
Policies and Procedures for the Review System for Human Subjects Research

**Pellissippi State Technical Community College
Institutional Review Board
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Pellissippi State Technical Community College
Policies and Procedures
for the Review System for Human Subjects Research

Summary

Guiding Legislation

Federal regulations (45 CFR 46) require that institutions that apply for federal funds must establish an Institutional Review Board (IRB) to protect the rights and welfare of human subjects who participate in research. The purpose of this document is to comply with federal policies to protect human subjects and to establish the Pellissippi State Technical Community College Institutional Review Board. The Pellissippi State IRB is responsible for reviewing and approving research before it may be conducted at or sponsored by Pellissippi State. This document also provides written procedures for IRB members and investigators to follow.

Applicability of Federal Policies and Jurisdiction of the Pellissippi State IRB

“Research” is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. “Human subject” means 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. Because virtually all education projects involve human subjects, the National Science Foundation and other federal agencies now require institutions to provide the registration number of the institution’s IRB and to indicate the status of human subjects review before grants can be submitted.

The IRB review process described in this document applies to all research involving human subjects conducted by Pellissippi State faculty, staff, or students; conducted with Pellissippi State property; or conducted by others who want to use Pellissippi State employees or students as human subjects. All course projects involving human subjects are subject to IRB review. Investigators who collect data must follow informed consent procedures. This includes collection of data from voice, video, digital, and image recordings as well as from telephone interviews and electronic mail. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by College officials. However, federal policy does not allow those officials to approve the research if it has not been approved by the IRB.

Membership of the IRB

The director of Institutional Effectiveness, Research and Planning, who serves as chair of the IRB, recommends candidates for the IRB to the president of Pellissippi State. After approval by the president, the names are reported to the federal government when the IRB is registered. The IRB must have five or more members of varying expertise and diversity, including at least one individual from the community and one nonscientist. All IRB members must undergo training in

human subjects protection (including ethical principles, federal regulations, and IRB procedures and policies) and sign a confidentiality agreement and a conflict of interest disclosure form. The Institutional Research office serves as liaison between the IRB, College staff, and investigators, and provides administrative support to the Pellissippi State IRB to ensure compliance with record keeping and reporting requirements.

Criteria for IRB Approval of Research

The Pellissippi State IRB is responsible for assessing whether the risks to research subjects are justified by the anticipated benefits to the subjects or to society. To approve research, the IRB must determine that all of the following requirements are satisfied: (1) risks to subjects are minimized; (2) risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may result; (3) selection of subjects is equitable; (4) informed consent will be sought from each prospective subject or the subject's legally authorized representative; (5) informed consent will be appropriately documented; (6) when appropriate to the research plan, adequate provision is made for monitoring the data collected to ensure the safety of subjects; and (7) when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Categories of Review

Projects involving human subjects in research settings fall in four categories: (1) exempt from IRB review, (2) eligible for expedited review procedures, (3) require full-board review, and (4) previously approved projects in need of continuing review at intervals appropriate to the degree of risk but not less than once per year. A key factor for projects in the first two categories of review is that the proposed research involves no more than minimal risk. Federal policy defines minimal risk as an anticipated risk of harm in the proposed research that is not greater, considering probability and magnitude, than the risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research that is Exempt from IRB Review: Many education projects will be exempt from IRB review if certain criteria are met, but the IRB must certify that the project is exempt. The researcher does not have this authority. The project (1) must involve no more than minimal risk and (2) must be in one of the six categories listed in federal regulations. Investigators use Form A to apply for certification as exempt from IRB review. Projects that are certified as exempt from IRB review are not exempt from ethical principles and informed consent. No research procedures involving child participants (under 18 years of age) is exempt from review by the Pellissippi State IRB.

Research that is Eligible for Expedited Review: Federal regulations allow IRBs to use an expedited review procedure (1) to review minor changes in previously approved research or (2) to review projects that involve no more than minimal risk and that appear in a list of nine categories established by the Department of Health and Human Services and published in the *Federal Register*. Under the expedited review procedure, the director of IR, serving as the IRB chair, reviews the research protocol and advises other IRB members of the research proposals that are approved. Investigators use Form B, checking Option B-1, to apply for expedited review.

Research Reviewed by the IRB Board at a Full Board Review (Convened Meeting): All proposed research projects involving human subjects that do not qualify for exempt or expedited review must be reviewed by the Pellissippi State IRB at convened meetings at which a majority of members are present for discussion and voting. These projects either involve more than minimal risk or are not a category of research eligible for exempt or expedited review. The IRB may meet via teleconferencing if certain criteria are met and documented. Applications are prepared using Form B, Option B-2.

Continuing Review of Previously Approved Research: Every approved research study has an expiration date. Investigators may not continue their research activities past the expiration date. The first expiration date is one year (minus one day) after the IRB initially reviewed the research. It is the primary responsibility of the investigator to keep track of this expiration date. Two months prior to the expiration date, the investigator must submit a continuing review application (Form C) to apply for IRB approval for the next 12 months.

Researchers may not implement changes to their approved research studies without IRB approval.

Projects that were certified as exempt from IRB review (Form A) do not need continuing review even if they extend past one year when the scope and nature of the project remain unchanged. Investigators must seek IRB approval before implementing changes in the scope or nature of exempt projects.

Informed Consent

Informed consent is a legal requirement and is a core element in the protection of research participants' rights and welfare. Informed consent is an ongoing process that ensures that participants have been provided information needed to knowledgeable and voluntarily decide whether to participate in the research. Federal regulations list many specific requirements for informed consent, including descriptions of procedures and foreseeable risks or discomforts to the subject, and a statement that the subject may discontinue participation at any time without penalty. Pellissippi State's *Policies and Procedures for the Review System for Human Subjects Research* requires investigators to use the Informed Consent Template when preparing forms to ensure that all of the required elements of informed consent are included. Informed consent is obtained from subjects aged 18 and older. For children under age 18, parental permission and assent from the child is required. When appropriate, informed consent is obtained from a participant's legally authorized representative. Videotaping participants or making other images or electronic records requires additional consent because of privacy and confidentiality issues. Researchers collecting data using recordings and other media records must also obtain a signed "Recorded Media Addendum To Informed Consent" from potential participants.

Steps in the IRB Approval Process

The Pellissippi State IRB must approve the research before the investigator makes any contact with the proposed subjects. Investigators must complete training in human subjects research and

document these activities. Investigators complete the appropriate application: Form A for exempt projects; Form B for expedited or full-board review; Form C for continuing review. Investigators must also draft the Informed Consent instrument using the appropriate template and prepare any surveys, questionnaires, or recruitment flyers that will be used in the research. Investigators submit the signed application, certification of training, curriculum vita, informed consent instrument, and research materials to the director of Institutional Research.

The director of Institutional Research, serving as the IRB chair, has the authority to certify the project as exempt or to approve it through the expedited process. If a full-board review is required, the director of Institutional Research will distribute the application and accompanying materials to the IRB members and convene an IRB meeting. The investigator may be invited to the meeting to answer questions.

The IRB can approve the application without reservation; approve the project with minor modifications; table approval of the project pending resubmission of the application, or disapprove the project if it determines that the human subjects are at a greater risk than the benefits to be accrued. If the project is not approved, the investigator can revise and resubmit the project or appeal the IRB's decision through the IRB chair.

IRB approval is granted for a maximum of one year from the date of IRB approval (minus one day). Investigators seeking a continuation must submit Form C, Continuing Review Report. Projects that continue without IRB approval are not in compliance with federal or College policies.

Investigators submit Form D to report changes or adverse events and to close out completed projects. The close-out report is very important because federal regulations require records, including all signed informed consent documents, to be maintained for three years after the end of a project. The confidentiality of data must be safeguarded at all times to protect research participants.

Conclusion

Pellissippi State established a Review System for Human Subjects Research to protect participants. The IRB does not assume the role of evaluating the soundness of proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to participants.

Statement of Principles

The following ethical principles govern Pellissippi State Technical Community College (also referred to as Pellissippi State) in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the College. These principles govern human subjects research regardless of whether the research is subject to federal regulation and cover both funded and non-funded human subjects research.

- Respect for Persons – acknowledgement of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy
- Beneficence – a responsibility to do no harm, to maximize possible benefits, and to minimize possible harm
- Justice – an expectation of fairness in distribution of benefits realized from research as well as its burdens

The College set up the procedures described below to ensure that in the conduct of research involving human subjects that

- Risks are minimized and reasonable in relation to anticipated benefits
- Participation is voluntary and subjects give informed consent
- Rights and welfare of subjects are maintained

These ethical principles are guided by the *Belmont Report* (see [Appendix L](#)), which Pellissippi State has adopted to fulfill its responsibilities to protect human subjects in research.

1.0 Introduction

Rational of this Policy

U.S. Department of Health and Human Services (HHS) regulations for the protection of human research subjects are published at Title 45 Code of Federal Regulations, part 46. These regulations require that institutions that apply for federal funds must establish and register an Institutional Review Board (IRB) and assure that proposals submitted are compliant with federal policy.

Pellissippi State has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. To comply with the legislation and to ensure that subjects are protected, the College has established the Pellissippi State Technical Community College Institutional Review Board (hereinafter referred to as the Pellissippi State IRB or the IRB). The IRB review process described in this document applies to all research involving human subjects conducted by Pellissippi State faculty,

staff, or students; conducted with Pellissippi State property; or conducted by others who want to use Pellissippi State employees and/or students as human subjects.

1.1 Guiding Legislation

The Code of Federal Regulations (CFR) is a collection of the regulations that have been promulgated under United States law. U.S. Department of Health and Human Services regulations for the Protection of Human Subjects (45 CFR 46) were published in 1991 and include four subparts: subpart A, also known as the “Common Rule”; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. The Common Rule was codified in separate regulations by 15 federal departments and agencies. Each agency includes in its chapter of the Code of Federal Regulations section numbers and language that are identical to those of the HHS codification at 45 CFR part 46, subpart A.

The National Science Foundation (NSF) is one of the agencies following the Common Rule (at 45 CFR 690). NSF policy is that all projects involving human subjects must either (1) have approval from an organization’s Institutional Review Board before issuance of the NSF award or (2) identify the applicable subsection of federal policy exempting the proposal from IRB review. The process investigators must use for (1) and (2) is described in this document. Other federal agencies, such as the U.S. Department of Education, have similar requirements. (See Appendix H for a brief history of regulations to protect human subjects and for a list of the federal agencies following the Common Rule.)

Applicability to Educational Projects

Until recently, it was often assumed incorrectly that if the “human subjects” box was not checked on grant application forms, the proposal was exempt from IRB overview. Because virtually all education projects involve human subjects, NSF now requires program directors to get this information from investigators before proceeding with an award recommendation. Many grants are submitted electronically via the Grants.gov website. In the future, this site will require grant proposals to indicate the status of human subjects review before grants can be submitted.

1.2 Scope of this Document

This manual was prepared to help investigators comply with Pellissippi State policies and federal regulations concerning the use of humans in research. Another purpose is to comply with 45 CFR 46, which requires written procedures to protect human subjects used in research conducted under the auspices of this College. Some essential material has been placed in the appendixes.

1.3 Responsibilities and Services of the Office of Institutional Effectiveness, Research and Planning

The office of Institutional Effectiveness, Research and Planning (also known as Institutional Research or IR) is responsible for the development of policies and procedures governing the implementation of federal regulations concerning the use of human subjects in research. The IR office also provides full support to the Pellissippi State IRB, serving as liaison between investigators at Pellissippi State and the Pellissippi State IRB. The director of Institutional

Research, who is also responsible for the Pellissippi State Grants Office, reports to the president of the College.

The IR office provides the following services:

Leadership for the Pellissippi State IRB: The director of Institutional Effectiveness, Research and Planning is chair of the Pellissippi State IRB. Investigators who need to discuss the review process or a proposed study with a member of the Pellissippi State IRB should contact the Pellissippi State IRB chair at (865) 694-6526.

Preliminary Review and Assistance: Staff members in the IR office review all research projects involving human subjects to determine applicability of federal regulations and institutional policy.

Policies and Procedures: The IR office develops the policies and procedures for the review of research involving human subjects in consultation with the Pellissippi State IRB.

Education: The IR office, in consultation with the Pellissippi State IRB, provides information and other educational assistance to departments and to investigators regarding regulations, policies, and procedures applicable to research involving human subjects. The Pellissippi State IRB and the IR office provide seminars for faculty and staff. Resources related to human subjects research are posted on the IR website.

Records and Files: The IR office maintains all IRB records including agenda and minutes, policies, regulations, forms, reference materials, and applications to conduct research that investigators submit to the Pellissippi State IRB.

1.4 Institutional Assurance of Compliance

Pellissippi State must file a Federalwide Assurance (FWA), which is an assurance of compliance with the federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S. Department of Health and Human Services. The assurance includes a statement of ethical principles, the registration number of the Pellissippi State IRB, and the name of the Human Protections Administrator (HPA) for the College. The HPA for Pellissippi State is the director of Institutional Research.

FWAs also are approved by OHRP for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects may rely on the FWA for the research that they conduct or support. If Pellissippi State engages in research conducted or supported by non-HHS federal departments or agencies, the HPA will consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question.

Pellissippi State's current **Federalwide Assurance** is in effect from 4/29/2009 through 4/29/2012. The assurance number assigned to Pellissippi State is FWA00014395. Pellissippi State voluntarily agreed to apply its FWA to the Common Rule and subparts B, C and D of the HHS regulations at 45 CFR 46 to all research, regardless of source of support, unless an agency

or department conducting or support the research determines that the research shall be conducted under a separate assurance.

2.0 Institutional Review Board

2.1 Purpose

The Pellissippi State IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Pellissippi State and to ensure that this research is conducted in full compliance with both the letter and the spirit of the regulations protecting human research subjects. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and College policy.

The first two questions the IRB faces is whether the activity involves *research*, and second, whether it involves *human subjects*. **Research** is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [Federal Policy §____.102(d)]. **Human subjects** are defined by the regulations as "living individual(s) 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" [Federal Policy §____.102(f)].

2.2 Jurisdiction of the Pellissippi State IRB

The use of human subjects in any experimental environment, whether it be research (funded or non-funded) or other scholarly activities (such as surveys, questionnaires, and classroom experiences) must be reviewed, and the use of human subjects as set forth in the proposed activity plan must be approved by the Pellissippi State IRB before such activities are initiated and before potential subjects are contacted about or recruited for the project. The Pellissippi State IRB is charged with evaluating each research project's compliance with ethical standards in regard to issues such as confidentiality and the protection of the rights and welfare of human subjects. The Pellissippi State IRB oversees the protection of human subjects by ensuring that risks to subjects are minimized and that participation by subjects is informed and voluntary. The Pellissippi State IRB is also responsible for certifying when projects are exempt from IRB review.

The goal of the Pellissippi State Review System for Human Subjects Research is to protect participants. The IRB does not assume the role of evaluating the soundness of proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to participants.

All proposals to conduct research at Pellissippi State must be initiated through the process described in Pellissippi State Policy 08:02:01, "Conducting Research at Pellissippi State." College officials may not, however, approve research if it has been disapproved by the Pellissippi State IRB [Federal Policy §____.112].

2.3 Authority and Organization of the IRB

The Pellissippi State IRB was created at Pellissippi State in 2008. Its formal name is Pellissippi State Technical Community College Institutional Review Board.

The Pellissippi State Institutional Review Board operates under the U.S. Department of Health and Human Services regulations for the Protection of Human Research Subjects (45 CFR 46). The Pellissippi State IRB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” commonly referred to as the *Belmont Report* (see [Appendix L](#)).

The Pellissippi State IRB reports to the director of Institutional Effectiveness, Research and Planning/Grant Development, who also serves as the IRB chair. The overall registration number that OHRP assigned Pellissippi State for its IRB organization (IORG) is IORG0005816. The registration for Pellissippi State’s IRB is IRB00007011 (IRB #1). The expiration date for both registrations is 4/21/2012.

2.4 Membership: Background and Training

The IRB is composed of a minimum of five (5) members. These members come from diverse backgrounds in order to promote the review of human subjects research activities and to provide the professional competency necessary for this review. The director of IR, serving as chair of the IRB, recommends members of the IRB to the president of Pellissippi State for approval. Members are selected with consideration to their experience and expertise, their racial and cultural backgrounds, and their sensitivity to such issues as community attitudes.

The IRB includes both male and female members. The IRB also includes among its members at least one individual whose primary expertise is in a nonscientific area, at least one individual whose expertise is in a scientific area, and at least one individual from the community who has no affiliation with Pellissippi State other than as an IRB member. In this manner, the composition of the IRB not only meets regulatory requirements but also ensures the expert and sensitive review of all projects submitted.

Members shall serve on the Pellissippi State IRB for a minimum period of three years with appointments becoming effective at the beginning of each fall semester. Appointments are made so that terms of the members are staggered with no more than three members’ terms expiring at the same time. All appointments are subject to renewal at the discretion of the president of the College. Members may be replaced prior to the end of their term if they are unable to fulfill their responsibilities. The director of Institutional Effectiveness, Research and Planning is a permanent (voting) member of the IRB, serving as chair of the IRB and as the designated reviewer for expedited research applications.

The Pellissippi State IRB will invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the Pellissippi State IRB. These individuals may not vote with the Pellissippi State IRB.

See [Appendix M](#) for more information on the membership of the Pellissippi State IRB.

Training

All Pellissippi State IRB members are required to undergo formal training at the time of their initial appointment. The self-paced training course is available on the IR website. The training is described in detail in [Appendix J](#), which also provides the certification form to document training. Retraining and recertification is required every three years for members who continue to serve on the IRB. [Appendix E](#) provides links to other training resources for IRB members, investigators, and other interested persons.

Volunteer Agreement

IRB members who are not employees of Pellissippi State must sign a “Volunteer Agreement” form available from the Human Resources website at http://www.pstcc.edu/departments/human_resources/docs/volunteer.doc

2.5 Operations of the IRB

- A. IRB meetings are scheduled as required.
- B. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least two weeks prior to the meeting.
- C. Voting requirements
 1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.
 2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. Although meetings conducted with all participating IRB members physically present are preferred, IRB meetings conducted via telephone conference call are permitted.
 3. Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).
- D. Grievances

The IRB chair is responsible for determining the disposition of any grievances (e.g., of a research subject against an investigator). The chair will inform the IRB of all grievances and, if requested, the board will act in an advisory capacity.

