**Florida State College at Jacksonville’s**

**Institutional**

**Review**

**Board (IRB)**

**Handbook**

 **Revised September 2022**

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## Introduction

A central purpose of this handbook, and its referent Institutional Review Board (IRB) process, is to ensure Florida State College at Jacksonville (College) is in compliance with federal guidelines by assuring that human beings exposed to any research procedures are adequately protected. Compliance is regulated by the [Office for Human Research Protections (OHRP)](http://www.hhs.gov/ohrp/) at the US Department of Health and Human Services (DHHS).

Authority: Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (Revised January 15, 2009; Effective July 14, 2009). Additional information and document specifics may be found at the following site:

[http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/)

##

## Intent

Each institution engaged in research involving human subjects that is supported by a department or agency to which the Federal Policy applies must establish an IRB to review and approve the research before it is conducted. These include: Department of Education; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency; Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; Department of Transportation; and Department of Agriculture.

Research covered by this policy that has been approved by the College’s IRB may be subject to further review and approval by officials of the institution. However, those officials may not approve the research if it has not been approved by the College’s IRB.

Funds for any project may be terminated or suspended if the College has materially failed to comply with the regulations.

If the College is the primary awardee in any cooperative agreement or the coordinating center for any federally supported research, it is the responsibility of the College for ensuring that all collaborating institutions and independent investigators operate under an approved IRB. If the collaborating institution does not have an IRB, it may operate under the College’s IRB with approval of the agency supporting the research.

***Independent investigators must sign a formal, written agreement of commitment to relevant human subject protection policies and IRB review***.

##

## IRB Registration

Any IRB that reviews research supported by any federal department must be registered with the OHRP and obtain a Federalwide Assurance for the Protection of Human Subjects (FWA). Under an FWA, the College commits to DHHS that it will comply with all federal human subjects’ regulations and policies. The Registration Form and Membership Roster was completed online, and is granted through 2025. Once the registration has been approved, the IRB will be reassigned a Federalwide Assurance Number and approval will be posted on its website. The College’s number is **FWA00026438**.

IRB registration is effective for five years and must be renewed at the end of that period of time to remain effective, even if no changes have occurred. The College must renew by 2023. Any changes to the composition or policies of the IRB must be submitted to OHRP within 90 days of the change.

## Written Assurance of Compliance, Institutional Procedures, and Guidelines

Florida State College at Jacksonville (College) submits the following Assurances:

1. The College assures ethical governing in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This will align with and support the college mission:Florida State College at Jacksonville provides an equitable, high quality, success-driven learning experience for our diverse community of students*.* In addition, the activities reviewed and approved by the IRB will uphold the College’s Vision:To promote intellectual growth for life-long learning, advance the economic mobility of our students, and transform the communities we serve.
2. The College will designate one IRB, established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.
3. The College will make available on its website a list of IRB members identified by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc. This list will be sufficient to describe each member’s chief anticipated contributions to IRB deliberations and any employment or other relationship between each member and the institution. Changes in IRB membership shall be reported via periodic updates as needed.
4. The College assures that written IRB procedures and policies (see 6Hx7-1.2; APM 10-1104)will be followed by the IRB for (i) conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
5. Assurance is given that the College’s IRB policies will include written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

Upon request, the College will provide a copy of these written procedures to Office for Human Research Protections (OHRP) and any department or agency conducting or supporting research.

##

## IRB Members

As outlined in Administrative Procedure Manual (APM) 10-1104, the College President will serve as the Institutional Signatory Official providing oversight on the performance and conduct of the IRB.

An IRB committee composed of the Associate Vice President of Institutional Effectiveness (IRB Chair), Director of Institutional Analytics and Research (Human Subjects Administrator), four (4) College administrators (Associate Vice-Presidents, Associate Provosts, or Deans), of which two (2) must have a background in science, the President of the Faculty Senate, or designee, and a non-affiliate to represent the community.

The IRB Chair will decide if the research is exempt from review, can be reviewed through the expedited process, or requires full committee review. Working with the wider IRB, the chair undertakes considerations concerning questions, such as:

* How will expedited or administrative review be conducted? Studies that pose minimal risk or proposals that are minor changes to studies that were previously approved by the IRB may not need to undergo a full IRB review.
* How will the IRB conduct initial and continuing review of research proposals? Studies that are ongoing (lasting more than 12 months) should have a follow-up review process at least once every 12 months.
* How will the IRB’s decision be communicated to the principal investigator?
* How will changes in proposed research activity be communicated to the IRB? If the IRB has already approved a proposal, will changes to that proposal require new review?
* How will unanticipated problems that pose subsequent risks to human participants be reported to institutional officials?
* What are the deadlines for submissions, and how often will the IRB meet?

