

**GUIDELINES FOR THE CONDUCT OF RESEARCH
INVOLVING HUMAN SUBJECTS**

**Central Ohio Technical College
Newark
Mount Vernon
Coshocton
Pataskala**

As of October 10, 2023

Dear Prospective Researcher,

Thank you for interest in using Central Ohio Technical College (COTC) for your proposed research activity. COTC's Institutional Review Board (IRB) is charged with ensuring that research on its students, faculty, staff, or other affiliated persons is conducted in compliance with Federal Regulations and to ensure that the risk to the subjects and potential harms to them are mitigated to the extent possible.

Both COTC and the researcher have an obligation to ensure that the rights and welfare of the participants in the research study are adequately protected. This responsibility extends to any mode of research development, instruction, training, or related activity, including classroom and questionnaire studies, whether sponsored solely by COTC or funded externally and conducted either on- or off-campus.

Prior to submitting [a research proposal](#) please review the guidelines in depth. They describe the composition and function of the IRB and lay out types of reviews conducted by the IRB, and its expectations of those who conduct research under the auspices of COTC.

Sincerely,

Chris Doll
Director, Institutional Research and Effectiveness

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I. DEFINITION OF HUMAN SUBJECTS

When people are involved as subjects in research or related activities conducted under College auspices, both the institution and the principal investigator incur responsibility for ensuring that the rights and welfare of participants are adequately protected. This responsibility extends to any mode of research development and related activity, including classroom and questionnaire studies, whether sponsored solely by the College or funded externally, and conducted either on or off-campus. Federal law defines a **human subject** as a living individual about whom an investigator (whether professional or student) conducting **research** obtains (1) data through **intervention** or **interaction** with the individual, or (2) identifiable **private information**. Inherent in this definition is the concept of **minimal risk**.

‘Research’ means a systematic investigation. It includes the development of a project that will aid in answering a question and involves testing and evaluation. Information gained from this project will contribute to generalizable knowledge. **‘Intervention’** includes both physical procedures and manipulations of the subject or the subject’s environment. **‘Interaction’** includes any kind of communication or interpersonal contact between investigator and subject. **‘Private information’** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). **‘Private information’** must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. **‘Minimal risk’** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

II. SCOPE OF REVIEW

The scope of the Institutional Review Board (hereafter called the IRB or the Board) is broad. Generally, any College research that uses humans, human tissue, surveys of human

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subjects or human subjects' records requires IRB review, irrespective of its funding source. The IRB's charge extends to research in the social and behavioral sciences as well as research in the health and biological sciences. Specifically, IRB review and approval is required for any research involving human subjects that:

- is conducted by College faculty, staff or students;
- is performed on the premises of the College;
- is a course offered under the auspices of our College;
- is performed with or involves the use of facilities or equipment belonging to the College;
- involves College patients, students, staff, or faculty;
- satisfies a requirement imposed by the College for a degree program or for completion of a course of study; or
- is certified by a dean or department head to satisfy an obligation of a faculty appointment at the College, including clinical or adjunct appointments.

IRB review is also required unless the researcher has a strict consulting relationship in which (1) the researcher is hired on his or her own time; (2) the researcher holds no rights in the work; and (3) neither the researcher nor the College retains any data. All three of these criteria must be met or the IRB will need to review the project.

The IRB *Guidelines* do **not** apply to the following:

- Administrative surveys such as the Student Entrance survey, the Noel/Levitz Faculty Staff Satisfaction Survey, and student satisfaction surveys.
- Field or clinical learning experiences which are under COTC direction and supervision (through contractual arrangements between the field agency and COTC and which are limited to the implementation of customary and usual practice of the appropriate profession.
- Assignments for classes which require students to obtain (1) data through intervention or interaction with individuals, or (2) identifiable private information where access to such information is confined to class use only.

In these circumstances it is understood that the COTC supervisor or instructor is responsible for assuring **confidentiality** and **informed consent** when required for the student's experience.

Additionally, COTC's IRB need not engage in further review of proposals that have IRB approval from another institution. Prior to engaging in research at COTC researchers should

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submit their IRB approval to the Chairperson. The Chairperson reserves the right to request further information from the researcher(s) if needs warrant.

III. Institutional Review Board

An institutional Review Board (IRB) is a body within a college, university, or other organization that oversees research activity to ensure that it is conducted ethically and consistently with accepted policies and practices within the institution¹.

