COLUMBUS STATE
INSTITUTIONAL REVIEW BOARD

Guidelines for
Expedited Human Subjects Protocol
Including Consent Form Template

1. Before completing the Expedited Human Subjects Protocol Form, review the applicability of this review procedure and the nine specific categories below. On pages 3 and 4 of the form, you must choose one of the nine categories that qualifies your research for expedited review.

A. Applicability
   1. Research activities that (a) present no more than minimal risk to human subjects, and (b) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
   2. The categories in this list apply regardless of the age of subjects, except as noted.
   3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
   4. The expedited review procedure may not be used for classified research involving human subjects.
   5. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB.
   6. Categories one through seven pertain to both initial and continuing IRB review.

B. Research Categories
   1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
      a. Research on drugs for which an investigational new drug application is not required.
      b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
   2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
      a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
      b. From other adults and minors, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
   3. Prospective collection of biological specimens for research purposes by noninvasive means.

- Category 1-3 Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (g) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (h) sputum collected after saline mist nebulization.

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. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
    - Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
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. This listing refers only to research that is not exempt.)
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 regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2. Enter today's date

3. Log # (leave this blank)

4. Enter the title of your research project

5. Provide the projected dates of your research. Determine these dates carefully. You cannot start your project prior to the stated date. If you need to extend it beyond the stated end date, you will need to submit a Modification Request (see IRB website for the form).

6. Provide the name, department, and email address for the Principal Investigator/Project Director. This person will manage the project and serve as the primary point of contact for the IRB. If this is student research, the Principal Investigator/Project Director is the faculty member supervising the research.

7. If you are doing doctoral dissertation research, please provide the name of your advisor, their Institution's name, and email address. Any research request from an external institution must first be approved by that institution's IRB. If necessary, an IRB Authorization Agreement can be arranged to establish one IRB as the primary IRB for review and approval.

8. Provide the name, department/external institution, and email address for any Co-Principal Investigator/Project Directors. These are team members who have a significant role in the project (e.g.: participating in the design, conduct, and reporting of the research). If this is a student research project, the student is a co-PI.

9. Provide the name, department/external institution, and email address for any Sub Investigators. These are team members who are assisting in the research project (e.g.: recruiting subjects or collecting study data).

10. Provide the name, organization, and email address for any External Evaluators for externally grant funded research projects.

11. List any collaborators that are part of this project: schools, community organizations, churches, etc. This includes places where you will solicit research subjects.

12. Your research may or may not be funded. If it is, please check the appropriate box. If your research is not funded, check non-funded research. If you check "Other", please provide an explanation. If your research is funded, the IRB wants to confirm that the protocol is consistent with the grant proposal. Provide the date the proposal was submitted and include a copy with the protocol form. If the proposal is not yet due, provide the date it is due and submit it as soon as it is complete.

13. Provide responses in sections A through G of Project Information regarding subject populations, number of subjects to be studied, all applicable data collection procedures you plan to use, and any consent waivers you may be requesting. Note: All consent waivers must be based upon clearly defensible grounds. Additional information contained in the "Protocol Narrative" #9 section below.

14. Select the expedited category that you think applies to your research. Check the box that corresponds to that criterion.

15. Required signatures - Sign and date the protocol form and obtain signatures for all members of the research team. In addition, obtain the signature of the dean or director of your department. Digital or wet ink signatures are required for submission.

16. Do not write below the area labeled FOR IRB USE ONLY.

17. Additional documents to be included with the completed form:

A. Protocol Narrative; see section below titled "Protocol Narrative"
B. Consent documents (and minor assent and parental consent documents if applicable); see section below titled "Consent Form Guidelines and Template"

C. All surveys, interview or focus group questions, and other testing instruments or data collections tools; include informational letters or scripts introducing the survey or other research instrument
D. Recruitment materials
E. Evidence of completion of the Social/Behavioral Research Investigator course within the past two years via CITI (Collaborative Institutional Training Initiative); any PI/Co-PI/Sub Investigator must be trained in human subjects protection and ethics; the training is free to Columbus State employees.
    - Click on "Register" on the CITI website
    - Select Columbus State Community College as your Organization Affiliation, agree to terms, and affirm your affiliation
    - Click on "Continue to create your CITI Program Username/Password"
    - Enter your personal information and continue through the steps to create your username and password, select an option to purchase CE credits for certain courses completed (Columbus State will not fund this option), and provide additional demographic and contact information
    - Basic Course – Human Research – Social/Behavioral Research Investigators is the course you need to complete; which contain multiple modules and quizzes
    - Include a copy of the certificate of completion for each research team member listed.
F. Multi-site and collaborative research – contact the IRB administrator about the possibility of a reliance agreement with the IRB of an external institution
G. For those completing doctoral dissertation research, the IRB approval letter from the external institution; see #7 above
H. Letters of support from outside institutions or entities that are allowing recruitment, research, or record access at their sites (if applicable); see #11 above
I. Grant proposal (if applicable); see #12 above

18. Submit the protocol electronically to irb@cscc.edu. It may be submitted as one large PDF document package or as individual attachments.

