IVY TECH COMMUNITY COLLEGE:

POLICY ON RESEARCH INVOLVING HUMAN SUBJECTS

PURPOSE

Ivy Tech Community College values and supports research efforts by and on behalf of our faculty, staff, and students. It is important for the College to ensure that those conducting research protect the rights and welfare of human subjects. As such, the purpose of this policy is to establish responsibility for review and approval for research involving human subjects. This policy refers to research projects sponsored by, or associated with, Ivy Tech Community College. This policy includes all proposed research projects that have one or more of the following characteristics: a) the human subjects of the project will be faculty, staff, students, Trustees (State Board or Campus Boards), or Foundation Directors of Ivy Tech Community College; b) the research project will be conducted by, or on behalf of, Ivy Tech Community College faculty, staff, students, trustees, or directors.

POLICY STATEMENT

To ensure the rights and welfare of human subjects involved in research are protected, it is the policy of Ivy Tech Community College that any research project involving the use of human subjects be reviewed and approved by the Institutional Research Board (IRB) or an approved designee or representative of the Board. Research covered by this policy includes dissertations, theses, publications, conference presentations, or coursework outside of instructional or administrative College purposes.

DEFINITIONS

For the purpose of this policy:

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes (see 46 CFR Sec. 102(d)).[1]

Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information (see 46 CFR Sec. 102(f)).

> **Intervention** includes both physical procedures by which data are gathered, as well as manipulations of the subject or subject's environment that are conducted for research.
> **Interaction** includes communication or interpersonal contact between investigator and human subject.
> **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking

[1] Note that research may include the use of pre-existing data or data that is obtained through a third party and that does not involve direct interaction with human subjects. See the TYPES OF RESEARCH section under Exempt.

place, and information which has been provided for specific purposes by an individual and which s/he can reasonably expect will not be made public. Private information must be individually identifiable (the identity of the subject is or could be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

Minimal risk is defined as the probability and magnitude of harm or discomfort that is anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Vulnerable population is defined as children, prisoners, pregnant women, persons who are mentally disabled, persons who are economically or educationally disadvantaged, individuals who are unable to give informed consent due to a physical or mental condition, or those whose circumstances may make them vulnerable to coercion.

Prisoner means a person involuntarily confined or detained in a penal institution. The term includes individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration, and individuals detained pending arraignment, trial, or sentencing. Prisoners receive additional protection under 45 CFR 46, Subpart C.

Child means an individual who has not yet attained the age of consent to treatments or procedures involved in the research, under applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protection under 45 CFR 46, Subpart C.

Parent means a child's biological or adoptive parent.

Guardian means an individual who is authorized under state or local law to consent on behalf of a child to general medical care.

Assent means a child's, or individual's otherwise unable or not competent to give a legally valid informed consent, affirmative agreement to participate in research. Failure to object should not, in the absence of affirmative agreement, be considered assent.

Adverse effect means an undesirable or unintended result of intervention that is directly or indirectly due to participation in a research study.

Principle investigator (PI) is defined as the individual who is primarily responsible for designing and carrying out a research project.

ROLE OF THE INSTITUTIONAL REVIEW BOARD

The purpose of the IRB is to protect the rights and welfare of human research subjects participating in research studies. The IRB reviews applications to conduct research projects with the primary aims of evaluating the risk to human subjects and appropriate protections against such risks. The Ivy Tech IRB reviews research proposal applications to ensure that rights and welfare of human subjects are protected; that PIs have considered risks to human subjects and made all efforts to minimize those risks; that the potential for benefit to human subjects has been identified and maximized; that human subjects are voluntary participants in the study and have been provided with informed consent; and that research is conducted in an ethical

manner. The IRB reviews each research project proposal to see that it is compliant with ethical standards with regards to informed consent, confidentiality, and risk to human subjects.

