INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

ABC Autonomous Shoe and Glove Test

You are invited to participate in a research study which involves testing our design for the various positive aspects, possible flaws in design, and user friendliness. You were selected as a possible subject because subjects were picked randomly from Wells Quad and people we know. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by: Annika Tharp, Brody Erb, Christian Gonzalez, in Intelligent Systems Engineering E-101 class.
It is funded by Intelligent Systems Engineering E-101 class.

STUDY PURPOSE

The purpose of this study is for the participant to interact with our product, giving us feedback on what worked, what didn't work, how we can improve to make the design easier to work with, and see whether device was user friendly or not. From a user-friendly standpoint, how it reacted to suggested turn and maneuvers and how easily the gloves and shoe strap were to put on.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of twelve subjects who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will do the following things:

This study will last exactly 15 minutes.
It will take place in the Geology Lab

(1) Put the Shoe strap onto your shoe
    (a) Place the shoe strap right side up (sensor side up) on the floor, position your foot onto the strap so that the strap is aligned with the arch of your foot, wrap the strap around shoe and buckle the clip on top of your laces

(2) Turn on the shoe strap making sure the blue lights are on
    (a) By pressing the power button

(3) Turn on the Car making sure the Blue and Green LEDs are on
    (a) By pressing the power button on the bottom of the car

(4) Put on the smart designed gloves
    (a) By sliding your hand into the gloves making sure the index finger and thumb are properly inserted into the gloves

(5) *** The Investigators conducting the study will make sure the shoe strap and smart designed gloves are properly attached before proceeding with the study
    (a) Investigator may touch your shoes
    (b) Investigator may touch the gloves on your hands

(6) Then begin to follow the course that we have created, doing as many laps as you can complete within the 15 minute study.

RISKS OF TAKING PART IN THE STUDY

While participating in the study, the risks [side effects, and/or discomforts] are:

- Running the car into your legs causing some slight skin irritation and or bleeding
- Getting a slight shock of electricity if the gloves are not properly worn
- The bright flashing lights may cause epilepsy
- The course for the car may be difficult and may cause stress

BENEFITS OF TAKING PART IN THE STUDY

There is no direct benefit to the participant.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in the study, you have the option of not participating at all.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal

agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) [for FDA-regulated research and research involving positron-emission scanning], the National Cancer Institute (NCI) [for research funded or supported by NCI], the National Institutes of Health (NIH) [for research funded or supported by NIH], etc., who may need to access your medical and/or research records.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.
The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.
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COSTS

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs: You will not be responsible for the study specific costs.

PAYMENT

You will not receive payment for taking part in this study.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

FINANCIAL INTEREST DISCLOSURE

One or more individuals involved in this research may benefit financially from this study. The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Brody Erb, at (574)-596-1061. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please call the IU Human Subjects Office at 800-696-2949 or irb@iu.edu.

In the event of an emergency, you may contact Emergency services at 911.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 800-696-2949 or irb@iu.edu.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University. Your participation may be terminated by the investigator without regard to your consent in the following circumstances: the participant does not follow the rules stated to them before beginning the experiment or causing damage to the project or study will result in an immediate termination.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:

Subject's Signature: **Date**:

(must be dated by the subject)

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Consent: **Date**:

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Consent: **Date**:

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Consent: **Date**: