Michigan Technological University

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

MEMO

DATE: April 9, 2014

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

FROM: Joanne Polzien, Executive Director

RE: M0540, [318164-6]

TITLE: PFI-AIR:TT (IIP 1414331) Blood Typing Device without Reagents and STTR Phase I (IIP 1417187): Microdevice for Rapid Blood Typing and Hematocrit Determination without Reagents

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 March 3, 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.

Project Participant Consent Form (M.D. – ERL Personnel) – version April 2014

Dear M.D. – ERL Researcher,

As you know, we have some exciting research ongoing in Tech's Medical microDevice Engineering Research Lab (M.D.-ERL) in chemical engineering, titled *"PFI-AIR:TT (IIP 1414331) Blood Typing Device without Reagents and STTR Phase I (IIP 1417187): Microdevice for Rapid Blood Typing and Hematocrit Determination without Reagents".* We are researching novel methods of analyzing blood to eventually diagnose disease and assessing health. This research includes the design of a small device, called a microdevice, which is being tested for its ability to obtain a variety of information in a matter of minutes from a single drop of blood.

For this research, participants must be willing to donate their blood for prototype testing of the microdevice. In addition, the plasma or liquid portion of your blood sample may also be used in cooperation with another project to design a microdevice to measure vitamin content in blood plasma. **Due to your proximity as a researcher in the lab, you may be asked if you would be willing to donate blood for this project. Please note that your participation is completely voluntary and has no impact on your coursework, evaluation, or tenure in the lab. If you feel uncomfortable pressure to donate, please contact Dr. Adrienne Minerick (906) 487-2796 and the Research Integrity and Compliance Office at (906) 487-2902.**

A certified phlebotomists (lab technician trained to draw blood) will collect a 4 mL vial of your blood at the SDC Portage Health Clinic. 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. Report any injury to Dr. Adrienne Minerick (906) 487-2796, and to the Research Integrity and Compliance Office (906) 487-2902. 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.

The type of blood used must be known, so we request that you provide proof of blood type via a blood donor card. This is the only health related information asked of you, and it will be kept **strictly confidential.** The M.D.-ERL researcher who you have talked with regarding this study will be coordinating your visit to the Health Center, will wait during your donation, and then will transport your blood sample to our research lab. This individual may be able to identify you, but has been carefully trained to NOT refer to the sample by donor name nor reveal identity to anyone. All email/phone correspondence will be deleted. Contact information will only be retained only if you directly indicate your interest. *Also, please note that these records will be held by a state entity and therefore are subject to disclosure if required by law. Since this study is regulated by the Food and Drug Administration (FDA), all research records are subject to inspection by the FDA.* Only blood type will be written on the vial of blood – your name will not be linked to the vial. The sample will be transported and stored in a secure location in our lab. Once the microdevice experiments are complete (6-14 days), the cells will be destroyed per Institutional Biosafety Regulations. The plasma will be pooled and saved for up to 12 months in the freezer, then destroyed per Institutional Biosafety Regulations.

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. The Michigan Tech Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact Joanne Polzien of the Michigan Tech-IRB at 906-487-2902 or email jpolzien@mtu.edu.

Please understand that your **participation is voluntary**, your **refusal to participate will involve no penalty or loss** of benefits to which you are otherwise entitled, and you **may discontinue your participation** at any time without penalty or loss of benefits. You may request a copy of this form for your records.

☐ ***Cells may be used for blood cell microdevice*** ☐ ***Plasma may be pooled for vitamin analysis***

Participant Printed Name & Signature	Date	Adrienne Minerick

DATE OF IRB APPROVAL: 04.09.14
IRB NUMBER: 318164-6, M0540
PROJECT EXPIRATION DATE: 03-03-15

MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DEPARTMENT OF CHEMICAL ENGINEERING AT MICHIGAN TECHNOLOGICAL UNIVERSITY

Project Participant Consent Form (Paid Donor) – version April 2014

Dear Project Participant,

There is some very exciting research taking place here in Tech's Medical microDevice Engineering Research Lab (M.D.-ERL) in chemical engineering, titled *"PFI-AIR:TT (IIP 1414331) Blood Typing Device without Reagents and STTR Phase I (IIP 1417187): Microdevice for Rapid Blood Typing and Hematocrit Determination without Reagents".* We are researching novel methods of analyzing blood to eventually diagnose disease and assess health. This research includes the design of a small device, called a microdevice, which is being tested for its ability to obtain a variety of information in a matter of minutes from a single drop of blood.