TYPES OF RESEARCH

The Institutional Review Board can grant approval at three levels:

- Exempt
- Expedited review
- Full review

Exempt: This type of research typically is low-risk research in which no personal identifiers are collected and that meets certain Federal regulations regarding IRB review and approval. Under 45 CFR 46.101(b), certain categories of activity are considered research but may be declared exempt by the IRB. Determination still must be made by the IRB before a study may be identified as exempt (in other words, a PI may NOT simply determine that his/her research is exempt and proceed without IRB approval). If a study falls under one of the six federal categories for exempt research, the PI still has a responsibility to protect the rights of the human subjects. The six categories are as follows.

a) Research conducted in established or commonly accepted educational settings, involving normal educational practices. This may include research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management techniques.

b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement); survey procedures (paper-based or online); interview procedures (in person or via technology); or observation of public behavior, UNLESS i) information obtained will be recorded in a manner that may allow human subjects to be identified, directly or through identifiers linked to them, except under explicitly agreed-upon conditions delineated in a data sharing agreement (DSA) with the college or ii) 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.

c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement); survey procedures (paper-based or online); interview procedures (in person or via technology); or observation of public behavior not exempt under (b) but involving public officials or candidates for public office, or where federal statutes require without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information will be recorded by the investigator in such a way that subjects cannot be identified, directly or through identifiers linked to the subjects.

e) Research or demonstration projects conducted by or subject to the approval of Department or Agency heads that are designed to study, evaluate, or examine public benefit or service programs; procedures for obtaining benefits or services; possible

changes in or alternatives to programs or procedures; or possible changes in methods or levels of payment.

f) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below a level and for a use found to be safe, or agricultural chemical and environmental contaminant 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 U.S. Department of Agriculture.

NOTE: While the vast majority of research applications submitted for IRB review at Ivy Tech Community College meet the definition of exempt, PIs should take care not to automatically assume that research that does not include the collection of personally identifiable information and that involves surveys, interviews, or observations will be exempt. The type of data collection does not assume the level of risk. For example, research involving surveys or interviews may pose more than minimal risk to participants due to sensitive questions or situations, which may lead to distress that exposes participants to greater than minimal risk. Further, loss of confidentiality may cause harm to human subjects. Research studies that involve more than minimal risk, despite the data collection procedures, may require expedited (or even full) review, both of which are described in the next sections.

Expedited review: Federal regulations allow certain types of research to quality for expedited review (45 CFR 46.110). This type of research typically involves no more than minimal risk. Expedited review may be conducted by a single IRB reviewer, without the involvement or approval of the full IRB. Research included under expedited review does not meet one of the categories described in exempt review. Research conducted under expedited review should present no more than minimal risk to human subjects. Research that falls under expedited review may include, but is not necessarily limited to, the following categories:

a).Clinical studies of drugs or medical devices one of the following conditions are met: i) research on drugs for which an investigational new drug application (21 CFR 312) is not required (although research on marketed drugs that significantly increase the risks or decreases the acceptability of risks associated with the use of the product are not eligible for expedited review); or ii) research on medical devices for which an investigational medical device application (21 CFR 812) is not required, or the medical device is cleared/approved for marketing and the device will be used in accordance with its cleared/approved labeling.

b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: i) 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 two times per week; or ii) from other adults and children, 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 two times per week.

c) Prospective collection of biological specimens for research purposes by noninvasive means.

d) 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.
e) 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). Some research in this category may be exempt from federal regulations for the protection of human subjects.
f) Collection of data from voice, video, digital, or image recordings made for research purposes.
g) 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. Some research in this category may be exempt from federal regulations for the protection of human subjects.
h) Continuing review of research originally approved through full review process where the research is permanently closed to the enrollment of new subjects; all subjects have completed research-related interventions; and the research remains active only for long-term follow-up of subjects, or where the remaining research activities are limited to data analysis; or where no subjects have been enrolled and no additional risks have been identified.

Full review: Any research that does not meet the criteria listed under exempt or expedited review is required to undergo full IRB board review. When full board review is necessary, the IRB application is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of voting members present.