To be recognized by the Federal Government an IRB must satisfy the following requirements²:

1. At least 5 members
 - a. At least 1 with a background in Science
 - b. At least 1 with a background not in Science
 - c. At least 1 outside party with no affiliation with the institution
2. At least 1 member should be an expert on most matters coming before the board.

The composition of COTC's IRB shall be determined by the President's Cabinet and at a minimum consist of:

1. A representative familiar with health sciences to serve as the Science representative
2. The Director of Institutional Research and Effectiveness (DIRE) to document and coordinate the IRB's activities
3. Other members as determined by the Cabinet

All members of the IRB shall undergo training in Human Subjects research and shall provide documentation to the DIRE that they completed such training. Training can be completed either [here](#) or [here](#).

The DIRE shall serve as the Chairperson of the IRB. The Chairperson will assign the reading of research proposals, call the Board together for Full Board decisions and on behalf of the IRB. The jurisdiction of the institutional IRB includes all research and related activities covered under these *Guidelines*. **No research project involving human subjects (save for administrative surveys as noted above), including those with IRB approval from another institution, may proceed without the explicit written approval of the Board.**

¹ <https://www.apa.org/advocacy/research/defending-research/review-boards>

² <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.107>

IV. Functions of the IRB

The IRB shall meet as needed to assess the suitability of the proposed research project relative to federal guidelines and applicable College policies. Dependent upon the type of request the IRB may choose to exempt the proposal from review, perform an expedited review, or engage in a full board review:

1. Exempted from Review

A proposal may be suitable for exempt review if it meets the following criteria:

- 1) The research is conducted in established or commonly accepted educational settings, involving normal education practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
- 2) The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observations of public behavior, *except* where any of the following conditions exist:
 - a. Information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
 - b. Any disclosure of this information outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation; or
 - c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol.
- 3) The research involves the use of educational tests, survey or interview procedures, or observations of public behavior when the human subjects are elected or appointed public officials or candidates for public office.
- 4) The research involves the collection or study of existing (1) data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available, or (2) if the information is recorded by the investigator in such a manner that those subjects *cannot* be identified directly or through identifiers linked to the subjects.
- 5) Research and demonstration projects which are conducted by or are subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine:
 - a. public benefit or service programs;
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in or alternatives to those programs or procedures; or
 - d. possible changes in methods or levels of payment for benefits or services under those programs.

- 6) Taste and food quality evaluation and consumer acceptance studies where:
 - a. wholesome foods without additives are consumed, or
 - b. a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant at or below a level determined to be safe by the Food and Drug Administration (or approved by the Environmental Drug Administration, the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture).

2. Expedited Review

Research activities involving *no more than minimal risk* and in which the only involvement of human subjects will be in one or more of the following 13 categories (carried out through standard methods) may be reviewed by the Chairperson and/or a designated voting member or group of voting members, rather than by the full IRB. The IRB shall adopt procedures for advising all members apprised of approved proposals under this process. Any proposal not subject to the 13 conditions outlined below, nor exempt from review, shall be subject to a full board review. Researchers must obtain informed consent of all participants and researchers must have procedures to keep personally identifiable information confidential unless the subject waives that right.

- 1) Research involving survey or interview procedures, except where *any* of the following conditions exist:
 - a. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
 - b. The subject's responses, if they became known outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or
 - c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- 2) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory or test development, where the investigator does not either manipulate the subjects' behavior and/or emotional state, or involve stress to subjects;
- 3) The study of existing data, documents, records, pathological specimens or diagnostic specimens. The consent of the subjects from whom the data, etc., were originally obtained is not needed if the data, etc., are publicly available. If the data, etc., are not publicly available, the custodian of the data, etc., may consent in place of the subjects

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only if the custodian is authorized to release the data, etc., for research. Otherwise, consent of the subjects must be obtained;

- 4) Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth and permanent teeth if patient care indicates a need for extraction;
- 5) Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membranes prior to or during labor;
- 6) Recording of data from non-pregnant subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example x-rays, microwaves);
- 7) Collection of blood samples by venipuncture, in amounts not exceeding 50 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant;
- 8) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- 9) Voice recordings made for research purposes such as investigations of speech defects;
- 10) Moderate exercise by healthy volunteers who are 18 years of age or older and are not pregnant. Moderate exercise is defined as less than 60% of age-adjusted maximums;
- 11) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required;
- 12) Minor modifications or additions to existing approved studies; and
- 13) Continuing review of activities which the IRB determined in an earlier full review could have expedited, continuing review.