2.6 Appeal Process

In virtually all instances, investigators work with the director of Institutional Research, serving as IRB chair, to reach agreement on the best ways to meet requirements to protect human research subjects. Nevertheless, the College maintains an appeals procedure should these less formal efforts fail to reach an accord. The appeals procedure should be used **ONLY** after all other avenues of discussion have been exhausted.

In the event an investigator wishes to appeal a decision of the Pellissippi State IRB with respect to approval or to requested modifications in the project, he/she may address a written request to the director of Institutional Research/IRB chair for a follow-up meeting of the Pellissippi State IRB. The request should contain sufficient information to identify the project, actions of the IRB, the means used to settle outstanding disagreements, and the reasons for the investigator's appeal.

The director of Institutional Research, serving as IRB chair, will convene the IRB.

If the IRB believes that the project should be approved in light of modifications, a new vote may be taken. The result of this vote is final; consequently, there are no other appeals.

2.7 Record Keeping and Reporting Requirements

The Pellissippi State Institutional Research office prepares and maintains adequate documentation of Pellissippi State IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.
2. Detailed minutes of IRB meetings, showing:
 - a. Members present (any consultants, guests, or others shown separately)
 - b. Initial and continued presence of a majority of members, including at least one nonscientist member (the minutes must note when members who have a conflict of interest absent themselves during discussion and voting on the research in which they have a conflict of interest)
 - c. Written summary of the discussion on debated issues and their resolution including
 - i. Whether the project requires review more often than annually
 - ii. For continuing review: Whether the project needs verification from sources other than the investigators that no material changes have occurred since the previous IRB review
 - iii. For projects funded by grants, whether a copy of the grant proposal was reviewed by the IRB

- d. The basis for requiring changes in or disapproving research
 - e. Actions taken by the IRB
 - f. The vote on such actions, including the number of votes for, against, and abstentions
 - g. For meetings convened via telephone conference, minutes must clearly document that each IRB member (i) received all pertinent material prior to the meeting and (ii) could actively and equally participate in the discussion of all protocols
3. Records showing which research projects were certified as exempt from IRB review by the director of Institutional Research, serving as IRB chair.
 4. Records showing which research projects were approved under the expedited review process.
 5. Records of continuing review activities, updated consent documents, and summaries of on-going project activities.
 6. Copies of all correspondence between the IRB and the investigators.
 7. A detailed list of IRB members (names; degrees; representative capacity; experience including board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the College).
 8. Any statements of significant new findings developed during the course of the research (unanticipated risks or adverse reactions) that are provided to subjects as required in 45 CFR 46.116(b)(5).
 9. Adverse reactions reports and documentation that the IRB reviews such reports.
 10. General project information provided to subjects (e.g., fact sheets, brochures).
 11. Written procedures for the IRB (See Appendix W).
 12. The director of Institutional Research, serving as IRB chair, will sign and date application forms ([Form A](#) and [Form B](#)) showing date of action and outcome. The director of Institutional research, serving as IRB chair, has authority to sign all IRB items.

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

The director of Institutional Research, serving as IRB chair, notifies the investigator of IRB decisions orally in person or by telephone; or electronically by e-mail. A copy of the minutes and

a copy of the signed [Form A](#) or [Form B](#), if approved, is forwarded to the investigator within 5 working days. To keep the College informed of IRB decisions, the IR director, serving as the IRB chair, notifies President's Staff of the findings, which are recorded in President's Staff Notes.

All forms submitted or retained as evidence of informed consent must be preserved by the investigator for at least three years after the project is officially closed (Form D must be submitted to close out the project). The IRB must be notified if there is a change of the investigator of grant funded research.

2.8 Alternates

Trained alternates may be formally appointed and listed as needed on the IRB roster to vote in place of an absent voting member. Although an alternate may be designated for more than one Pellissippi State IRB member, each alternate may represent only one regular member at a convened meeting. Alternates will have similar expertise and background to members to ensure that all core areas are represented at every IRB meeting. Generally, only one member of each pair will participate in a given meeting, counting towards quorum and the vote. If the primary member has a conflict of interest and cannot conduct an assigned review, and the alternate does not have a conflict, he or she may conduct the review, count towards quorum, and vote for that research protocol.

2.9 Confidentiality and Conflict of Interest

All Pellissippi State IRB members must sign a confidentiality agreement and conflict of interest disclosure form prior to being assigned research projects for review. See [Appendix F](#) for the Confidentiality Agreement form. Also see Pellissippi State Policy 06:17:02, "Conflict of Interest" (see [Appendix E](#) for an electronic link to this policy).

No member of the Pellissippi State IRB may participate in the initial or continuing review by the IRB of any project in which the member has conflicting interest, except to provide information requested by the IRB.

Pellissippi State IRB members should identify any potential conflicts on the agenda prior to the beginning discussions of the research activity and absent themselves from the meeting room when the IRB discusses and votes on the research in which they have a conflict of interest.

3.0 Review Categories for Research

Determination as Research

As defined in the Code of Federal Regulations (45 CFR 46.102), *research* means a systematic investigation – including research development, testing and evaluation – designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service projects may include research activities.

As discussed in the Office of Human Research Protection *IRB Guidebook* (see [Appendix L](#) for an electronic link to the *Guidebook*), the definition above is interpreted comprehensively to

include as research any project in which any part of the project is to be a contribution to generalized knowledge and/or its results may be made public in some way. This includes presentation at a conference or other professional meeting, distribution of a model to other organizations, or potential utilization of the data or strategies by another institution. The following factors are considered when determining whether an activity is subject to IRB review:

- Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?
- Does research involve obtaining information about living individuals?
- Does the research involve intervention or interaction with the individuals?
- Is the information individually identifiable?
- Is the information private? (The designation of private would include behavior that occurs in the context in which an individual can reasonably expect that no observation or recording is taking place or which the individual can reasonably expect will not be made public.)

3.1 Four Categories of Review

There are four categories of review for projects involving human subjects in research settings:

1. Exempt from Review
2. Expedited Review
3. Full Board Review (requires review by the convened Pellissippi State IRB with a quorum of IRB members)
4. Continuing Review (of projects that were approved under an expedited review or full-board review)

Each category is explained below.

Important: Individuals seeking to conduct research on human subjects may *never* make the decision that their research is exempt from review. This determination is made through the Pellissippi State IRB process described below.

The chart below summarizes the four categories of human subjects research projects, the type of review corresponding to each category, and the type of form that the investigator must submit to the IRB.

Table 3.1: The Four Categories of IRB Review for Human Subjects Research

Type of Review	Project Meets These Conditions	Form Required
<p>(1) EXEMPT: May apply for certification by the Pellissippi State IRB as <u>exempt from Pellissippi State IRB review</u></p>	<p>Project meets both conditions:</p> <ol style="list-style-type: none"> 1. <u>no more than</u> minimal risk AND 2. research is in one or more of the six exempted research categories listed in "Instructions for Form A" (see section 3.3.1 for an overview) <p>Note: research with subjects under 18 years old is not eligible for exempt review. It will be considered under expedited or full board review.</p>	<p>Form A</p>
<p>(2) EXPEDITED: May also be used to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized.</p>	<p>Project meets both conditions:</p> <ol style="list-style-type: none"> 1. <u>no more than</u> minimal risk AND 2. research is in one or more of the nine categories eligible for expedited review listed in "Instructions for Form B" (see section 3.4.1 for an overview) 	<p>Form B, option B-1</p>
<p>(3) FULL-BOARD REVIEW:</p>	<p>Project does not meet the criteria for exempt or expedited review. One or more of the following conditions exist:</p> <ol style="list-style-type: none"> 1. Project involves no more than minimal risk but does not fall in a category eligible for exempt or expedited review or 2. Project involves <u>more than</u> minimal risk 	<p>Form B, option B-2</p>
<p>(4) CONTINUING REVIEW: For projects that were approved under Form B.</p>	<p>Required at least annually for ongoing projects that were approved by the IRB (under expedited procedures or full-board review). Continuing review is not required for research that was exempted from IRB review unless changes are proposed to the scope of the research. These proposed changes cannot be undertaken until the IRB has approved them.</p>	<p>Form C</p>

3.2 Definition of Minimal Risk

A key factor for projects in the first two categories of review is that the proposed research involves no more than minimal risk.

Federal regulations define minimal risk in a research activity as an anticipated risk of harm in the proposed research that is not greater, considering probability and magnitude, than risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3.3 Exempt Review (no more than minimal risk to human subjects)

The federal regulations in 45 CFR 46 allow for six classifications of research to be exempted from IRB review. Only the director of Institutional Effectiveness, Research and Planning, who also serves as IRB chair, may certify the research as “exempt from IRB review.” To determine whether the research qualifies as exempt from IRB review, a Form A and its associated procedures have been developed (see [Appendix A](#)). Investigators who are planning an activity involving human subjects that (1) involves no more than minimal risk and (2) falls into one of the six categories listed in section 3.3.1 must submit Form A to the director of Institutional Effectiveness, Research and Planning, who serves as IRB chair. Projects that are certified as exempt from IRB review are not exempt from ethical principles and require informed consent.

Note: research with subjects under 18 years old is not eligible for exempt review but will be considered under expedited or full board review.

3.3.1 Overview of the Six Categories of Research Eligible for Exemption from IRB Review

The six (6) classifications of research eligible for certification of exemption from the federal policy on human subjects research are summarized below. See “[Instructions for Form A](#)” in Appendix A for the full language from the federal policy for each category.

Category 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices (e.g., research on instructional strategies and techniques, curricula, or classroom management methods).

Category 2. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior. **IMPORTANT EXCEPTION:** if the information in the study is recorded in such manner that the identity and responses of human subjects might be determined and could be harmful (e.g., financially, legally, professionally or personally) to the subject if revealed, then this research is NOT exempt from formal IRB review).

Category 3. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior that is NOT exempt as explained in the exception in Category 2 *can* be eligible for an exemption if (1) the human subjects are public officials or candidates for public office or (2) federal statutes protect the confidentiality of personally identifiable information.

Category 4. Research involving the collection or study of existing information (such as data, documents, or records) if these sources are publicly available or if the information is recorded by the investigator so that the identity of the subjects cannot be determined.

Category 5. Research and demonstration projects that are approved by federal department or agency heads designed to study public benefit or service programs (see Form A instructions in Appendix A for more information).

Category 6. Taste and food quality evaluation and consumer acceptance studies (see Appendix A for more information).

3.4 Expedited Review (no more than minimal risk to human subjects)

An application ([Form B](#)) must be prepared for projects that place human subjects at minimal risk and that fall in one nine (9) classifications established by the federal government (see Section 3.4.1). However, because these projects may be eligible for expedited review, investigators may check the “Expedited Review” option (check box B-1) on Form B. The IRB will review this request. If the director of IR, serving as IRB chair, does not approve expedited review, the IR director/IRB chair will forward the application for full board review (option B-2 on Form B).

Expedited review procedures are described in HHS regulations at 45 CFR 46.110. Under an expedited review procedure, Pellissippi State’s director of Institutional Research, serving as IRB chair, reviews the research protocol. In conducting expedited review, the IR director, serving as IRB chair, may exercise all of the authorities of the IRB except that the chair may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the nonexpedited procedure set forth in 45 CFR 46.108(b) and described in Section 3.5 below.

3.4.1 Nine Research Categories Eligible for Expedited Review

See “[Instructions for Form B](#)” in Appendix B for the specifics of each category, as written by OHRP. This summary is to provide investigators and others with an overview of the categories. A full application for review of research involving human subjects is required (Form B), but the project may meet the criteria for expedited review (option B-1 on Form B).

Category 1. Clinical studies of drugs and medical devices meeting specific conditions (see Appendix B).

Category 2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, with specific limitations on age, weight, and health of subjects; on the collection procedure; on the amount of blood collected; and on the frequency with which it will be collected (see Appendix B).

Category 3. Prospective collection of biological specimens for research purposes by noninvasive means (see Appendix B for examples, such as hair and nail clippings, skin cells, saliva, and others).

Category 4. Collection of data through noninvasive procedures such as physical sensors, weighing or testing sensory acuity, muscular strength testing, body composition assessment, and others (see Appendix B for more detailed information about this category).

Category 5. Research that involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). Note: Some research in this category may be eligible for certification as exempt from IRB review. This listing refers only to research that is not exempt.

Category 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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 methodologies. Note: Some research in this category may be eligible for certification as exempt from IRB review. This listing refers only to research that is not exempt.

Category 8. Continuing review of research previously approved by the convened Pellissippi State IRB as follows:

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

where no subjects have been enrolled and no additional risks have been identified; or

where the remaining research activities are limited to data analysis.

Category 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where Categories 2 through 8 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.

3.5 Full IRB Review

All research projects involving human subjects that do not qualify for any of the above two categories (exempt or expedited) must be reviewed and approved by the full Pellissippi State IRB at a convened meeting. Investigators should plan well in advance to avoid processing delays. Investigators preparing Form B applications must submit one original paper copy with original signatures and must e-mail one electronic version to the director of Institutional Research, serving as IRB chair, at least four weeks before approval is needed to allow time for IRB members to review the material and for an IRB meeting to be scheduled. Included in the application is a checklist of attachments that are a required part of the application. Investigators should contact the director of IR/IRB chair for the date of the IRB meeting.

3.6 Continuing Review

Approved research is subject to continuing IRB review and must be reevaluated at least annually (and more frequently if required by the IRB) [Federal Policy §____.109(e)]. Continuing review is required only for projects that were submitted to the Pellissippi State IRB on a Form B application and that were approved through either an expedited or full-board review process.

Please see the section 8.0, “Continuing Review Report on Human Subjects Research,” for the procedure to follow for the annual review.

Note: Projects that were certified as exempt from IRB review (Form A application) do not need continuing review even if they extend past one year unless the scope or nature of the project changes from that reported on the Form A application that was submitted.

3.7 Acceptance of IRB Approval from Another Institution

Investigators who would like to conduct human subjects research at Pellissippi State must follow the Pellissippi State process to conduct research and receive approval from the Pellissippi State IRB before commencing research.

3.8 Course Activities

Faculty members are responsible for contacting the director of Institutional Research, who serves as IRB chair, when students are involved in course activities that require IRB approval. These activities will be reviewed by the IRB chair based on the nature of the course activity and the extent of student and subject involvement. The instructor is encouraged to complete a Form A for exemption from IRB approval and submit it along with the protocol and any accompanying consent form(s), cover letter(s), and/or questionnaire(s) to obtain the guidance of the IRB regarding these activities.

Approval of the IRB may never be obtained retroactively. Course projects, assignments, and activities that have undergone human subjects review by the IRB (such as surveys, questionnaires, and media recordings) will allow faculty, staff, and students to present and publish the results of their projects, activities, and research in public forums, including educational and professional conferences. In the absence of IRB review, the results of these activities may not be presented outside the classroom.

4.0 Review Procedures/Steps (The Approval Process)

The Pellissippi State IRB must approve the research project **before** the investigator makes any contact with the proposed subjects. Investigators must also comply with Pellissippi State Policy 08:02:01, “Conducting Research at Pellissippi State.” Investigators can also find a description of the process in Appendix K, “Steps for Investigators.” Appendix V provides a timeline for IRB review and procedures, including responsibilities of investigators.

1. The investigator reads this document, *Policies and Procedures for the Review System for Human Subjects Research*
2. The investigator completes the appropriate IRB review application form, either Form A or Form B.
 - a. Form A: Exempt Review (See section 3.3)

- b. Form B: Full-Board Review (See section 3.5) – For projects of no more than minimal risk that meet the criteria for expedited review, investigators can apply for expedited review (Box B-1).
3. The investigator gathers all documentation required as explained in the instructions for Form A or Form B.
4. The investigator submits the application packet (one copy) with original signatures to the director of Institutional Research, who is IRB chair. The investigator also emails an electronic version to the director of Institutional Research/IRB chair.
5. Pellissippi State IRB reviews are conducted on an as-needed basis. For planning purposes, investigators should allow the following time line from the date that the IRB receives the completed application. Longer time lines will be required for incomplete applications.
 - a. Expedited Review: Two weeks (Form B, Option B-1).
 - b. Full Board Review: Four weeks (Form B, Option B-2).

Important: The Pellissippi State IRB must approve the research project before the investigator makes any contact with the subjects.

6. The director of Institutional Research, serving as IRB chair, will distribute the application packets to IRB members as appropriate.
7. Approval is for a maximum of one year (minus one day) from the date of the IRB meeting considering the application. There are no extensions or grace periods.
8. Two months before the IRB approval expiration date, the investigator must submit for the Continuing Review Report (Form C) to the director of Institutional Research, who serves as IRB chair, for IRB review and approval. The investigator has primary responsibility to keep track of the expiration date and for submitting all IRB forms in a timely manner.
9. Upon completion of the project, the investigator **must** submit a close-out report on Form D (“Project Status Report: Changes and/or Close-Out”) to the IRB.