All projects must be reviewed and re-approved by the IRB Chair once a year for the duration of the project (see *Review of Approved Projects Form*).

The Human Subjects Administrator defines the procedures, makes sure they are followed, sets up meetings, tracks the process, conducts record keeping, and distributes minutes of IRB meetings. The Human Subjects Administrator ensures compliance with the following list of specific considerations of an administrative nature that support the IRB process:

* Use of established routing form(s) with review questions to be signed off and rules for timeline of processing to facilitate an expedient process.
* Record minutes at review board meetings. Meetings might be required for any routing form that does not receive unanimous exemption status and approval by the chair.
* Maintain a filing system or database of approval/processing.

At least one member from a scientific area, one from a nonscientific area, and one who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The nonaffiliated member of the IRB should be drawn from the local community-at-large. Ministers, teachers, attorneys, business persons, or homemakers are possible candidates. The person selected should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to the type of community from which the institution will draw its research subjects.

Committees must be diversified by race, gender, cultural backgrounds and profession, and sensitive to such issues as community attitudes. They must also include persons knowledgeable about the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the institution conducts research that involves a vulnerable category of subjects, such as children, prisoners, or handicapped persons, the committee must include individuals who are knowledgeable about and experienced in working with these subjects. No member can participate in the review of any project in which the member has a conflicting interest.

The IRB may invite individuals with competence in special areas to assist in the review of issues, but these individuals may not vote with the IRB. See Appendix A for a full list of membership.

## Definitions

As used here, *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 purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A *human subject* is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.[[1]](#footnote-1)

*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.

*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. For additional information as well as full descriptions of exemption categories reference Subpart A - Basic HHS Policy for Protection of Human Research Subjects.

## Special Protections for Children as Research Subjects[[2]](#footnote-2)

When a proposed research study involves children (any person under 18 years old), the IRB must take into consideration the special [regulatory requirements](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) (45 CFR part 46, subpart D) that provide additional protection for the children who would be involved in the research. When reviewing research with children as subjects, the IRB also must consider the potential benefits, risks, and discomforts of the research to children and assess the justification for their inclusion in the research. In assessing the risks and potential benefits, the IRB should consider the circumstances of the children to be enrolled in the study and ability to understand what is involved in the research, as well as potential benefits to subjects.

For any protocol involving children, the IRB must determine which of the four categories of research apply to that study, if any. OHRP recommends that the IRB document the rationale for this choice.

[45 CFR 46.404](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) – *Research not involving greater than minimal risk to the children.* The research presents no greater than minimal risk to the children; and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

[45 CFR 46.405](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) – *Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.* The risk is justified by the anticipated benefits to the subjects; the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

[45 CFR 46.406](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) – *Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject’s disorder or condition*. The risk of the research represents a minor increase over minimal risk; the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations; the intervention or procedure is likely to yield generalizable knowledge about the subject’s disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

[45 CFR 46.407](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) *– Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children*. This category requires a special level of HHS review beyond that provided by the IRB.

Exemptions at [46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at [46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at [46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

All IRB applications for research involving human subjects must include a description of plans for including children. The plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

##

## Level of IRB Review

Members of an IRB shall determine the level of IRB review required for submitted research proposals (e.g., “exempt,” “expedited,” or “full” IRB review). Studies that meet the definition of “research” and that involve human participants may be considered exempt if they meet certain requirements (outlined in this document).

Exempt

An “exempt” IRB review is selected when the research falls into one of the six approved categories of exempt research (45 CFR 46.101 [b]) and is not applicable to research in a covered research category (e.g., FDA regulation - 21 CFR 50.20). Exempt research does not mean that a research project has no review. Rather, for studies that are determined to be exempt, it means that the exemption (and its corresponding category) is documented in the IRB records and that the decision is communicated in writing to the investigator. The IRB Chair shall determine exempt status of a proposed research project in accordance with the following exempt categories of research:

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 (b)(2) of this section, 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 department or agency heads, and which are designed to study, evaluate, or otherwise examine: 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, (i) if wholesome foods without additives are consumed or (ii) 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 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.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under 46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency. For additional information see *Applications and proposals lacking definite plans for involvement of human subjects* ([45 CFR 46.118](https://www.gpo.gov/fdsys/granule/CFR-2007-title45-vol1/CFR-2007-title45-vol1-sec46-118)).

