



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 Montgomery County Community College's Institutional Review Board Chair. The researcher 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 researcher.

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 Executive Director of Institutional Research, Effectiveness, and Planning.

____/____/____
Date Submitted

Montgomery County Community College
Institutional Review Board

Expedited Review of Research Form

Title of Research Project

Researcher	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
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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. Attach copy of the Informed Consent Form and/or the measures (questionnaires) to be used in the project.

A. PROPOSED RESEARCH RATIONALE

Please briefly describe why you are conducting the study. Identify the research question(s) being asked.

B. PROCEDURES TO BE FOLLOWED

Describe in sequential order your research procedure. Identify all data you will collect.

C. SUBJECTS

Please identify the subjects targeted for your research. Please identify any inclusion/exclusion criteria. (e.g. gender, age, ethnic background, etc.). Additionally, please provide the maximum number of subjects you seek approval to enroll from all of the subject populations you intend to use and justify the sample size. If you need to increase your sample size at a later time you will need to submit a request to the IRB.

D. RECRUITMENT OF SUBJECTS AND OBTAINING INFORMED CONSENT

Please describe your recruitment process in a step-by-step manner. The IRB needs to know all the steps you will take to recruit subjects in order to ensure subjects are properly informed and are participating in a voluntary manner.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.

E. PROCEDURES FOR PAYMENT OF SUBJECTS

Describe any compensation that subjects will receive. Please note that Montgomery County Community College policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

F. PRIVACY AND CONFIDENTIALITY

Participants must be able to control their right to participate in research (such as the timing and location of data collection).

- Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study.
- Describe what steps you will take to maintain the confidentiality of subjects.
- Describe how research records, data, specimens, etc. will be stored and for how long. The IRB generally recommends locked storage, such as a cabinet, for identifiable information. Please note, consent forms signed by subjects, parents and/or legally authorized representatives ARE considered research records.
- Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes.

G. POTENTIAL RISKS TO SUBJECTS

There are always risks associated with research. If the research is minimal risk, which is no greater than every-day activities, then please describe this fact. Describe the risks to participants and steps that will be taken to minimize those risks. Risks can be physical, psychological, economic, social, legal, etc. Where appropriate, describe alternative procedures or treatments that might be advantageous to the participants. Describe provisions for ensuring necessary medical or professional intervention in the event of adverse effects to participants or additional resources for participants.

H. BENEFITS TO BE GAINED BY THE INDIVIDUAL AND/OR SOCIETY

Describe the possible direct benefits to the subjects. If there are no direct benefits, please state this fact. Describe the possible benefits to society.

I. RESEARCHER'S EVALUATION OF THE RISK-BENEFIT RATIO

How does the researcher evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

J. WRITTEN INFORMED CONSENT FORM

Submit a copy of an informed consent document in the form that it will be disseminated to subjects. If children are subjects, provide the Parental Consent Form, and, if appropriate, a Child Assent Form. If recruiting subjects who do not speak English, submit both an English version as well as a version translated into the appropriate language.

K. WAIVER OF INFORMED CONSENT OR SIGNED CONSENT

If requesting either a waiver of consent or a waiver of signed consent, please address the following:

For a Waiver of Consent Request, address the following:

- a. Does the research pose greater than minimal risk to subjects (greater than everyday activities)?
- b. Will the waiver adversely affect subjects' rights and welfare? Please justify.
- c. Why would the research be impracticable without the waiver?
- d. How will pertinent information be reported to subjects, if appropriate, at a later date?

For a Waiver of Documented (signed) Consent, address the following:

- a. Does the research pose greater than minimal risk to subjects (greater than everyday activities)?
- b. Does a breach of confidentiality constitute the principal risk to subjects?
- c. Would the signed consent form be the only record linking the subject and the research?
- d. Does the research include any activities that would require signed consent in a non-research context?
- e. Will you provide the subjects with a written statement about the research (an information sheet that contains all the elements of the consent form but without the signature lines)?