Submission Packet Checklist:

1. Vita of investigator and co-investigator
2. Certifications of Human Subjects Protection Training completed by investigator/co-investigator
3. Completed and signed application Form A or B for review (this includes the research plan/proposal)
4. Samples of informed consent/assent/permission forms (use the templates provided in Appendix T and the Recorded Media Addendum, if needed, in Appendix P).
5. Recruitment and information brochures and flyers, instruments, surveys, questionnaires, etc., that the investigator proposes to use for the activity

4.1 The Investigator

4.1.1 Responsibilities

To comply with the polices established by the Pellissippi State Institutional Review Board, investigators who sign an application commit themselves to abiding to the principles stated in *The Belmont Report* (see Appendix L) and standards of professional ethics in all research, development, and related activities involving human participants conducted under the auspices of Pellissippi State. All investigator(s) further agree to the following:

1. The investigator/co-investigator will obtain approval from the IRB prior to instituting any change in a research activity. The investigator is responsible for promptly reporting proposed changes in a research activity to the IRB. The only exception to the requirement to obtain IRB review and approval prior to implementing changes in approved research is when necessary to eliminate apparent immediate hazards to the subject.
2. The investigator/co-investigator must promptly report to the IRB any unanticipated problems involving risks/adverse events to subjects or others (see Form D, “Project Status Report: Changes and/or Close Out”).
3. The investigator/co-investigator is responsible for completing and submitting a continuing review report (Form C) for reporting progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to participants, but not less than once per year. Investigators must submit a completed Form C two months before the project approval expiration date.
4. The investigator/co-investigator is responsible for keeping signed informed consent documents for the duration of the project and for at least three years thereafter at a location approved by the IRB.
5. Investigators are responsible for obtaining professional development IRB training needed to conduct their research in compliance with federal regulations to protect human subjects.
6. The investigator/co-investigator is responsible for protecting the confidentiality of the participants in the research project. The passage of time does not diminish this responsibility. The rights of a participant do not expire at the end of a research project, or after any other period of time.
7. Investigators who are employees of Pellissippi State are responsible for completing a conflict of interest form in compliance with Pellissippi State Policy 06:17:02, “Conflict of Interest,” as appropriate. Any conflicts of interest with the proposed research must be disclosed to the IRB.

The investigator is the responsible official for ensuring that these procedures are followed. The Pellissippi State IRB has the authority to suspend or terminate approval of the project if these procedures are not followed. Federal regulations require the IRB to report serious and continuing non-compliance and all suspensions of approval to federal officials (and to the funding agency, if applicable).

4.1.2 Training Required

Investigators conducting human subjects research at Pellissippi State must maintain continuing knowledge of, and comply with, the following:

- Relevant ethical principles
- Relevant federal regulations
- Written IRB procedures
- State and local laws
- College policies for the protection of human subjects and Pellissippi State Policy 08:02:01, “Conducting Research at Pellissippi State”

Investigators are required to take a self-paced training course available through the Institutional Research website. See Appendix J for the details of the training requirement and certification form needed to document training.

4.1.3 Record Keeping and Reporting Requirements

As described in 4.1.1, investigators must complete the following forms:

- Form C, “Continuing Review Report” annually (or with greater frequency if required by the Pellissippi State IRB)
- Form D, “Project Status Report: Changes and/or Close Out” for reporting changes to the project (such as a change to the title of the project or in investigators’ names), adverse affects or injuries, termination of the project, or to request changes in the research protocol.
- Identifiable records on human subjects must be kept confidential and in a secure location for at least three years after the completion of the research.

5.0 Informed Consent

Informed consent is a core element in the protection of research participants’ rights and welfare, and is a legal requirement. Investigators must also recognize that informed consent is an ongoing process that assures participants have been provided information needed to knowledgeably and voluntarily decide whether to participate in the research.

Investigators should seek consent under circumstances that (1) provide the prospective participants sufficient opportunity to consider whether to participate and (2) minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

Informed consent must also include a statement that participation is voluntary and may be discontinued at any time without penalty or loss of benefits to which the subject is otherwise entitled. The principles of informed consent are found in 45 CFR 46.116 and are presented in section 5.1 below.

Also refer to the appendixes listed below:

- See Appendix I for more on the requirements for obtaining informed consent.
- See Appendix T for Pellissippi State IRB templates that investigators must use to prepared informed consent forms. Different forms are required depending on the age of the subject:
 1. Template for General Informed Consent Form (for subjects age 18 and older)
 2. Template for Parent/Guardian Permission and Assent from Children
- See Appendix P for the template for the Recorded Media Addendum to the informed consent form that must be used when projects include collection of data from voice, video, digital, and image recordings.
- See Appendix Q for the Informed Consent Checklist for use by both investigators and IRB members. It lists all the necessary elements of informed consent documents.

5.1 Principles of Informed Consent

Pellissippi State IRB template forms and letters meet all elements of informed consent and are required to be used by investigators in their human subject projects. *Note: Any deviation from these templates must be approved prior to use by the IRB.*

Investigators must obtain the signed ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the signed permission of parents or legal guardian and all reasonable attempts must be made to obtain each participant's *assent*, which is defined as the participant's agreement to participate in the study.

Elements of Informed Consent

The following information, which must be provided to each subject, is included in the Pellissippi State IRB informed consent templates:

1. General information about the study:
 - a. A statement indicating that the study involves human subject research.
 - b. An explanation of the purposes of the research (see “note” below on research designs that are “deceptive” for an exception)
 - c. The expected duration of the subject’s participation
 - d. A description of the procedures to be followed (see “note” below)
 - e. Identification of any procedures that are experimental
2. A description of risks or discomforts to the subject
3. A description of the benefits, if any, to the subject or to others
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 to which confidentiality of records identifying the subject will be maintained
6. For research involving *more than* minimal risk:

An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they are or whether further information may be obtained
7. An explanation of (a) whom to contact for information about the research and research subjects' rights and (b) whom to contact in the event of a research-related injury to the subject
8. A statement that participation is
 - a. Voluntary
 - b. Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
 - c. The subject may discontinue participation at anytime (also without penalty or loss of benefits to which the subject is otherwise entitled)

Additional elements of informed consent

The legislation lists six other elements of informed consent to be provided to subjects when appropriate. These are as follows:

1. A statement that the treatment or procedure may involve risks to the subject (or to the subject's embryo or fetus if she becomes pregnant) that are currently unforeseeable
2. Circumstances under which the subject's participation may be terminated by the investigator
3. Additional costs to the subject that may result from participation in the research
4. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. A statement that the subject will be notified of significant new findings developed during the research that may relate to the subject's willingness to continue participation in the research
6. The approximate number of subjects in the study

The implied consent form also provides contact information for all investigators and for the Pellissippi State IRB chair (the chair is the director of Institutional Effectiveness, Research and Planning, telephone 865-694-6526).

Signatures must be obtained on the consent form of participants and/or parents or legal guardian except for questionnaire research in which return of the questionnaire gives implied consent (see Appendix I).

Note: In situations where participants will be **deceived**, the purpose and methodology are omitted and participants are told (on the signed form) that disclosure of the purpose and/or

methodology could bias the outcome of the study. In this case, **after the study is complete**, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants “after the fact” in order to guarantee informed consent.

IRB Waiver of Written Documentation of Informed Consent

Normal informed consent procedures call for a written consent document and the signature of the participant. If the only document linking the identities of the participants to the research is the signed informed consent form, then the requirement for written consent may be waived by the IRB upon the investigator’s request and justification on Form A or Form B. *Verbal consent is still required after providing the subject with a fair and reasonable explanation of the research, the participant’s role in it, anticipated risks and protection measures, and a statement that the participant is free to withdraw at any time without penalty.* The potential subject should understand that his/her participation is voluntary, and he/she should have an opportunity to ask questions about the research. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. **These requirements apply to all direct contacts with subjects and to such research methods as telephone surveys.**

Section 46.116 (c) and (d) of 45 CFR 46 provide conditions under which an IRB may approve a consent procedure that does not include all of the elements of informed consent.

5.2 Vulnerable Populations

Vulnerable populations include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. For these populations, additional safeguards must be included in the study to protect the rights and welfare of these subjects. To document informed consent, the written consent form must be signed by the subject or the subject’s legally authorized representative (LAR). An LAR is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. Section 46.117 of 45 CFR 46 describes procedures to be followed if the elements of informed consent required by law are presented orally to the subject or the subject’s LAR. The Pellissippi State IRB must approve a written summary of what is to be said to the subject or representative.

See Appendix S for special considerations when seeking to use children as research subjects.

5.3 Obtaining Assent from Subjects Who Are Minors

See Appendix T for the template for the informed consent form for use by subjects who are under age 18. Investigators must obtain permission from the parents of minor children and signed assent by children who are from 7 to 18 years of age. See Appendix I for procedures for obtaining oral assent from subjects less than 7 years of age.

6.0 IRB Considerations and Criteria for Review

To review and approve a project, the Pellissippi State IRB must determine that it satisfies the following requirements:

A. Risks to Subjects: Risks to the subject are minimized by using procedures that are consistent with sound research and that do not unnecessarily expose the subjects to risks (e.g., physical, psychological, social, or economic) and by using, whenever appropriate, procedures already being performed on subjects for diagnostic and treatment purposes.

B. Risks vs. Benefits: Risks to the subject are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies or services that subjects would receive even if they do not participate in the research). The IRB does not consider the long-range effects of applying the knowledge gained in the research as among those research risks or benefits that fall within its responsibility.

C. Subject Selection: The selection of subjects must be equitable. In making this assessment, the IRB takes into account the purposes of the research, the setting in which the research will be conducted, and the population from which the subjects will be recruited.

D. Informed Consent: Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be legally documented.

E. Confidentiality and Privacy: The research plan must provide for monitoring the data collected to ensure the subjects' privacy and the confidentiality of the data.

F. Other Considerations: The IRB also considers the acceptability of the research project in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and special vulnerabilities of the subjects.

7.0 Results of the IRB Review Process: Actions of the IRB

Overview

The director of Institutional Research, serving as the Pellissippi State IRB chair, screens all applications to determine whether the proposal should be submitted to the full IRB for review or to determine that the proposal qualifies for expedited review. Even if a proposal is submitted for expedited review, the IR director/IRB chair has the authority to refer a project to the full IRB for review and action. As part of the initial screening process, the IR director/IRB chair may require the investigator to revise an application to bring the proposal into compliance with institutional and federal policies and guidelines and IRB review criteria.

In preparation for a convened meeting of the IRB, the director of Institutional Research, serving as IRB chair, sends all members of the IRB the proposal and all attachments. Within 5 days of the scheduled meeting, the reviewers may request the attendance of the investigator at the meeting to answer specific questions of concern. A staff member in the Institutional Research office will contact the investigator and notify him/her of this request.

The director of Institutional Research, serving as the IRB chair, leads the discussion of the project at the meeting, but all members participate fully and freely. If the reviewers invited the investigator, the investigator may attend the first part of a meeting at which his/her project will

be reviewed to answer questions from the IRB membership but is not present during the ensuing discussion or the final vote.

Actions of the Pellissippi State IRB

After a full discussion, the IRB may take one of the following actions. Findings of the IRB will be recorded in the minutes of IRB meetings.

A. Approve without Reservation: IRB may approve the project as submitted without any changes noted for a maximum period of 12 months.

B. Approve with Minor Modifications: The IRB may approve a project contingent upon modifications to be completed by the investigator. The director of Institutional Research, serving as IRB chair, will compare the modifications received with the actions requested by the IRB. If the modifications are in compliance with the IRB directives, the director of Institutional Research, serving as IRB chair, will approve the project for a maximum period of 12 months.

C. Table Approval Pending Resubmission: If the IRB deems that the proposal and/or informed consent as submitted require major revisions, the IRB will require the investigator to resubmit the application and attachments with all of the changes required. In some cases, the director of Institutional Research, serving as IRB chair, may request one or more IRB members to assist the investigator in resubmitting the application. If no IRB member has been designated, the investigator is strongly urged to consult with the office of Institutional Effectiveness, Research and Planning to receive assistance in the preparation of a new application. Approval of the revised proposal is contingent on the results of discussion and vote by the reconvened IRB.

D. Disapprove: The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. The director of Institutional Research, serving as IRB chair, will notify the investigator in writing. Notification will include all of the reasons and rationale behind the disapproval.

Upon disapproval, the investigator has the option of one or the following two actions:

1. Revise and resubmit the project, reducing the risks to the subjects; or
2. Appeal the IRB's decision by sending a written request documenting the basis of the appeal to the director of Institutional Research, serving as IRB chair.
3. Only one appeal may be rendered.

8.0 Continuing Review Report of Human Subjects Research

As described in section 3.6, the Pellissippi State IRB is responsible for continuing review of all human subjects research projects that it approves (under either the expedited and full board review procedures). IRB approval is granted for a maximum of one year (minus one day). For example, if the IRB convened and granted approval to a research study on 6/27/2008, then the IRB approval date is 6/27/2008. The IRB expiration date is 6/26/2009. The IRB may require more frequent continuing review if it feels that the project warrants it.

When the research study is approved subject to modifications at a convened meeting, the date of IRB approval will be the date that the requested changes are verified by the IR director, serving as the IRB chair. The date of expiration, however, will continue to be one year from the date of the convened meeting (minus one day). For example, if during the 6/27/2008 meeting the IRB approved a research study subject to modification, the investigator subsequently responds on 7/5/2008, and the director of IR/IRB chair verifies that response on 7/6/2008, then the date of IRB approval is 7/6/2008. The IRB expiration date is 6/26/2009 (one year from the date of the convened meeting, minus one day) for annual approval.

When the research is reviewed and approved through an expedited review process, the date that approval is granted by the IR director/IRB chair will be the date of IRB approval. The expiration date will be one year from that date (minus one day).

Two months (8 weeks) prior to the expiration of the approval, the investigator must submit **Form C**, "Continuing Review Report," to the director of Institutional Research, who serves as IRB chair. If the investigator is also a student, the project coordinator/instructor is also responsible for ensuring that **Form C** is submitted. The IR office maintains a tracking system to help ensure compliance.

The Continuing Review Report (**Form C**) is a required component for the annual review. Federal regulations (45 CFR 46.115(3)) require the IRB to maintain records of continuing review activities. The procedures for annual review require the investigator to submit an annual Continuing Review Report to the Pellissippi State IRB, including descriptions of all adverse effects encountered and any changes contemplated in the research protocol and/or informed assent/consent forms. A copy of the approved informed consent and/or assent form(s) that was used for the project must accompany the annual Continuing Review Report. Incomplete or unsigned reports will not be submitted to the IRB for review and approval and will be returned to the investigator for completion.

If the director of Institutional Research, serving as IRB chair, does not receive the annual Continuing Review Report and one copy of the approved project informed consent/assent form(s) as required in time to allow a continuing review to occur before the IRB expiration date, IRB approval will automatically expire. The director of Institutional Research, serving as IRB chair, notifies the investigator and the project coordinator or instructor that the project has expired. Note: Federal regulations do not permit a grace period for continuing research without IRB approval.

Projects that are found to be continuing without IRB approval will be considered to be in non-compliance with Pellissippi State policy and federal regulations. For projects that are under the direction of Pellissippi State faculty or staff, the director of Institutional Research, serving as IRB chair, will file a non-compliance report to the investigator's dean and area vice president; for students the non-compliance report will be filed with both the student's instructor and the department dean. Federal regulations give the IRB the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and appropriate College officials. The director of Institutional Research, serving as IRB chair, will also notify the funding agency, if applicable, and OHRP.

9.0 Changes and Other Actions to Approved Projects

The IRB has regulatory authority to observe, or have observed, the consent process and the research.

Changes to existing approved projects, as well as project terminations, require submission of a Form D, “Project Status Report: Changes and/or Close Out,” to the director of Institutional Research, who is the IRB Chair. Such modifications may include, but are not limited to, the following: change of project title, change of or co- investigator or other collaborators, changes which affect participation of human subjects, changes to informed consent forms and/or assent forms, additional sites for conducting the research, unexpected risks to subjects, or notification of early project completion. **No changes to projects may be implemented until approval has been granted.**

Change of mailing address of the investigator may be made at any time without the need for a Form D. Staff members in the office of Institutional Research rely upon the investigator to notify them of any change of mailing address. Subjects must also be notified of changes in contact information.

9.1 Adverse Events

Adverse events are events or circumstances that were unintended and unanticipated at the time the project was approved by the IRB. Any illness, injury, or trauma that required medical or psychological treatment must be reported to the IRB, to the funding agency, and on Form D, “Project Status Report: Changes and/or Close Out.” In the event of unexpected serious harm to subjects or if a project is not being conducted in accordance with the Pellissippi State IRB's decisions, conditions, or requirements, the IRB has the authority to suspend or terminate its approval of the research.

Appendix A: Form A

Application for Certification for Exemption from IRB Review for Research Involving Human Subjects

For use by IR: Date Received in Institutional Research: / / IRB File No.

Pellissippi State Technical Community College Institutional Review Board

Please note:

- 1. See the instructions for completing Form A that follow this form.**
2. The six exemptions listed on this form corresponding to categories described in 45 CFR 46 do **not** apply to projects that include participants from vulnerable populations, such as children, prisoners, or pregnant women. If your project involves participants from a vulnerable population, submit Form B. Children are minors under age 18.
3. **ALL** research involving human participants must follow the provisions of applicable regulations regardless of whether or not IRB review is required. This includes the elements of informed consent.

I. Identification of Project

Investigator	Title
Department	Phone
Email address	Mailing address
Co-investigator	Title
Department	Phone
Email address	Mailing address

Project Title

External Funding Agency and ID Number (if applicable):

Funding Source	ID Number
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Grant Solicitation Title

Attach a copy of the grant solicitation, if applicable, for review by the IRB.

Grant Submission Deadline (if applicable)	Project Start Date
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(No research may be initiated until both the Pellissippi State IRB certification and IERP authorization to conduct research are granted.)

Estimated Completion Date	Projected Duration of Research
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(Include length of time for all aspects of research including final reporting and closing out of budget.)

Other organizations and/or agencies, if any, involved in the study

Contact Person at other agency Title

Department Phone

Email address Mailing address

=====
Location of Research Project activities (List all)

II. Exemption Category

Category for Exempt Research per 45 CFR 46 (see definitions on Form A instruction page)

1 2 3 4 5 6

III. Research Project Concept (Review Criteria required by 45 CFR 46)

- 1. Goal of the Project**
- 2. Objective(s) of the Project**
- 3. Human Subjects (population and how selected)**
- 4. Methods and Procedures (describe)**
- 5. Specific Risks to Subjects and Protection Measures**
- 6. Benefits**
- 7. Method of Obtaining “Informed Consent” from Participants**
- 8. Confidentiality and Privacy: Describe the plan for monitoring the data collected to ensure the subjects’ privacy and the confidentiality of the data.**
- 9. Facilities and Equipment To Be Used in the Research (e.g., identify sites, computers, labs, buildings)**

IV. Responsibilities of the Investigator(s):

By compliance with the policies established by the Pellissippi State Technical Community College Institutional Review Board, the investigator(s) subscribe to the principles stated in the “Belmont Report” and standards of professional ethics in all research, development, and related activities involving human subjects under the auspices of Pellissippi State. The investigator(s) further agree that:

- a. Written approval will be obtained from the Pellissippi State Institutional Review Board prior to instituting any change in this research project.
- b. Development of any unexpected risks will be immediately reported to the director of Institutional Effectiveness, Research and Planning, who serves as IRB chair.
- c. Signed informed consent documents, as appropriate, will be kept for the duration of the project and for at least three years thereafter at a location approved by the Pellissippi State Institutional Review Board.