### Expedited Review

An “expedited” IRB review is selected when the research is not exempt, involves no more than minimal risk to subjects and falls into one of the categories below. The IRB Chair shall determine expedited status of a proposed research project in accordance with the following expedited categories of research:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
2. 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.)
3. 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.
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
5. Prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings, saliva dental plaque and buccal swabs.
6. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
7. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes.
8. Collection of data from voice, video, digital, or image recordings made for research purposes.
9. 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.
10. Continuing review of research previously approved by the convened IRB as follows:
11. 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
12. Where no subjects have been enrolled and no additional risks have been identified; or
13. Where the remaining research activities are limited to data analysis.
14. 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.

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 standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or full – used by the IRB.

### Full Review

A “full” IRB review is required when the research is defined as (a) a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (38 CFR 16.102d); (b) that involves human subjects (i.e., a living person about whom a researcher collects either identifiable private information OR data through an intervention or interaction); and (c) involves greater than minimal risk to those human subjects. A full IRB review usually requires attendance from a quorum of IRB appointed members.

Research that does not fit into the exempt or expedited categories are covered by the regulations and must be reviewed by the IRB under the following conditions:

* The IRB reviews the proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas.
* In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The committee has the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
* The IRB shall require that information be given to research subjects as part of informed consent and may require documentation.
* The investigator will be notified in writing of the decision to approve or disapprove the proposed research activity, or if modifications are required to secure IRB approval. If the IRB decides to disapprove a research activity, it shall include a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
* The IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

## Informed Consent

Elements of Informed Consent

Researchers must obtain a signed ***informed consent*** from all participants under circumstances that provide the participant/parent/guardian sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. For those less than 18 years of age, the researcher must obtain the signed informed consent of their parents or legal guardians and all reasonable attempts must be made to explain the project and obtain each minor participant's ***assent***, which is defined as the participant's agreementto participate in the study.

The consent form must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.
2. Short description of methodology, duration of involvement and approximate number of participants.
3. Statement of benefits, risks and discomforts to the participant, including any unforeseeable risks.
4. A disclosure of alternative procedures that may be advantageous to the participant.
5. Any additional costs to the participant that may result from participation in the project.
6. Statement describing the extent to which confidentiality of records identifying the participant will be maintained.
7. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs.
8. Statement that participation is voluntary, refusal to participate will involve no penalty of any kind and that participants can withdraw at any time without negative consequences, penalties or loss of any College benefits to which the participant is otherwise entitled.
9. An offer to answer any questions the participant may have and contact information for all Principal Investigators and the College’s Institutional Review Board Administrator.
10. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.
11. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

No informed consent may include any language through which the participant/parent/guardian is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.

### Conditions for Waiver of Informed Consent

An IRB may waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The project is to be conducted by or subject to the approval of state or local government officials and is 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; and the research could not practicably be carried out without the waiver or alteration; or
2. The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consent Form Checklist

|  |  |
| --- | --- |
| 1. Is the consent form written in “lay language”?
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. If minors are included in the study, is provision made for obtaining parental consent?
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Does the consent form include each of the following basic elements of informed consent?
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. A statement of purpose of the study.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. A description of the procedures to be followed, duration of involvement and number of participants.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. A description of any benefits, risks and discomforts to the subject or others.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. A disclosure of alternative procedures to the participants (if any).
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Additional costs to the participant (if any).
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Explanation as to whether any compensation or medical treatments are available if injury occurs.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. A statement that participant is voluntary, and that subject may refuse to participate or withdraw at any time without any negative consequences.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Signature line for participants and parents/legal guardians (if under 18),
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Statement that participant is 18 years of age or older unless parent/legal guardian has given consent.
 | Yes [ ]  No [ ]  N/A [ ]  |
| 1. Appropriate FERPA notice and waivers (if appropriate).
 | Yes [ ]  No [ ]  N/A [ ]  |

If there was a “no” response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why is it appropriate as submitted.