IRB REVIEW PROCESS

Those wishing to engage in research involving Ivy Tech faculty, staff, students, trustees, or directors may not begin the proposed research project (including subject recruitment and data collection) until IRB approval has been sought and gained, either through exempt, expedited, or full review processes. It is the responsibility of each PI to seek review by the IRB prior to beginning a research project. Note that only projects that meet the definition of research are subject to IRB review. Normal educational practices, including activities solely for instructional purposes, as well as data collection solely for use by college faculty or staff in making determinations for best practices in education and administration for the college, are typically not subject to IRB review. However, if a student, faculty, staff, trustee, or director wishes to collect or utilize data in order to present or publish the information, whether for a college or graduate school research project, thesis, or dissertation; in conjunction with other researchers wishing to present or publish; or for other reasons that will result in presentation or publication in a context beyond the class or situation in which it was gathered, the activity is considered research and must be reviewed by the IRB. Any Ivy Tech student, staff, faculty, trustee, or director who is unsure about whether an activity constitutes research should contact the IRB.

If review is required, the PI must submit an IRB application for review. The IRB application is available at https://ivytech.qualtrics.com/jfe/form/SV_8AroWGWz3pNZReB. If the research involves the approval of other colleges, universities, agencies, governmental entities, or other related organizations, the information and related approval must be attached to the application. The application requires:

- Description of the purpose and area of focus of the research;
- Description of the data sources, data collection methods, and types of human subjects that will be included;
- Description of recruitment processes, including any recruitment materials that will be utilized (as applicable);
- Description of anticipated risks and benefits to human subjects;
- Description of processes for obtaining informed consent, including any informed consent documents that will be used (as applicable);
- Description of processes that will be in put in place to maintain confidentiality.

Once submitted, IRB personnel will review the application and make a determination. The determination may be one of the following:

- The activities do not constitute research as defined in this policy; therefore, IRB approval is not necessary.
- The research is determined to be exempt (see description under TYPES OF RESEARCH). If research is determined to be exempt, an exempt notification will be sent to the PI and no further action is required. The approximate timeline for exempt review is ten (10) business days.
- The research is determined to fall under expedited review (see description under TYPES of RESEARCH). Under the expedited review process, the reviewers may take one of the following actions:
    - Approve the research application and determine the length of time the study is approved. An approval notification will be sent to the PI and no further action is required. The approximate timeline for expedited review, when no additional information or revisions are required, is fifteen (15) business days.
    - Require additional information or revisions. The designated IRB reviewer will contact the PI to request the additional information; the designated reviewer may determine that additional IRB members need to review the information. If the reviewer(s) are satisfied that the research application meets the IRB review criteria, the research project will be approved for a designated period of time. An approval notification will be sent to the PI upon determination that the research application meets the IRB criteria.
    - Determine that the application requires full board review. If full board review designation is determined, notification will be sent to the PI, along with an anticipated timeline for full board review.
- The research is determined to fall under full board review (see description under TYPES OF RESEARCH). Under the full board review process:
    - An IRB reviewer will first review the application, prior to presenting it to the full IRB. The initial reviewer may contact the PI and request clarification or modifications to the application. Once the completed application, with revisions

(as needed) is received, the application will be reviewed at the next full IRB meeting or a special meeting may be called. The application materials will be distributed to IRB members at least five (5) business days prior to the meeting. The PI will be notified of the meeting and may attend if desired.

- The IRB may take one of the following actions, following full review:
  - Approve the research application for a determined period of time. An approval notification will be sent to the PI and no further action is required.
  - Require additional information or revisions. During the IRB meeting at which the application is being reviewed, the IRB may request additional information from the PI. If the PI does not have the additional information available at the meeting, the PI must submit the information to the designated IRB reviewer. The IRB may also request modifications. Once the modifications have been submitted, the designated IRB reviewer (and other IRB members, as deemed necessary), will review the modifications and may approve the application. An approval notification will be submitted to the PI. If the modifications are determined to be insufficient, the IRB reviewer may continue to assist the PI until the modifications are determined to be sufficient and the application may be approved. Approval may require an additional full IRB meeting.
  - Deny the research application. If an application is denied, notification (along with the reasons for denial) will be submitted to the PI. The PI may revise the research application and resubmit for review or withdraw the research application.