19. Upon receiving the protocol, the IRB administrator gives the protocol a preliminary review. If the protocol does not follow the guidelines, is incomplete, is unsigned, or contains a number of typos and grammatical errors, it will be returned for revision. The IRB will review the protocol and determine one of the following: Approved, Modification Required, Referred for Full IRB Review. You will receive an IRB Action Response Letter. If the determination is anything other than approved, the letter will contain additional details.

If you have any questions, please contact the IRB administrator at irb@cscc.edu.

Protocol Narrative

The narrative addresses all the points listed for these sections. In writing the narrative, you are providing details as well as describing and explaining the rationale for the research methodology. As you write, consider the following:

- The IRB will have no knowledge about your project except what you provide. Give them context and good information.
- The IRB makes no assumptions about your research abilities. Tell them how you will handle confidentiality, how you will store data, etc.
- The role of the IRB is to protect human subjects. Members engage in thoughtful debate about what you write in the narrative. They will not routinely approve or dismiss any protocol.

Writing Tips

You are writing a scholarly document that supports a research project. The document is reviewed by IRB members knowledgeable about research and the protection of human subjects.

- Write the protocol as you would any academic or professional paper.
- Proofread for grammar and typos.
- Give sufficient detail so that the IRB members can understand what you plan to do.
- By thinking and writing in a step-by-step manner, you will discover any potential risks and concerns.
- If you are supervising a student's research, read the protocol before it is submitted to the IRB.

Purpose, Research Variables, and Population

1. Purpose of study: State concisely and realistically what the study is intended to accomplish. Provide research questions, if applicable. If your study will have multiple phases or sequential aims, please describe the purpose of each phase and whether you are only seeking IRB approval for certain phases of the study at this time. State the benefit of this project to Columbus State Community College.

2. Background: Briefly state the background of the study, including some relevant references and identify the main questions the current study is intended to address.

3. Characteristics of the Subject Population: The following information should be provided:
    A. Age Range - What is the age range and why was it chosen?
    B. Sex - What is the sex of the subject? If there is a restriction, provide the rationale.
    C. Number - What is the estimated number of subjects? Provide a justification for the sample size – explain why this number of subjects is needed to answer your research questions. Indicate if there will be multiple study sub-groups and describe each sub-group.
    D. Inclusion Criteria - What are the specific inclusion criteria?
    E. Exclusion Criteria - What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.
    F. Vulnerable Subjects: If vulnerable subjects will be included (minors, pregnant women, fetuses, prisoners, adults unable to consent/cognitively impaired), provide justification of the need to use these subjects in research.

Methods and Procedures

1. Method of Subject Selection: Describe the study's method(s) of identification and recruitment of prospective subjects. Provide a copy of any planned advertisements and other recruitment materials. Describe any eligibility screening activities performed to ensure subjects are qualified for the study. Explain how the screening process will occur and what you will do with the data for people who are eligible and do participate in your study and for people who turn out not to be eligible for your study or are eligible and decide not to participate. Include a copy of the screening questions/criteria.

2. Methods and Procedures Applied to Human Subjects: Describe in detail the study design and all procedures (sequentially) to be applied to subjects. Include the duration of an individual's participation in the study for each study activity/procedure and the estimated total time for each subject to complete all study activities. Attach copies of any instruments to be used, such as surveys, ratings scales, or questionnaires. Ensure all procedures checked off on the protocol forms are included in the description.

    If you will be analyzing secondary data as part of your study, specify what datasets/records you plan to access and which variables will be included in the data. If the data you will be receiving will contain identifiers, explain why it is necessary for the information to include identifiers and whether you will retain the data with identifiers or will strip the identifiers from the data.

An informational letter or script is required to introduce a survey or other research instrument, provide instructions, and explain options to a research subject. For surveys conducted online, this information should be provided at the beginning of the survey. Include this with the protocol.