Sample Informed Consent Language

The following sample is offered as a guideline. The bolded headings must be included in your consent form. Insert study specific information using the guidelines from the bracketed information. Delete the bracketed information from your final consent form. Remember to keep the language simple and your explanations concise. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the form conforms to the regulations for ***informed consent*** and may request revisions or additions as required.

**SAMPLE INFORMED CONSENT FORM**

**PURPOSE OF THE STUDY**

You are invited to be a participant in a research study about <insert general statement about the study>. You were selected as a possible participant because <explain how participant was identified>.

We ask that you read this document carefully and ask any questions you may have before agreeing to be in the study. The purpose of this study is <explain research purpose and questions in lay language>

**DURATION OF THE STUDY**

Your participation will require <indicate approximate time commitment>.

**PROCEDURES**

If you agree to be in this study, we will ask you to do the following things: <describe activities>

**RISKS/BENEFITS**

The following risks may be associated with your participation in this study: <describe risks>. The following benefits may be associated with your participation in this study: <describe benefits>.

**CONFIDENTIALITY**

The records of this study will be kept private. In any report that is published or presented, we will not include any information that will make it possible to identify a participant.

**RIGHT TO DECLINE OR WITHDRAW**

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. Your decision whether or not to participate will not affect your current or future relations with the College or any of its representatives. If you decide to participate in this study, you are free to withdraw from the study at any time without any consequences or affecting those relationships.

**CONTACT INFORMATION**

The researcher(s) conducting this study is(are):

You may ask any questions you have right now. If you have questions later, you may contact the researchers at:

If you have questions or concerns regarding this study and your rights as a research participant, you may contact the College IRB Chair.

**STATEMENT OF CONSENT**

I have received a copy of this form to keep for my records. I have read the information in this consent form and agree to participate in this study. I was given a chance to ask questions about this study and they have been answered.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature/Printed Name of Participant Signature of Person Obtaining Consent**

**Date Date**

## Unanticipated Issues, Non-Compliance, or Changes

* Issue should immediately be reported to the IRB Chair.
* Any changes to a project’s protocol must be reviewed and approved by the IRB Chair before the changes can be made (see *Review of Approved Projects Form*).
* Chair should convene an IRB Committee Meeting and record minutes.
* The Committee should determine the steps and timelines according to IRB policy.

## Training

Standardized knowledge associated with IRB training includes resources available from a wide variety of recognized sources. The following is a partial list of recommended sources:

[American Psychological Association (APA)](http://www.apa.org/research/responsible/human/index.aspx)

[Recommendations of the 2007 APA Presidential Task Force on Institutional](http://www.apa.org/research/responsible/irb-task-force.pdf)

[IRBs and Psychological Science: Ensuring a Collaborative Relationship](http://www.apa.org/research/responsible/irbs-psych-science.aspx)

Other web resources:

* [Office for Human Research Protections (OHRP)](http://www.hhs.gov/ohrp/)
* [Health Resources and Services Administration (HRSA)](http://www.hrsa.gov/publichealth/clinical/humansubjects/)
* [Collaborative Institutional Training Initiative (CITI)](https://www.citiprogram.org/)
* [National Institutes of Health (NIH) Office of Extramural Research](http://phrp.nihtraining.com/users/login.php)
* [IRBs and Research on Teaching and Learning](http://teachpsych.org/Resources/Documents/otrp/resources/martin14.pdf)

To better accommodate researchers internal to the institution, Florida State College at Jacksonville is also in the process of implementing an AFPD session entitled "Human Subjects Research, Institutional Review Board (IRB) Orientation." Facilitated by the FSCJ Human Subjects Administrator, this session will provide instruction and certification for internal researchers as required.

## Record Keeping

The institution, or when appropriate the IRB, must prepare and maintain adequate documentation of IRB activities (45 CFR 46.115). In addition to the written IRB procedures and membership lists required by the Assurance process (45 CFR 46.103), such documentation must include copies of all research proposals reviewed, scientific evaluations, approved consent documents, progress reports, reports of injuries, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects (as required by 45 CFR 46.116(b)(5)).

Minutes of IRB meetings must be kept in sufficient detail to record the following information: attendance at each meeting; actions taken by the IRB; the vote on actions taken (including the number of members voting for, against, and abstaining); the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution (45 CFR 46.115(a)(2)).

IRB records must be retained for at least three years. Records pertaining to research that is conducted must be retained for three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner (45 CFR 46.115(b)).