Modification Requests (All Research)

Any modifications to approved research applications (whether approved as exempt or through expedited or full review) must be communicated to the IRB. The PI may contact the IRB reviewer by email to make notifications of modifications. Any modifications to the research, including (but not limited to) changes to the purpose or focus of the research; changes to the types of human subjects used in the research; changes to data collection or instrumentation methods; changes to recruitment procedures or methods; and changes to informed consent documentation and processes must be submitted for IRB review. It is the responsibility of the PI to submit notification of any modifications. If the PI has any questions as to whether something constitutes a modification, the PI must contact the IRB. Modification requests will be reviewed by the designated IRB reviewer. Should modifications be determined to be more than minimal, the PI may be required to submit a new application for review (if the modifications are determined to have significantly changed the research) or the existing application may be re-reviewed (expedited or full), dependent upon the determination of the IRB reviewer (and additional board members, if determined necessary).

Reporting of Incidents

Adverse events and incidents that occur during the course of the research must be reported immediately to the IRB representative. The incident(s) may be reported via email but should include a detailed description of the incident and an assessment of the situation, to determine whether the protocol requires modification to minimize risk, whether the informed consent must

be revised, or if subjects should be contacted to re-consent to participate in the study. Incident reports should include a detailed description of the event; an explanation as to why the event was unexpected and related to the research study; a description of changes to the protocol to minimize further risk or a rationale if no changes are required; description of changes to the informed consent or a rationale if no changes are required; a description of the plan to obtain re-consent or a rationale if none is required; and an explanation of why the risks and benefits of the research are still acceptable after the incident(s).

Continuation Requests (Expedited or Full Review)
Research projects approved under expedited or full review are approved for a specific timeframe, which is noted in the approval document. Continuing research activities beyond the approval period requires submission of a continuation request. A continuation request may be submitted via email to the IRB. A continuation request for research that was approved under expedited or full review may be reviewed through the expedited review process, if modifications are minor or nonexistent. The PI must submit a continuation request and additional documents, as requested. The IRB reviewer will verify the appropriate level of review for the continuation request and will inform the PI if full review is necessary. For continuation requests without any or with minor modifications that do not fundamentally change the project, the IRB reviewer will conduct the review and submit a determination. For continuation requests originally approved under expedited review, with modifications that are beyond minor, the expedited review process, timeline, and actions will be the same as those for a new application reviewed under the expedited procedures. For continuation requests originally approved through full review with modifications that are beyond minor, the full review process, timeline, and actions will be the same as those for a new application reviewed under the full review process.

If the PI fails to request a continuation or to submit required information along with the continuation request, IRB approval will be terminated upon the expiration date determined in the original approval. Should termination occur, all research activities must cease.

Completion Notification (Expedited or Full Review)
For a completed research project that was approved through expedited or full review, the PI must submit a completion of research notification on or before the IRB approval expiration date. The completion notification may be submitted by email to the IRB.

PI RESPONSIBILITIES
All PIs must comply with IRB decisions, conditions, and requirements and obtain informed consent to ensure that no human subject will participate or be involved in the research without consent. PIs must obtain and retain consent documents, provide progress reports on the research (as requested), and report any amendments for changes in the research, as well as submitting reports about any adverse events. In some cases (and upon request), PIs must submit final reports at the conclusion of the research project. PIs and others involved in conducting the research are responsible for maintaining strict confidentiality about names, characteristics, data gathered from research instruments, and other information on subjects.

Recruitment of Participants

If the PI will recruit human subjects to participate in a research study, the PI must ensure that recruitment is conducted in a way that makes it clear that participation is voluntary. This is particularly important when Ivy Tech faculty/staff or students are the human subjects, or for studies that may include subjects who are likely to be vulnerable to undue influence. As part of the research application, the PI must submit all recruitment materials, as well as a description of how participants will be recruited, and Ivy Tech IRB will review the materials. Procedures should be clearly outlined in the application to assure that information collected will be handled appropriately. Prior to recruiting students or faculty for studies involving Ivy Tech students or faculty, PIs should contact the Chancellor or Vice Chancellor of each campus for which they intend to recruit students or faculty to obtain their approval. Note that it is the sole responsibility of the PI to recruit subjects for the study. **The IRB and the Decision Support team will not assist in participant recruitment.** While the PI may request assistance in subject recruitment from other Ivy Tech faculty or staff, the faculty and staff have no responsibility to assist in the recruitment, and any assistance will be voluntary.

