA 21 CFR 50.53)

- Research involves greater than minimal risk to children AND
- Presents no prospect of direct benefit to the individual child BUT
- the risk represents a minor increase over minimal risk AND
- Interventions or procedures present experiences that are reasonably commensurate with those inherent in the child's actual or expected medical, dental, psychological, social, or educational situations AND
- Interventions or procedures are likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the child's disorder or condition AND
- Adequate provisions are made for soliciting the assent of the child and the permission of the parent/guardian**.**

a. Explain why the risk represents a minor increase over minimal risk.

b. Please compare the actual or expected medical, dental, psychological, social, or educational experiences of the child subjects with the experiences presented by the research interventions or procedures:

c. Please explain why the interventions or procedures are likely to yield generalizable knowledge about the child's disorder of condition that is of vital importance for the understanding or amelioration of the child's disorder or condition:

d. Please explain how assent of the child and permission of one parent will be Obtained.

☐**45 CFR 46.407** (FDA 21 CFR 50.54)

- Research not otherwise approvable under one of the above categories BUT
- Presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children AND Adequate provisions are made for soliciting the assent of the child and the permission of the parents.

Research in this category must be sent to a federal panel for determination before final IRB approval can be obtained, and the recruitment and enrollment of subjects can begin.

a. Please explain why the proposed research presents an opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:

e. b. Please explain how assent of the child and permission of one parent will be obtained

SECTION 11: INFORMED CONSENT/ASSENT

Please indicate all of the types of consent processes to be used in the research, and submit copies of all relevant documents with this application.

☐Prospective Written Informed Consent
☐Waiver of Informed Consent
☐Waiver of Documentation of Consent
☐Alteration of Consent
☒Parental Permission
☐Waiver of Parental Permission
☐Assent – Written for ages
☐Assent – Verbal for ages
☒Waiver of Assent----For our newborn population

Procedures to Obtain Informed Consent

Request for Waiver of Consent, Alteration of Consent, or Waiver of Documentation

An IRB may (1) approve a consent process that does not include, or alters, some or all of the elements of informed consent, or (2) the IRB may waive the requirement to obtain written consent (called a waiver of documentation), or (3) the IRB may waive the requirement to obtain informed consent entirely.

A. Are you requesting a waiver of informed consent or an alteration of consent under 45 CFR 46.116 (d) for all or part of the research?
☒No
☐Yes

If YES, are you requesting a:

☐Waiver for all of the research Skip to Section B.
☐An alteration of consent - Skip to Sections B & C.
☐Waiver for part of the research Which part?- Skip to Section B.
☐Waiver of documentation of informed consent - Skip to Section D.

Version 3/12/2019
Amended previously on 9/6/2017 for assent of one parent, not two and contact info
Created 6/7/2017

B. Waiver for All of the Research

1. Please provide a written explanation as to why you believe the proposed research (or portion of the research) will present no more than minimal risk to the subjects who participate:
2. Please explain whether or not a waiver or alteration of informed consent would adversely affect the rights and welfare of subjects:
3. Please explain whether or not it would be possible to conduct this research without a waiver or alteration of informed consent:
4. Please explain your plans, when appropriate, for providing any pertinent information to the subjects at a later date (e.g., after their participation in the study):

C. Alteration of Consent

Please describe in detail how you wish to alter the consent process and justify the need for this alteration:

D. Waiver of Documentation of Informed Consent

Please indicate which of the following justifications is being used to request a waiver of documentation and then provide protocol specific justification for the waiver under either criteria:

☐The only record linking the subject and the research would be a signed consent document, the principal risk or harm of the research would be a breach of confidentiality, and each subject will be asked whether they want documentation linking themselves and the research and the subject's wishes will govern. Explanation:

☐The research involves no more than minimal risk or harm to the subject and involves no procedures for which written consent is normally required outside of the research context. Explanation:

Procedures to Obtain Assent

A. Assent will be solicited from:

☒All children

☐A sub-group of children (request waiver of assent in **Section B & C**)

☐None of the children (request waiver of assent in **Section B & C**)

B. I am requesting waiver of the requirement for assent from:

☒All children

☐A sub-group of children (request waiver of assent)

C. Indicate justification for waiving assent for these children: (Check all that apply)

☐The intervention or prospect involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child/children and is *available only in* the context of the research.

☒The children are not capable of providing assent based on the age, maturity, or psychological state.

☐The capability of the children is so limited that they cannot reasonably be consulted.

SECTION 12: HIPAA COMPLIANCE

A. For your research, will you **ACCESS OR COLLECT** Protected Health Information (PHI)?

☐No – **Skip to Section 13.**
☒Yes

For exempt or recruitment purposes

B. Please indicate the authorization processes that will be used in the research.

☒Waiver/Alteration of Authorization for identifying potential subjects for the recruitment phase
A waiver/alteration is a request to forgo the authorization requirement based on the fact that the use and/or disclosure of PHI involves minimal risk to the subject's privacy and the research cannot be practically done without this waiver/alteration and access to/use of PHI. ***Complete C1 a.***

☐Waiver/Alteration of Authorization for MAIN research project
Remember that if you are seeking a waiver/alteration of Authorization for other than recruitment purposes, you should request the parallel waiver/alteration of informed consent in your research protocol application submitted for initial review. ***Complete C1 b.***

☐Patient Authorization
A patient authorization is a document, signed by the subject that gives the researcher permission to use/disclose PHI collected during the research study for defined purposes. An Authorization Form may be a separate document or be combined with the Informed Consent Document.