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- d. Certification of Exemption by the Pellissippi State IRB does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity and meet all elements of informed consent.
- e. Follow the office of Institutional Effectiveness, Research, and Development process to request permission to conduct a research study at Pellissippi State Technical Community College.

V. Attachments:

1. **Attach vita of investigator and co-investigator to this application**
2. **Attach certification of Human Subjects Research Training for investigator and co-investigator**
3. **Attach grant solicitation, if applicable.**
4. **Attach completed Informed Consent Document using the appropriate Pellissippi State IRB template(s).**
5. **Attach other documents used that are described in the Form A Instructions.**

VI. CERTIFICATION: The research described herein is in compliance with 45 CFR 46.101(b) and presents with no more than minimal risk as defined by applicable regulations.

Print Investigator Name	Investigator Signature	Date
Print Co-Investigator Name (if appropriate)	Co-Investigator Signature	Date
Print Department Dean Name	Department Dean Signature <i>(Project support authorized)</i>	Date

For Use of IRB Chair only:	<input type="checkbox"/> Exemption approved <input type="checkbox"/> Exemption denied For further consideration please submit Form B application.
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Signature of IRB Chair:	Date:

Instructions for Completing Form A

For questions and/or additional information regarding Form A, contact [Sharon Yarbrough](#), the Director of Institutional Effectiveness, Research and Planning, who serves as IRB chair, by e-mail or by phone at (865) 694-6526.

Investigators:

Please discuss your proposed research with the director of Institutional Effectiveness, Research and Planning/IRB chair before you begin preparing an IRB Form A application. If your project only exposes your subjects to minimal risks and you do not intend to use subjects from vulnerable populations, then complete the Form A application. Research using human subjects that meets category requirements must be certified as exempt by the Pellissippi State IRB before the subjects are contacted and research begins. With this approval you are assured that the research is in compliance with policies and procedures of Pellissippi State and the Tennessee Board of Regents.

Submission process requires two forms of the application to be submitted simultaneously, as described below (the submission date must be the same on both forms):

1. One application form must be submitted electronically directly to the Pellissippi State Institutional Review Board Chair: slyarbrough@pstcc.edu
2. One original hard copy of the application including original signatures must be submitted to the Pellissippi State Institutional Review Board Chair.

Note: The signature of the department dean confirms department support and approval to submit the request to the Pellissippi State IRB.

I. Identification of Project

- Investigator and Co-Investigator (if applicable):
- *Complete Name, Title, Department, Phone, Email address, Mailing address*
- Project Title (indicate if this is a temporary/working title)
- External Funding Source/ID#/Grant Solicitation Title/ Deadline: if not applicable to your project, mark "NA"
- Project Start Date: *Anticipated start date upon IRB approval and if funds are awarded if requested. Note: No research may be initiated until both the Pellissippi State IRB certification and IERP authorization to conduct research at Pellissippi State are granted.*
- Project Completion Date: Estimated ending date
- Duration of Research: Please estimate
- Other organizations and/or agencies involved: List all
- Other contact person(s): *Complete Name, Title, Department, Phone, Email address, mailing address*
- Location of Research Project Activities: List *Pellissippi State campus location and/or off-site locations*

II. CATEGORY or CATEGORIES FOR EXEMPT RESEARCH PER 45 CFR

46: After reading the categories from the federal regulations (see below), please check the appropriate box or boxes from the six options provided on Form A.

Note: The following exemptions **do NOT** apply when (a) **deception and/or withholding** of information from subjects is needed for adequate testing of a hypothesis; (b) subjects are **under the age of eighteen**; (c) the activity may expose the subject to **discomfort or harassment beyond levels encountered in daily life**; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

Categories

Referring to the extracts below from Federal regulations, cite the paragraph(s) by number which you deem entitle this research project to certification as exempt from review by the Institutional Review Board. **45 CFR 46.101(b): Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review pending IRB certification:**

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminants at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to the Director, Office of Institutional Effectiveness, Research and Planning, who serves as the IRB chair.

III. RESEARCH PROJECT CONCEPT

1. Goal of the project

- Provide a brief rationale of the project in non-technical language so that reviewers from other disciplines can understand and identify the goals and objectives of the project.
- State the benefit to be accomplished and expected significance.

2. Objective(s) for the period of the project

- Briefly state, in non-technical language, the purpose of the research, with special reference to human subjects involved.
- If you are seeking external support for this project, the objectives listed must coincide with the goals and objectives made in any application for support.
- The objectives listed in this section should coincide fully with the objectives described to participants in the consent form.
- Objective statement(s) are to be specific and, measurable describing quantitative expectations including process and outcomes of what will be achieved during the project.

3. Human Subjects

- Describe participants, population, and sample explaining rationale for using any special groups, such as children, pregnant women, prisoners, students, cognitively impaired, institutionalized individuals, or any participants whose ability to give voluntary and informed consent may be questioned. Give rationale for projects that restrict participants based on gender.

- State how you will gain access to those participants identifying the source of your participants (school systems, college and universities, hospitals, private companies, religious groups, governmental entities, community groups, etc.). Describe the method for recruiting participants including letters of permission and/or assent that are required from entities other than Pellissippi State. Letters of permission should authorize the investigators to contact potential participants, authorize use of the facilities and/or access to records of that entity. These letters must accompany the Form A.
- Include the criteria for selection and exclusion disclosing any relationship between researchers and participants (such as teacher/student; employer/employee; or superintendent//teacher).

If an incentive is to be used, identify the incentive for participation, payment procedures, and provide a rationale for using the incentive. Keep in mind that the value of incentives to participants is relative, and reviewers may consider highly valued incentives coercive.

Investigators who plan to recruit Pellissippi State students and offer extra course credit for student participation must follow the procedures maintained in the department whose classes are used. Departmental letters of permission must be attached to the Form A application.

Include the number of participants you anticipate using. Include the duration of involvement and any special characteristic necessary to the research.

4. METHODS and PROCEDURES

- Briefly enumerate, in non-technical language, the research methods that directly involve use of human subjects.
- State the procedures for data collection and experimental research methods used in the project.
- State measures: instruments, survey, questionnaire, instructions, and cover letters to be used in the project. Describe how data will be analyzed and interpreted.
- Clearly distinguish between control and comparison, and experimental and treatment participant groups.
- State whether data will be confidential or anonymous, how data will be disposed, and who will have access to the data.
- Information provided in this section should be consistent in every detail with the description provided to participants in the consent form or procedure. (Any omission or deviation in the methods and procedures information provided in the consent process must be justified.)
- Include non-technical descriptions of stresses to participants, experimental manipulations, tests or measures, surveys, interviews, observations, photography, and video and audio recordings.
- If the project involves audio taping, videotaping, or photography of participants, explain the need for these methods and describe how the data will be used. Describe how the film or tapes will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the tapes and film, and on what basis they will have access. If the tapes or film are to be used in the future, explain the procedures for obtaining the participants' informed consent for those uses, and the conditions under which the tapes or film would be used.
- Attach a single copy of the Informed Consent Form with IRB application A.

5. SPECIFIC RISKS AND PROTECTION MEASURES

- Provide sufficient detail to permit reviewers, who may not be familiar with your area of study, to evaluate any specific risks to the participants of this research.
- Specify all potential risks to participants of the proposed research.
- Estimate the nature and amount of potential risk, stress, or discomfort and assess the likelihood and its seriousness.
- Describe the precautions you will take to reduce risk and assess the effectiveness of these protective measures.
- Identify specific controls, screening methods, and follow-up to assure no residual physical, psychological, or social damage to the participants.
- If appropriate, include a description of the means you will use to assist or treat participants who may incur injury from one or more of the risks identified in this section.

6. Benefits

- Evaluate the reasonableness of the risks stated in Section 5 in relation to the anticipated benefits (e.g., desired outcomes), if any, to the participants and/or to society.
- If the risks are minimal, state that the risks are minimal and include a statement of anticipated benefits.
- Note that in most research projects, the only relevant benefits are those that contribute to generalizable knowledge in a field of research. In these cases, participant benefits are incidental. Do not inflate the significance of incidental benefits to participants in your Form A application or your informed consent procedures.
- Please note that payment for participation in research is an incentive for participation, and should not be considered a “benefit” of the research.

7. Method of Obtaining “Informed Consent” from Participants

- Investigators are required to use the Pellissippi State IRB “Informed Consent Templates” to ensure that all federal regulations in 45 CFR 46 are met. investigators are responsible for completing the template with information that accurately describes participation in the project.
- Any modifications of the template must have IRB approval. Investigators should contact the director of Institutional Research, who serves as IRB chair, for further information.
- Additional information regarding informed consent is found in Section 5.0 and in Appendix I.

8. Confidentiality and Privacy

- Describe the plan for monitoring the data collected to ensure the subjects’ privacy and confidentiality of the data.
- Include the methods and provisions by which you will address the issue of anonymity of data. Note that anonymity is only possible if the investigator cannot discover the participant’s identity from data collected.

- Identify security measures, such as limiting access to data, purging identification information from data, securing files, and other appropriate measures. Identify to whom access is given.
- If the confidentiality of the participants' identities or data cannot or will not be protected, state how you will inform participants of this fact before their participation.

IV. Responsibilities of the Investigators

- Investigators are responsible for reading and understanding their responsibilities to comply with federal regulations.

V. Attachments to Form A

- Attach professional curriculum vita to the application. Include any past experiences as a investigator or co-investigator on projects or experience with human subject research.
- The investigator and co-investigator are required to document training in human subject research and federal regulations. See Appendixes E and J.
- Attach a copy of the grant solicitation proposal, if applicable
- Attach a copy of the informed consent document after completing the fields in the Pellissippi State IRB "Informed Consent Template"

VI. Certification

- Original signatures are required on the hard copy of Form A that the investigator submits to the office of Institutional Effectiveness, Research and Planning.

Appendix B: Form B

Application for Review of Research Involving Human Subjects

For use by IR: Date Received in Institutional Research: / / IRB File Number
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**Pellissippi State Technical Community College
Institutional Review Board**

Instructions for Completing Form B follow this form.

Indicate Type of Request:

Form B-1: Expedited Review Request

Form B-2: Full Board Review

I. Identification of Project

Investigator Title

Department Phone

Email address Mailing address

Co-investigator Title

Department Phone

Email address Mailing address

Project Title

External Funding Agency and ID Number (if applicable):

Funding Source ID Number

Grant Solicitation Title

Attach a copy of the grant application, if applicable, for review by the IRB.

Grant Submission Deadline (if applicable) Project Start Date

(No research may be initiated until both the Pellissippi State IRB certification and IERP authorization to conduct research are granted.)

Estimated Completion Date Projected Duration of Research

(Include length of time for all aspects of research including final reporting and closing out of budget.)

Other organizations and/or agencies, if any, involved in the study

Contact Person at other agency Title

Department Phone

Email address Mailing address

Location of Research Project Activities (List all)

II. Expedited Category

Category for Expedited Research per 45 CFR 46 (see definitions on Form B instruction page)

1 2 3 4 5 6 7 8 9

III. Research Project Concept (Review Criteria required by 45 CFR 46)

1. Goal of the Project
2. Objective(s) of the project
3. Human Subjects (population and how selected)
4. Methods or Procedures (describe)
5. Specific Risks to Subjects and Protection Measures
6. Benefits
7. Method of Obtaining “Informed Consent” from Participants
8. Confidentiality and Privacy: Describe the plan for monitoring the data collected to ensure the subjects’ privacy and the confidentiality of the data.
9. Facilities and Equipment To Be Used in the Research (e.g., identify sites, computers, labs, buildings)
10. Qualifications of the Investigator(s) To Conduct This Research

IV. Responsibilities of the Investigator(s):

In compliance with the policies established by the Pellissippi State Technical Community College Institutional Review Board, the investigator(s) subscribe to the principles stated in the *Belmont Report* and standards of professional ethics in all research, development, and related activities involving human subjects under the auspices of Pellissippi State. The investigator(s) further agree that:

1. Written approval will be obtained from the Pellissippi State Institutional Review Board prior to instituting any change in this research project (submit Form D).
2. Development of any unexpected risks will be immediately reported to the director of Institutional Effectiveness, Research and Planning, who serves as IRB chair (also report on Form D).
3. All required forms will be submitted in a timely manner. Human subject research must receive continuing review and approval by the IRB not less than once per year. Investigators are responsible for submitting Form C, “Continuing Review Report,” to the IRB two months prior to the expiration date of the IRB project approval. Note: Federal regulations do not allow a grace period.

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4. Signed informed consent documents will be kept for the duration of the project and for at least three years after project completion at a location approved by the Pellissippi State Institutional Review Board.
5. When the project is completed (or if it is not completed), investigators will submit Form D, "Project Status Report: Changes and/or Close-Out."
6. Follow the office of Institutional Effectiveness, Research, and Development process to request permission to conduct a research study at Pellissippi State Technical Community College.

V. Attachments:

1. **Attach vita of investigator and co-investigator to this application**
2. **Attach certification of Human Subjects Research Training for investigator and co-investigator**
3. **Attach grant proposal, if applicable.**
4. **Attach completed Informed Consent document using the Pellissippi State IRB template.**
5. **Attach other documents used that are described in the Form B Instructions.**

VI. CERTIFICATION:

For projects applying for expedited review: The research described herein is in compliance with 45 CFR 46.101(b) and presents with no more than more than minimal risk as defined by applicable regulations. (Note: check appropriate risk level and mark through the other level.)

Print Investigator Name	Investigator Signature	Date
Print Co-Investigator Name (if appropriate)	Co-Investigator Signature	
Print Department Dean Name	Department Dean Signature <i>(Project support authorized)</i>	Date

For use of IRB Chair only:	<input type="checkbox"/> Approved under Expedited Review Procedure <input type="checkbox"/> Referred to Full IRB for Review
Signature of IRB Chair:	Date:

Instructions for Completing Form B

For questions and/or additional information regarding Form A, contact [Sharon Yarbrough](#), the Director of Institutional Effectiveness, Research and Planning by e-mail or by phone at (865) 694-6526.

Investigators: Please discuss your proposed research with the director of Institutional Effectiveness, Research and Planning, who serves as IRB chair, before you begin preparing an IRB Form B application. If your project only exposes your subjects to minimal risks and you do not intend to use subjects from vulnerable populations, then it may be possible to use a Form A application. Remember that all research using human subjects must be approved by the Pellissippi State IRB before the subjects are contacted and research begins. With this approval you are assured that the research is in compliance with policies and procedures of Pellissippi State and the Tennessee Board of Regents.

Submission process requires two forms of the application to be submitted simultaneously, as described below (the submission date must be the same on both forms):

1. One application form must be submitted electronically directly to the Pellissippi State Institutional Review Board Chair: slyarbrough@pstcc.edu
2. One original hard copy of the application including original signatures must be submitted to the Pellissippi State Institutional Review Board Chair.

Note: The signature of the department dean confirms support by the department and approval to submit the request to the Pellissippi State IRB.

I. Identification of Project

- Investigator and Co-Investigator (if applicable):
- *Complete Name, Title, Department, Phone, Email address, Mailing address*
- Project Title (indicate if this is a temporary/working title)
- External Funding Source/ID#/Grant Solicitation Title/ Deadline: if not applicable to your project, mark "NA"
- Project Start Date: *Anticipated start date upon IRB approval and if funds are awarded if requested. Note: No research may be initiated until both the Pellissippi State IRB certification and IERP authorization to conduct research at Pellissippi State are granted.*
- Project Completion Date: Estimated ending date
- Duration of Research: Please estimate
- Other organizations and/or agencies involved: List all
- Other contact person(s): *Complete Name, Title, Department, Phone, Email address, mailing address*
- Location of Research Project Activities: List *Pellissippi State campus location and/or off-site locations*

II. Expedited Review Procedure

A. Overview of Expedited Review

- Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. 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.
- The categories in this list apply regardless of the age of subjects, except as noted.
- 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 subjects' 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.
- The expedited review procedure may not be used for classified research involving human subjects.
- Investigators are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

B. Expedited Research Categories

After reading the categories from the federal regulations (see below), please check the appropriate box or boxes on Form B from the nine options provided.

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 (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which:

- i) an investigational device exemption application (21 CFR Part 812) 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:
 - c. 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; or
 - d. from other adults and children², 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. Examples are:
 - 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. placenta removed at delivery;
 - g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - h. 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;

- i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - j. 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 are:
 - 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. magnetic resonance imaging;
 - d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - e. 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. [45CFR 46.101](#) (b)(4). 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 HHS regulations for the

- protection of human subjects. [45 CFR 46.101](#) (b)(2) and (b)(3). 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 (2) through eight (8) 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.
-

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#)
Source: 63 FR 60364-60367, November 9, 1998.

III. RESEARCH PROJECT CONCEPT

1. Goal of the project

- Provide a brief rationale of the project in non-technical language so that reviewers from other disciplines can understand and identify the goals and objectives of the project.
- State the benefit to be accomplished and expected significance.

2. Objective(s) for the period of the project

- Briefly state, in non-technical language, the purpose of the research, with special reference to human subjects involved.
- If you are seeking external support for this project, the objectives listed must coincide with the goals and objectives made in any application for support.
- The objectives listed in this section should coincide fully with the objectives described to participants in the consent form.
- If investigators have reason to withhold information about the objectives from participants, they must justify this action in “Methods of obtaining informed consent.”
- Objective statement(s) are to be specific and, measurable describing quantitative expectations including process and outcomes of what will be achieved during the project.

