Michigan Technological University

Office of Compliance, Integrity, and Safety
302 Lakeshore Center
1400 Townsend Drive
Houghton, MI 49931
906.487.2902

MEMO

DATE: June 9, 2014

TO: Adrienne Minerick, Ph.D., Chemical Engineering

FROM: Joanne Polzien, Executive Director

RE: M0934, [336669-5]

TITLE: Rapid Nutritional Analysis from Infant Tears

SUBMISSION TYPE: Amendment/Modification

STATUS: **Request for Change(s) during approval period, APPROVED**

Thank you for your submission of materials requesting review of change(s) in your approved research study. **Your request has been reviewed by the Institutional Review Board (IRB) and has been APPROVED.**

Your project retains its original expiration date of June 9, 2015.

A pdf of this signed memo and any stamped approved documents, if applicable, have been placed in the review details under "board documents" for this project.

This approval applies only for this project, and only under the conditions and procedures described in the application. If/when changes become necessary but are not limited to: changes in protocol, personnel, study location, participant recruitment, etc., as set forth in this approval, you must follow the **INSTRUCTIONS** and complete the **FORM: Change Request during approval** found in the IRBNet Library. Submit the **FORM** indicating ALL changes along with any other appropriate modified documents as a new package under this study title. You must receive notification of approval PRIOR to implementing the change(s).

Approvals are granted for up to a one year period. You are responsible for submitting requests for continuation in advance of the expiration date for each year of the project. You will need to request a continuation six weeks prior to the end date indicated above. It is very important that the expiration date is not missed. **Failure to submit annual review materials on time will result in the termination of this protocol on the expiration date listed above.**

Please note the following in order to comply with federal regulations and IRB policy:

1. Please remember that informed consent is a process beginning with a description of the study and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

2. Individual identification of human subjects in any publication is an invasion of privacy. Before beginning a project involving human subjects, and only if required, the principal investigator must obtain a properly executed informed consent from each subject and/or the person legally responsible for the subject. **If a consent form has been reviewed and approved it has been attached with an official date stamp on it. Only copies of the official date stamped informed consent are to be distributed to participants relating to this project. If any changes or modifications are needed regarding this form, you must first submit the revised document for review and approval prior to use.** The PI must retain informed consent forms on file for at least three years after the end of the project.
3. The approved project will be subject to periodic review. This review will consist of consulting with the PI and examining the appropriate project records. **All required research records must be securely retained in either paper or electronic format for a minimum of three years following the closure of the approved study. This includes signed consent documents from all participants.**
4. **All Unanticipated Problems / Serious Adverse Events to participants or other parties affected by the research** must be reported to this office within two days of the event occurrence. All instances of non-compliance or complaints regarding this study must be reported to this office in a timely manner. Please use the **INSTRUCTIONS and FORM: Unanticipated Problem / Serious Adverse Event** found both on our web site and the IRBNet Library.

If you have any questions, please contact the Compliance, Integrity, and Safety Office at 906.487.2902 or send your message via email through IRBNet using the Send Project Mail feature.

1. TITLE: Rapid Nutritional Analysis from Infant Tears

2. RESEARCHERS: Dr. Adrienne R. Minerick, Chemical Engineering, Michigan Tech, (906) 487-2796, minerick@mtu.edu, Dr. Colleen Vallad-Hix, Pediatrician, Portage Medical Group (906) 483-1700, cvalladhix@portagehealth.org

3. PROJECT FUNDING: Gerber Foundation, http://www.gerberfoundation.org/

4. PURPOSE: The purpose of this research study is to determine if vitamin levels can be detected in tears at comparable levels to the vitamin levels in blood. Tears are much easier to sample from an infant. If they can provide the same information as blood, your doctor won't need to take blood samples to test vitamin levels for your infant.

5. PARTICIPANT SELECTION: Any parent(s) and infant from newborn to 1 year old who is a patient at Portage Health is welcome to participate.