C. **Waiver/Alteration of Authorization -** Complete this section to request a waiver of authorization for **identifying potential subjects for the recruitment phase, the entire research protocol, for a portion of the research**, or to request an **alteration of authorization process,** such as no signed documentation.

1. Describe the identifiable health information that will be used under these waivers: See below under B

a. **Partial waiver** of HIPAA Authorization for screening purposes (what variables will be ACCESSED through a query or review to determine patient eligibility for the research?):
b. **Waiver of HIPAA Authorization for the MAIN** research project (what variables will be COLLECTED and maintained for the research project/):

- We will need access to the following PHI
  a. Name
  b. DOB
  c. Sex
  d. MRN
  e. Mother's Name and DOB
  f. Room Number while in the hospital
  g. Phone number
  h. Address (street, city, state, and zip code)
  i. Clinic schedule for lactation
  j. Inpatient rounding list for lactation

PLEASE NOTE: You will be limited to ACCESSING (1a) and COLLECTING/MAINTAINING (1b) the data listed here. Please ensure this list includes EVERYTHING you will need to perform

your study, (i.e. name, MRN, phone number, address, clinic schedule, etc.)

2. Criteria for a Partial Waiver/Alteration of HIPAA Authorization for screening purposes (complete if B box 1 is marked above)

    a. Explain how the use and disclosure of the information presents no more than minimal risk to the privacy of the individual:

    b. Describe the plan to protect the identifiers from improper use and disclosure (i.e., where will the identifiers will be stored and who will have access):

    c. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or if such retention is required by law, please provide this information as well

    d. Explain why the research could not be practicably conducted without the alteration or waiver:

    e. Explain why the research could not be conducted without access to and use of the PHI:

    f. The Privacy Rule requires that when a waiver is granted that only the minimum necessary health information be ACCESSED AND COLLECTED. Therefore, provide justification that the PHI being requested is the minimum necessary information reasonably necessary to accomplish objectives of the proposed research:

3. Criteria for Waiver/Alteration of HIPAA Authorization for the **MAIN** study (complete if B box 2 is marked above)

    a. Explain how the use and disclosure of the information presents no more than minimal risk to the privacy of the individual: This information will be used by the research team only to 1) identify if the newborn qualifies for admission into the study, 2) identify the correct patient prior to beginning treatment.

    b. Describe the plan to protect the identifiers from improper use and disclosure (i.e., where will the identifiers will be stored and who will have access): The information will be stored in a password protected document that will be only available to the researchers on the team, all of whom has undergone CITI training. When possible (ie: for the statistician) the information will be de-identified.

    c. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or if such retention is required by law, please provide this information as well: All PHI will be held for the duration of the study so that if there are any adverse outcomes we can see if the participant was in the control vs. treatment group. This data will be held as long as deemed necessary by UnityPoint Health and/or OSF St. Francis Medical Center.

    d. Explain why the research could not be practicably conducted without the alteration or waiver: Without this PHI we can not 1) identify if the newborn qualifies for admission into the study, 2) identify the correct patient prior to beginning treatment.

    e. Explain why the research could not be conducted without access to and use of the PHI: Without this PHI we can not 1) identify if the newborn qualifies for admission into the study, 2) identify the correct patient prior to beginning

treatment.

f. The Privacy Rule requires that when a waiver is granted that only the minimum necessary health information be ACCESSED AND COLLECTED. Therefore, provide justification that the PHI being requested is the minimum necessary information reasonably necessary to accomplish objectives of the proposed research: We require this PHI so that our research team can: 1) identify if the newborn qualifies for admission into the study, 2) identify the correct patient prior to beginning treatment.

SECTION 13: RESEARCH RECORDS

1. Indicate the source(s) from which data will be collected:

☐**Data containing no health information** **(Skip to Section 14).**
☒Physician/Clinic Records
☐Lab, Pathology and/or Radiology Results
☐Biological Samples
☐Interviews/Questionnaires
☐Photographs
☐Internet Research Data
☒Hospital/Medical Records (in and outpatient)
☐Mental health records
☐Psychotherapy notes*
☒Data previously collected for research purposes
☐Audio/Video Recordings
☐Billing Records
☐School Records
☐Information related to drug abuse, alcoholism or alcohol, testing for or infection with human immunodeficiency virus (HIV)*
☐Other: Describe:

Please contact the IRB for assistance.** **This information is considered "sensitive information." Any sensitive information collected for this study may be more protected than other information collected for this study. For this reason, you may be asked to sign additional forms if multiple disclosures of the sensitive information are needed.

2. Indicate the identifiable elements that will be collected:

☒ Names	☐ Social Security Numbers	☐ Device Identifiers/Serial Numbers
☒ Phone Numbers	☒ Medical Record Numbers	☐ Web URLs
☒ Street Address	☐ Health Plan Numbers	☐ IP Address Numbers
☒ City or State	☐ Account Numbers	☐ Biometric
☒ Zip Code	☐ Fax Numbers	☐ Vehicle ID Numbers
☐ E-mail Address	☐ License/Certificate Numbers	☐ Facial Photos/Images

☐ Financial Account Information (including student ID)

☐ All Elements of Dates (except year) for dates directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age
☒Date of Birth
☐Any Other Unique Identifier – Specify:
☐None of the Identifiers Listed Above

*If **social security numbers** will be collected, explain why they are necessary and how will they be used:
**Biometric identifiers are observable biological characteristics which could be used to identify an individual (i.e., fingerprints, iris/retina patterns, and facial patterns).