L. INTERNATIONAL RESEARCH

When conducting international research researchers must provide additional information to assist the IRB in making an appropriate risk/benefit analysis.

Research projects must be approved by the local equivalent of an IRB before MCCC's IRB can grant approval to the protocol. If there is not equivalent board or group, researchers must rely on local or experts or community leaders to provide approval and affirm the research procedures are appropriate for that culture. The MCCC's IRB requires documentation to be submitted of this "local approval" before granting approval of the protocol. Additionally, please provide information about the IRB equivalent and provide contact information for it. The body or individual providing the local approval should be identified in the application narrative as well as information as to that body's or individual's expertise.

In the application narrative describe the experience and/or other qualifications the researchers have related to conducting the research with the local community/culture. Describe if the researchers have the knowledge or expertise of the local or state or national laws that may

impact the research. The researchers must understand community attitudes to appreciate the local laws, regulations or norms to ensure the research is conducted in accordance with U.S. regulations as well as local requirements.

- For more information on specific requirements of different countries and territories, researchers can consult the Office for Human Research Protections International Compilation of Human Research Protections (<http://www.hhs.gov/ohrp/international>).
- In the application narrative, describe how the researchers will have culturally appropriate access to the community. If the researchers were invited into the community to conduct the research, please submit documentation of the collaboration.
- In the application narrative, explain the researchers' ability to speak, read or write the language of potential participants. Describe the primary language spoken in the community. Explain provisions for culturally appropriate recruitment and consent accommodations translated materials or translators.
- Attention should be given to local customs as well as local cultural and religious norms when writing consent documents or proposing alternative consent procedures. This information should be provided in the application narrative, and as appropriate, provide justification if requesting the IRB to waive some or all requirements of written consent.
- In the application narrative, describe how researchers will communicate with the IRB while you are conducting the research in the event the project requires changes or there are reportable events. Also, if the researcher is a student, describe how the student will communicate with the researcher during the conduct of the research and how the researcher will oversee the research.
- If this research is federally funded by the United States, additional documentation and inter-institutional agreements may be required. Contact the IRB Administrator for assistance.
- Submit copies of consent documents and any other materials that will be provided to subjects (e.g., study instruments, advertisements, etc.) in both English and translated to any other applicable languages.

M. SUPPORTING DOCUMENTS *(check all document that you will be submitting to IRB)*

- ☐ Recruitment advertisements, flyers, emails and letters.
- ☐ Survey instruments, questionnaires, tests, debriefing information, etc.
- ☐ Consent Form, Parental Permission, Assent Form
- ☐ Translated consent and recruitment documents (if applicable)
- ☐ If the research is a collaboration with another institution, that institution's IRB or ethical board approval for the research or request for IRB deferral.
- ☐ Local review approval or affirmation of appropriateness for international research.
- ☐ If the research will be conducted in schools, businesses or organizations, include a letter from an appropriate administrator or official permitting access to the research site.
- ☐ If the study involves an investigational drug/device, include product information or research brochure.
- ☐ Other (please list in blank space below):

RESPONSIBILITIES OF THE RESEARCHER:

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 researcher is responsible for retaining informed consent documents for a period of three years after the project. Other institution's/organization's IRB approval forms should be attached for an expedited review.

_____/____/____ Researcher 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

SAMPLE Consent to Participate in a Research Study
(all areas in yellow are filled in by the researcher – highlighted text
is an example only, but all areas in gray must be addressed)

Title of the Study: (Name of Study)

Principal Researcher: Researcher Name

Invitation to Participate in a Research Study

You are invited to participate in a research study. Taking part in this research project is voluntary. Add other information about the study, number of participants, etc.

What is this study about and why is it being done?

The purpose of this study is to understand: (taken from IRB Application)

What will happen if you agree to participate in this study?