## Websites and References

Code of Federal Regulations, Title 45 (45 CFR Part 46) Protection of Human Subjects; US Department of Health and Human Services, Office for Human Research Protections (OHRP): <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/>

The revised [Common Rule](https://www.hhs.gov/ohrp/exception-determination-required-sirb-use-certain-research.html) applies to all research initially approved by an IRB on or after January 21, 2019. See 45 CFR 46.101(l)(5). As of January 20, 2020, the compliance date for the single IRB requirement, all cooperative research subject to the revised Common Rule will be required to use a single IRB, whether the research was initially approved by a single IRB or multiple IRBs.

Federalwide Assurance (FWA) for the Protection of Human Subjects; US Department of Health and Human Services, Office for Human Research Protections (OHRP):http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm

## Code of Federal Regulation

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

I. Background

 The Federal Policy for the Protection of Human Subjects (hereafter referred to as the Federal Policy) was promulgated by 15 Federal departments and agencies on June 18, 1991 (56 FR 28003). The Central Intelligence Agency also is required to comply with this policy under Executive Order 12333. On July 10, 1996, the Department of Housing and Urban Development revised its codification of the Federal Policy at 24 CFR part 60 to cross-reference the provisions of the Department of Health and Human Services (HHS) regulations at 45 CFR part 46, subpart A (61 FR 36462).

 Except for research that is exempt under Sec. ll.101(b), the Federal Policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal department or agency which has taken appropriate administrative action to make the Federal Policy applicable to such research. The basic provisions of the Federal Policy include, among other things, requirements related to the review of human subjects research by an institutional review board, the obtaining and documenting of informed consent of human subjects, and the submission of a written assurance of institutional compliance with the Federal Policy.

II. Description of Changes to the Federal Policy

 The Federal Policy has several provisions that reference OPRR. For example, the Federal Policy includes provisions that require submission of certain reports and notices to OPRR (see Sec. ll.101(i), Sec.ll.103(a), and Sec.ll.103(b)(3)). At the time the Federal Policy was promulgated, OPRR was a unit of the National Institutes of Health, HHS, and was responsible for fulfilling responsibilities set forth in section 491 of the Public Health Service Act (42 U.S.C. 289). On June 18, 2000, OPRR was dissolved, OHRP was established, and all responsibilities and authorities for human subject protections held by OPRR were transferred to OHRP (65 FR 37136, June 13, 2000). The Federal Policy is being amended throughout to reflect this name and organizational change from OPRR to OHRP.

 At the time the Federal Policy was promulgated, the HHS regulations for the protection of human subjects at 45 CFR part 46 included the following three subparts that provided additional protections for specific groups of vulnerable subjects: subpart B (Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization); subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects); and subpart D (Additional Protections for Children Involved as Subjects in Research). These subparts are not part of the Federal Policy. However, the Federal Policy includes a footnote at the end of Sec.ll.101(i) which states, in part, that ''the exemptions at 45 CFR 46.101(b) do not apply to research involving \*\* \* fetuses, pregnant women, or human in vitro fertilization, subparts B \* \* \*.''

 On November 13, 2001, HHS published a revised version of 45 CFR part 46, subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) after soliciting public comment through a Notice of Proposed Rulemaking (66 FR 56775; 66 FR 35576). The revised subpart B, which became effective on December 13, 2001, states that the exemptions at 45 CFR 46.101(b)(1) through (6) are applicable to this subpart. In order to make the footnote at the end of Sec.ll.101(i) of the Federal Policy consistent with the revised subpart B of 45 CFR part 46, references to research involving fetuses, pregnant women, or human in vitro fertilization and subpart B are being deleted from the footnote.

 Finally, the information collection requirements of the Federal Policy (see Sections.ll.103, 109, 113, 115, 116, and 117) were approved by OMB on July 30, 1991 under Control Number 9999-0020. OMB approval under Control Number 9999-0020 expired on December 31, 1997. The current OMB approval of the information collection requirements of the Federal Policy is under Control Number 0990-0260. Therefore, all references to Control Number 9999-0020 are being changed to Control Number 0990-0260.

