Michigan Technological University

Compliance, Integrity, and Safety

302 Lakeshore Center | 1400 Townsend Drive Houghton, MI 49931-1295

906-487-2902 | f. 906-487-2245

DATE: February 13, 2018

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

FROM: Cheryl A Gherna, CIP, Coordinator Regulatory Review Boards

RE: M0540, [318164-12]

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: Continuing Review/Progress Report

STATUS: **RENEWAL APPROVAL**

Thank you for your submission of renewal materials for this research study. **The Institutional Review Board (IRB) has reviewed your request for renewal, *with no change(s)* as indicated, and has APPROVED your submission.** All research must be conducted in accordance with this renewal approval.

APPROVAL DATE: February 13, 2018
EXPIRATION DATE: February 27, 2019

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.

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 consent document.

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

1. Any modification to previously approved materials or personnel must be approved by this office prior to initiation. Please use the **INSTRUCTIONS and FORM: Change Request during approval** found in the IRBNet library and follow the steps. This includes, but is not limited to changes in procedures, personnel, study location, participant selection process, etc.
2. 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. Please use the **INSTRUCTIONS and FORM: Unanticipated Problems or Serious Adverse Events** found in the IRBNet library and our web site.

All instances of non-compliance or complaints regarding this study must be reported to this office in a timely manner. There are no specific forms for this report type.

3. 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. This project requires continuing review by our office on an annual basis.

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 March 2018

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. The titles of the projects are *"PFI-AIR:TT (IIP 1414331) Blood Typing Device without Reagents," "STTR Phase I (IIP 1417187): Microdevice for Rapid Blood Typing and Hematocrit Determination without Reagents," and "GOALI (CBET 1510006) Graphene Paper Sensor for Disease Detection".* 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:

1. Prototype testing of microdevices for ascertaining cell responses for applications like blood type analysis, hematocrit, and disease diagnose to assist in health decisions
2. Testing of a microdevice to measure vitamin content in blood plasma
3. Determining the blood compatibility of nanomaterials
4. Testing of a graphene paper device to diagnose disease

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 phlebotomist (lab technician trained to draw blood) will collect a 4 mL vial of your blood at the UP Health System: Portage SDC University Center. 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 Compliance, Integrity, and Safety Office 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 Tech 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

Michigan Tech IRB APPROVAL

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Expires on:	02-27-2019
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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 Michigan Tech IRB at 906-487-2902 or email irb@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***

☐ ***Cells and plasma may be used for material compatibility and device development***

Participant Printed Name & Signature	Date	Adrienne Minerick

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Project Participant Consent Form (Paid Donor) – version March 2018

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. The titles of the projects are *"PFI-AIR:TT (IIP 1414331) Blood Typing Device without Reagents," "STTR Phase I (IIP 1417187): Microdevice for Rapid Blood Typing and Hematocrit Determination without Reagents," and "GOALI (CBET 1510006) Graphene Paper Sensor for Disease Detection".* 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.

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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*

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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 and are hereby informed that you need to report this compensation as income when filing taxes to the IRS. You may request a copy of this form.

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☐ ***Plasma may be pooled for vitamin analysis***

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Participant Printed Name & Signature	Date	Adrienne Minerick

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Project Participant Consent Form (True Volunteer) – version March 2018

Dear Project Participant,

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