TOPIC:	Institutional Review Board (IRB) for Treatment of Human Subjects - Procedures	Policy Number: F28

The Institutional Review Board

The IRB reports to the President through the Vice President for Academic Affairs and has the responsibility of ensuring all policies related to research activities involving human subjects adhere to college guidelines. The chair and members are appointed by the Vice President for Academic Affairs with recommendations from faculty. Board membership should be diverse with a minimum of five members representing varying academic disciplines, as specified in 45 CFR 46.101. No member of the board shall participate in a review process for any project in which they have a conflict of interest (see Board Policy F20). Examples of activities creating a conflict of interest may include: a) teaching a student in an assigned class who is involved in a research project for another professor; b) having supervision over anyone involved in the research project, whether a student, employee, or faculty member; c) being a member within the same department where the research project is conducted; or d) having a professional interest in the outcome. When necessary, the board may request the participation of an outside expert.

The board is responsible for reviewing all 'human subjects' related research activities conducted by faculty members, students, staff, or outside researchers using college students, personnel, or facilities.

Research is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102). Research subject to review includes, but is not limited to, faculty research projects, classroom projects and student supervised projects aimed for publication and student organization projects. Research subject for review also includes all outside investigators requesting use of college students, personnel or facilities.

Types of Review

All research, regardless of review type, must be submitted to the IRB chair for confirmation of correct review category. Each category is based on a determination of 'at risk' and is described below (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107):

There are three levels of IRB review: Exempt, Expedited, and Full Board Review. An applicant should review all three before making a determination about your specific project. When in doubt, contact the IRB Chair for assistance. Final determination of review level is made by the IRB.

Exempt

Research that is classified as Exempt will not require any further review after the initial approval and only needs to be reviewed by the chair of the IRB.

Categories of Research that qualify as Exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education 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 (if minors are involved, full board review is required), interview procedures (if minors are involved, full board review is required), 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 and/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 already Exempt under #2 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 confidentiality of the personally identifiable information will be maintained throughout the search and thereafter.

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

5. Research and demonstration projects which are conducted by or subject to the approval of (Federal) Department or Agency heads and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs, (ii) procedures for obtaining benefits or services under these programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) 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.

Expedited Review

Research that is classified as Expedited only needs to be reviewed by the chair or by a qualified member designated by the chair. It is, however, subject to annual review.

A research project is appropriate for Expedited Review if it involves only minimal risk, and is not classified as Exempt. Minimal risk is defined as risk that is not greater than what one encounters in ordinary daily life or during the performance of routine physical or psychological examinations or tests.

Full Board Review

If a project involves more than minimal risk to participants as defined previously, it requires a Full Board Review. Projects involving **any** of the following will also require full Board Review:

1. Minor subjects (children 17 years of age or younger).

2. Vulnerable populations (e.g., children, prisoners, pregnant women, individuals with disabilities, economically or educationally disadvantaged persons, individuals with a mental-disability, or foreign students).

3. Collection or recording of behavior which, if known 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.

4. Asking questions that may be highly embarrassing or compromising (e.g., sexual behavior, sexual orientation, alcohol consumption, personal finances, problems in the workplace).

5. Any research proposed by investigators outside the college.

Other Requirements (45 CFR 46.101(c) - (h))

1. Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

2. Department or agency heads may require that specific research activities or classes or research activities conducted, supported, or otherwise subject to regulation, department, or agency but not otherwise covered by this Policy, comply with some or all of the requirements of this Policy.

3. Compliance with the Policy requires compliance with pertinent federal laws or regulations which provide additional protection for human subjects.

4. This Policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

5. This Policy does not affect any foreign law or regulation which may otherwise be applicable and which provide additional protections for human subjects of research.