3. Study Site/Research Location: State the location(s) where the study will be conducted. Include letters of approval to conduct the study from all non-Columbus State sites. If your study will collect data through or from online sources, describe specifically which survey platforms or websites you plan to use for data collection. If you will be doing research using online activities, explain whether you anticipate your subjects might be located outside the United States.

4. Multi-site Research (research that involves external collaborating institutions and individuals): For each institution involved, briefly describe which activities that institution will be carrying out for this study. Describe the processes you have in place to ensure successful coordination of activities among collaborating institutions. If you will be collaborating with an individual who is not affiliated with another institution (e.g., an independent contractor or consultant), describe which study activities will be carried out by that individual. If the study has grant funding, explain who the primary grant awardee is.

Authorization Agreements:
Authorization agreements are formal arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human research. Investigators working with multiple institutions, each having an IRB, may request to have one IRB become the IRB of record with oversight over some or all participating institutions. However, the IRB at each engaged institution makes the final decision on whether it will rely on another IRB or serve as the IRB of record. NOTE: If your research is grant funded, you may be required to identify one IRB to serve as the IRB of record for the study.

5. International Research (data collection will occur outside the United States and U.S. territories): Describe any research activity that will take place internationally, including online activity with subjects located outside the United States. The HHS Office of Human Research Protections annually updates a compilation of international laws and regulations governing human research, available at: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html.

6. Research with vulnerable populations: If the research will involve individuals who are vulnerable or susceptible to coercion or undue influence, describe any applicable additional safeguards included to protect their rights and welfare. Vulnerable populations include prisoners, cognitively impaired adults, and pregnant women where the research activities are expected to affect the pregnancy (other populations may be vulnerable as well – this is not an exclusive listing of subjects who may be considered vulnerable).

If members of the research team have roles that can give rise to concerns about undue influence with subjects (such as physician-patient, teacher-student), please explain the steps you will take to minimize the possibility of undue influence/coercion.

7. Incomplete Disclosure or Deception: If the study will use incomplete disclosure (withholding information about the study purpose during the consent process because disclosing the study purpose in detail could significantly impact the validity of your study results) or deception (purposely misleading subjects by providing them with overt misdirection or false information about some aspect of the research during the consent process), describe the incomplete disclosure or deception and provide a rationale explaining why it is necessary to the research. Because deception and incomplete disclosure alter the information presented during the consent process, the debriefing process serves as the remedy by completing the consent process. If debriefing is appropriate, explain how you will conduct the debriefing process.

8. Audio/Video Recording/Photography: Describe the type of recording being utilized, why the type of recording is necessary to the research, and whether recording is mandatory or optional to participate in

the research. Describe how the recordings will be utilized in the research. If the intent is to use recordings or images for public presentation or publication, you must obtain the subjects' consent to those uses of the data. If audio/video-recording is mandatory for participation, a rationale must be provided here and the consent form must include this detail.

9. Consent Process: Describe the process you will use to obtain informed consent (written, verbal, online, etc.) from subjects, including where and when the consent process will occur. If consent will be obtained in different ways for different subject groups or study phases, describe the consent process that will be used for each subject group and/or study phase.

Consent is not merely a document. It is a process, in which the subject gains an understanding of the research procedures and the potential study benefits and risks in order to make an informed, voluntary decision on whether to participate in a research study.

The *standard* is that consent should be documented by having the subject sign a consent form after having the study explained to them, the opportunity to have any questions answered, and time to think about whether to agree to participate. The subject then retains a copy of the consent for their records.

Waiver of Written Consent: There are a variety of reasons why a research study might not find it feasible to obtain the subject's signature on the consent form. For example, if consent and data collection will take place via telephone, Skype, or through an online survey, obtaining the subject's signature on the consent is cumbersome and can render obtaining consent infeasible. In other studies (e.g., studies of illegal or socially stigmatized activities), the subject's signature on the consent could create additional risks for the subject.

If you are requesting a Waiver of Written Consent, you must explain why in the narrative in addition to requesting it on the Expedited Human Subjects Protocol Form. Your justification for the request must fall within one of these categories:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject/legally authorized representative (LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. If the subjects/LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Being granted a waiver of documentation of written consent does not eliminate the investigator's obligation to obtain informed consent from subjects before they begin their participation in the project.

General Waiver or Alteration of Consent: For some studies, not obtaining consent is appropriate (e.g., studies that only involve analysis of secondary data). For other studies, omitting certain information in the consent process may be necessary to render the research feasible and to produce valid data (research that is using deception as a technique).