3. **Will any identifiable data, or coded data, where a master list to the codes exist, be retained for future studies or entered into an existing databank as a result of the research?**
☒No – **Please skip to Question 4**
☐Yes - If **YES**, **complete a-k.**

a. Describe what data will be retained or entered into an existing databank.
b. Will identifiable or coded data **from children/minors** be retained for future research or entered into an existing database?
☐No
☐Yes - Please describe the procedures for soliciting consent from subjects that "age-up" to use their identifiable or coded data for future studies or to retain in an existing databank. Please provide an "age of majority" consent.

c. Will the information collected and stored with the data include individually identifiable health information subject to the HIPAA Privacy Rule requirements (45 CFR Parts 160 and 164)?
☐No
☐Yes - If **YES**, please describe the protections in place to maintain confidentiality and prevent an inadvertent breach of confidentiality.

d. Describe the purpose of retaining/banking the data?

e. Will any information/results of this research be shared with the subjects during or after the current research is completed?
☐No
☐Yes - If **YES**, please explain:

f. Please indicate which risks of participation are present with the retention or banking of data (mark all that apply):

☐Identification
☐Inadvertent or inappropriate use of individually identifiable information (breach of confidentiality)
☐Freedom of Information Act (data becomes a government record)
☐Law enforcement access (Example: genetic information may be used to link a subject, or a family member, to a crime)
☐Risks to specific groups, populations, communities (Example: redlining neighborhoods at risk for lead poisoning)
☐Risks related to return of research results (Example: subject misunderstanding of the clinical

importance of results in relation to individual cases)

g. Where and for how long with the specimens be stored?

h. Will the principal investigator "own"/be custodian of the data?
☐No - If **NO,** please explain who will "own"/be custodian of the data:
☐Yes

i. Will data be shared with others internal to your institution?
☐No
☐Yes - If **YES**, explain how and with whom data will be shared, and if the data will include codes or identifiers (i.e., describe the mechanism for sharing):

j. Will data be shared with investigators outside your institution?
☐No
☐Yes - If **YES**, explain how and with whom data will be shared, and if the data will include codes or identifiers (i.e., describe the mechanism for sharing):

k. Has all of the above information been included in the consent document (i.e., purpose, type of information stored, identifiability, for how long, share information back, re-consent for future research uses, confidentiality safeguards, risks related to potential breach of confidentiality, etc.)?
☐No
☐Yes

4. Will any specimens be stored for the current or future (planned or unplanned) research?
☒No – **Please skip to Section 14**
☐Yes - If **YES, complete a-l.**

a. Describe the specimen(s).

b. Will specimens from children/minors be banked for current or future research?
☐No
☐Yes – Please describe the procedures for soliciting consent from subjects that "age-up" during the course of the current study or for future studies. Please provide an "age of majority" consent.

c. Will the information collected and stored with the data include individually identifiable health information subject to the HIPAA Privacy Rule requirements (45 CFR Parts 160 and 164)?
☐No
☐Yes - If **YES**, please describe the protections in place to maintain confidentiality and prevent an inadvertent breach of confidentiality.

d. Describe the purpose of storing the specimen(s)?

e. Will any information/results of this research be shared with the subjects during or after the current research is completed?
☐No
☐Yes - Please explain:

f. Please indicate which risks of participation are present with the specimen storage (mark all that apply):

☐Identification
☐Inadvertent or inappropriate use of individually identifiable information (breach of confidentiality)
☐Freedom of Information Act (data becomes a government record)
☐Law enforcement access (Example: genetic information may be used to link a subject, or a family member, to a crime)
☐Risks to specific groups, populations, communities (Example: redlining neighborhoods at risk for lead poisoning)
☐Risks related to return of research results (Example: subject misunderstanding of the clinical importance of results in relation to individual cases)

g. Where and for how long with the specimens be stored?

h. Will the specimen(s) be destroyed after the current research purpose is served?

☐No - If **NO**, how will the specimen(s) be stored after use in the current research is completed (i.e., no identifiers, indirect identifiers, or direct identifiers)?
☐Yes

i. Will the principal investigator "own"/be custodian of the specimen(s)?

☐No - If **NO**, please explain who will "own"/be custodian of the specimen(s):
☐Yes

j. Will specimen(s) be shared with other investigators internal to your institution?

☐No
☐Yes - If YES, explain how and with whom specimen(s) will be shared, and if the specimen(s) will include codes or identifiers (i.e., describe the mechanism for sharing):

k. Will specimen(s) be shared with investigators outside your institution?

☐No
☐Yes - If **YES**, explain how and with whom specimen(s) will be shared, and if the specimen(s) will include codes or identifiers (i.e., describe the mechanism for sharing):

l. Has all of the above information been included in the consent document (i.e. purpose, type of information stored, identifiability, for how long, share information back, re-consent for future research uses, confidentiality safeguards, risks related to potential breach of confidentiality, etc.)?

☐No
☐Yes

SECTION 14: DATA SECURITY PLAN

PLEASE NOTE: Flash drives, or any laptops, portable hard drives, flash drives, USB memory sticks, smart phones, mp3 players, or similar portable storage devices, **must be encrypted.** For encryption software applications other than those supported by the UI Health System, **the investigator must provide the IRB with documentation confirming the software's compliance with the HITECH Act standards.**

1. Outline the process for data collection (Paper or electronic medical records, paper forms completed at a site,

local electronic data capture systems or central web based systems, etc.)

- Data collection will occur through accessing the patients' chart to obtain LATCH scores throughout the study. This will be done through computers and laptops that have been encrypted through UnityPoint Health and/or OSF St. Francis Medical Center- no personal laptops will be used.
- Paper documentation will be held in a LOCKED cabinet in the PI office and will be scanned into the chart after 2 weeks. Once it is scanned into the chart, the paper copy will be destroyed.