III. Implementation

Pursuant to 5 U.S.C. 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 551-559, the agencies find that there is good cause to issue these amendments without advance notice and an opportunity for public comment. Because these amendments merely (i) change references in the Federal Policy from the OPRR to the OHRP, to

reflect the organizational change that already dissolved OPRR and moved its responsibilities to OHRP; (ii) delete references to research involving fetuses, pregnant women, or human in vitro fertilization and to subpart B of 45 CFR part 46 to conform the Federal Policy to recent amendments to subpart B of 45 CFR part 46;

and (iii) update the Control Number for the approval by OMB of the information collection requirements of the Federal Policy, public comment is unnecessary. Pursuant to 5 U.S.C. 553(d)(3) of the Administrative Procedure Act, the agencies also find there is good cause to make these amendments effective immediately because the

changes in the Federal Policy are merely conforming amendments to reflect changes that have already been made and are in effect with respect to OHRP and 45 CFR part 46.

IV. Legal Authority

Department of Agriculture, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Energy, 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v-1(b). National Aeronautics and Space Administration, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Commerce, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Consumer Product Safety Commission, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Agency for International Development, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Justice, 5 U.S.C. 301; 28 U.S.C. 509-510; 42 U.S.C. 300v-1(b). Department of Defense, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Education, 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; 42 U.S.C. 300v-1(b). Department of Veterans Affairs, 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v-1(b). Environmental Protection Agency, 5 U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Health and Human Services, 5 U.S.C. 301; 42 U.S.C. 289; 42 U.S.C. 300v-1(b). National Science Foundation, 5U.S.C. 301; 42 U.S.C. 300v-1(b). Department of Transportation, 5 U.S.C. 301; 42 U.S.C. 300v-1(b).

V. Executive Order 12866

Executive Order 12866 requires that all regulatory actions of Executive Branch departments and agencies reflect consideration of the costs and benefits that they generate and that they meet certain standards, such as avoiding imposition of unnecessary burdens on the affected public. If an action is deemed to fall within the scope of the definition of the term ''significant regulatory action'' contained in Sec. 3(f) of the order, a pre-publication review by OMB's Office of Information and Regulatory Affairs (OIRA) is necessary. OMB deemed these amendments of the Federal Policy not to be a significant regulatory action. Therefore, these amendments were not submitted to OIRA for review prior to publication.

VI. Regulatory Flexibility Act

 Under the Regulatory Flexibility Act (5 U.S.C. 601-612), an agency is generally required to review proposed regulations to analyze whether they create a significant impact on a substantial number of small entities unless the agency can certify that there is no such impact. Agencies must similarly analyze any final rules that were preceded by proposed rules.

Because these technical amendments did not require the agencies to publish a proposed rule, they are not required to prepare a Regulatory Flexibility Act analysis for this final rule. However, even if the agencies were required to consider that impact, the agencies would certify that there was no impact at all on small entities because these amendments make no substantive change to the Federal Policy.

VII. Paperwork Reduction Act of 1995

These amendments to the Federal Policy do not contain any new information collection requirements which are subject to OMB approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

VIII. Federalism

These amendments to the Federal Policy have been analyzed in accordance with the principles set forth in Executive Order 13132. These amendments to the Federal Policy do not contain policies that have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the departments and agencies that have promulgated the Federal Policy have concluded that these amendments do not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

## Terms of the Federal-wide Assurance

A comprehensive description of the Federalwide Assurance (FWA) for the Protection of Human Subjects is available at <http://www.hhs.gov/ohrp/sites/default/files/ohrp/documents/terms092310rev.pdf>