3. Full IRB Review Procedures

Research projects that do not meet the exempt or expedited review criteria *require* a full IRB review. For projects requiring full review by the IRB, the Chairperson will request an electronic copy of:

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Part I: Application for Approval to Use Human Subjects in Research;
Part II: Research Protocol;
and Part III: Summary of Proposal.

Where a proposal for an external grant is involved, an assessment will be made for the entire program proposed and will occur prior to or concurrent with the submission of the proposal. If a grant is **not** involved, the research proposal should reach the Chair at least 30 days in advance of the proposed implementation date for the research project.

Copies of the research proposal will be distributed to each IRB member at least a week prior to the next convened meeting. The researcher may be asked to answer questions or meet with the IRB to clarify specific points regarding the involvement of human subjects in the proposed activity. Conversely, if specific questions are anticipated as a consequence of the proposal, the researcher may request a meeting with the IRB prior to the submission of the final draft. This meeting will not necessarily take the place of a regular review.

V. Criteria for Approval

In reviewing activities covered under these *Guidelines*, the IRB seeks to determine that **all** the following requirements are satisfied:

- 1) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 2) Risks to subjects are reasonable in relation to any anticipated benefits to subjects, and in relationship to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- 3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research

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involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

- 4) Informed consent will be sought from each prospective subject or from the subject's legally authorized representative in accordance with, and to the extent required by, Section VII of these *Guidelines*.
- 5) Informed consent will be appropriately documented in accordance with, and to the extent required by, Section VII of these *Guidelines*.
- 6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as might be the case for children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Once the IRB determines that all the above points have been satisfied, approval may be given for the project to proceed, subject to further review or disapproval by other agencies. However, other agencies may **not** approve the project if it has been disapproved by the IRB. The IRB may suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects. Any suspension or termination shall include a statement of reasons for such action and shall be reported promptly to the investigator; appropriate College officials; and/or the funding agency, if applicable.

The IRB may suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects. Any suspension or termination shall include a statement of reasons for such action and shall be reported promptly to the investigator; appropriate College officials; and/or the funding agency, if applicable.

VI. Possible Actions of IRB Review

After review by the IRB, one of the following four actions will be taken:

Action 1: Approve the research procedures;

Action 2: Approve the research procedures, subject to modifications;

Action 3: Disapprove the research procedures; or

Action 4: Defer action on the proposal pending receipt of additional information or further clarification of specific items that may be identified.

Additions or changes made after approval must be brought to the attention of the IRB Chair. The Chair will then direct the IRB to consider whether the original assessment should be modified. If modifications are needed, the IRB will treat the matter as a new case and no new procedures should be implemented until Board approval has been obtained.

At the time of approval, the IRB will determine which projects require review more often than annually or that require verification from sources other than the researcher that no material changes have occurred since IRB approval. The IRB chair, or other appropriate COTC official, will follow-up on projects so designated.

Each project not granted “exempt” status will be reviewed annually by the IRB to assure that researchers continue to follow approved procedures and practices regarding the use of human subjects. If subjects behave as if personal rights have been violated in any form, the researcher should inform the IRB Chairperson in writing.

APPEAL PROCEDURES

If a proposal or procedure receives final disapproval by the IRB and the principal investigator wishes a further hearing on the matter, an appeal may be made to the Board. In this case, an ad hoc appeals committee will be convened by the Chairperson of the IRB.