2. How will data be collected from source documents and incorporated into the research record (paper case report forms, eCRFs, patient diary, eDiary, patient monitoring device, etc.)
   - Data will only be pulled from EPIC and only the patients' LATCH score will be recorded.
3. Describe the methods of storage of data (i.e., electronic, hard copy, specimens, artifacts, etc.)
   - A secure database of those enrolled in the study, which arm of the study they are enrolled, and their de-identified number will be stored in REDCap or Qualtrics or similar database
   - Data collection will occur through accessing the patients' chart to obtain LATCH scores throughout the study. This will be done through computers and laptops that have been encrypted through UnityPoint Health and/or OSF St. Francis Medical Center - no personal laptops will be used.
   - Paper documentation will be held in a LOCKED cabinet in the PI office and will be scanned into the chart after 2 weeks. Once it is scanned into the chart, the paper copy will be destroyed.
4. Describe where each method of data will be stored and how each method will be maintained in a secured manner (i.e., encryption, password protection, use of Qualtrics or REDCap, etc.)
   - A secure database of those enrolled in the study, which arm of the study they are enrolled, and their de-identified number will be stored in REDCap or Qualtrics or similar database
   - Paper documentation will be held in a LOCKED cabinet in the PI office and will be scanned into the chart after 2 weeks. Once it is scanned into the chart, the paper copy will be destroyed.
   - REDCap or Qualtrics or similar database will be used for data compilation. Members of the research team will have access
   - Statistician will have access to de-identified data.
5. Describe who will have access to each method of data and how each method of data will be transferred to any collaborators.
   - The medical students and attendings that are CITI certified and are members of the research team will have access to:
     - REDCap or Qualtrics or similar database
     - EPIC chart
     - Paper documentation
     - They will see PHI and will not be blinded
   - The medical students and attendings who are not CITI certified OR are not members of the research team will be have access to:
     - EPIC chart, when appropriate for direct patient care
     - Will document in the paper chart and then will hand over the information to the research team.
     - May request access to the paper documentation
   - Support staff for this research project, including but not limited to the statistician will have access to:
     - REDCap or Qualtrics or similar database to help compile data

6. Describe the plans for destruction/removal of identifiers. (Identifiers should be removed at the earliest opportunity.) ***(If you requested a partial waiver of HIPAA Authorization for screening purposes in Section 12 by marking Box 1, please mark OTHER and explain that identifiers will be destroyed after data collection.)***

☒End of study
☐ Years after study completion
☐Other (specify)

Consider the following when answering item 6:

- The consent document must describe if or when and how the data will be de-identified or destroyed, or if identifiers will be maintained.
- Investigator must adhere to sponsor requirements or procedures outlined in the grant, if applicable.
- If the research involves a waiver of authorization, to conform to the HIPAA regulations accounting requirements related to a waiver of authorization [Privacy Rule, 45 CFR Part 164]; please indicate that records (including the documentation of waiver approval) will be maintained for a minimum of 6 years following study completion.

SECTION 15: SUBJECT RECRUITMENT

1. How will potential subjects be initially identified for this research study?

☒PI/collaborators will recruit their own patients (face to face)

☒Advertisements/media. ***All material must have IRB approval.*** **See attached**

☐Registry or bank (either pecimens or data) Is it an IRB-approved registry?
☐No
☐Yes - If **YES**, IRBNet #:

☐Query of records (e.g.: medical, employment, school)***(You MUST request a partial waiver of HIPAA Authorization for screening purposes in Section 12, B box 1 by completing C1a and C2.)***

☒Patient schedules (e.g. clinic, surgery, admission) ***(You MUST request a partial waiver of HIPAA Authorization for screening purposes in Section 12, B box 1 by completing C1a and C2.)***
- We will use lactation outpatient schedule and lactation's rounding list for recruitment.

☐Other (specify):

2. Initial Contact

Indicate who will make the initial contact with the potential subjects for the purpose of recruiting them for the research.

☒Principal Investigator
☒Co-Investigators
☒Other Authorized Study Personnel

Newborns that are on the lactation rounding list and that meet criteria of our study will be given this brochure and offered admission into the study by the nurse or the lactation specialist caring for the newborn. If the parent is interested in participation in the study, the nurse or lactation specialist will page a member of the research team who will then consent the parent.

3. Describe how, where, and when subjects will be recruited for the research

   Newborns that are on the lactation rounding list and that meet criteria of our study will be given this brochure and offered admission into the study by the nurse or the lactation specialist caring for the newborn. If parent is interested in participation in the study, the nurse or lactation specialist will put in a consult to the OMT and page a member of the research team who will then consent the parent.. All subjects will be recruited from UnityPoint Health Methodist and/or OSF St. Francis Medical Center

4. Will any identifiable data obtained at recruitment, including screening data from records, be retained without consent from subjects who failed to qualify or declined to participate?

   ☒No
   ☐Yes - Describe and justify:

SECTION 16: PRECAUTIONS AND SAFEGUARDS

1. If there is a reasonable possibility that in the course of the research, it may come to the attention of the investigator or research team that a subject is having suicidal thoughts, please provide a description of how the investigator will handle this. ☒NA

NOTE: If the research does not involve physical or therapeutic intervention with subjects, or subject trauma or distress is not an anticipated risk, this portion of the consent document/application may not be applicable.

