

# MEDICAL MICRODEVICE ENGINEERING RESEARCH LAB

DEPARTMENT OF CHEMICAL ENGINEERING AT MICHIGAN TECHNOLOGICAL UNIVERSITY

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## Project Participant Consent Form (True Volunteer) – version April 2012

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. 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 microdevices. 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 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.

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

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Participant Printed Name & Signature

Date

Adrienne Minerick

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MINERICK@MTU.EDU

DATE OF IRB APPROVAL: 05-07-12 HTTP://WWW.MDERL.ORG

IRB NUMBER: M0540

PROJECT EXPIRATION DATE: 03-05-13