If you are requesting a General Waiver of Consent OR an Alteration of Consent, you must explain why in the narrative in addition to requesting it on the Expedited Human Subjects Protocol Form. Your justification for the request must fall within one of these categories:

1. the study is no more than minimal risk to the subjects;
2. the research could not practicably be carried out without the requested waiver or alteration

3. if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. whether subjects will be provided with additional pertinent information after participation (i.e, whether debriefing will occur)

Minors and Informed Consent: In the case where minors are involved in research, the IRB requires the permission of the minors' parents or legal guardians, along with the assent (affirmative agreement) of the minors to participate in research. The IRB shall determine that adequate provisions are made for soliciting the assent of the minors, when in the judgment of the IRB, the minors are capable of providing assent and that adequate provisions are made for soliciting the permission of the minors' parents or guardians. In most cases, the assent of the minor will take the form of a signature alongside the consent signature of the parent or guardian. Verbal assent of the minor may also be possible on a case-by-case basis while taking into consideration the age, maturity, and degree of literacy of the minors that may be participating in the study.

If minors may be participating in your project, the consent documents *must* include provisions for parental consent and minor assent.

10. Debriefing: Describe the procedure for post-study debriefing of subjects.

11. Alternative to Participation: Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

Risk/Benefits

1. Potential Risks: Identify the potential risks, discomforts, hazards, or inconveniences related to the subject's participation in the study. Specify the types and levels of risks. Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks as well as community or group harms. Note: A breach of confidentiality is a common risk in social and behavioral research.

2. Protection against Risks: Specify the procedures for preventing or minimizing any potential risks.

3. Potential Benefits: Describe any potential benefits of the study, both for subjects and for society in general. Note: Participation in the research itself and payment for participating in the research are not benefits.

4. Compensation for Participation: Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation.

There is no requirement to compensate research subjects.

5. Cost to Subjects: Describe any costs that subjects may be responsible for because of participation in the research, such as parking, cell phone-related costs, etc.

6. Additional Types of Compensation: If the research involves more than Minimal Risk to subjects, describe the available compensation, available resources, or options in the event of research related injury.

Privacy and Confidentiality

1. Subject Privacy: Describe the steps that will be taken to protect subjects' privacy interests. "Privacy" refers to a person's desire to place limits on with whom they interact or to whom they provide personal

information. For example, will you conduct interviews that ask sensitive questions in areas where the interview cannot be overheard by others?

2. Confidentiality of Data: Describe explicitly how confidentiality of data will be maintained throughout the life-cycle of the study (initial collection, data management, and storage). If any information with subject identifiers will be released, specify the recipients.

   Discuss the following elements, as applicable to your study:
   - Will subject identifiers be included and stored with the data/specimens? Will identifiers be stripped at some point? Keep in mind that some subjects may be identifiable from video or audio-recordings.
   - If no direct subject identifiers will be collected, will you use a coding system with a key? Where will the key to the coding system be stored and who will have access to the key?
   - Do you plan to transcribe audio-recordings, and if so, will you delete the audio-recordings when transcription is completed?
   - How will data be transported from point of collection to point of storage?
   - Where and how will data/specimens be stored? How long will the data be stored? What will happen to the data at the end of your study?

   Include a statement that all data will be retained for a minimum of three years after the completion of the study in compliance with federal regulations. Refer to Research Data Security and Disposal guidelines listed under Additional Forms & Guides on the IRB website

Qualifications and Roles of the Research Team

Describe the qualifications of the research team to conduct this research. The IRB is looking for information such as area(s) of expertise, past research experience, relevant certifications, etc. In addition, explain the role of all research team members named on the form. For international research or research with vulnerable populations, describe the qualifications the research team to conduct the research and/or knowledge of the local study sites, culture, and of society.

Consent Form Guidelines and Template

Create and provide a Consent Form referring to the Consent Form Template as an example. Use the Essentials of Informed Consent as an additional guide in drafting your form. Use language understandable to the subject.

Essentials of Informed Consent:

- Title of Research Project

- Who is involved in the research: Identify the principal investigator, faculty sponsor (if applicable), and any funding/sponsoring organizations or collaborating institutions.

- Key Information: Invite subjects to participate and tell them the purpose of the study. Give a brief description of the procedures to be used and the time required, providing enough detail to enable subjects to make an informed decision. Provide the requirements for eligibility to participate, if there are any. Include any important exclusion criteria as well. Discuss audio/video recording, if applicable. It might be helpful to ask yourself what information you would need to have as a potential subject in order to feel that you could make such an informed decision.