2. Please describe any provisions for providing medical care to subjects in case of an accident, injury, or complications related to the research procedures. ☐ NA
   - Risk to the newborn from receiving OMT is minimal.
   - The attendings providing care to the newborns all have newborn admitting privileges and would be expected to either provide emergent care immediately themselves or call for assistance.
   - UnityPoint Health Methodist and/or OSF St. Francis Medical Center has onsite 24/7 neonatology specialists as well.

3. Is the language explaining provisions for medical care in the consent document?
   ☐No
   ☒Yes
4. Will there be a data safety monitoring board (DSMB)/ Data Monitoring Committee (DMC) assigned to this study?

☒No - If **NO**, skip to Question 5.
☐If **YES,** describe the DSMB/DMC structure and meeting plan (for example: how often they will meet) and how the findings will be reported back to the individual investigators and the IRBs.

5. Does the research protocol have a data and safety monitoring plan?

☐Not Applicable. All of the following criteria are met: research is minimal risk, does not involve physical or therapeutic intervention with subjects, subject trauma or distress is not an anticipated risk and the sponsor does not require a monitoring plan.
☒No - If **NO**, please describe the methods to be used in this study to monitor the ongoing safety of the subjects (please refer to the paragraph below for information to be provided.)
☐Yes - If **YES**, please describe the data safety monitoring plan in detail here:

Data and safety monitoring plan should contain the following: safety information (including serious adverse events) to be collected, methods for collecting information (e.g., case report forms, at study visits, by telephone calls), frequency of data collection, frequency of cumulative safety data reviews, responsibility for oversight and reporting of safety data, if applicable, statistical tests for analyzing the safety data to determine if harm is occurring when not using DSMB and, if applicable, conditions that trigger an immediate suspension of the Research.

- Built in to our protocol is a way for any practitioner who is involved in the direct patient care of any of our subjects to reach out to the research team to request documentation of the procedures performed. This would reveal if the subject was in the control or treatment arm.
- Any inquiry of this sort will be further investigated by the research team, including but not limited to:
    - Inquiring about adverse reaction
    - Determining if the participant was in the control or treatment arm
    - Further investigation as deemed necessary if the participant was in the treatment arm
- Because there is a paucity of research in this area, all report adverse reactions will be taken seriously and investigated
- Hazard ratios will be assessed

6. Is this a multi-center trial?
☐No
☒Yes

7. Is your site the lead site or serving as the data coordinating center?
☐No-----NA
☐Yes - If **YES**, describe the plan for managing and communicating the following information among the multi-center sites:
- Unanticipated problems involving risks to subjects or others-The PI is available 24/7 for discussion of any unanticipated outcomes. The PI is responsible for communicating all outcomes to the IRB.
- Interim results-Reported yearly as part of scholarly work.
- Protocol modifications-The PI sends out updates to the research team when any updates occur to the protocol. This has been clarified through meetings and emails with the research team.

8. Will you be applying for a Certificate of Confidentiality?
☒No

☐No - Certificate already in place.
☐Yes - If **YES**, please include this information (as well as any exceptions — for example: mandatory reporting, threats of self-harm) in the consent document. When the IRB approves your research, submit a request for a Certificate of Confidentiality to the appropriate federal agency. After you receive the Certificate of Confidentiality, you must submit an Amendment to the IRB and receive IRB approval. Research subjects may only be enrolled after IRB approval of the Amendment and Certificate of Confidentiality.

9. Does anything you are going to do have any effect on fetal development?
☐Unknown
☒No. This will be performed on newborns.
☐Yes
If the answer is **YES** or **UNKNOWN**, briefly describe, including a statement in the consent form for a woman of child-bearing potential (if she is presently pregnant or should she become pregnant) describing the risks involved and indicating the safeguards you will employ.

10. To your knowledge, has this protocol been reviewed and subsequently disapproved by any IRB?
☐No
☒Yes - If **YES**, please provide the details of the disapproval including the reviewing IRB name, the date of review, the issues resulting in disapproval, and how these issues have been resolved. When the first version of the protocol was submitted, clarification of the protocol and OMT techniques were necessary to inform the IRB about the safety of the techniques. The IRB then TABLED WITHOUT ACTION. The PI and another Investigator met with the IRB and answered all questions AND a video demonstration of the techniques was provided. IRB approval was obtained after this clarification.

SECTION 17: COMPENSATION AND COSTS OF PARTICIPATION

1. Will subjects receive any compensation (for example: money, gifts, or gift certificates) before, during, or after participation in the study?
☒No - If **NO,** please go to number 5.
☐Yes ☐ Monetary (total amount:) ☐ Non- Monetary ☐Both

If YES, this information must be outlined in the consent document.
If monetary payments total $600+/calendar year, the subjects' social security numbers and addresses must be collected for IRS reporting purposes. The consent form should include this information.

2. If compensation will be given, please describe whether it is compensation for travel expenses, for time, for both, or for something else:
☐For travel expense
☐For time
☐For both
☐Other:

3. Indicate whether compensation will be provided in cash, via check, or as gift cards:
☐Cash
☐Check
☐Gift Card – Type (VISA, Amazon, food, etc):

4. Describe in detail how and when compensation will be provided:
   Will subjects be compensated per session/task and/or will their compensation be pro-rated?
   ☐No
   ☐Yes - If **YES,** please provide detail regarding the compensation per session/task and/or pro-ration schedule:

5. List what research-related expenses are a) provided for free and b) not being covered by the research (e.g., research-related procedures, additional clinic visits, longer hospitalization period or extra tests related to the research). Include estimated amounts for any expenses not being covered, if possible:

   ☒There will be **NO** expenses incurred as a research participant in this study.