6. No research shall take place in a foreign country.

7. No research shall involve pregnant women.

8. No research shall be conducted or supported by any Federal Department or Agency.

The IRB Review Process

All faculty, staff or students requesting approval for research or projects using human subjects are required to complete the NIH Web-based training course “Protecting Human Research Participants”. A certification number will be provided upon successful completion of the course and will be required on the review application. (https://phrp.nihtraining.com/users/login.php)

Application. Faculty members, staff, or students seeking approval for research or projects using human subjects are responsible for beginning the review process by submitting the Request for Approval of Human Subjects Research form to the chair of the IRB, along with all applicable supporting documents (informed consent, etc.). The IRB chair will determine the review category as Exempt, Expedited, or Full Review. Any proposal determined as Exempt will be reviewed only by the Chair. Proposals determined to be Expedited will be reviewed by the Chair and a second member of the IRB chosen appropriately with respect to his/her area of expertise. After determining that a project is Exempt or Expedited, the Chair shall forward a copy of the Application and notice of the determination that the proposed research is Exempt or Expedited to all members of the IRB.

Proposals determined as needing full review will be forwarded to all members for review. In order to approve research covered by the Policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures currently being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits to subject, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks, and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating

in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purviews of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research using vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with this Policy.

5. Informed consent will be appropriately documented, in accordance with this Policy.

6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data will be required or documented.

After the review, investigators will receive a notice of the outcome. There are four possible outcomes from a review:

Approved: No further action is required by the investigator prior to initiating the study.

Approval contingent on designated changes: The investigator may initiate the study after requested changes are made, the IRB receives the revisions, and notifies the investigator that he/she may proceed.

Revise and Resubmit: More extensive changes are required before the study may begin. Additional information must be submitted to the IRB prior to approval.

Denied: Because of the level of risk involved, proposed research, cannot be initiated.

Typically, approval is given for research for a period of one year from the approval date. If necessary, that time frame can be extended past the expiration date by submitting a request for extension. Annual updates must be submitted for research approved for longer than one year. Annual updates, requests for time

extensions or any requests for modifications shall be reviewed and approved by the IRB.

Investigators shall immediately report to the IRB any problems with the research, any problem that any subjects are having with the research, or any illnesses, sicknesses, or injuries to any subject from the research.

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (45 CFR 46.113).

Appeals

In the event that an application is denied because the Institutional Review Board determines the risks outweigh the benefits of the research and the investigator disagrees with the committee's disapproval decision, the researcher may appeal the decision by re-submitting the same application form and: 1) a letter of appeal presenting the researcher's arguments for approval; and 2) any other pertinent information in support of the appeal. The letter should be directed to the Chair of the Institutional Review Board. Applications submitted for appeal will be considered by the full IRB. The final decision of the IRB will be stated in writing to the investigator. If the proposal is not approved, the research cannot be conducted.

Unanticipated Problems

In the initial approval letter, investigators are asked to promptly report any problems or adverse effects of the research to the IRB, including what steps the investigator has taken in response. Any changes in the procedures of collecting data from human subjects must be reported and re-reviewed and approved.

Informed Consent

Except as provided in this Policy, no investigator may involve a human being as a subject in research covered by this Policy unless the investigator has obtained legal informed consent of the subject or the subject's authorized representative. An investigator shall seek such consent only after they have provided the prospective subject or the representative sufficient opportunity to consider whether or not to participate and they have minimized the possibility of coercion or undue influence. The information provided to the subject or the representative shall be in the language understandable to the subject or representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or

representative is made to waive any of the subject's legal rights, or releases the investigator, the sponsor, the institution, or its agents from liability for negligence. The informed consent shall be a written consent form approved by the IRB and signed by the subject or the subject's authorized representative. A copy shall be given to the person signing the consent form. The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent as set out herein. The investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A written consent document stating that the elements of informed consent, as set out herein, have been presented orally to the subject or the subject's authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. The witness, however, shall sign both the short form and a copy of the summary; and the person obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. The only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. The research presents no more than a minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases wherein the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

All informed consent documents must include the following elements:

- An explanation of the purpose of the research
- Description of procedures including duration of participation, any experimental procedure, and any reasonably foreseeable risks, discomforts or inconvenience from participation
- For research with more than minimal risk of injury (physical, social, psychological, etc.) describe any voluntary compensation or treatment that will be provided

- Describe the extent to which personally identifiable private information will be protected
- Describe any benefits participants may reasonably experience
- Describe appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- Include an explanation of whom to contact for answers to questions about the research, participant rights and any research-related injury
- Include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled. Subjects must have sufficient information to make an informed decision to participate in the research study. If subjects cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under 18) or when they are mentally incapacitated, legal representatives are required. Consent requests are to be clearly written in a manner understandable, using language that is non-technical. Scientific, technical, or medical terms should be plainly defined.
- Describe the extent to which confidentiality of records identifying the subject will be maintained.