- Risks and Benefits: Describe any reasonable foreseeable risks or discomforts associated with the study. If there are no known risks, this should be stated. Also, give a description of the likely benefits to subjects or to others.

- Compensation and Cost: Provide a statement of any compensation available to subjects, along with information on how it can be obtained. Describe any potential cost to the subject, like parking or cell phone related expenses. If there is no compensation or cost, indicate that.

- Handling Discomfort or Injury: If appropriate, tell subjects what treatment will be available and how it can be obtained.

- Confidentiality and Privacy: Specify the procedure for maintaining the confidentiality of records that identify subjects and who will have access to the records.

- Voluntary Participation: Explicitly state that the subject may refuse to participate or may withdraw for any reason and at any time without penalty. Describe the procedures for electing to participate and for declining. Include a statement regarding the disposition of data collected from subjects who later elect to withdraw.

- For More Information, Questions, or Concerns: Tell subjects who to contact and how.

- Include the following statements at the end of the form:
    - This research has been reviewed and approved by the Columbus State Community College Institutional Review Board (IRB). The IRB is a committee that protects the rights of people who participate in research studies. If you have any questions, concerns, or reports regarding your rights as a subject of research, please contact the IRB by email at irb@cscc.edu. [Note: if the Columbus State IRB is ceding authority to another institution's IRB, provide the appropriate contact information.]
    - Do not sign this form if an IRB approval stamp does not appear at the top of the page. Do not sign this form if the dates under the stamp have expired.

- Signature: Provide a space for signatures indicating consent, include a space for the date, and printed name. Also include a space for the name, date, and signature of the person obtaining consent. Make sure a second copy is available for the subject to keep. If minors are involved in the project, ensure there are areas for parental consent and minor assent.
    - Verbal consent: If you request and are granted a waiver of written consent, provide a space for the subject's name (or study ID if not recording the name minimizes the risk to the subject), the subject's verbal response, and the signature, name, and date of the person obtaining consent.
    - Online consent: Replace the signature area with a method for which the subject can either expressly agree or disagree to participate. Explain they can screen print the consent information for their records.

Standard Consent Form Template

<Allow space at the top for the IRB approval stamp>

Consent to Participate in a Research Study

Study Title: <Insert title>

Principal Investigator

<Insert Name, Title, Institution, contact information of the PI and Doctorial Advisor, if applicable>

Supported By: <Include only if applicable; insert name of funder or sponsor organization>

Collaborating Institutions: <Include only if applicable>

Description and Purpose
<Provide enough key information and detail to enable subjects to make an informed decision>

Eligibility to Participate
<Explain why they are being asked to participate, include exclusion if applicable>

What Your Participation Will Involve
<Explain the procedure and the time required; include if audio/video recordings will be involved>

Benefits and Risks
<Explain how being in this study will help the subject or others; list and explain reasonably foreseeable risks and the magnitude of the risk>

Resources
<Include only if appropriate, tell subjects what treatment will be available and how it can be obtained>

Compensation and Costs
<Explain any compensation or potential costs to the subjects; indicate if there are none>

Confidentiality and Privacy
<Explain the procedure for maintaining the confidentiality of records and who will have access to the records>

Right to Withdraw
You do not have to take part in this study. If you start the study and later decide that you do not want to continue, simply contact me at <insert contact information>. If you withdraw from the study, any information already collected in relation to you will be discarded. Your decision to participate or withdraw will in no way affect <insert what the subject may be concerned about, like their standing in the course or in the College>, and it will not cause you to lose any benefits to which you are entitled.

For More Information
If you have any concerns or questions, you can contact me <insert contact information>. I'll be glad to talk to you any time about questions or concerns related to the study.

IRB Approval
This research has been reviewed and approved by the Columbus State Community College Institutional Review Board (IRB). The IRB is a committee that protects the rights of people who participate in research studies. If you have any questions, concerns, or reports regarding your rights as a subject of research, please contact the IRB by email at irb@cscc.edu. [Note: if the Columbus State IRB is ceding authority to another institution's IRB, provide the appropriate contact information.]

Statement of Consent
I have read the above information. I have been given a copy of this form. I have had an opportunity to ask questions, and I have received answers. I consent to participate in the study.

Do not sign this form if an IRB approval stamp does not appear at the top of the page.
Do not sign this form if the dates under the stamp have expired.

_____
Printed Name of Participant

Signature of Participant Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Note: Printed name and signature line required for Parental/Guardian Consent when the study involves participants under the age of 18. Participant signature then conveys assent.