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POLICY ON RESEARCH WITH HUMAN PARTICIPANTS

All research and experimental activities in which living human beings participate as subjects must be approved by the Institutional Review Board (IRB) of Cedar Crest College. The procedures contained herein are applicable to all research conducted by Cedar Crest College faculty, staff, or students and to class projects designed either by the instructor or the student. Further, any research involving Cedar Crest faculty, staff, or students by individuals not associated with the College is subject to these procedures, unless the project has received prior IRB approval. Approval must be obtained prior to involving subjects and prior to distributing any information or written materials to subjects that would require approval. This applies to all research sponsored by external funding agencies, to un-sponsored research, and to continuing education and instructional projects and activities conducted by college students, staff, and faculty. This applies to all research conducted under college auspices or as a part of an investigator’s professional activities as an employee of the college. It does not apply to research entirely unrelated to the College or to an employee’s professional activities (e.g., conducting research for an external agency) unrelated to his or her College responsibilities, though employees may choose to submit such research for IRB review. This policy is designed to safeguard the rights and well-being of human subjects, and to ensure that the principles of respect for persons, beneficence, and justice are met by the proposed activities involving human subjects.

IRBs must comply with the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations in 45 CFR part 46, known as The Common Rule, and 21 CFR parts 50 and 56, respectively, when reviewing research subject to those regulations. Both the HHS regulations at 45 CFR 46.103(b)(4) and (5) and the FDA regulations at 21 CFR 56.108(a) and (b) state that IRBs must follow written procedures for the following functions and operations:

1. Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution;
2. Determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
3. Ensuring prompt reporting to the IRB of proposed changes in a research activity and ensuring that 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 where necessary to eliminate apparent immediate hazards to the human subjects;
4. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i.e., OHRP) for research conducted or supported by HHS, and FDA for FDA-regulated research of any:
   • Unanticipated problems involving risks to human subjects or others;
   • Instance of serious or continuing noncompliance with the applicable HHS and FDA regulations or the requirements or determinations of the IRB;
   • Suspension or termination of IRB approval (HHS, 2018).
DEFINITION OF TERMS (as defined in the federal policy)

Clinical Trial- Exact definitions of what type of studies constitute a clinical trial are different depending on the applicable oversight agency. See agency for more information.

Educational Activities that ARE Human Subjects Research- If an instructor determines that there is a possibility that a student’s proposed research project may result in a formal presentation or publication, he/she should recommend that the student submit the project for IRB review before beginning the study.

Educational Activities that ARE NOT Human Subjects Research- All human subjects research requires prior institutional approval, but not all data gathering by students constitutes human subjects research. The definition of research below establishes that an activity must be designed with the intent to develop or contribute to “generalizable knowledge.” Classroom activities designed to teach research techniques or allow students to practice those techniques are not considered research with human subjects. Simulations of human experimentation and course-assigned data collection do not constitute human subjects research if the activities are designed for educational purposes only; and

- the data will not be generalized outside the classroom (reporting of data within the class is acceptable because the activities were performed solely for teaching purposes); and
- the data will not result in a master’s thesis, doctoral dissertation, poster session, abstract or other publication or presentation; and
- the student volunteers or other participants are clearly informed that the activities are an instructional exercise and not actual research.

Human Participant means 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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Minimal risk means that the probability and magnitude of harm or discomfort 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.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information is individually identifiable when the identity of the subject is or may be readily ascertained by the investigator or associated with the information.
**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. **Secondary research** is re-using identifiable information and/or identifiable bio specimens that are collected for some other “primary” or “initial” activity (HHS 2017). For example, social work files, medical records, leftover tissue/samples from a hospital’s pathology specimen repository, or excess blood drawn for clinical purposes. Secondary research is not surveys, interviews, or collection of samples by the investigator (that would have a primary research purpose).

**PRINCIPLES FOR PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH**

The following principles are based on findings of The Belmont Report. The Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles.

A. Research serves to advance the study of human thought, behavior, and physical makeup and ultimately the knowledge base of science. This positive outcome of research is defined as **beneficence**. However, research also has potential risks and hazards to human subjects. The purpose of the Institutional Review Board is to evaluate all research proposals, to determine what risks may be present for subjects, and to assess how these balance against benefits to subjects and the advancement of knowledge.