If you agree to participate in this study, you will be asked to participate in focus groups, one-on-one interviews, and participation in discussions forums, online survey. The types of questions that will be asked are all thought provoking and reflect as follows:

What questions you will ask/address

Describe how, when, where, what, of data collection to be done.

What are the benefits of this study?

The highlighted block is for example only. Please replace with your IRB application information.

All participants will benefit from this study with some of the benefits conducted from this study include effectively addressing and resolving how to recognize and adapt to different organizational transgressions. The result for the participants is this will make them productive for organizational success. Other benefits are developing further behavioral understandings, strategies, and providing recommendations to deal with different behaviors effectively. The last benefit involves developing robust and productive communication methods that will afford participants the capability to make good decisions.

What are the risks of participating in this study?

The highlighted block is for example only. Please replace with your IRB application information.

You may experience some risks from being in this study, but there are no practices that cause physical bodily harm to any participants. A potential risk from this study is being ostracized by peers that are present during a focus group or during observation. This approach towards minimize the risks to participants is to determine the benefit to cost ratio. This measure involves comparing potential benefits of the research study with the participants potential risks. Another potential risk is confidentiality. This risk will be minimized by having informed consent from every participant and all information from discussions, observations, and one-on-one interviews will be safeguarded with no personally identifiable information.

If you experience any issues related to participation in the study, please notify the researcher.

COVID-19 Risk Reduction (Only include if you are doing face to face interviews)

To reduce the risk of COVID-19 for research participants, study will follow current public health recommendations including those provided by the U.S. Department of Health and Human Services. Do not participate in the study or sessions if you are sick or awaiting the results of COVID-19 testing.

How do we protect your information?

The highlighted block is for example only. Please replace with your IRB application information. The researcher will have access to information that identifies you. This will be in the form of field notes only to identify the speakers during focus groups, one-on-one interviews, and observations. Field notes will be secured daily in a locked space which only the primary researcher has access to.

The researcher will protect the confidentiality of your research records by (field notes) by securing them daily in a locked space. Only the primary researcher will have access to the information collected about you. The data will be kept for at least three years. All field notes that identify participants will be destroyed using a high-security crosscut shredder. The final report will not include any personal information that will directly identify you. The researcher will not use any information for any purposes outside this research project. The researcher will not share the participant's anonymous research data with other investigators without asking for consent again.

Payment for Participation

Provide payment info if applicable.

Who can profit from study results?

Disclose any identified conflict of interest as well as any information regarding potential or confirmed profit from the study results.

Your Participation in this Study is Voluntary

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You do not have to answer any questions you do not want to answer. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw before this study is completed, the data that we collect from you to the point of withdrawal may be included in the study.

The researcher may also withdraw participants from the study if they become hostile towards participants or the researcher. The researcher may do this without the consent of the subject.

Questions about the Research

If you have questions about this research, you may contact:

Researcher Name:

Phone:

Email:

Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, please contact:

Institutional Review Board
Montgomery County Community College
IRB# - IRB00007072
Blue Bell, PA 19422
Chair: Dr. Bridget A. Haines-Frank
Telephone: (215) 619-7453
Email: bhainesfrank@mc3.edu

Your Consent

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. If you have questions at any time during the study, you may contact the researcher using the information provided above.

I understand what the study is about and my questions have been answered to my satisfaction. I have been given a copy of this form. I agree to take part in this study.

Printed Subject Name

Signature

Date

Consent to be Audio/Video Recorded (not applicable)

I agree to be audio/video recorded.

YES _____ NO _____

Signature

Date

Permission from Parent or Legally Authorized Representative (not applicable)

By signing this document, you are agreeing the participation of the person named below. Make sure you understand what the study is about before you sign. If you have questions at any time during the study, you may contact the researcher using the information provided above.

I/We will give you a copy of this document for your records. I/We will keep a copy with the study

I understand what the study is about and my questions have been answered to my satisfaction. I have been given a copy of this form. I agree for the person named below to take part in this study.

Printed Subject Name

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

Signature

Date