VII. INFORMED CONSENT OF RESEARCH SUBJECTS

Unless a waiver has been approved by the IRB, the researcher must obtain and

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document in writing the subject's informed consent (see [Appendix II](#) for an example of an Informed Consent form). The key elements of **informed consent** are:

- 1) A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which would be considered ground breaking;
- 2) A description of any reasonably foreseeable risks or discomforts to the subject;
- 3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- 4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and how such identifiable information will be used now and in the future;
- 6) For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;
- 7) The name(s) of the person(s) to contact for answers to pertinent questions about the project and the subject's rights, and whom to contact in the event of a research-related injury. In the case of student research this should include the principal investigator(s) and research advisor;
- 8) A statement that participation is voluntary and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

For research involving minors, that is, individuals who have not attained the legal age of consent, **a custodial parent or guardian must be given a preservice briefing in written or oral form**, and a written consent form must be obtained from said custodial parent or guardian for each child. In the case of children over seven years of age, the child must also give assent. In research where the minor is old enough to give fully informed consent to non-sensitive, non-risky research procedures, researchers may request a waiver of parental consent. **Waiver of parental consent can only be granted by the IRB.**

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Whatever forms are used as documentary evidence of informed consent, it is essential that all such evidence be preserved by the principal investigator for at least 36 months following termination of the project. If the investigator leaves campus before the 36 months have expired, copies of the appropriate documents must be filed with the Chairperson. If the project was carried out at another institution, the files may be retained at that institution, but the IRB should be informed of their location. Regardless, records are subject to audit by the College as well as federal officials and must be retained for easy and quick access if requested. The investigator must specify to the IRB the procedures which will be used to preserve the confidentiality of these signed consent forms.

The IRB may choose to waive the requirement for informed consent if the proposed research poses virtually no risk to the rights and welfare of participants. Such action must be based upon clearly defensible grounds, and the researcher must include these justifications in the proposal submitted to the IRB. This applies to waiver of parental consent for research with minors, as well.

VIII. GUIDELINES MODIFICATIONS

The Institutional Review Board shall have the ability to address issues not presented herein. These *Guidelines* shall be amended or modified as any applicable laws are changed.

COTC INSTITUTIONAL REVIEW BOARD

Application for Approval to Use Human Subjects in Research

Please complete the form below to the best of your ability and return an electronic copy to [Chris Doll](#) the Institutional Review Board (IRB) Chairperson. The information provided will help COTC’s IRB assess the risks and benefits of the proposed research and what type of review is appropriate. Prior to completion please review the document COTC Guidelines for the Conduct of Research (insert link). Attach additional pages as needed.

PRINCIPAL INVESTIGATOR _____
(type name)

INSTITUTION _____

EMAIL _____ PHONE () _____

CO-INVESTIGATOR(S) _____
(type name)

CO-INVESTIGATOR(S) _____
(type name)

PROJECT TITLE _____

BEGINNING DATE OF RESEARCH (MONTH/YEAR) _____

ANTICIPATED ENDING DATE OF RESEARCH (MONTH/YEAR) _____

DOES THIS PROJECT HAVE IRB APPROVAL FROM YOUR NSTITUTION?

| | | | |
|---|--|---|--|
| Y | | N | |
|---|--|---|--|

If the project has prior IRB approval from your institution, please forward that documentation to the email address above. You need not complete the rest of the form.



TYPE OF PROJECT

- _____ Faculty Research
- _____ Class Project
- _____ Staff Research
- _____ Externally Funded; Agency _____
- _____ Student (Honors College research)
- _____ Thesis; _____ Dissertation; _____ Other

I certify that the research procedures for this project, and the method of obtaining consent (if any), as approved by the Institutional Review Board, will be followed during the period covered by this research project. Any future changes will be submitted for Board review and approval prior to implementation.

| | | | |
|------------------------|------|---------------|------|
| Principle Investigator | Date | Dean/Director | Date |
|------------------------|------|---------------|------|

PART I: Please answer the following by circling the correct response:

- | | | | |
|---|---|----|--|
| Y | N | 1. | Will subject be identifiable to anyone other than the researchers through records, responses or identifiers linked to the subject? |
| Y | N | 2. | Could subjects be at risk of criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, if responses became known outside this research project? |
| Y | N | 3. | Does research deal with sensitive aspects of subjects' behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol? |
| Y | N | 4. | Does research involve the collection or study of <u>existing</u> data from sources <u>not publicly available</u> ? (existing data can be documents, records, pathological specimens or diagnostic specimens) |
| Y | N | 5. | Will subjects be video/audio taped? |
| Y | N | 6. | Are subjects free to withdraw at any time and have you explained this to them? |
| Y | N | 7. | Is there deception of subjects? |

PART II: Summarize proposed project and procedures to which humans will be subjected. Consent form(s), questionnaire(s), etc. should be included with the application.**PART III: Please answer all of the following items. If not applicable to your project, write "None" or "NA", as appropriate. Attach additional pages as needed.**