6. PROCEDURES: As a parent/guardian, you'll be asked to fill out a brief nutritional questionnaire. We will then collect tear and blood samples from you and from your infant at the six well-baby checkups in the first year (1 month, 2 months, 4 months, 6 months, 9 months, 12 months). Your physician will make a clinical diagnosis and the nurse will record growth metrics. A certified phlebotomists (lab technician trained to draw blood) will draw blood from your arm and also perform a heel needle prick to collect 1 mL vial (volume is about ¼ teaspoon) of your child's blood. Next, the lab technician will obtain tear samples from both you and your infant using sterile ophthalmological strips. Sample collections are expected to take 10-15 minutes. No expenses will be charged to you for the collection of these samples.

7. RISK: For the blood collection, the risk involved is no greater than having blood taken at a routine doctor's visit with the possibility of a bruise or local infection at the site of the blood draw. During tear collection, the only risk involved is possible corneal abrasion or minor eye irritation.

8. VOLUNTARY PARTICIPATION STATEMENT: Participation in this study is voluntary. Your decision whether or not to participate or allow your infant to participate will not affect the services normally provided to your child by Portage Medical Group. Your infant's participation in this study will not lead to the loss of any benefits to which he or she is otherwise entitled. You and your infant are free to end participation at any time. You and your infant are not waiving any legal claims, rights, or remedies because of participation in this research study.

9. PRIVACY & CONFIDENTIALITY: Only the Portage Pediatric Clinic staff will have access to medical information from your child. You will be asked to fill out a nutritional questionnaire at each visit. Your responses (no identifying medical information) and the samples (no names or identifying information) will be analyzed in the lab of Dr. Adrienne Minerick at Michigan Tech. Portage staff will label samples with a Gerber Tech number, which will be kept in your infant's medical file. The samples, nutritional questionnaire, physician's clinical diagnosis, growth chart, and technicians observations during sample collection will be transported and stored in a locked lab (samples) and locked filing cabinet (paperwork) in the Minerick lab. Once the experiments are complete (6-14 days), the samples will be frozen for the duration of the study (2 years) and then destroyed per Institutional Biosafety

Regulations. All the information collected from you or about you will be kept confidential to the fullest extent allowed by the law. In very rare circumstances, specially authorized university or government officials may be given access to our research records.

10. RESEARCH RELATED INJURY: In the event of physical and/or mental injury resulting from participation in this research□project, Michigan Technological University does not provide any medical, hospitalization□or other insurance for participants in this research study, nor will Michigan Technological University provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law. If your child is taking medications, it is your responsibility to consult with your physician regarding your child's participation in this research study. Any problems experienced throughout this study should be discussed immediately with your physician.

11. POTENTIAL BENEFITS TO YOU: For most participants, no direct benefits will arise from participating in this study. However, if a vitamin imbalance is detected, this will be shared with your infant's pediatrician and standard medical tests may be recommended.

12. POTENTIAL BENEFITS TO SOCIETY: Indirect benefits to society are evident in the potential development of noninvasive tests using infant tears.

13. RESEARCH STUDY RESULTS: If you wish to learn about the results of this research study you may request that information on the designated section of the nutritional questionnaire or by contacting: Dr. Adrienne Minerick, Associate Professor of Chemical Engineering at Michigan Technological University at (906) 487-2796 or minerick@mtu.edu.

14. QUESTIONS REGARDING THIS STUDY: If you should have any questions about this research project, please feel free to contact Dr. Adrienne Minerick, Associate Professor of Chemical Engineering at Michigan Technological University at (906) 487-2796 or minerick@mtu.edu.

15. HUMAN SUBJECT RIGHTS: If you have any questions about your rights as a research subject, you may contact the Office of Compliance, Integrity, and Safety at Michigan Tech, which serves as the point of contact for both Michigan Tech and Portage Health, by mail at 1400 Townsend Drive, Houghton, MI 49931, by phone at (908) 487-2902, or by e-mail at IRB@mtu.edu.

16. AGREEMENT TO PARTICIPATE: Please indicate whether or not you and your infant wish to participate in this project by printing and signing your name. The details of this research study have been explained to me including what my infant and I are being asked to do and the anticipated risks and benefits;□ I have had an opportunity to have my questions answered;□I am voluntarily agreeing to participate in the research as described on this form; □I have been given a copy of this document for my records;□I may ask more questions or stop participating at any time without penalty. □

Parent/Guardian Printed Name	Signature
Printed Name of Infant	Date