6. Does this study provide payments in exchange for referrals of potential participants (finder's fees) or payments designed to encourage or accelerate recruitment by being tied to the rate or timing of enrollment (bonus payment) to individuals **OR** to institutions?
   ☒No
   ☐Yes - Please describe:

SECTION 18: CONFLICT OF INTEREST

Please complete the Conflict of Interest Disclosure Forms located in the IRBNet Forms Library.

- Non-sponsored minimal risk studies: ***Non-Sponsored Conflict of Interest Disclosure Form* (NSCOIDF)**. The PI may submit one form on behalf of the entire research team.
- Sponsored research OR Non-sponsored greater than minimal risk research: ***Part I: Significant Financial Interest Disclosure Form* (SCOIDF).** Each Authorized Study Personnel, listed in Section 5 of this form, must sign an individual SCOIDF.

As Principal Investigator, I understand and accept responsibility for ensuring the safety and welfare of human subjects who participate in the proposed research study. I certify that all Authorized Study Personnel, including myself, co-investigators and study coordinators, have completed required training on human subjects protections. I agree to a continuing exchange of information with the IRB including the requirements to (i) obtain IRB approval before making non-emergency changes/revisions to the protocol, (ii) provide progress reports to the IRB at their request (and at least annually), and (iii) report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.

☒Please mark this box to certify your acknowledgement of the statements listed above.

Please send all correspondence to:
Site Name: UnityPoint Health Methodist- Family Medical Center
Attention: Dominique Fons, MD
Email: Dominique.Fons@unitypoint.org
Phone: (309) 672-4221
Fax: (309) 672-4790

SECTION 19: SUBMISSION CHECKLIST

IRB Exemption:

☐Project/Protocol Review Form
☐Protocol summary (must follow outline in section 6 of this form)
☐Responsibilities of Investigators Form
☐Non-sponsored Conflict of Interest Disclosure Form (PI may complete on behalf of Authorized Study Personnel listed in Section 5 of this form)
☐Any applicable advertising, **grant proposals**, etc. **NA**
☐Current CITI certifications and current CV for all those listed in section 5 of this form, if not already submitted to the IRB.
☐Any applicable questionnaires, surveys, data extraction sheets-----See Appendix for Protocol, Informed Consent, OMT Brochure, and Risk-Benefits and Information about OMT Handout

Expedited Review:

☐Project/Protocol Review Form
☐Informed Consent (if applicable)
☐Protocol Summary (must follow outline in section 6 of this form)
☐Responsibilities of Investigators Form
☐Conflict of Interest Disclosure Form (for each Authorized Study Personnel listed in Section 5 of this form)
☐Full Protocol (if applicable)
☐Any applicable advertising, **grant proposals**, etc.
☐Current CITI certifications and current CV for all those listed in section 5 of this form, if not already submitted to the IRB.
☐Any applicable questionnaires, surveys, data extraction sheets

Full Review:

☒Project/Protocol Review Form
☒Informed Consent, please be sure the footer includes a version date
☒Protocol Summary (must follow outline in section 6 of this form)
☒Responsibilities of Investigators Form
☒Conflict of Interest Disclosure Form (for each Authorized Study Personnel listed in Section 5 of this form)
☒Full Protocol
☐Investigator's Brochure (if applicable)
☐Device Technical Manual (if applicable)
☒Any applicable advertising, **grant proposals**, etc.
☒Current CITI certifications and current CV for all those listed in section 5 of this form, if not already submitted to the IRB.
☒Any applicable questionnaires, surveys, data extraction sheet

Appendix A- Research Protocol

Objective: The objective of this project is to see if Osteopathic Manipulative Treatment (OMT) as an adjunct protocol to lactation support for infants with feeding dysfunction improves outcomes. Null hypothesis: Term newborns with feeding dysfunction do not improve with the addition of OMT compared to lactation support. Primary Question Alternative: In term newborns with feeding dysfunction, OMT added to lactation support will significantly improve feeding outcomes.

Background. Osteopathy, founded by Andrew Taylor Still, MD, adds manual medicine, which stresses the importance of structure and function, to pre-existing medical philosophy and education. Doctors of Osteopathy (DOs) use Osteopathic Manipulative Treatment (OMT) to treat somatic, or bodywork, dysfunction which can include one or multiple body systems, such as muscular, skeletal, arthrodial, vascular, lymphatic, myofascial, connective tissue, or visceral (organ). Doctors of Osteopathy use OMT to treat somatic dysfunction which will improve structure and in turn, improve function. There are an array of techniques of therapy used by DO's, the type of treatment based on the diagnosed dysfunction, practioner comfort, and the needs/limitations of the patient.

Nipple feeding requires a complex set of actions to coordinate suck and swallow. There is a three phase process including oral, pharyngeal, and esophageal phases. Effective oral and pharyngeal phases depend on normal function of the intrinsic muscles of the tongue as well as the extrinsic stabilizing muscles. Normal feeding is also dependent upon action of the Vagus, Glossopharyngeal, and Hypoglossal Nerves and therefore normal anatomy of the jugular and hypoglossal foramen.

Research has shown there are common physiological dysfunctions/cranial strains associated with infant labor and delivery that may impair feeding function through abnormal structure affecting the muscles and/or nerves needed for normal suck and swallow function.

Past studies such as Dr Fraval's 1998 pilot study on osteopathic treatment of infants with a suckling dysfunction have found OMT efficacious in conjunction to lactation support in infants with feeding dysfunction. Other studies on OMT in newborns have found the practice to be safe, cost effective, and shown to decrease length of stay.