1. How will the subjects be selected? (Please note the college will not allow the inclusion of the following groups of vulnerable classes of subjects such as pregnant women, minors, institutionalized mentally disabled, inmates, or those whose ability to give voluntary informed consent may be in question).
2. Briefly describe the characteristics of your population(s): the size of your sample, the ethnic background, sex, age, state of health and the criteria for inclusion or exclusion of subjects.
3. Identify any risks - physical, psychological, and/or social to which your subjects may be exposed as a result of participation in your project (beyond the risks normally encountered in everyday life). What safeguards will you use to protect the subjects from these risks, as well as to protect their rights, welfare and privacy?
4. How will the subjects be informed of the risks to which they will be subjected?

5. Describe how "Informed Consent" will be obtained? (Append form(s) to be used if required after IRB Review)

6. How may this research benefit the participants or contribute to the advancement of knowledge? (This must include any direct benefits to the subjects as well as any general gain in knowledge).

7. Where and how will the signed consent forms be kept if required by the IRB after the review? (Consent forms must be securely stored for 3 years and destroyed thereafter). If the study does not involve consent forms, answer "NA."

8. If deception is involved, describe its nature, why it is necessary, and how subjects will be debriefed. Include any feedback, educational or otherwise, which subjects will receive.

9. What do you intend to do with the data collected? (e.g., publish data, present paper, erase digital recordings, etc.)

- 10
 - a. If the subjects' personal files (school, medical, etc.) will be read, where are the files kept and who will gather the information?

 - b. Has permission been obtained to gather this information? (Attach documentation)

 - c. Do the subjects know that these files will be read? If no, explain.

11. Will test results be disseminated to the subjects?

12. Survey questions must be submitted at the same time as this application.

**Informed Consent Form
Central Ohio Technical College**

Title of Project:

Primary Investigator:

Please note: Participation in this study is voluntary. Additionally, participants may withdraw from the study at any time.

Purpose of Study

Foreseeable Risks

Potential Benefits of the Research Study

Protection of Confidentiality

_____ (initials here and sign below or on the following page)

I understand that this research study has been reviewed and approved by the Institutional Review Board at Central Ohio Technical College.

For research-related problems or questions regarding subjects' rights, I can contact the Institutional Review Board through Mr. Chris Doll, Chairperson, Institutional Review Board, at 740-366-9383 or doll.4@mail.cotc.edu.

_____ I am 18 (eighteen) years old or older.

_____ I am 17 (seventeen) years old or younger. (Your parents will need to sign this form as well).

ONLY For students 17 years old and younger:

I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to allow my child to participate in this study. I have been given a copy of this consent form.

Parent's Signature _____ Date _____

If I do NOT wish to participate, I will not return this form. No adverse actions will be taken against me or my grades if I choose this option. I will still participate in all the same tests, assignments, and other classroom activities as the rest of the class.

Researcher's Signature _____ Date _____

Consent

I have read and understand the explanation provided to me. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study. I have been given a copy of this consent form.

Name (printed) _____

Signature _____ Date _____

Informed Consent Form Specifications

As part of most research activities it is necessary to obtain an informed consent. The key to the consent form is to provide participants with enough information so that they understand your research. Examples have been provided on the website. Make sure to include the following information:

1. Your name and how to contact you.
2. A description of your project including the number of participants, the time the participant will need to devote to the project, how the participant will be involved with the project (interview, test, survey, etc.).
3. **How you will maintain the information to ensure confidentiality**
4. The identification of risks, benefits, and alternative treatments available to the participant.
5. A statement regarding the ability of the participant to not answer some questions or to opt out of the study at any time.
6. A space for the participant's signature and date. If the form is more than one page, include a place for initials on each page other than the signature page.
7. If the person is under the age of 18, the top half of the consent form will be for the child to sign and date while the bottom half will need a space for the guardian's signature and date. **Remember the information about the project must be in a language that is understandable to the child.**
8. You need to also have the IRB chairperson's name and how to contact him/her.

If you have any questions regarding the project's procedures at Central Ohio Technical College, please contact Mr. Chris Doll, IRB Chairperson at 740-366-9383 or email doll.4@mail.cotc.edu.