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## Appendix A: IRB Members

As of June 2022

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| **Institutional Signatory Official** |
| John Avendano, Ph.D., President, Florida State College at Jacksonville |
| **Qualifications:** Dr. John Avendano is the sixth president and CEO of Florida State College at Jacksonville. With more than 30 years of community college experience, Dr. Avendano was previously the president and CEO of Kankakee Community College in Illinois. He also served as the president of the Illinois Council of Public Community College Presidents and the past chair of the South Metropolitan Higher Education Consortium President’s Council in Illinois. Dr. Avendano received his associate degree from Waubonsee Community College, bachelor’s degree in exercise physiology from Northern Illinois University, master’s degree in adult continuing education from Northern Illinois University, and his doctorate in educational administration and foundations from Illinois State University. He recently finished serving in his sixth year as the presidents’ liaison for the Illinois region of Phi Theta Kappa (PTK). He was recognized by PTK with the following awards: Distinguished Administrator, Shirley B. Gordon Award and the 2019 Michael Bennett Lifetime Achievement Award. In addition, Dr. Avendano was inducted into Illinois State University’s Educational Administration and Foundations Hall of Fame. He also received the 2017-18 Illinois Community College Trustees’ Association Advocacy Award. Additionally, The Daily Journal recognized Dr. Avendano as its 2019 Citizen of the Year. |
| **IRB Role:** As the Institutional Signatory Official, provides oversight on the performance and conduct of the IRB. |
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| **IRB Chair** |
| Dr. Jerrett Dumouchel, Ed.D., Interim Vice President, Institutional Effectiveness and Advancement  |
| **Qualifications:** Ed.D. in Educational Leadership, University of North Florida, Jacksonville, FL; Master of Pure Mathematics, Western Michigan University, Kalamazoo, MI; B.S., Mathematics (minor in Philosophy), Illinois State University, Normal, IL. **Professional Affiliations:** Association for Institutional Research, American Mathematical Association of Two-Year Colleges, Mathematical Association of America, Florida Two Year College Mathematical Association, Association of Florida Colleges, American Association of Community Colleges, American Association of Colleges and Universities.  |
| **IRB Role**: Approves IRB Written Procedures and provides committee members with a copy of the College APM/Policy, including Code of Federal Regulation and the Terms of the Federal-wide Assurance for Institutions within the US. Determines if the research is exempt from review, can be reviewed through the expedited process, or requires full committee review. Approves and signs necessary assurances for filing of approval/processing; chairs all IRB Committee Meetings. |
| **Human Subjects Administrator** |
| Dr. Greg V. Michalski, Ph.D., PMP®, Director of Institutional Analytics and Research |
| **Qualifications:** Ph.D. Educational Research and Evaluation, University of Ottawa, Ontario Canada; M.A. Educational Leadership, Human Resource Development, Western Michigan University, Kalamazoo, Michigan; M.S. Virginia Polytechnic Institute and State University, Blacksburg, Virginia; B.S., Southern Illinois University, Carbondale, Illinois. **Professional Affiliations***:* [Association for Institutional Research](http://www.airweb.org/AboutUs/Pages/default.aspx). The Association for Institutional Research (AIR) is the world's largest professional association for institutional researchers. The organization provides educational resources, best practices and professional development opportunities for more than 4,000 members. Its primary purpose is to support members in the process of collecting, analyzing, and converting data into information that supports decision-making in higher education. *Selected Publications*: <https://scholar.google.com/citations?user=Zb9Cc9IAAAAJ&hl=en>*Professional Certifications:* **Project Management Professional**, PMP® #246701. The PMP is the gold standard of project management certification. Recognized by organizations worldwide, the PMP validates professional competence to perform in the role of a project manager, leading and directing projects and teams. [Project Management Institute (PMI)](http://www.pmi.org/) is the world's leading not-for-profit professional membership association for the project, program and portfolio management profession. Founded in 1969, PMI delivers value for more than 2.9 million professionals working in nearly every country in the world through global advocacy, collaboration, education and research. |
| **IRB Role:** Identifies and reviews applicable research designs, methodologies, analysis strategies, and statistical procedures; monitors research progress, responds to research questions, facilitates project communications, meetings, and ad hoc information requests; supports IRB Chair. |

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| **IRB Member – Science** |
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| Dr. Sondra Evans, Dean of Natural Sciences  |
| **Qualifications:** Doctorate of Podiatric Medicine, Temple University, Philadelphia, PA.; Bachelor of Science in Biology, Clark Atlanta University, Atlanta, GA. **Professional Affiliations:** Association of Florida Colleges, Human Anatomy and Physiology Society; Florida Association of Blacks in Higher Education. |
| **IRB Role**: Serves to provide strategic direction, leadership and management as well as leadership pertaining to research proposals and topics related to the School of Health Sciences; shares knowledge about the acceptability of proposed health sciences research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Also attends IRB meetings and follows procedures and regulations as outlined in the in the handbook. Reports any conflicts of interests and advises as necessary. |

