Madison Area Technical College
Institutional Review Board

EXPEDITED REVIEW OF RESEARCH FORM

Human subject research activities involving no more than minimal risk to the subjects may be eligible for expedited review by Madison College's Institutional Review Board Chair. The principal investigator/project director is authorized to make the first determination of eligibility for expedited review; however, the College bears the responsibility for concurring in that determination based on information provided by the principal investigator.

Research activities eligible for expedited review:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3) Prospective collection of biological specimens for research purposes by noninvasive means.
4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(4)).
6) Collection of data from voice, video, digital, or image recordings made for research purposes.
7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects according to 45 CFR 46.101(b)(2) and (b)(3)).

Expedited review may also be used to review minor changes in previously approved research. Questions about whether a research activity may be appropriate for expedited review can be directed to the office of the Vice Provost.

__/__/__ **Date Submitted**

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_____ **File Number**

Expedited Review of Research Form

Title of Research Project

Principal Investigator/Project Director	**Department**	**Phone Extension**	**Email address**
Co-investigator/Student Investigator	**Department**	**Phone Extension**	**Email address**
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: _____

Expedited Review Category (see categories on page 1–check one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐

SUMMARY ABSTRACT: Please supply the following information below: BRIEF description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data. <u>Attach copy</u> of the Informed Consent Form and/or the measures (questionnaires) to be used in the project.

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.

_____ __/__/__
Investigator/Project Director Signature

_____ __/__/__
Co-Investigator/Student Signature (if appropriate)

Signature of IRB Committee Chair:			**Date:** __/__/__
IRB Chair: Check 1 box:	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer to Full Committee Review**

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ELEMENTS OF INFORMED CONSENT

Researchers must obtain the signed ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the signed 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.

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.

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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.

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