3. Human Subjects

- Describe participants, population, and sample explaining rationale for using any special groups, such as children, pregnant women, prisoners, students, cognitively impaired, institutionalized individuals, or any participants whose ability to give voluntary and informed consent may be questioned. Give rationale for projects that restrict participants based on gender.
- State how you will gain access to those participants identifying the source of your participants (school systems, college and universities, hospitals, private companies, religious groups, governmental entities, community groups, etc.). Describe the method for recruiting participants including letters of permission and/or assent that are required from entities other than Pellissippi State. Letters of permission should authorize the investigators to contact potential participants, authorize use of the facilities and/or access to records of that entity. These letters must accompany the Form B application at the time of submission for review.
- Include the criteria for selection and exclusion disclosing any relationship between researchers and participants (such as teacher/student; employer/employee; or superintendent//teacher).
- If an incentive is to be used, identify the incentive for participation, payment procedures, and provide a rationale for using the incentive. Keep in mind that the value of incentives to participants is relative, and reviewers may consider highly valued incentives coercive.
- Investigators who plan to recruit Pellissippi State students and offer extra course credit for student participation must follow the procedures maintained in the department whose classes are used. Departmental letters of permission must be attached to the Form B application.
- Include the number of participants you anticipate using. Include the duration of involvement and any special characteristic necessary to the research.

4. METHODS and PROCEDURES

- Briefly enumerate, in non-technical language, the research methods that directly involve use of human subjects.
- State the procedures for data collection and experimental research methods used in the project.
- State measures: instruments, survey, questionnaire, instructions, and cover letters to be used in the project. Describe how data will be analyzed and interpreted.

- Clearly distinguish between control and comparison, and experimental and treatment participant groups.
- State whether data will be confidential or anonymous, how data will be disposed, and who will have access to the data.
- Information provided in this section should be consistent in every detail with the description provided to participants in the consent form or procedure. (Any omission or deviation in the methods and procedures information provided in the consent process must be justified.)
- Include non-technical descriptions of stresses to participants, experimental manipulations, tests or measures, surveys, interviews, observations, photography, and video and audio recordings.
- If the project involves audio taping, videotaping, or photography of participants, explain the need for these methods and describe how the data will be used. Describe how the film or tapes will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the tapes and film, and on what basis they will have access. If the tapes or film are to be used in the future, explain the procedures for obtaining the participants' informed consent for those uses, and the conditions under which the tapes or film would be used.
- Attach a single copy of the Informed Consent Form with IRB application B.

5. SPECIFIC RISKS AND PROTECTION MEASURES

- Provide sufficient detail to permit reviewers, who may not be familiar with your area of study, to evaluate any specific risks to the participants of this research.
- Specify all potential risks to participants of the proposed research.
- Estimate the nature and amount of potential risk, stress, or discomfort and assess the likelihood and its seriousness.
- Describe the precautions you will take to reduce risk and assess the effectiveness of these protective measures.
- Identify specific controls, screening methods, and follow-up to assure no residual physical, psychological, or social damage to the participants.
- If appropriate, include a description of the means you will use to assist or treat participants who may incur injury from one or more of the risks identified in this section.

6. Benefits

- Evaluate the reasonableness of the risks stated in Section 5 in relation to the anticipated benefits (e.g., desired outcomes), if any, to the participants and/or to society.
- If the risks are minimal, state that the risks are minimal and include a statement of anticipated benefits.
- Note that in most research projects, the only relevant benefits are those that contribute to generalizable knowledge in a field of research. In these cases, participant benefits are incidental. Do not inflate the significance of incidental benefits to participants in your Form B application or your informed consent procedures.
- Please note that payment for participation in research is an incentive for participation, and should not be considered a "benefit" of the research.

7. Method of Obtaining "Informed Consent" from Participants

- Investigators are required to use the Pellissippi State IRB “Informed Consent Templates” to ensure that all federal regulations in 45 CFR 46 are met. investigators are responsible for completing the template with information that accurately describes participation in the project.
- Any modifications of the template must have IRB approval. Investigators should contact the director of Institutional Research, who is the IRB chair, for further information.
- Additional information regarding informed consent is found in Section 5.0 of this document and in the Informed Consent Appendix I. See Appendix T for templates for Informed Consent.

8. Confidentiality and Privacy

- Describe the plan for monitoring the data collected to ensure the subjects’ privacy and confidentiality of the data.
- Include the methods and provisions by which you will address the issue of anonymity of data. Note that anonymity is only possible if the investigator cannot discover the participant’s identity from data collected.
- Identify security measures, such as limiting access to data, purging identification information from data, securing files, and other appropriate measures. Identify to whom access is given.
- If the confidentiality of the participants’ identities or data cannot or will not be protected, state how you will inform participants of this fact before their participation.

9. Qualifications of the Investigator(s)

Investigators must specify their relevant qualifications and those of other investigators involved in this project to perform the proposed research. Include qualifications of personnel working on portions of the research where special training, certification, or licensing is required for the performance of tasks. Experience and expertise is required when involving participants classified as vulnerable, such as children, pregnant women, prisoners, cognitively impaired, or institutionalized individuals.

IV. Responsibilities of the Investigators

Read these carefully so you understand what your responsibilities are to comply with the federal regulations.

V. Attachments to Form A

1. Attach your curriculum vita to the application. Include any past experiences as a investigator or co-investigator on projects or experience with human subject research.
2. The investigator and co-investigator are required to document training in human subject research and federal regulation. See Appendixes E and J.
3. Attach a copy of your grant proposal, if applicable

4. Attach a copy of your informed consent document, completing the fields in the Pellissippi State IRB “Informed Consent Template”

VI. Certification

- Original signatures are required on the hard copy of Form B that the investigator submits to the chair of the Pellissippi State Institutional Review Board
- Only research that involves no more than minimum risk is eligible for expedited review.

Appendix C: Form C

Continuing Review Report

**Pellissippi State Technical
Community College
Institutional Review
Board**

Date Submitted _____ **IRB File Number** _____

/ /

Investigator:		Project Title:	
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Federal Regulations mandate that all human subject research protocols receive continuing review and approval **not less than once per year**. In order to comply with this policy on research involving human subjects, sufficient information must be collected to allow the IRB to conduct a "substantive and meaningful" review. Therefore, in order for the Pellissippi State Technical Community College IRB to comply with this and other directives and to grant continuing approval of your research protocol, the following information/documents are required:

1. *a completed continuing review questionnaire and*
2. *copies of all informed consent documents, surveys and/or questionnaires currently being used.*

If a question does not apply to your research protocol, so indicate (e.g., "Not Applicable" or "N/A").

I. Briefly summarize the study objectives and procedures: (attach additional pages if required)

II. Dates covered by this continuing review report: Previous 12 months
 Other period as described:

III. Project Summary

A. **Leadership:** have there been any changes in leadership, responsibility, or major personnel?

Yes No

If Yes, then fully describe:

--

B. Objectives: have there been any changes?

Yes No

If Yes, then fully describe:

--

C. Procedures: have there been any changes?

Yes No

If Yes, then fully describe:

--

D. Informed consent documents: have there been any changes?

Yes No

If Yes, then fully describe:

--

E. Research subjects:

- List each group, cohort, etc., if applicable, including control groups, on separate lines. If only one group, description would be "All."

Group	NUMBER OF SUBJECTS (at all sites for which you are the investigator)		AGE RANGE OF SUBJECTS (at all sites for which you are the investigator)		GENDER (of subjects to date)	
	This Period	Next Period (anticipated)	This Period	Next Period (anticipated)	% Male	% Female

--	--	--	--	--	--	--

2. Was the subject population representative of the population base from which subjects could be selected with respect to:

a. Gender representation? Yes No

If No, explain:

b. Minority representation? Yes No

If No, explain:

3. Have any subjects withdrawn from study since the study began?

Yes No

If Yes, explain:

4. Are you aware of any breach in confidentiality? (e.g., unauthorized access to records)

Yes No

If Yes, describe:

F. Unexpected problems:

1. Have there been any **unexpected** problems?

Yes No N/A

If Yes, please summarize these unexpected problems, the number of occurrences, and indicate if they required consent document changes, particularly in the “risks” section. If risks are affected, describe how they are

minimized and reasonable in relation to expected benefits. If available, attach copies of data safety monitoring reports.

G. Proposed Revisions/Amendments/Modifications:

1. Are there revisions/amendments to the research protocol, consent form(s), questionnaires, etc., that are included with this renewal?

Yes No

If Yes, provide a brief description below and highlight the changes on the document(s) to be reviewed.

2. Will the revisions/amendments change the scope or research objectives of the research protocol? Following are examples of actions considered to change the scope or research objectives: A change in the specific aims approved at the time of award (funding); a change from the previously approved use of human subjects; shifting the emphasis of the research from one disease to another.

Yes No N/A

If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation.

3. Will the revisions/amendments change risks to subjects?

Yes No N/A

If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

H. Publications, Presentations, Reports: Provide a listing of all publications, presentations, and reports that have resulted from this work since the last review. If none, so state.

Did you submit an annual progress report to a funding agency?

Yes No N/A

If you marked “yes” in the check box above, please attach a copy of your report.

As **Investigator**, I acknowledge that I am responsible for reporting any emergent problems; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval; that unless otherwise directed by the director of Institutional Research, serving as IRB chair, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's understanding and recommendations; that the IRB is provided all the information on the research project necessary for its complete review; and that this research project will not be put into effect until final IRB approval is received.

Signature of Investigator

Date

Signature of Department Dean

Date

For use of IRB Chair only:	<input type="checkbox"/> Continuation Approved	<input type="checkbox"/> Continuation Approved with Conditions	<input type="checkbox"/> Continuation Refer to Full Committee Review
Signature of IRB Chair:			Date: ___ / ___ / ___

Appendix D: Form D

Project Status Report: Changes and/or Close Out

Use only to report project changes, completions, or terminations for research that was approved by the Pellissippi State IRB on a Form B Application for Review of Research Involving Human Subjects

1. IRB No.: _____
2. Investigator: _____
Department: _____
3. investigator Telephone Number: _____
4. Project Title: _____

PLEASE CHECK THE APPROPRIATE BOX(S) BELOW (see instructions on next page):

5. Change of Project Title
6. Change of or Co- Investigator(s), Other Collaborators, or student sponsor (faculty or staff member at Pellissippi State)
7. Change(s) to Project that Affect Participation of Human Subjects
8. Change(s) to Informed Consent Forms and/or Assent Form(s)
9. Additional Locations for Conducting Project
10. Adverse Events
11. Project Completed -- Please Close the IRB Files.

12. SIGNATURES

Investigator: _____ **Date:** _____

Sponsor (if applicable) _____ **Date:** _____

Instructions for Completing Form D

Form D is used to report completion of a project or to request minor changes in a previously IRB-approved research project that was prepared under a Form B. Such changes may include, but are not limited to: change of project title, minor grammatical changes to an informed consent and/or child's assent form, addition or deletion of collaborators and/or co-investigators, change in student sponsor, additional sites for the performance of the research (include a letter from the authorized individual for a new location), minor project changes which do not change the original goal, and reporting unexpected risks encountered in carrying out the project.

The Pellissippi State IRB will employ an expedited review procedure to determine if approval can be granted outright, if further information is required, whether the change must be reviewed by the full IRB, or if a new application must be submitted for review and approval. When a Form D is approved, it does not affect the renewal date of the overall project.

NOTE: DO NOT USE THIS FORM FOR MAJOR CHANGES THAT AFFECT THE ORIGINAL GOAL OF THE RESEARCH! IN THIS CASE A NEW FORM B MUST BE SUBMITTED!

INSTRUCTIONS FOR FORM D COMPLETION - (*This form may be typed or printed in ink*)

1. Insert the IRB number, followed by the letter "B" in accordance with the number and letter assigned on your initial approval letter.
2. Enter the name of the investigator and Department or Division.
3. Enter your phone number.
4. Enter the Project Title (exactly as shown on the last approval letter received). *If the Project Title has changed, enter the new title and check box 5 below.*
5. CHECK this box if the project title in item 4 is different from your last approval letter.
6. CHECK this box if there is a change of investigator or co- investigators, other collaborators, or a change in student or project sponsor. **Attach a memo delineating the changes in investigators.**
7. CHECK this box if there are minor changes to the project. **Revise and amend any relevant sections of the Form B and submit these changes with Form D. There is no change too small to report.**
8. CHECK this box if there are changes to informed consent forms and/or assent form(s), and/or assent form(s). **Submit the new consent/assent forms with Form D.**
9. CHECK this box if there are additional locations or organizations where the research involving human subjects will be conducted. **Submit a copy of the letter(s) from those organizations which have given permission for you to conduct your research in their institution. The letters should be on the institution's own letterhead.**
10. CHECK this box if you have encountered an adverse event to research subjects (*e.g., breaches of confidentiality*) or to yourself (*e.g., angry parents, threats of violence*). **Submit a copy of the incident(s) with Form D and describe how you have or will resolve the problem.**

Pellissippi State Review System for Human Subjects (Version: 10.01)

11. CHECK this box if the project is now completed or if the project will not be conducted at all. For dissertation research: IRB-approved projects should NOT be terminated until the dissertation committee has accepted the dissertation.
12. The primary investigator must sign this Form D.

Appendix E: Educational and Training Materials for IRB Members and Investigators

<p>OHRP workshops on responsibilities of investigators, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research</p>	<p>http://www.hhs.gov/ohrp/education/conference.html</p>
<p>IRB Guidebook Online (OHRP site)</p>	<p>http://www.hhs.gov/ohrp/irb/irb_guidebook.htm</p>
<p>OHRP Educational materials and announcements of conferences</p>	<p>http://www.hhs.gov/ohrp/education/</p>
<p>"EVOLVING CONCERN: Protection for Human Subjects" traces the development of today's comprehensive program to protect human subjects of research out of earlier ethical codes and societal concerns. This film selected historic events in behavioral and biomedical research to show why protection is needed and how it came about.</p>	<p>Videotape available from Pellissippi State IR Office. Also available on DVD.</p>
<p>BALANCING SOCIETY'S MANDATES: Criteria for Protocol Review" depicts an Institutional Review Board (IRB) in action. Dr. Edmund Pellegrino, Director of the Kennedy Institute of Ethics, explains the basis for the criteria that an IRB follows in reviewing research. In commenting on IRB deliberations he points out why the IRB seeks clarification and information from the investigator.</p>	<p>Videotape available from Pellissippi State IR Office. Also available on DVD.</p>
<p>"THE BELMONT REPORT:</p>	<p>Videotape available from Pellissippi State IR</p>

<p>Basic Ethical Principles and Their Application" describes the basic ethical principles that underlie research involving human subjects; respect for persons, beneficence, and justice. This film illustrates their application in case studies of biomedical and behavioral research and shows the principles at work in the resolution of ethical conflicts.</p>	<p>Office. Also available on DVD.</p>
<p>Training CDs that the IR office will be able to obtain after it receives its FWA number</p>	<p>http://www.hhs.gov/ohrp/references/cdrom.pdf</p>
<p>Human Subject Assurance Training (required for IRB Chair and HPA for FWA application). Pellissippi State procedures also require this training of Pellissippi State IRB members and investigators of nonexempt research.</p>	<p>http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp</p>
<p>National Cancer Institute: Human Participant Protections Education for Research Teams</p>	<p>http://cme.cancer.gov/c01/nih_intro_01.htm</p>
<p>Training Required for National Institutes of Health Researchers and Staff; Also includes a link to IRB training for other interested persons.</p>	<p>http://ohsr.od.nih.gov/cbt/index.html</p>
<p>Pellissippi State Policy 06:17:02, "Conflict of Interest"</p>	<p>http://www.pstcc.edu/misc/ppm/06-17-02.htm</p>

Appendix F: Form for Confidentiality Agreement

Pellissippi State Technical Community College Office of Institutional Effectiveness, Research, and Planning

Information in Pellissippi State’s data systems must be maintained in a confidential manner at all times. These systems include but may not be limited to the following:

- President’s Office
- Learning
- Student Success and Enrollment Management
- Business and Community Services
- Business and Finance
- Information Services
- College Advancement

This agreement also covers non-public, personal, and private data obtained through research.

As a member of the Pellissippi State Institutional Review Board who may have access to records in computer information systems and other sources, you are required to maintain this information in a confidential manner. The unauthorized access to or modification, deletion, or disclosure of information in any such system may compromise the integrity of the system or otherwise violate individual rights of privacy.

Distribution and/or reproduction of any record or information outside the intended and approved use are prohibited. You are also responsible for insuring that your actions do not compromise the security of the systems that house these data (such as sharing passwords). You are responsible for knowing and understanding the content of College policies, including those that cover use of computer systems and student records confidentiality. These include Pellissippi State Policy 08:13:05, “Computer System Use” (<http://www.pstcc.edu/misc/ppm/08-13-05.htm>) and Pellissippi State Policy 04:03:00, “Student Records Confidentiality” (<http://www.pstcc.edu/misc/ppm/04-03-00.htm>), and others.

Discretion in all communications, including oral and e-mail, is required.

Failure to retain confidentiality—or illegal access to or misuse of—information covered by terms of this agreement may result in disciplinary action, up to and including termination.

By signing below, you understand and agree to the terms of this agreement.