Informed Consent

When an individual participates in a research project, the individual is entitled to certain information, including a full disclosure of the facts and probabilities which a reasonable person might be expected to consider prior to giving consent.

Informed consent documentation, as well as a description of how informed consent will be obtained, is required as part of the IRB application. While each informed consent document will need to be tailored to the specific study, informed consent documents should include, at a minimum, the following information:

- The purpose of the study and statement that the study involves research;
- A description of the procedures for the study, including duration and types of activities;
- A statement of any risks and benefits to the participants
- A statement that all information collected will be confidential; will be stored confidentially; and will be reported in a manner that individual identity cannot be ascertained;
- A statement that participation is voluntary and that there are no adverse effects for electing not to participate, and that persons may withdraw from the study at any time with no penalty or consequence.
- A description of incentives, if any;[2]
- The contact information of the principal investigator and faculty advisor (if applicable);
- A verification that participants are 18 years of age or older; and
- Date and signature lines for the participant or legally authorized guardian.

Informed consent documents must be written in a manner that is clearly understood and should be absent of jargon or technical language. Acronyms should be avoided, if possible; if acronyms

[2] Incentives for participation may be offered, provided that incentives are of a nominal value and a value that could not be considered coercive. Incentives, if offered, must be clearly explained in the informed consent document(s). The amount and schedule of incentives also should be presented in the informed consent document.

are used, they should be clearly spelled out and explained. If a study involves minors or participants with impaired decision-making ability, the consent of the legally authorized representative of the minor or individual with impairments must be provided, along with assent of the minor or individual with impairments. Signed consent forms must be retained and stored so as to be available upon IRB request. Consent forms should be stored securely in locked files or files maintained by the PI.

Waiving the consent procedure may be approved if the research is considered minimal risk or justification is provided for informed consent waiver in the application for approval. To obtain a waiver, the justification must include documentation that the research involves minimal risk to participants; that waiver or alteration will not adversely affect the rights of the participants; that research could not be carried out without the waiver or alteration; and that participants will be provided with additional pertinent information after participation, if appropriate. Approval to waive informed consent is at the sole discretion of the Ivy Tech IRB. The Ivy Tech IRB will approve waiver of informed consent in cases where a) the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or b) where the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context – this may include surveys or interview data collection techniques.

Note that additional detail on informed consent may be required if the proposed study will involve human subjects who fit the definition of vulnerable populations.

Confidentiality/Anonymity

In any research study, the PI and any other researchers involved in the study must make every effort to ensure the confidentiality of the data gathered. The IRB application requires the PI to describe the processes that will be used to maintain confidentiality, including the ways in which data will stored; ways in which quantitative and qualitative data will be coded; and the ways in which access to the data will be limited. The IRB recommends that informed consent include a statement that all efforts will be made to protect the privacy and confidentiality of participants, but there may be a slight risk of disclosure from participating in any research study.

COOPERATIVE RESEARCH

Cooperative research projects involve Ivy Tech and another institution or entity. Each institution or entity is responsible for safeguarding the rights and welfare of human subjects and for complying with federal and institutional policies. PIs at Ivy Tech who are conducting research with another institution or entity must abide by Ivy Tech IRB requirements, as well as the requirements of the other institution or entity. The PI may be required to submit evidence of IRB approval from the other institution along with his/her IRB application to Ivy Tech.

Research that is not being conducted by an Ivy Tech faculty or staff member or student, but which involves Ivy Tech faculty, staff, students, trustees, or directors as human subjects, or when research is being conducted on behalf of Ivy Tech, but the PI is not an Ivy Tech faculty or staff member or student, the PI must submit an application to the IRB, as well as confirmation of IRB approval from the institution that will be conducting the study. Ivy Tech IRB, at its discretion,

may agree to waive IRB review and approval and instead accept IRB review and approval from the partner institution. However, the PI (and Ivy Tech faculty or staff involved in the research) must contact Ivy Tech IRB prior to the research being conducted. Ivy Tech IRB will review the research and may require the non-Ivy Tech PI to submit a full research application or may agree to sign a joint letter waiving Ivy Tech IRB review.