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| \_\_\_/\_\_\_\_/\_\_\_\_ | **Montgomery County Community College**  |  |
| **Date Submitted** | **Institutional Review Board** |  |

**FULL IRB REVIEW PROTOCOL SUMMARY FORM**

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**Title of Research Project**

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**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**

|  |  |
| --- | --- |
| **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
1. **Project Information:**
2. **Project Activity Status:**

[ ]  **New Project**

[ ]  **Periodic Review of Continuing Project**

[ ]  **Revision to Previously Approved Project**

**B. Does this project involve Montgomery County Community 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 ensure 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 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.

***I certify that the protocol and method of obtaining informed consent as approved by the Montgomery County Community 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.***

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| --- | --- | --- | --- |
|  | \_\_/\_\_/\_ |  | \_\_/\_\_/\_\_ |
| Researcher Signature |  | Co-Investigator/Student Signature (if appropriate) |  |
|  |  |  |  |
| **Signature of IRB Committee Chair:** | **Date:** \_\_/\_\_/\_\_ |
| **IRB Chair: Check 1 box:** | **[ ] Approved** | **[ ]  Approved with Restrictions** | **[ ]  Tabled** | **[ ]  Disapproved** |

**Montgomery County Community College Community College**

**Human Subjects Research Project**

**Consent Form Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| **N/A** | **YES** | **NO** |  |
|  |  |  | 1. Is the consent form written in “lay language”?
 |
|  |  |  | 1. Is it free of any language that requires the subjects to waive their legal rights, including any release of the researcher, sponsor or college or its agents from liability for negligence?
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|  |  |  | 1. If minors are included in the study, is provision made for obtaining parental consent?
 |
|  |  |  | 1. Does the consent form include each of the following basic elements of informed consent?
 |
|  |  |  | 1. A statement that the study involved research, an explanation of the purposes of the research and the expected duration of the subject’s participation.
 |
|  |  |  | 1. A description of the procedures to be followed.
 |
|  |  |  | 1. A description of any benefits to the subject or others.
 |
|  |  |  | 1. A description of any reasonably foreseeable risks or discomforts.
 |
|  |  |  | 1. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
 |
|  |  |  | 1. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
 |
|  |  |  | 1. 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.
 |
|  |  |  | 1. 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 researcher can satisfactorily justify why is it appropriate as submitted.

**Montgomery County Community College Community 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 agreementto 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. Brief 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 researchers, and also contact information for Montgomery County Community College’s Institutional Review Board (Executive Director of Institutional Effectiveness, 215-619-7453).

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 areomitted 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 conducted and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

**Montgomery County Community College Community College**

***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 aCOVID-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.*

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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.*

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Printed Subject Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

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