When appropriate, one or more of the following elements of information shall also be provided to each subject (45 CFR 46.116(b)):

1. A statement the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant);

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. Any consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

Assent

When investigating children (those under 18) as research subjects or participants, the institution of origin must have and provide documented parental/guardian approval of research participation prior to seeking consent to conduct research at Cloud County Community College. Children should be given an explanation - at a level appropriate to the child's age, maturity, experience, and condition - of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should be asked if they wish to participate in the research or not. In the proposal, the investigator should indicate: 1) how assent will be obtained (what the investigator will say to the child and whether or not the child's parent(s) or guardian(s) will be present); 2) how assent will be documented. The child may either sign a very brief assent form or verbally indicate a willingness to participate (45 CFR 46). During any phase of the research project the child conveys discontinuance of participation, the child's involvement with the project must terminate immediately.

Circumstances in Which a Written Consent Form May Not Be Required

In all research involving human beings, respondents must be made aware of the nature and purpose of the research, the voluntary character of their participation, the benefits and risks – if any – they may incur as a result of participation, and the ways in which their privacy will be protected. The method, by which informed consent is obtained, however, differs according to the type of research in question. In many cases, the use of informed consent forms signed by respondents, is the best means of obtaining consent. This is particularly true in biomedical or clinical research, or in social scientific research that utilizes similar formats. However, this method may be impossible to utilize in some types of social-scientific and humanistic investigations, especially in research of the "participant-observation" type involving the researcher's immersion in the everyday life of a community. In this type of research, knowledge is typically gained through the give and take of ordinary conversation, often casual and in unstructured situations, and by observing activities and interactions in their living context. In such cases, the Institutional Review Board may authorize oral informed consent – by which is meant consent obtained orally without the use of written forms – under the following conditions: 1) that the research involves no more than minimal risk to respondents, 2) that the substitution of an oral format will not harm respondents, 3) that the research could not be carried out without the substitution and that 4) where appropriate, respondents will be provided additional information after their participation. Oral consent will also be allowed in research requiring the use of telephone interviews, provided that the aforementioned conditions are met. In addition, oral consent will be authorized in cases in which a breach of confidentiality might be dangerous to respondents and the consent form is the one and only link between the respondent and the research. However, whether consent documents are used or not, researchers have an obligation to ensure that respondents understand the purpose and nature of the research. (45 CFR 46)

Some research requires the use of mailed or emailed questionnaires. In such cases, a mailed or emailed response will itself be regarded as evidence of informed consent, provided that the questionnaire clearly explains the purpose and nature of the research.

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Use of Deception in Research

The use of deception or incomplete disclosure in research is sometimes necessary research technique. Deception occurs when participants are deliberately given false or incomplete information about some aspect of the research. More information regarding criteria for the use of deception and debriefing of participants can be found online: (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107).

Final Reporting

All investigators shall submit a short final summary upon completion of their research project to the IRB. This report should include any plans to disseminate research results.

IRB Reporting

Cloud County Community College, or when appropriate the IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions 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.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and the investigators including all e-mails.

5. A list of IRB members in the same detail as described in 45 CFR 46.103(b)(3).

6. Written procedures for the IRB in the same detail as described in 45 CFR 46.103(b)(4) and 45 CFR 46.103(b)(5).

7. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5).

8. The records required by this Policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

Investigators shall keep all documentation pertaining to their research for at least 3 years after completion of the research.

Adopted:	Revised	Revised/Reviewed	Revised/Reviewed	Revised/Reviewed
9/29/15	2/23/21			