Name: _____

Signature: _____ Date: _____

Appendix G: Glossary

Term	Definition
Approval	IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
Assent	Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
Certification	Certification means the official notification by Pellissippi State that a research project or activity involving human subjects has been reviewed and approved by the Pellissippi State IRB. The IRB also certifies projects that are exempt from IRB review.
Children	Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research.
Common Rule	<p>The "Common Rule" is the term used by eighteen federal agencies that have adopted the same regulations governing human subjects of research. Each agency's regulations are printed in the Code of Federal Regulations (CFR) with different preface numbers but the same section (§) numbers. The text of the regulation in each case is identical.</p> <p>The Common Rule is also referred to as "Subpart A" of the DHHS regulations of human research 45 CFR 46, to distinguish it from the other subparts, listed below:</p> <p>Subpart B relates to research on fetuses, neonates, and pregnant women;</p> <p>Subpart C relates to research with prisoners, and in general stipulates that the IRB include a prisoner or prisoner representative (among other requirements);</p> <p>Subpart D relates to research with children, and in general mandates that adequate provisions be made for soliciting the assent of children and permission of their parents or guardians.</p> <p>The Common Rule indicates that vulnerable populations include subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons.</p>

Term	Definition
Convened Board	The Pellissippi State Institutional Review Board meets as needed to review Form B Applications to conduct human subject research. The IRB can meet via telephone conference call if certain requirements and conditions are met. IRB meetings via non-simultaneous e-mail are not defined as meetings of the “convened board.” “Full IRB Board,” is used interchangeably with “meetings of the convened board.”
Co-Investigator (Co-investigator)	An individual involved with the investigator in the scientific development or execution of a project. A Co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the investigator's roles and responsibilities as specified in this document.
Full IRB Board	See “Convened Board.” “Full IRB Board,” is used interchangeably with “meetings of the convened board.”
FWA or Federalwide assurance	The Federalwide Assurance (FWA) is an assurance of compliance with the federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the Department of Health and Human Services (HHS). The FWA is also approved by OHRP for Federalwide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support.
HPA or Human Protections Administrator	The Human Protections Administrator (HPA) is the primary contact person for human subjects protection issues for Pellissippi State. The director of Institutional Effectiveness, Research and Planning serves as the College’s HPA and has operational responsibility for Pellissippi State’s program for protecting human subjects in research. The name of the HPA is designated on the College’s Federalwide assurance (FWA).

Term	Definition
Human Subject	<p>Human subject means 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.</p> <p>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. (These definitions are from §46.102 (f) of 45 CFR 46.)</p>
Informed Consent	<p>Informed consent is a legal condition whereby a person can be said to have given consent to participate in research based upon an appreciation and understanding of the facts and implications (including the risks) of this participation. The individual needs to be in possession of relevant facts and without an impairment of judgment at the time of consenting (such as might occur due to mental disabilities or due to economic or educational disadvantages).</p> <p>Federal regulations protecting human research subjects specify several basic elements that must be included in informed consent. One of these basic elements is a statement that participation is voluntary and may be discontinued at the subject’s discretion and without penalty at any time.</p> <p>No informed consent, whether written or oral, may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agency from liability for negligence.</p> <p>Consent may be obtained from a legally authorized representative (see glossary) of a human research subject. The Pellissippi State IRB is charged with ensuring that adequate provisions are made for soliciting the assent of children involved as subjects in research and the permission of their parents or guardians (also see glossary for definitions of “assent” and “permission”).</p>
IRB	<p>IRB means an institutional review board established in accord with and for the purposes expressed in 45 CFR 46.</p>

Term	Definition
IRB approval	IRB approval means the determination of the Pellissippi State IRB that the research has been reviewed and may be conducted at the College within the constraints set from by the Pellissippi State IRB and by other College and federal requirements.
Legally authorized representative (LAR)	Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.
Minimal Risk	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 (see §46.102(f)).
Permission	Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.
Investigator (investigator)	A Investigator (investigator) is the person designated on the required forms as the individual responsible for the administrative and programmatic aspects of the proposed project. The Investigator must have the technical competence and substantive capabilities (scientific, administrative and otherwise) to direct the project or program.
Protocol (Research Protocol)	The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the process for informed consent, and the proposed methods of analysis that will be performed on the collected data.
Research	Research is defined in 45 CFR 46 as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”
Vulnerable Populations	Vulnerable populations include children, prisoners, pregnant women, mental disabled persons, or economically or educationally disadvantaged persons.

Appendix H: History of Human Subjects Regulations

The Common Rule

The current U.S. system of protection for human research subjects is heavily influenced by the *Belmont Report* (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>), written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, HHS and the Food and Drug Administration revised, and made as compatible as possible under their respective statutory authorities, their existing human subjects regulations.

The Federal Policy for the Protection of Human Subjects or the “Common Rule” was published in 1991 and codified in separate regulations by 15 federal departments and agencies, as listed below. Each agency includes in its chapter of the Code of Federal Regulations [CFR] section numbers and language that are identical to those of the HHS codification at 45 CFR part 46, subpart A. For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. The list below displays the agencies and departments that have signed onto the Common Rule and their CFR numbers.

Agency for International Development (22 CFR part 225)
Consumer Product Safety Commission (16 CFR part 1028)
Department of Agriculture (7 CFR part 1c)
Department of Commerce (15 CFR part 27)
Department of Defense (32 CFR part 219)
Department of Education (34 CFR part 97 subpart A)
Department of Energy (10 CFR part 745)
Department of Health and Human Services (45 CFR part 46 subpart A)
Department of Housing and Urban Development (24 CFR part 60)
Department of Justice (28 CFR part 46)
Department of Veterans Affairs (38 CFR part 16)
Department of Transportation (49 CFR part 11)
Environmental Protection Agency (40 CFR part 26)
National Aeronautics and Space Administration (14 CFR part 1230)
National Science Foundation (45 CFR part 690)

In addition, the Central Intelligence Agency must comply with all subparts of 45 CFR part 46 under Executive Order 12333.

Several non-HHS federal departments and agencies have additional regulations in place for research involving special populations or for human subjects research in general. Investigators are encouraged to review the regulations of the funding agency to determine whether additional regulations apply. Also, many agencies have not adopted subparts B, C, or D and grantees of those agencies are not necessarily bound by them. Grantees should consult their funding agency for guidance.

Appendix I: Informed Consent

Pellissippi State IRB template forms and letters meet all elements of informed consent and are required to be used by investigators in their human subject protects. **Note: Any deviation from these templates must be approved prior to use by the Pellissippi State IRB.**

Investigators must obtain the signed *informed consent* of participants. **ALL** research involving human participants must follow the provisions of applicable regulations regardless of whether the activity is exempt from IRB review or not. For subjects who are less than 18 years of age, the investigator must obtain the signed permission of parents or legal guardian, and all reasonable attempts must be made to obtain each participant's *assent*, which is defined as the participant's agreement to participate in the study.

The principles and basic elements of informed consent are provided in Section 5.0 of this document and are found in 45 CFR 46.116.

Normal informed consent procedures call for a written consent document and the signature of the participant. If the only document linking the identities of the participants to the research is the informed consent document, then the requirement for written consent may be waived by the IRB upon the investigator's request and justification on Form A or Form B. Verbal consent is still required after providing the subject with a fair and reasonable explanation of the research, the participant's role in it, anticipated risks and protection measures, and a statement that the participant is free to withdraw at any time without penalty. The potential subject should understand that his/her participation is voluntary, and he/she should have an opportunity to ask questions about the research. These requirements apply to all direct contacts with subjects and to such research methods as telephone surveys.

Questionnaires and Surveys

With mail questionnaires and drop-box surveys, where the respondent remains anonymous, the researcher should provide a similar explanation about the purpose of the research and the procedures for completing the questionnaire. This material may be contained in the cover letter accompanying the questionnaire or at the head of the questionnaire itself. The explanation should close with a statement to the effect that "return of the questionnaire will constitute your informed consent to participate."

If the respondent does not remain anonymous – that is, if the investigator can initially identify each return with a subject, as is often the case where follow-up questionnaires may be sent – this fact should be revealed to the subject and written consent procedures used.

Other Considerations for Investigators Who Are Obtaining Legally Effective Informed Consent from Prospective Subjects

- State the methods you will use to obtain legally effective informed consent, assent, or permission (as applicable) from participants or participants' legally authorized representatives (LAR).
- Clearly describe how you will seek consent from participants in a manner that allows them sufficient opportunity to consider whether to participate, and that minimizes the possibility of coercion or undue influence.
- Use language in your informed consent procedure that is understandable to your participants or their LARs.
- Use a written consent document that contains all the basic elements of informed consent (use the Pellissippi State IRB required template). This form is signed by the participant or a LAR and an extra copy is provided for participant's use and information.
- Any exceptions to the Pellissippi State IRB informed consent template(s), such as presenting the basic elements of informed consent orally, must be approved by the Pellissippi State IRB prior to contact with prospective subjects. Written summaries of what is to be said to the participant should be attached to Form A or Form B applications.
- The Pellissippi State IRB may approve other procedures, if investigators explain the need for an alternative consent process. Provision of informed consent by alternative means must be approved by the Pellissippi State IRB.
- Criteria for approval of alternative means of securing informed consent include (but are not limited to) the following:
 1. The research involves no more than minimal risk to the participants;
 2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
 3. The research could not practicably be carried out without the waiver or alteration; and
 4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- On Form A or Form B, investigators must state how and where they will store the signed consent documents. During the research project, storing signed informed consent forms at locations other than at Pellissippi State may be necessary; however, the Pellissippi State IRB must approve these sites.

Note: For legal purposes, signed consent documents must be kept at Pellissippi State for three (3) years following completion of the research and must be accessible to authorized Pellissippi State personnel.

In addition, all records of participants must be maintained in a secure location to guarantee confidentiality. The informed consent template addresses the following issues:

Pellissippi State Review System for Human Subjects (Version: 10.01)

1. A statement describing the procedure for maintaining the participant's files/records.
 2. A statement that the records identifying the participant will remain confidential.
 3. A description of where they will be stored.
 4. A statement of who will have access to them.
- On the informed consent document, compensation is not defined as a benefit of research.
 - Additional elements of informed consent may be required in some cases. Check with the director of Institutional Effectiveness, Research and Planning, who serves as IRB chair, for further information.

Appendix J: Documentation for Training

Note to IRB Members and Investigators: There are two forms in this appendix. Please choose the appropriate training and documentation form for your role.

**Pellissippi State Technical Community College
Institutional Review Board Member
Protection of Human Subjects Education and Training Certification**

IRB Member Training

The federal Office for Human Research Protections (OHRP) requires IRB members to demonstrate that they have completed education on the protection of human research participants. The education requirement may be fulfilled in a variety of ways including specific courses or reading materials.

Effective April 2008, at the time of their appointments, all persons serving as IRB members at Pellissippi State Technical Community College will be required to complete a Pellissippi State IRB tutorial on the regulations and roles of the research investigator and the IRB, entitled "Research Ethics: the Protection of Human Subjects." Certificates of completion for the tutorial, which is in the form of a PowerPoint slide show, must be and filed with the director of Institutional Research, serving as IRB chair, to document training.

I, a responsible member of the Pellissippi State IRB, verify the above requirement is completed and documented with current and accurate certificate(s) on record with the director of Institutional Research, serving as IRB chair.

IRB Member _____ Date _____

Note: Retraining in Human Subjects Research and recertification is required every three years.

IRB members may also be interested in taking an elective training course offered by the Office for Human Research Protections (OHRP) available online at

<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

**Pellissippi State Technical Community College Institutional Review Board
Investigator
Protection of Human Subjects Education and Training Certification**

Human Research Investigator Training

Effective April 2008, prior to submitting a request for IRB certification to conduct human subjects research, investigators at Pellissippi State Technical Community College are required to complete a Pellissippi State IRB tutorial on the regulations and roles of the research investigator and the IRB, entitled “Research Ethics: the Protection of Human Subjects.” Certificates of completion for the tutorial, which is in the form of a PowerPoint slide show, must be signed and filed with the director of Institutional Research, serving as IRB chair, to document training.

In addition, other education training requirements may be required by the research funding sources such as:

Office for Human Research Protections (OHRP) Informational Tutorial
<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

National Cancer Institute
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

National Institute of Health
<http://ohsr.od.nih.gov/cbt/index.html>

I, the investigator for Pellissippi State IRB research, verify the above requirement(s) are completed and documented with current and accurate certificates on record with the director of Institutional Research, serving as IRB chair.

Type of training: “Research Ethics: the Protection of Human Subjects” and

(list other training if applicable):

Investigator _____ Date _____

Appendix K: Steps for Investigators

Pellissippi State Institutional Review Board Research Request Involving Human Subjects IRB Procedure Steps

The Research Approval Process for Investigators

The purpose of the Pellissippi State Institutional Review Board (IRB) is to protect the rights and welfare of human subjects in research projects by minimizing risks and ensuring informed and voluntarily participation. These objectives are in compliance with the U.S. Department of Health and Human Services (HHS) regulations for the protection of human research subjects as published at Title 45 Code of Federal Regulations, part 46. The following ethical principles govern the Pellissippi State IRB in the discharge of its responsibilities for human subjects research regardless of whether the research is subject to federal regulation and covers both funded and non-funded human subjects research:

Ethical Principles from the *Belmont Report*

- Respect for Person – acknowledgement of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy
 - Participation is voluntary and subjects give informed consent
- Beneficence – a responsibility to do no harm, to maximize possible benefits, and to minimize possible harm
 - Risks are minimized and reasonable in relation to anticipated benefits
- Justice – an expectation of fairness in distribution of benefits realized from research as well as its burdens
 - Rights and welfare of subjects are maintained

All Pellissippi State research involving human participants must be reviewed following Pellissippi State IRB procedures and approved prior to the initiation of research activity and contact with potential human participants. The best place to start this process is by contacting Dr. Sharon Yarbrough, director of Institutional Effectiveness, Research and Planning at 865-694-6526 or slyarbrough@pstcc.edu. The director of Institutional Research is chair of the IRB. Although certain research is exempt from review, these projects must be certified as exempt by the Pellissippi State IRB.

Investigator Action Steps for Research Involving Human Subjects

1. Discuss your proposed research with the director of Institutional Research, who serves as chair of the IRB
 - Complete the Grant Interest Form as appropriate (available on the Grant Development website)
2. Review Pellissippi State policies and federal regulations

- Pellissippi State Policy 08:02:01, “Conducting Research at Pellissippi State”
 - Pellissippi State Institutional Review Board Policy
 - Federal Regulations 45 CFR 46: Protection of Human Subjects
3. Complete the Investigator Training for human subjects research (start with the Pellissippi State PowerPoint presentation available on the Institutional Research website)
 4. Prepare research application (use Form A or Form B, as appropriate) for IRB review
 - a. Form A: use to apply for an exemption from the IRB for projects that
 - a) Involve no more than minimum risk and
 - b) Fall into one of the government’s six exempted categories and
 - c) Involve no children or other vulnerable populations
 - b. Form B, Option B-1: use to apply for expedited review for projects that
 - a) Involve no more than minimum risk and
 - b) Fall into one of the government’s nine categories of research eligible for expedited review
 - c) Minor changes to approved research can also be reviewed under expedited procedures
 - c. Form B, Option B-2: use for research requiring full-board review (projects that are not eligible for exempt or expedited review)
 - d. Form Contents
 - a) Goal of the project
 - b) Objective(s) for the period of the project
 - c) Description of human subject participation
 - d) Methods and procedures
 - e) Specific risks and protection measures
 - f) Benefits
 - g) Method of obtaining informed consent from participants
 - h) Confidentiality and privacy plans
 - i) Commitment of investigator to comply with federal regulations
 - j) Original signatures required on application forms
 5. Prepare informed consent documents using the appropriate Pellissippi State IRB informed consent template
 - General Informed Consent
 - Permission from parents or legally authorized representative (LAR) and assent of child (for minors and other vulnerable populations)
 - Video/Media addendum, if appropriate
 6. Submit Form A or Form B to the director of Institutional Research/IRB chair with the required attachments
 - Curriculum Vita of PI and Co-PI including past experience with human subjects research

- Certificate of human subjects research training
 - Completed informed consent documents
 - Copies of all surveys and/or questionnaires, brochures, information sheets, and advertising that will be used
 - Transcript of oral instructions when used in lieu of a written informed consent document (e.g., if this approach is used for vulnerable populations)
 - Video/Media Addendum to informed consent document if applicable
7. Prepare for continuing review by the IRB for non-exempt projects (projects approved on Form B application), as required by federal regulations
- a. IRB approval of research does not extend past one year (minus one day) from the date of IRB approval
 - b. The IRB will determine if a project requires review by the IRB more often than annually
 - c. Two months prior to the expiration date of the approval, Form C (Continuing Review Report) is due to the IRB. For example, if the IRB approved the project on July 1, 2008, the approval to conduct the research expires on June 30, 2009; Form C would have to be submitted to the director of Institutional Research/IRB chair by April 30, 2009.
 - d. Form C required attachments:
 - Copies of all informed consent documents
 - Surveys and/or questionnaires currently being used
 - A copy of the annual report submitted to the funding agency (if applicable)
 - e. Continuing review by the IRB can be conducted through expedited review procedures or full-board review, as determined by the IRB
8. Submit Form D, Project Status Report: Changes and/or Close-Out, before making any minor changes in the protocol of approved projects. Also submit any other minor changes, such as
- Any changes in the project such as title, participants, adverse affects, informed consent, or project location
 - Major modifications to protocol require resubmission of Form B.
9. Maintain documentation for the research project, including copies of all signed informed consent forms, for at least three years after the project is closed out.
10. Report any non-compliance issues with the project to the director of Institutional Research/IRB chair immediately
11. Promptly submit the closing report for the research project to the director of Institutional Research/IRB chair

- Use Form D: Project Status Report: Changes and/or Close-Out
- Also use Form D to report terminations of projects that were submitted to the IRB for approval but that were never started

Timeline for Human Subjects Review System at Pellissippi State

Two weeks before study is to begin	Investigator submits application for exemption from review (Form A) or expedited review (Form B, option B-1) to Director of Institutional Research, serving as IRB chair,
Four weeks before study is to begin	Investigator submits application for full-board review (Form B, option B-2) to Director of Institutional Research, serving as IRB chair, for distribution to IRB
Two weeks before IRB meeting	IRB members receive all application materials for review
Within 5 days of IRB meeting	Investigators are notified if they have been invited to attend the IRB meeting to answer questions on their research
Two months prior to the anniversary date of the IRB approval	Investigator submits Form C, Continuing Review Report, to the director of Institutional Research, serving as IRB chair, for processing/distribution
At conclusion of research project	Investigator submits Form D, Project Status Report: Changes and/or Close-Out, to the director of IR/IRB chair.
Three years following the conclusion/close-out of the research	Investigators must keep signed informed consent documents and other identifiable records in a secure location to ensure the privacy participants and the confidentiality of their records.