1. Cerritelli F, Cicchitti L, Martelli M, et al. Osteopathic manipulative treatment and pain in preterms: Study protocol for a randomised controlled trial. *Trials*. 2015;16:84-015-0615-3. doi: 10.1186/s13063-015-0615-3 [doi].

2. Cerritelli F, Martelli M, Renzetti C, Pizzolorusso G, Cozzolino V, Barlafante G. Introducing an osteopathic approach into neonatology ward: The NE-O model. *Chiropr Man Thera*. 2014;22(1). Accessed 27 September 2016. doi: 10.1186/2045-709X-22-18.

3. Cerritelli F, Pizzolorusso G, Ciardelli F, et al. Effect of osteopathic manipulative treatment on length of stay in a population of preterm infants: A randomized controlled trial. *BMC Pediatr*. 2013;13:65-2431-13-65. doi: 10.1186/1471-2431-13-65 [doi].

4. Cerritelli F, Pizzolorusso G, Renzetti C, et al. A multicenter, randomized, controlled trial of osteopathic manipulative treatment on preterms. *PLoS One*. 2015;10(5):e0127370. doi: 10.1371/journal.pone.0127370 [doi].

5. Cerritelli F, Pizzolorusso G, Renzetti C, et al. Effectiveness of osteopathic manipulative treatment in neonatal intensive care units: Protocol for a multicentre randomised clinical trial. *BMJ Open*. 2013;3(2):10.1136/bmjopen-2012-002187. Print 2013. doi: 10.1136/bmjopen-2012-002187 [doi].

6. Fraval, Maxwell MPR. A Pilot study: osteopathic treatment of infants with a sucking dysfunction. *Journal of the American Academy of Osteopathy* 1998; 8(2): 25-33.

7. Herzhaft-Le Roy et al. Efficacy of an Osteopathic Treatment Coupled With Lactation Consultations for Infants' Biomechanical Sucking Difficulties: A Randomized Controlled Trial. *I Journal of Human Lactation*. 1 –8. 2016

8. Lund GC, Edwards G, Medlin B, Keller D, Beck B, Carreiro JE. Osteopathic manipulative treatment for the treatment of hospitalized premature infants with nipple feeding dysfunction. *J Am Osteopath Assoc*. 2011;111(1):44-48. doi: 111/1/44 [pii].

9. Martelli M, Cardinali L, Barlafante G, Pizzolorusso G, Renzetti C, Cerritelli F. Do placebo effects associated with sham osteopathic procedure occur in newborns? results of a randomized controlled trial. *Complement Ther Med*. 2014;22(2):197-202. doi: 10.1016/j.ctim.2014.01.009 [doi].

10. Pizzolorusso G, Cerritelli F, Accorsi A, et al. The effect of optimally timed osteopathic manipulative treatment on length of hospital stay in moderate and late preterm infants: Results from a RCT. *Evid Based Complement Alternat Med*. 2014;2014:243539. doi: 10.1155/2014/243539 [doi].

11. Pizzolorusso G, Cerritelli F, D'Orazio M, et al. Osteopathic evaluation of somatic dysfunction and craniosacral strain pattern among preterm and term newborns. *J Am Osteopath Assoc*. 2013;113(6):462-467. doi: 113/6/462 [pii].

12. Wescott N. The use of cranial osteopathy in the treatment of infants with breast feeding problems or sucking dysfunction. *Aust J Holist Nurs*. 2004;11(1):25-32.

Study Method.

This study is a single blinded, randomized- controlled, prospective study. The study will be conducted at UnityPoint Health Methodist and/or OSF St. Francis Medical Center.

Enrollment and advertising: Because this research study will be open to all newborns at UnityPoint Health Methodist and/or OSF St. Francis Medical Center who meet inclusion criteria, this might mean that patients of providers who are unfamiliar with OMT are enrolled in the study. It is important to our team that all providers are comfortable with this research project. As such, overview of our research has been presented at the Pediatric and Perinatal Interdisciplinary Team Committees. Further information about the research project and about OMT in general has been compiled into a brochure entitled "Osteopathic Manipulative Treatment and Your Baby" which is included in this IRB submission. Once approved, this brochure will be sent to all Family Medicine, Pediatric, and Neonatology providers that admit to UnityPoint Health Methodist and/or OSF St. Francis Medical Center.

Randomization: Newborns that are on the lactation rounding list and that meet criteria of our study will be given this brochure and offered admission into the study by the nurse or the lactation specialist caring for the newborn. If the parent is interested in participation in the study, the nurse or lactation specialist will put in a consult for the OMT team and page a member of the research team who will then consent the parent.. The newborn will then be single blinded (to lactation) and randomized to either the treatment or control group. No new patients will be enrolled into the study on Fridays as our goal for all the newborns is to have at least *two* treatments before discharge and the OMT research team is only available Monday-Fridays. New enrollment will only occur Monday-Thursdays. Newborns that meet inclusion criteria will then be offered into the research study after obtaining informed consent from the parent~~s~~. After listing all qualifying newborns alphabetically, newborns will be randomized into treatment/control groups in an alternating fashion.

Protocol for Control Group: Because OMT is a manual therapy, blinding to other participants in the study (lactation team and parents) would be difficult without a sham protocol occurring in the control group. As such, our protocol for the Control Group will be evaluation of cranial strain patterns and cervical motion. These findings will be evaluated, documented, but no corrective treatment will be delivered.