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| **IRB Member – Science** |
|  Dr. Linda Roy, Dean of Nursing**Qualifications:**  BSN at Widener University, MSN in Nursing Education at Villanova University, MSN in Adult Health and Illness at Gwynedd Mercy University, PhD at Widener University.Professional experience includes clinical experience as an RN and Advanced Practice Nurse, Teaching experience in the academic and clinical setting along with teaching NCLEX-RN review courses. Dr. Roy is an accreditor for the ACEN, Accrediting Commission for Education in Nursing, and also sits on the Evaluation Review Panel for ACEN. She is a member of Sigma Theta Tau, and Florida Deans and Directors. She is a board member for Healthy Neighbors International, a group that provides healthcare to patients in developing countries. This alliance has provided her the opportunity to work with Nursing Students from Nicaragua as they see patients on behalf of the group for continuity of care. Dr. Roy moved to the Jacksonville area in September 2021 from Pennsylvania, she has a daughter in San Diego and one in New Jersey. She enjoys kayaking, fishing and relaxing with family and friends.  |
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| **IRB Role**: Serves to provide strategic direction, leadership and management as well as leadership pertaining to research proposals and topics related to the School of Health Sciences; shares knowledge about the acceptability of proposed health sciences research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Also attends IRB meetings and follows procedures and regulations as outlined in the in the handbook. Reports any conflicts of interests and advises as necessary. |

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| **IRB Member – Non-Science** |
| Dr. Cedrick Gibson, Associate Vice President of Workforce Development and Entrepreneurship  |
| **Qualifications:** Doctor of Philosophy in Business Administration, Northcentral University, Prescott Valley, AZ; Master of Educational Leadership & Administration, Jones International University, Centennial, CO; Master of Aeronautical Science, Embry Riddle Aeronautical University, Daytona Beach, FL; Master of Business Administration in Aviation, Embry Riddle Aeronautical University, Daytona Beach, FL; Bachelor of Business Administration, University of Florida, Gainesville, FL.**Professional Affiliations:** National Educators Association, MBA Association, Gold Key Honor Society, Rotarian – Westside Jacksonville.   |
| **IRB Role**: Serves to share knowledge about Work Force education trends, policy, and applied research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Also attends IRB meetings and follows procedures and regulations as outlined in the in the handbook. Reports any conflicts of interests and advises as necessary.

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| **IRB Member – Non-Science** |
| Ms. Jacquelyn Thompson, Associate Vice President of Enrollment Management and Student Success |
| **Qualifications:** BS, University of Florida, Gainesville, FL; MEd University of Florida, Gainesville, FL**Professional Affiliations:** National Association of Student Personnel Administrators (NASPA); American Association of Community Colleges, Association of Florida Colleges, Association of Florida Colleges Student Development Commission, The American Association of Collegiate Registrars and Admissions Officers (AACRAO). |
| **IRB Role:** Serves to share knowledge about the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Also attends IRB meetings and follows procedures and regulations as outlined in the in the handbook. Reports any conflicts of interests and advises as necessary.  |
| **IRB Member – Non-Science** |
| Dr. John A. Woodward, Ph.D., Professor of Humanities and Film Studies  |
| **Qualifications:** Ph.D., Faculty Florida State College at Jacksonville |
| **IRB Role**: Serves to share knowledge about the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Also attends IRB meetings and follows procedures and regulations as outlined in the in the handbook. Reports any conflicts of interests and advises as necessary. |

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| **IRB Member – Non Affiliate** |
| Mari Kuraishi President, Jessie Ball duPont Fund |
| **Qualifications:** B.A. in History, Harvard-Radcliffe College, M.A. in Soviet Studies, Harvard University, Executive MBA World Bank Executive Development Program at Harvard  **Professional Affiliations:** Cummer Museum and Gardens, DataKind, GlobalGiving, Mission Investors Exchange, JAX Chamber, Davis Center for Russian and Eurasian Studies at Harvard University. |
| **IRB Role**: To serve as the nonaffiliated member of the IRB, representing the local community-at-large. Share knowledge about the local community and will be willing to discuss issues and research from that perspective. Attend IRB meetings and follow the procedures and regulations as outlined in the handbook. Reports any conflict of interest situation, if one should occur. To serve with the highest ethical and professional manner. |

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1. Note: Vulnerable populations include children, prisoners, pregnant women, or people with intellectual disability. People with intellectual disability are not officially considered a vulnerable population in the current code of federal regulations as there is no subpart devoted to this group. They are included here as their inclusion appears to be consistent with the spirit of the regulations. [↑](#footnote-ref-1)
2. For Dual Enrollment students, parental consent for exempt studies is part of the dual enrollment contract. [↑](#footnote-ref-2)