Appendix L: Links to Web-Based Resources for Human Subjects Research

Link to 45 CFR 46	http://www.hhs.gov/ohrp/documents/OHRPRegulations.pdf
OHRP Website with FAQs	http://www.hhs.gov/ohrp/
Belmont Report	http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
<i>Office of Human Research Protections (OHRP) IRB Guidebook</i>	http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
Criteria for meetings conducted by conference call	http://www.hhs.gov/ohrp/references/irbtel.pdf

Appendix M: Membership of the Pellissippi State IRB

The Pellissippi State IRB consists of the following members appointed by the College president in accordance with the approved procedures for appointment:

A minimum of five (5) persons as members with varying backgrounds to promote complete and accurate review of research and related activities. Federal policy does not permit an IRB to consist entirely of members of one profession.

A membership that includes (1) at least one member with purely scientific interests and one member with mainly ethical interests, (2) at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; (3) both male and female members, and (4) as many faculty/staff members from academic departments and divisions at the College with interests in human subjects as is appropriate to ensure disciplinary diversity.

All members appointed to the committee shall be able to ascertain acceptability of proposed research and related activities in terms of institutional commitment and regulations regarding research, applicable law and standards of professional conduct and practice.

All members shall be sufficiently qualified through experience and expertise, as well as through diversity (including consideration of race, gender and cultural backgrounds), to possess a level of sensitivity to issues and attitudes that will promote respects for its counsel and advice in safeguarding the rights and welfare of all human subjects.

The Pellissippi State IRB may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The Pellissippi State IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Appendix N: (Reserved)

Appendix O: Reserved

Appendix P: Photo/Video/Audio/Media Materials: Guidelines and Template for the Recorded Media Addendum to Informed Consent

General Information About Preparing Form B Applications and Informed Consent Forms When Your Research Methods Include Media Records of Participants

I. Procedural Information

Videotaping, photographing, or audiotaping research participants is a valid and useful data collection method; however, the use of these media records increases an investigator's need to clearly specify the steps taken to maintain the confidentiality of this identifiable information. Investigators meet this need by describing the steps they will take to protect the confidentiality of research videotapes and other media materials in their Form B applications, and in their informed consent forms. All research in which participants will be recorded or photographed requires the use of a Form B application. Expedited review of Form B applications is possible when the research does not involve participants from vulnerable populations and the information collected is not of a sensitive nature (e.g., sexual behavior, illegal activities, etc.).

II. Form B Application Information

Section IV (the Methods and Procedures section) of an investigator's Form B should clearly specify the purposes and uses of the videotapes (or media records). An investigator should directly relate the purposes and uses of the recorded images to achieving the objectives of the project stated in Section II of her/his Form B. The investigator's recording procedures should be presented along with a discussion of the measures used to avoid the inclusion of non-participants in the photographs or on the video- or audiotapes. Investigators should describe media storage procedures, the storage location, and the duration of storage. Section IV should also contain a description of the investigator's procedures for controlling access to and use of the recordings, and the disposal of the media materials.

Section VII (the “Methods for Obtaining Informed Consent From Participants” section) of a Form B should clearly specify the investigator's consent procedures. The Pellissippi State IRB usually requires full informed consent when media records are made. **Use the template for the Addendum to Informed Consent for Media Materials.** The Pellissippi State IRB may allow the use of deception or incomplete disclosure about the real purpose of the research in the informed consent, if the proposed consent procedures are exposed to no more than minimal risk. If a degree of deception and/or withholding of information is necessary for adequate testing of the hypothesis and in the absence of any practical alternative, then the investigator should address her/his plan for giving participants full information about their participation following the completion of their involvement in the study.

III. Informed Consent Form Information

In addition to all other basic elements of informed consent, a full informed consent should identify the purposes and uses of the electronic images. The informed consent should provide information about who will have access to the recordings and how access will be controlled. Storage information should state how long the investigator will store the media records and what the investigator will do with the media records at the end of the storage period. The information provided in the informed consent should match similar information provided in the Form B application. Because the contents of videotapes and other images are identifiable, participants must give their explicit consent for any public use of the materials, such as use in the classroom or use in a public presentation of research results. The Addendum to Informed Consent for Media Materials must be used to obtain a participant's explicit consent for the public use of his/her image or recording. Videotapes or other media records of participants in studies using limited or deceptive informed consent procedures may not be publicly used without the explicit written consent of the participant, after full disclosure.

IV. Storage and Future Use Considerations

If you expect to store your videotapes in ways that will enable others to use the videotapes, or if you expect to use the videotapes in additional research projects that are not directly related to the objective of the study under which they were initially created, please explicitly state these expectations in your research protocol and in your informed consent form. Given that the identities of your participants remain on the videotapes until the tapes are erased or destroyed, you must inform participants about the possibility that others may use the videotapes or that the videotapes may be used in additional research projects. There are many legitimate reasons why you might want to use the videotapes in future research projects, or to allow others to use the videotapes, but the participants in your initial study need to know about these uses when they consent to participate.

If you anticipate that other investigators may request to use the videotapes outside your research project, then you must specify the procedures you will use to grant other investigators access to your videotapes in the Form B. The participant's informed consent form should state that other investigators may use the videotapes in the future.

If you expect to archive the media in a manner in which access to them will be controlled by other individuals, libraries, or collections, please explicitly state the qualifications of the guardians of the records and the procedures they will follow to protect the confidentiality of the participants when other investigators request access to the media. The participants in your study need to know about your plans to allow others to control future access to these images when they consent to participate, and these plans should be clearly stated in your research protocol and informed consent.

The passage of time does not diminish your responsibility to protect the confidentiality of the participants in your research. The rights of a participant do not expire at the end of a research project, or after any other period of time. Videotapes and other media records cannot be considered secondary data as long as they contain identifiable information.

Pellissippi State Review System for Human Subjects (Version: 10.01)

If you have any questions about the development of your Form B application, please contact the director of Institutional Effectiveness, Research and Planning, Dr. Sharon Yarbrough, who serves as IRB chair, at slyarbrough@pstcc.edu or at (865) 694-6526. Research involving human participants may not be initiated until you receive final written IRB approval.

Template: Recorded Media Addendum to Informed Consent

Institutional Review Board
Pellissippi State Technical Community College

Recorded Media Addendum to Informed Consent

For use with general informed consent documents for studies that involve audio, video, photographic, or any other recording (hereafter referred to as recording) of research subjects.

Project Title: Project Title

Date: Date

Investigator: Investigator

Department or Division Department or Division

Email Address Email address

Phone Phone

Description:

The researchers would also like to take photographs or make video or audio recordings (or insert appropriate recorded media) of you performing (insert activity) in order to illustrate the research in teaching, presentations, and/or or publications.

Confidentiality:

You would not be identified by name in any use of the photographs or videotapes. Even if you agree to be in the study, no photographs or video or audio recordings of you will be taken unless you specifically agree to this. (All consent material should always advise subjects how anonymity of confidentiality will be maintained. The confidentiality statement should address how the tapes will be stored to maintain confidentiality. The form should describe how long the tapes or other media will be stored and what will happen to the films, tapes, or other media records at the completion of the study.)

Voluntary Consent:

By signing below, you are granting to the researchers the right to use your likeness, image, appearance, and performance – whether recorded on or transferred to videotape, film, slides, photographs, or other media – for presenting or publishing this research. No use of photos or video images will be made other than for professional presentations or publications. The researchers are unable to provide any monetary compensation for use of these materials. You can withdraw your voluntary consent at any time.

If you have any questions later on, the researchers should be able to answer them: (include the contact information for the investigators). If at any time you feel pressured to

participate, or if you have any questions about your rights or this form, then you should contact the Institutional Review Board Chair at Institutional Effectiveness, Research and Planning, telephone 865-694-6526.

Subject's Printed Name & Signature	Date
Parent / Legally Authorized Representative's Printed Name & Signature (If applicable)	Date
Investigator's Printed Name & Signature	Date

Appendix Q: Informed Consent Checklist

Consent Checklist

These elements must be included in all consent forms:

- A statement that the study involves research.
- An explanation of the purposes of the research.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights.
- A statement that participation is voluntary
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

The following must be included for studies which are greater than minimal risk:

- An explanation of whom to contact in the event of a research related injury.
- Whether any compensation is available if injury occurs.
- If compensation is available if injury occurs, an explanation of what it consists of, or where further information may be obtained.
- Whether any medical treatments are available if injury occurs. .
- If medical treatments are available if injury occurs, an explanation of what it consists of, or where further information may be obtained.

The following must be included if:

- the research is FDA-regulated:** A statement that notes the possibility that the Food and Drug Administration may inspect the records.
- relevant animal data are available:** An explanation of its significance.
- any measures to prevent pregnancy should be taken while in the study:** An explanation of these measures.
- alternative procedures or courses of treatment might be advantageous to the participant:** A disclosure of these alternative procedures or courses of treatment.
- the risks of any research procedure are not well known, for example because of limited experience in humans:** A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.
- the research includes women of child bearing potential or pregnant women, and the effects of any research procedures on embryos and fetuses is not well known:**

A statement that, if the participant is or may become pregnant, the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable.

there are anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent:

Anticipated circumstances under which participation may be terminated by the investigator without the participant's consent.

there are costs to the participant that may result from participation in the research: Additional costs associated with study participation.

there are adverse consequences (e.g., physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research:

Consequences of a participant's decision to withdraw from the research and procedures for an orderly termination of participation.

significant new findings during the course of the research that may relate to the participant's willingness to continue participation are possible: A statement that new findings developed during the course of the research that may relate to the participant's willingness to continue in the research study will be provided to the participant.

the approximate number of participants involved in the study might be relevant to a decision to take part in the research: Approximate number of participants involved in the study.

The following must be included for studies involving:

Blood samples: A statement naming and describing the method through which blood will be sampled, the frequency with which this method is used, any possible side-effects of the method, who will obtain the sample and how much they will obtain, and what the blood will be analyzed for.

Blood tissue or body fluid for possible genetic research: A statement explaining the fact that the specimens will be maintained without identifiers, the risk level to the subject if they agree to participate, where the specimens will be stored, who owns the specimens and how the specimens will be used in the future.

Physical risk: A statement that includes the following: the University does not have a plan to provide facilities or insurance to cover research-related injuries; Only UT student participants will be afforded access to the designated services available through The University of Texas Student Health Center. If emergency treatment for research-related injuries is arranged, that should be stated, but a disclaimer for extended care should be added.

Risk to a fetus: A statement informing the female participant of the risk and the methods to be used (such as a pregnancy test) to minimize the risk.

Drugs: A statement including: known side effects, possible drug interactions (including interactions with alcohol), and a warning about activities that may be dangerous (such as driving with a drug that has a sedative effect).

Psychological risk: A statement informing the participants of the risk and indicating that UT does not have a plan for providing treatment; a list of names and telephone numbers of agencies that may alleviate mental concerns, such as a crisis hot line. If the principal investigator or the faculty sponsor of a student investigator is qualified to treat mental health problems, that person may be listed as a resource. Only UT student

participants will be afforded access to the designated services available through The University of Texas Student Health Center.

Sensitive topics: A statement that some of the questions are of a personal or sensitive nature and examples of the topics or questions; a statement that they can skip a question if they do not wish to answer it; if questionnaires or interviews may generate reports of child physical or sexual abuse, a statement that the researcher is legally required to report this information to Child Protective Services; if the questionnaires or interviews may generate reports that the participant plans to harm him or herself or others, a statement that the investigator is ethically required to report that information to the local police department. Information about the legal obligations to report abuse and threats of harm to oneself or others may be omitted if the responses are anonymous. In the event that the Privacy rule is more restrictive than the procedures described in the consent requirements, the more restrictive rule must be followed.

Audio or video recordings: A statement that the interviews or sessions will be audio or videotaped, the cassettes will be coded so that no personally identifying information is visible on them, the recordings will be kept in a secure place, and the recordings will be heard or viewed only for research purposes by the investigator and his or her associates. A statement that either recordings will be erased after they are transcribed or coded or they will be retained for possible future analysis. If the researcher wishes to present the recordings at a convention or to use them for other educational purposes, the statement (after the signature lines), “We may wish to present some of the tapes from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with the tape of your performance” Additionally, a second signature line should be added with the preface, “I hereby give permission for the video (audio) tape made for this research study to be used for educational purposes”.

Monetary or other compensation: A statement describing the amount and types of compensation and clearly specifying the requirements to earn them.

Deception: If deception is a necessary part of the experiment, a preliminary consent, in which the investigator informs the subject of the research, should be obtained. After the experiment, the subject should be informed of the deception and its purpose. In rare instances, the IRB may approve a study even if no consent can be obtained or debriefing done. Deception requires a waiver of informed consent.

Appendix R: Recording Template for Minutes of IRB

**Pellissippi State Technical Community College
Institutional Review Board
Meeting Record Template**

Date _____

Time _____

Members Participating

Convened (present or conference call)

1. _____

2. _____

3. _____

4. _____

5. _____

Non-Member(s) (Consultant/Guest)

Meeting Agenda

Identify IRB review request application materials are complete and can be placed on meeting agenda: Copies of IRB request form, research proposal, and consent form completed and submitted by Investigator. If continuation request, new consent forms and Form C: Continuing Review Report must also be submitted for review.

- **Confirm IRB members received applications request prior to meeting**

Document for each request reviewed:

IRB #	Investigator	Research Project
_____	_____	_____
_____	_____	_____

Criteria for review discussion regarding request and debated issues:

- 1. Risk to subjects**
- 2. Risks vs. Benefits**
- 3. Subject Selection**
- 4. Informed Consent**
- 5. Confidentiality and Privacy**
- 6. Other considerations**
(Also identify who was present during discussion and who excused themselves from discussion points and vote by leaving room or disconnecting phone connection)

Voting record for reviewed request

#For _____ **#Against** _____ **#Abstentions** _____

Document IRB review decision for each reviewed request:

Request approved ____

1. IRB Request Form signed and dated by Director of Institutional Research, serving as IRB chair, as approved certification- Yes ____
2. Consent form stamped by Director of Institutional Research, serving as IRB chair, to show IRB approval and date of expiration by IRB- Yes ____

Request denied ____

1. IRB Review Request Form signed and dated by Director of Institutional Research, serving as IRB chair, as denied- Yes ____
2. Director of Institutional Research, serving as IRB chair, will communicate IRB denial decision to Investigator

Continuing Review Request:

Request Approved _____ Request denied _____

1. Description(s) and Summaries of on-going project activities acceptable
2. New Consent Forms stamped by Director of Institutional Research, serving as IRB chair, to show IRB approval and date of expiration by IRB-Yes ____

Other items: Document IRB Acknowledgements, Reviews, Discussions, Resolutions

- Acknowledge copies of all correspondence between Director of Institutional Research, serving as IRB chair, and the investigator(s)
- Identify and review any statements of significant new finding (unanticipated risks or adverse reactions) provided to subjects
- Identify and review any adverse reactions reports
- Identify and review any emergency use reports
- Identify general project information provided to subjects (e.g. fact sheets, brochures)

Meeting Documents and Records shall be retained for at least (3) years after completion of the research

Appendix S: Special Considerations for the Protection of Children Participating in Research Sponsored by Pellissippi State

The information in this section is provided to clarify the Form B preparation and review process for investigators who plan to include children as participants in their research projects. This information is intended to facilitate the compliance approval process. If you have additional questions about your research project, please contact the director of Institutional Effectiveness, Research and Planning, Dr. Sharon Yarbrough, who serves as IRB chair, at slyarbrough@pstcc.edu or at (865) 694-6526.

General Information

Federal regulations [Title 45 CFR Part 46, Subpart D] require that the investigators explicitly address the measures taken to protect the welfare and rights of children participating in research projects. At Pellissippi State Technical Community College, the adequacy of these measures is assessed by the Pellissippi State IRB during the approval process. Because of the potential vulnerability of children, a higher standard of protection must be demonstrated for approval. **As a result, almost all research** involving children requires expedited or full-IRB review of Form B applications. The only exception to this rule (discussed in part 5 of this section) occurs when the research involves observation of public behavior. All other projects of no more than minimal risk that would normally be considered exempt from IRB review (Form A applications) are not exempt when children are involved.

Please note that you may not initiate contact with potential child-participants, or begin data collection, before you have received final approval from the IRB.

Although Form B applications take longer to prepare and review than Form A applications, most Form B applications are reviewed within four weeks of submission. However, the approval process sometimes takes longer than this, especially if significant revisions are required. Therefore, researchers must allow adequate time to prepare and submit applications. The complexity of the project and the initial quality of the application affect the time required for approval.

The following section addresses several significant areas of concern that commonly arise during IRB reviews of research involving children. When preparing your Form B application, investigators must follow the Form B Application Guidelines (see Appendix B). Investigators who have additional questions about their specific research project or who need further clarification are encouraged to contact the director of Institutional Effectiveness, Research and Planning, Dr. Sharon Yarbrough, who serves as IRB chair, at slyarbrough@pstcc.edu or at (865) 694-6526.

1. Identifying and Recruiting Potential Child-Participants

The investigator must clearly describe the methods used to identify and recruit potential child-participants. Measures taken to prevent potential concerns about coercion or

breaches of confidentiality in the identification and contact stages of the research project must be described. Copies of notices or advertisements that will be used should be included in the application.

Only after permission from the appropriate authorities has been granted in writing may potential child-participants' identities be obtained from school classrooms, care-giving programs, or other agencies. For example, investigators wishing to study students in public school systems must obtain written permission from the school board or its authorized representative before students can be contacted. This approval cannot be used to require teachers or students to participate.

Sometimes permission from the school board or other institutional authorities will not be given until the Pellissippi State IRB has approved the project. If a project must receive IRB approval prior to the granting of any institutional permission, the investigator should contact the director of Institutional Effectiveness, Research and Planning, Dr. Sharon Yarbrough, who serves as IRB chair, at slyarbrough@pstcc.edu or at (865) 694-6526. This is a common complication that can be easily remedied without delaying the approval process.

2. Consent Procedures

Federal law recommends the **assent** of the child and requires the **permission** of the parent(s), or guardian(s), in place of consent of the child before a child may be involved in a research project. Research involving "mature" or emancipated minors may not need parental permission, but approval of the full Pellissippi State IRB must be obtained to waive the parental permission requirement.

Note: A **guardian** is an individual who is authorized under applicable state or local law to give permission for a child [45 CFR, 46.402(3)].

