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Date Submitted

Madison Area Technical College  
Institutional Review Board

\_\_\_\_\_  
File Number

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**FULL IRB REVIEW PROTOCOL SUMMARY FORM**

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Title of Research Project \_\_\_\_\_

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Principal Investigator/Project Director      Department      Phone Extension      Email address

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Co-investigator/Student Investigator      Department      Phone Extension      Email address

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Co-investigator/Student Investigator      Department      Phone Extension      Email address

Anticipated Funding Source: \_\_\_\_\_

Projected Duration of Research: \_\_\_\_\_ months      Projected Starting Date: \_\_\_\_\_

Other organizations and/or agencies, if any, involved in the study: \_\_\_\_\_

**Please answer the questions below and return this form with:**

- ◆ A memo that briefly describes the intent of the project
- ◆ A completed copy of the Consent Form Checklist
- ◆ A copy of the Consent Form that will be provided to the participants

**I. Project Information:**

**A. Project Activity Status:**

- New Project
- Periodic Review of Continuing Project
- Revision to Previously Approved Project

**B. This project involves Madison Area Technical College students**

- Yes       No

**C. Human Subjects from the following populations will be involved in this study**

- Minors       High School Students
- Mentally Disabled       Prisoners
- Elderly       None of the above

**D. Total number of subjects to be studied:** \_\_\_\_\_

**II. Abstract Describing Project and Purpose** (Include a description of all experimental methods to be used and design and program activities; what measures or observations will be

taken in the study? If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument.)

**III. Protocol** (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document; How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary)

**IV. Precautions** (What steps will be taken to insure that each subject’s participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?)

**V. Confidentiality of data** (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc)

**VII. Consent** (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject)

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:**

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

*I certify that the protocol and method of obtaining informed consent as approved by the Madison College Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.*

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Investigator/Project Director Signature                      Co-Investigator/Student Signature (if appropriate)

<b>Signature of IRB Committee Chair:</b>				
<b>IRB Chair: Check 1 box:</b>	<input type="checkbox"/> <b>Approved</b>	<input type="checkbox"/> <b>Approved with Restrictions</b>	<input type="checkbox"/> <b>Tabled</b>	<input type="checkbox"/> <b>Disapproved</b>

**Madison Area Technical College  
 Human Subjects Research Project  
 Consent Form Checklist**

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N/A	YES	NO	
			1. Is the consent form written in “lay language”?
			2. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
			3. If minors are included in the study, is provision made for obtaining parental consent?
			4. Does the consent form include each of the following basic elements of informed consent?
			a. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject’s participation.
			b. A description of the procedures to be followed.
			c. A description of any benefits to the subject or others.
			d. A description of any reasonably foreseeable risks or discomforts.
			e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
			f. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
			g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.
			h. Appropriate FERPA notice and waivers (if appropriate).

If there was a “NO” response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why it is appropriate as submitted.

**Madison Area Technical College  
Institutional Review Board**

**ELEMENTS OF INFORMED CONSENT**

Researchers must obtain the *informed consent* of participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's *assent*, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have.
7. Contact information of all Principal Investigators, and also contact information for Madison College's Institutional Review Board (Provost 608-246-6516).
8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.
9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

## Madison Area Technical College

### SAMPLE INFORMED CONSENT

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving *informed consent*. (Note: that in the case of children, it is *assent*).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine \_\_\_\_\_. In this study, you (your child/ward) will be asked to \_\_\_\_\_. Your participation should take about \_\_\_\_\_ minutes.

There are no risks to you (your child/ward).

*or*

The only risks to you (your child/ward) include \_\_\_\_\_.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply \_\_\_\_\_.

Please feel free to contact \_\_\_\_\_ (names(s), title(s) of principal researchers) at \_\_\_\_\_ phone) if you have any questions about the study. Or, for other questions, contact Madison College's Provost at 608-246-6516.

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*If the participant is of age (18 years old or older), use:*

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

\_\_\_\_\_  
Signature of Participant                      Date

*If the participant is not of age, use:*

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

\_\_\_\_\_  
Signature of Parent/Guardian                      Date

*ASSENT format:*

I understand what I must do in this study and I want to take part in the study.

\_\_\_\_\_  
Signature of Child/Ward                      Date

**Attach Consent Form that will be provided to the participants**