For this research, participants must be willing to donate their blood for prototype testing of the microdevice. In addition, the plasma or liquid portion of your blood sample may also be used in cooperation with another project to design a microdevice to measure vitamin content in blood plasma. A certified phlebotomists (lab technician trained to draw blood) will collect a 4 mL vial (volume is less than a teaspoon) of your blood at the SDC Portage Health Clinic. 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. Report any injury to Dr. Adrienne Minerick (906) 487-2796, and to the Research Integrity and Compliance Office (906) 487-2902. 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.

The type of blood used must be known, so we request that you provide proof of blood type via a blood donor card. This is the only health related information asked of you, and it will be kept **strictly confidential.** The M.D.-ERL researcher who you have talked with regarding this study will be coordinating your visit to the Health Center, will wait during your donation, and then will transport your blood sample to our research lab. This individual may be able to identify you, but has been carefully trained to NOT refer to the sample by donor name nor reveal identity to anyone. All email/phone correspondence will be deleted. Contact information will only be retained only if you directly indicate your interest. *Also, please note that these records will be held by a state entity and therefore are subject to disclosure if required by law. Since this study is regulated by the Food and Drug Administration (FDA), all research records are subject to inspection by the FDA.* Only the blood type will be written on the vial of blood – your name will not be linked to the vial. The sample will be transported and stored in a secure location in our lab. Once the experiments are complete (6-14 days), the cells will be destroyed per Institutional Biosafety Regulations. The plasma will be pooled and saved for up to 12 months in the freezer, then destroyed per Biosafety Regulations.

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. The Michigan Tech Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact Joanne Polzien of the Michigan Tech-IRB at 906-487-2902 or email jpolzien@mtu.edu.

Please understand that your **participation is voluntary**, your **refusal to participate will involve no penalty or loss** of benefits to which you are otherwise entitled, and you **may discontinue your participation** at any time without penalty or loss of benefits. As a thank you for your voluntary donation, you will receive $5 in monetary compensation. To be compensated for your participation, you must complete and sign a Receipt of Compensation Form including a W-9, and are informed that you need to report this compensation as income when filing taxes to the IRS. You may request a copy of this form.

☐ ***Cells may be used for blood cell microdevice*** ☐ ***Plasma may be pooled for vitamin analysis***

_____	_____	_____
Participant Printed Name & Signature	Date	Adrienne Minerick

MINERICK@MTU.EDU

HTTP://WWW.MDERL.ORG

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IRB NUMBER: 318164-6, M0540
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MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DEPARTMENT OF CHEMICAL ENGINEERING AT MICHIGAN TECHNOLOGICAL UNIVERSITY

Project Participant Consent Form (True Volunteer) – version April 2014

Dear Project Participant,

There is some very exciting research taking place in Tech's Medical microDevice Engineering Research Lab (M.D.-ERL) in chemical engineering, titled *"PFI-AIR:TT (IIP 1414331) Blood Typing Device without Reagents and STTR Phase I (IIP 1417187): Microdevice for Rapid Blood Typing and Hematocrit Determination without Reagents".* We are researching novel methods of analyzing blood to eventually diagnose disease and assessing health. This research includes the design of a small device, called a microdevice, which is being tested for its ability to obtain a variety of information in a matter of minutes from a single drop of blood.

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Participant Printed Name & Signature	Date	Adrienne Minerick

MINERICK@MTU.EDU

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