Permission is the explicit agreement of parent(s) or guardian to the participation of their child or ward in research. Failure to object or other forms of passive permission cannot be construed as permission [45 CFR, 46.402(c)].

Both parents must give their permission in any research that places the child-participant at *greater* than minimal risk [45 CFR, 46.406 and 46.607], unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child [45 CFR 46.408 (b)].

The permission of one parent is sufficient for any research that places that child-participant at no more than minimal risk [45 CFR 46.404]. The Pellissippi State IRB may consider that the permission of one parent is sufficient for research involving greater than minimal risk, if there is a clear prospect of direct benefit to the child-participant [45 CFR 46.408 (b)].

The requirement of parental permission may be waived in those cases where it is clear that the parents' interests do not adequately reflect the child's interests (e.g., research on child abuse or neglect). These cases require investigators to develop special procedures,

which must be approved by the full Pellissippi State IRB, that protect the rights and welfare of the children asked to participate.

When permission is required, the information contained in the permission procedure should include all the elements normally required in an informed consent (see Appendix I).

Assent is a child's affirmative agreement to participate in research. Assent is an ethical concept. However, failure to object cannot be construed as assent [45 CFR, 46.402(b)]. Investigators who include children in their research should be especially mindful of the rights of children participating in their research. Even when assent is not required, investigators are asked to demonstrate a good faith effort to enlist the cooperation of children who participate in their research.

It is the responsibility of the Pellissippi State IRB to decide if investigators should seek a child's assent as part of a project's consent procedure. The determination of a child's capacity to provide assent is based on the nature of the research, and the child's age (typically the Pellissippi State IRB requires assent from children age seven and older), maturity, and psychological state of the population of children from whom participants will be drawn. The decision to require assent depends on the capacity of the children to appreciate the nature, extent, and probable consequences of their participation in a research project.

Assent is especially important in cases where there is no direct benefit to the child-participants. When assent is required, the procedure should include an explanation of the proposed research in language that is appropriate for to the child's age and maturity. The investigator should indicate on Form B what the children will be told about the research and how the information will be conveyed. The investigator should discuss how the information provided might vary with the age, maturity, and level of experience of the children involved in the study. The assent process should be free from coercion and unfair inducements. All children who are capable of providing assent must be informed that they are free to withdraw from participation at any time. (See Appendix T for a template for the assent form.)

3. Risk and Benefit Assessment

Risk Assessment:

Federal regulations require IRBs to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the proposed research study. **The four categories of research involving children that may be approved by the Pellissippi State IRB, based on degree of risk and benefit to individual participants are as follows:**

1) Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [[45 CFR 46.404](#)].

Examples of research in this category might include: research on children's attitudes about food preferences, surveys about play activities, etc.

2) Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant. Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the participant; and (b) the relationship of risk to benefit is at least favorable as any available alternative approach [45 CFR 46.405].

Examples of research in this category might include research on the coping strategies of children living in foster care or research on the effectiveness of drug-use intervention programs for children testing positive for drug use.

3) Research involving greater than minimal risk, with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition is approvable provided: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participant's disorder or condition [45 CFR 46.406].

Examples of research in this category might include research using abused children that is designed to identify early warning signs of potential abuse in the general population of school-aged children; or research on the effectiveness of corporal punishment.

4) Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research that is not approvable under 45 CFR 46.604, 46.405, or 46.606 may be conducted or funded by the Department of Health and Human Services provided that the IRB, and the Secretary of DHHS, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health or welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles [45 CFR 46.407].

No examples of research in this category are provided because projects in this category are unique and require federal approval.

Assessing probable risks is a central consideration of the Pellissippi State IRB's approval process. The assessment of the probability and magnitude of the risk may differ depending on conditions child-participants may have. The issue of what is considered "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations" may vary depending on the circumstances or conditions of the population from which the children are drawn. The Pellissippi State IRB considers the extent to which research procedures would be a burden to a child. Behavioral interventions likely to cause psychological stress may be considered to exceed minimal risk.

Benefit Assessment:

Investigators preparing Form B applications must carefully identify and describe all reasonably anticipated benefits that may be received by child-participants. As noted in the risk assessment subsection, anticipated benefits to child-participants must exceed anticipated risks when research procedures expose child-participants to greater than minimal risk.

4. Use of Educational Records

Federal law [34 CFR 99, 99.03 through 99.37] governs the privacy and access to elementary and secondary school records. The primary rights of access to these records are given to parents, guardians, and to students (once they have reached 18 years of age). Except for administrative purposes, schools must withhold access to personally identifiable information from educational records except with the written permission of the students' parents, or students once they have reached 18 years of age. To be valid, a written consent for disclosure of educational records must include three items: a specification of the records to be disclosed, the purpose(s) of the disclosure, and the party or class of parties to whom the disclosure will be made.

The requirement for written permission applies to all research, except that conducted by or for educational agencies or institutions developing, validating, or administering predictive tests, administering student aid, or improving instruction (provided such studies will not permit the identification of individual students and that personally identifying data will be destroyed upon completion of the study).

5. Exempt Research Involving Children

At this time, the only research procedure involving child-participants exempt from Pellissippi State IRB review (Form A is the appropriate application form) is observation of public behavior. The definition of observation of public behavior requires that investigators not interact in anyway with the children, record their identities (this includes the use of audio- or videotaping procedures), or place the children at risk.

Examples of Cases When the Pellissippi State IRB Exemption Involving Children Does Not Apply

The observation of public behavior exemption does **not** apply when a) the child-participants have a reasonable expectation of privacy (e.g., a private conversation in a public park); b) survey instruments are used (this would constitute an interaction, even if conducted by an independent third-party, such as a teacher); and c) the investigator rearranges or changes the setting/environment in which the public observation takes place.

See Appendix T for the template for obtain parent/guardian permission and assent for children under age 18 who are subjects.

Appendix T: Templates for Informed Consent

1.1 Adult Consent Form

Consent Form for Participation in a Research Study Pellissippi State Technical Community College

(For Adult Participants 18 Years of Age and Older)

Sample for Investigator:

- *Insert content for your study.*
- *Delete instructions and additional elements on last page upon completion of the consent document to assure appropriate page numbering.*
- *Prepare and attach the Recorded Media Addendum to Informed Consent if appropriate.*

**(Insert title of study,
matching the title of the research protocol submitted to the IRB)**

Description of the research and your participation

You are invited to participate in a research study conducted by (insert the investigator's name here, along with the student's name if the research is being performed by a student under the direction of the investigator). The purpose of this research is (explain the purpose of the study in easily understood language).

Your participation will involve (describe the procedures to be followed in easily understood language).

The amount of time required for your participation will be (provide an estimate of the expected duration of the participant's participation in the study).

Risks and discomforts

There are no known risks associated with this research. OR There are certain risks or discomforts associated with this research. They include (describe any reasonably foreseeable risks or discomforts to the participant. You may also describe the measures you will take to minimize these risks and discomforts.)

Potential benefits

(Describe any benefits to the participant and to others that may reasonably be expected from the research.) OR There are no known benefits to you that would result from your participation in this research. If appropriate, add: This research may help us to understand (limit to a brief statement).

Protection of confidentiality

(Describe the extent to which confidentiality of records identifying the participant will be maintained. State: Your information will be confidential and reported in aggregated format. If appropriate, follow this description with: Your identity will not be revealed in any publication that might result from this study.)

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact (insert the investigator’s name here) at Pellissippi State Technical Community College at (insert investigator’s telephone number with area code and investigator’s email address). If you have any questions or concerns about your rights as a research participant, please contact Dr. Sharon Yarbrough, Director of Institutional Effectiveness, Research and Planning, and Chair of the Pellissippi State Institutional Review Board, by phone at 865.694.6526 or by email at slyarbrough@pstcc.edu.

Consent

I have read this consent form and have been given the opportunity to ask questions. I am 18 years of age or older and I agree to participate.

Participant’s Name (please print)_____

Participant’s signature: _____ Date: _____

A copy of this consent form should be given to you.

Investigator's signature _____ Date _____

Co-investigator’s signature _____ Date _____

(delete or add as needed for number of co-investigators)

(When appropriate, the consent document should include the following additional information. Delete the material on this page upon completion of the consent document to assure appropriate page numbering.

1. Experimental procedures: Identification of any procedures which are experimental.
2. Alternative procedures or treatments: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
3. Research-related injury: For research involving more than minimal risk, identification of the person to contact in the event of a research-related injury, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
4. Unforeseeable risks: A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
5. Termination of participation by the investigator: Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
6. Additional costs: Any additional costs to the participant that may result from participation in this research.
7. Consequences of discontinuing research participation: The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
8. Notification of significant new findings: A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.
9. Approximate number of participants: The approximate number of participants involved in the study.
10. Exclusion requirements: Any pre-existing conditions (e.g., pregnancy) or other factors (e.g., age) that might exclude a potential participant from participation in the study.

1.2 *Template for Parent/Guardian Permission*



Parental Permission Form for Participation of a Child in a Research Study Pellissippi State Technical Community College

Sample for Investigator:

- ***Insert content for your study.***
- ***Delete instructions and additional elements on last page upon completion of the consent document to assure appropriate page numbering.***
- ***Prepare and attach the Recorded Media Addendum to Informed Consent if appropriate.***

(Insert title of study, matching the title of the research protocol submitted to the IRB)

Description of the research and your child's participation

Your child has been invited to participate in a research study conducted by (insert the investigator's name here, along with the student's name if the research is being performed by a student under the direction of the investigator). The purpose of this research is (explain the purpose of the study in easily understood language).

Your child's participation will involve (describe the procedures to be followed in easily understood language).

The amount of time required for your child's participation will be (provide an estimate of the expected duration of the child's participation in the study).

Risks and discomforts

There are no known risks associated with this research. OR There are certain risks or discomforts associated with this research. They include (describe any reasonably foreseeable risks or discomforts to the child. You may also describe the measures you will take to minimize these risks and discomforts.)

Potential benefits

(Describe any benefits to the child and to others that may reasonably be expected from the research.) OR There are no known benefits to your child that would result from the

child’s participation in this research. If appropriate, add: This research may help us to understand (limit to a brief statement).

Protection of confidentiality

(Describe the extent to which confidentiality of records identifying the child will be maintained. If appropriate, follow this description with: Your child’s identity will not be revealed in any publication that might result from this study.)

Voluntary participation

Participation in this research study is voluntary. You may refuse to allow your child to participate or withdraw your child from the study at any time. Your child will not be penalized in any way should you decide not to allow your child to participate or withdraw your child from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact (insert the investigator’s name here) at Pellissippi State Technical Community College at (insert investigator’s telephone number with area code and investigator’s email address). If you have any questions or concerns about your rights as a research participant, please contact Dr. Sharon Yarbrough, Director of Institutional Effectiveness, Research and Planning, and Chair of the Pellissippi State Institutional Review Board, by phone at 865.694.6526 or by email at slyarbrough@pstcc.edu.

Consent

I have read this parental permission form and have been given the opportunity to ask questions. I give my permission for my child to participate in this study.

Parent’s Name (please print): _____ Date: _____

Parent’s signature: _____ Date: _____

Child’s Name: _____

A copy of this parental permission form should be given to you.

Investigator's signature _____ Date _____

Co-investigator’s signature _____ Date _____

(delete or add as needed for number of investigators)

(When appropriate, the parental permission form should include the following additional information. Delete the material on this page upon completion of the permission form to assure appropriate page numbering.

1. Experimental procedures: Identification of any procedures which are experimental.
2. Alternative procedures or treatments: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
3. Research-related injury: For research involving more than minimal risk, identification of the person to contact in the event of a research-related injury, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
4. Unforeseeable risks: A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
5. Termination of participation by the investigator: Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
6. Additional costs: Any additional costs to the participant that may result from participation in this research.
7. Consequences of discontinuing research participation: The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
8. Notification of significant new findings: A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.
9. Approximate number of participants: The approximate number of participants involved in the study.
10. Exclusion requirements: Any pre-existing conditions (e.g., pregnancy) or other factors (e.g., age) that might exclude a potential participant from participation in the study.

1.3 Student Assent to Participate in a Research Study

Form for investigator to complete.

- *Replace bullets with content for your study*
- *Add a section on how you will use recorded media, if appropriate to your study.*
- *Delete instructions*

Title of the Research

You are being invited to participate in a research study. Below you will find answers to some of the questions that you may have.

What is it for?

- Include a brief explanation why the study is being conducted

Why me?

- Include a brief explanation why the participant is being selected to participate in the research.
- If appropriate, include a sentence that participation will not have a negative impact on participants

What Will I Have to Do?

- Include a brief explanation of the procedure and the duration of participation
- If appropriate, include a sentence if the procedure will be painful and the level of discomfort anticipated

Did My Parents Say It Was Okay?

- Include a sentence that indicates that the child's parent has already signed a consent form for their participation
- If appropriate, include a sentence that indicates if the child's parent will be present during their participation in the research.

Who Will Be Helped By This Research?

- Include a brief description of the anticipated benefits of the research, both to the participant (if appropriate) or to other children or to society in general

Appendix U: User’s Guide to Acronyms and Initialisms

Acronym	Definition
CFR	Code of Federal Regulations
FWA	Federalwide Assurance
HHSS	U.S. Department of Health and Human Services
HPA	Human Protections Administrator
IERP	Institutional Effectiveness, Research and Planning
IR	Office of Institutional Effectiveness, Research and Planning (or “Institutional Research”)
IRB	Institutional Review Board
LAR	Legally Authorized Representative
NSF	National Science Foundation
OHRP	Office for Human Research Protections
Pellissippi State IRB	Pellissippi State Technical Community College Institutional Review Board

Appendix V: Timeline for IRB Review

Two weeks before study is to begin	Investigator submits application for exemption from review (Form A) or expedited review (Form B, option B-1) to Director of Institutional Research, serving as IRB chair,
Four weeks before study is to begin	Investigator submits application for full-board review (Form B, option B-2) to Director of Institutional Research, serving as IRB chair, for distribution to IRB
Two weeks before IRB meeting	IRB members receive all application materials for review
Within 5 days of IRB meeting	Investigators are notified if they have been invited to attend the IRB meeting to answer questions on their research
Two months prior to the anniversary date of the IRB approval	Investigator submits Form C, Continuing Review Report, to the Director of Institutional Research, serving as IRB chair, for processing/distribution
At conclusion of research project	Investigator submits Form D, Project Status Report: Changes and/or Close-Out, to the director of IR/IRB chair.
Three years following the conclusion/close-out of the research	Investigators must keep signed informed consent documents and other identifiable records in a secure location to ensure the privacy participants and the confidentiality of their records.

Appendix W: Written Procedures of the Pellissippi State IRB

Written procedures of the Pellissippi State IRB are included throughout this document (for example, see Section 2.0, “Institutional Review Board”). The purpose of this appendix is to provide references to the written procedures that the Pellissippi State IRB follows to comply with the requirements listed in section 103 (b) (numbers 4 and 5) of Federal Regulation 45 CFR 46.

1. Conducting Initial Review of Research

See Section 4.0, “Review Procedures/Steps”

2. Conducting Continuing Review of Research

See Section 8.0, “Continuing Review Report of Human Subjects Research”

3. Reporting IRB Findings and Actions to Investigators and the College

See Section 2.7, “Record Keeping and Reporting Requirements”

4. Determining Which Projects Require Review More Often Than Annually

The Board will determine which projects require review more often than annually for those projects requiring full-board review. Results of discussion on this issue will be recorded in the minutes. The director of Institutional Research, serving as IRB chair, will determine which projects require review more often than annually for research reviewed under expedited procedures. Criteria to consider for this decision include the following:

- a. Studies involving more than minimum risk to participants
- b. Studies involving medical procedures
- c. Studies that report adverse events, unanticipated risks, or protocol changes
- d. Studies managed by investigators whose previous project(s) received an audit finding or report of noncompliance with requirements or determinations of the IRB

5. Determining Which Projects Need Verification from Sources Other Than the Investigators that No Material Changes Have Occurred Since Previous IRB Review

These procedures apply to continuing review of projects. Results of discussion will be recorded in the minutes of the IRB for full-board continuing review or in the report of the director of IR, serving as IRB chair, for continuing review for projects approved under expedited review procedures. Criteria to consider when determining whether outside verification is needed include the following:

- a. Projects that involve partnerships

- b. The same criteria as in item 4, above.

6. Ensuring Prompt Reporting to the IRB of Proposed Changes in a Research Activity and for Ensuring Initiation of Changes Only With IRB Approval

See Section 9.0, “Changes and Other Actions to Approved Projects.” Investigators are required to complete Form D, “Project Status Report: Changes and/or Close Out” and submit it to the director of Institutional Research, who serves as IRB chair. The IRB has the authority to suspend or terminate its approval of the research if these procedures are not followed.

Section 4.1.1 lists the responsibilities of the investigator and states that the “investigator is the responsible official for ensuring that these procedures are followed. The Pellissippi State IRB has the authority to suspend or terminate approval of the project if these procedures are not followed.”

7. Ensuring Prompt Reporting to Appropriate Authorities of Unanticipated Risks, Continuing Noncompliance with IRB Requirements, or Withdrawal of IRB Approval

- a. Reporting for unanticipated problems involving risks: Section 2.7, “Record Keeping and Reporting Requirements,” describes the responsibilities of the Institutional Research office for maintaining IRB records. Any statements of significant new findings developed during the course of the research, such as unanticipated risks or adverse reactions, must be provided to subjects and to the IRB. The director of Institutional Research, serving as IRB chair, will report these problems to College and federal officials (and to the funding agency if applicable).

Section 9.1 provides guidelines and procedures established by the IRB for reporting adverse events.

- b. Reporting of noncompliance: From section 4.1.1: “The Pellissippi State IRB has the authority to suspend or terminate approval of the project if these procedures are not followed. Federal regulations require the IRB to report serious and continuing non-compliance and all suspensions of approval to federal officials (and to the funding agency, if applicable).”

Section 8.0, “Continuing Review of Human Subjects Research,” provides researchers and others with information on how noncompliance is reported to authorities.

- c. Reporting of any suspension or termination of IRB approval: The director of Institutional Research, serving as IRB chair, will report any suspension or termination of IRB approval to the president of the College, OHRP, and the funding agency if the project is supported by outside funding.