Protocol for Treatment Group: Each newborn in the treatment arm of our research group will receive the same OMT treatment protocol, regardless of somatic dysfunction. The benefits of using a protocol approach are: 1) All OMT providers can be trained and achieve comfort in the treatment options, 2) Eliminates the variable of different treatment options being more/less effective, 3) More accurate information regarding risks/benefits can be communicated to parents, 4) Minimizes inter-researcher outcomes.

The protocol was established by conducting interviews with OMT practitioners both locally and faculty at Osteopathic Medicine faculty at schools in different states. The finalized protocol is as follows:

Protocol:

1. Condylar Decompression
2. Still Technique to Cervical Region, including the Sternocleidomastoid Muscle
3. Balancing of the Hyoid Bone
4. Myofascial Release of Thoracic Inlet

Schedule: The OMT research team will conduct research Monday- Fridays. Newborns meeting criteria will be

enrolled on Monday-Thursdays. Treatment or sham treatment for the control group will take place Monday-Friday. The OMT research team will provide treatment and sham treatment to both inpatient and outpatient infants who are enrolled in the study. This will occur in the newborn nursery, patient room, or the lactation office. Residents and attending physicians will provide treatment and sham treatments, all residents will be directly supervised by an attending physician.

Documentation: It is important to blind the lactation team to which newborns receive treatment, as it is lactation who will assign the L.A.T.C.H. scores. In an effort to blind the study, the OMT research team will document in each study participants' chart (regardless of if they are control or treatment group) a Progress Note that read "This newborn is part of the Osteopathic Manipulative Treatment for the Management of Feeding Dysfunction in Breastfed Newborns Research Study. They may be in either the control or treatment group. Their documentation is available immediately by contacting the research team or by looking under Media tab in the next two weeks." This will allow someone to access the information immediately if needed due to any side effects but also allows for blinding of the lactation team.

Scoring and follow up: Infants in both control and treatment groups will have a L.A.T.C.H. assessment at baseline, daily during hospitalization, and at the first two outpatient lactation visits. The L.A.T.C.H. assessment will evaluate Latch, Audible swallow, Type of nipple (mother's nipple), and Hold. While OMT can affect most components of the L.A.T.C.H. assessment, it cannot affect the mother's type of nipple. Therefore, although the L.A.T.C.H. assessment will evaluate the nipple type, this data will not be used in our research. For research purposes the highest L.A.T.C.H. assessment score will be 8 (eight). We will collect baseline, daily assessments, and the two outpatient assessments which will result in 4-5 data points for each infant. These scores will be used to assess the benefit of the addition of OMT to the infants' care plan for feeding dysfunction.

Inclusion Criteria for Subjects.

- Term Infants greater than or equal to 37 weeks gestation
- Level I newborn
- Receiving lactation support
- Identified by lactation as having a newborn component to feeding dysfunction
- Admitted to UnityPoint Health Methodist hospital and/or OSF St. Francis Medical Center and available for follow up with Methodist lactation specialists and/or OSF St. Francis Medical Center lactation specialists.
- Available for at least 2 inpatient OMT sessions
- Informed Consent

Exclusion Criteria for Subjects.

- Infants <37 weeks of gestation
- Level II or III newborns
- Infants who are wards of the state
- Term infants who are receiving speech therapy or physical therapy
- Infants already receiving OMT

- Infants who are not breastfeeding
- Infants who have a feeding dysfunction mostly attributed to maternal factors (including but not limited to: abnormal nipples, maternal comorbidities, etc).
- Infants with Down's Syndrome or other contraindications for OMT(acute infection, fractures, etc.).

Population Sample Size:

A. Estimated number of subjects: 78 (39 each group)
   A recent trial (Herzhaft-Le Roy 2016) has a significant improvement of LATCH score at the third day after intervention (mean=9.22, SD=0.92; mean=8.18, SD=1.60; p=0.001). Given the effect size, a power of 90% and a significance level of 0.05, a minimum total sample size of 70 is estimated. Considering an attrition rate of 10%, at least 78 (39 each group) subjects are needed for this trial.
B. Age (inclusive) - Term Infants greater than or equal to 37 weeks gestation.
C. Sex (estimate M:F ratio) – We estimate a 1:1 M:F ratio
D. Describe the population from with which the sample will be drawn- please see above information.

Comment [RJ1]: Paper is attached.

Comment [RJ2]: If you think there is a higher attrition rate, the sample size needs to be adjusted.

Theoretical risks and potential benefits :

OMT is extremely safe and non-invasive. The OMT technique used per the protocol are gentle and indirect. No direct thrusting techniques will be employed. Investigators utilize minimal pressure during these techniques, so that there is no blanching of the investigator's nailbeds. However, as with any medical procedure, OMT carries some risk. Risks associated with the treatments to be used in this study include fatigue, headache, stiffness, tenderness, redness or mild swelling to the area after treatment. If treatment does not work, while patients do not appreciate any benefit they also do not usually show side effects. Patients who respond to treatment often begin feeling better within a day and then noticing improvement of their original symptoms (in this case, improved feeding). Potential benefits of treatment are improved feeding which includes improved latch of the baby, improved swallow, and reduced pain related to feeding for both mom and baby.

Alternative treatments to patients (if applicable).

No alternative treatments to OMT will be offered in addition to the lactation support already provided to breastfeeding infants and mothers who do not need a speech and/or physical therapy consult. Our OMT will augment the current standard for care which includes lactation support. Infants needing a speech and/or physical therapy consult in addition to lactation support will be excluded from the study.

Describe subject compensation, including plans for prorating.

Patients will not be billed for OMT. No monetary patient compensation will be offered