B. The IRB requires that researchers recognize and practice the principle of **respect for persons**, that is, upholding their choice about whether to participate in any proposed research and their right to be properly informed about the nature and conduct of such research. Potential subjects must be given the opportunity to indicate their assent by signing an informed consent document; this signals their awareness of the research to be performed and their understanding of the potential risk to them. In the case of minors or others not capable of determining this, their legally appointed representative (LAR) must be consulted for informed consent. The IRB will review all proposals to insure that the participation of the subjects is voluntary and their consent is based on adequate information about the project.

C. Both the benefits and burdens of participation in research must be distributed fairly across all populations to ensure **justice**. Researchers must take care not to overburden vulnerable populations who, by virtue of their status, may be coerced to participate. These populations include fetuses, pregnant women, children, prisoners, physically or mentally disabled persons, persons with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline. The IRB will assure that fair and appropriate selection procedures are followed so that no one group is disproportionately burdened.
D. The College’s policy places primary responsibility for the protection of human subjects with the principal investigator. This responsibility is shared by Cedar Crest College, by any sponsoring agency where outside support is provided, and by any faculty member involved in supervising student-conducted research.

RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR

The individual investigator has the responsibility to bring research proposals that involve human subjects to the IRB. In accordance with federal regulations, approval of a project extends one full year from the anticipated start time. If the project extends beyond that date, the proposal must be reviewed 30 days prior to the end of the first and any subsequent years. If the project changes in any way, the investigator should apprise the IRB of those changes. The IRB reserves the right during the review process to seek clarification from the investigator and/or require alteration and resubmission.

SIGNIFICANT CHANGES TO THE COMMON RULE/FINAL RULE

The Common Rule is a 1981 rule of ethics regarding biomedical and behavioral research involving human subjects in the United States. The regulations governing Institutional Review Boards for oversight of human research followed the 1975 revision of the Declaration of Helsinki, and are encapsulated in the 1991 revision to the U.S. Department of Health and Human Services Title 45 CFR 46 (Public Welfare) Subparts A, B, C and D. Subpart A, The Common Rule is the baseline standard of ethics by which any government-funded research in the US is held; nearly all academic institutions hold their researchers to these statements of rights regardless of funding (HHS 2017).

The Final Rule (effective January 21, 2019) established new exempt categories of research based on their risk profile. Under some of the new categories, exempt research would be required to undergo review by the IRB chair to ensure that there are adequate privacy safeguards for identifiable private information and identifiable bio specimens (HHS 2017).

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<td>1 – Revised</td>
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<td>3 – Replaced*</td>
<td>Revised</td>
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<td>5 – Revised</td>
<td>Unchanged</td>
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<td>7 – New</td>
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* (Pre-2018 Rule Category Eliminated /New Category Added for Final Rule)

THE EIGHT EXEMPTION CATEGORIES UNDER THE COMMON RULE/FINAL RULE (Eligible for Review by IRB Chair)

Category 1: Research in Established or Commonly Accepted Educational Settings
Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact
students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods (HHS, 2017).

Applicability to vulnerable populations:
- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption (See page 4 notation on presentation/publication of data involving children).

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects’ responses outside the research* would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review (HHS, 2017).

*If the results are to be presented or published outside the research, IRB will review this as an expedited proposal to examine the safeguards for anonymity.

Applicability to vulnerable populations
- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption only when it related to educational tests or observations in which the investigators do not participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IRB review.

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects (New Category)
Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data
entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

**Important Notes about Category 3**

- Deception is allowed if certain criteria are met
- This exemption is only for benign behavioral research with adults, and is not applicable to children (HHS, 2017).

Applicability to vulnerable populations:

- Pregnant women who are adults may be included in this type of research
- Research that targets a prisoner population is not eligible for this exemption.
- Research that could include children is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving persons with decisional-impairments is not eligible for this exemption.

Category 4: Secondary Research for Which Consent Is Not Required

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable bio specimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable bio specimens are publicly available;

(ii) Information, which may include information about bio specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private
information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act (HHS, 2017).

Applicability to vulnerable populations:
- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn’t designed to recruit prisoners and prisoners were only incidental subjects of the research.
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

Category 5: Research and Demonstration Projects That Are Conducted or Supported by a Federal Department or Agency
Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects (HHS, 2017).

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies
Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental 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

Applicability to vulnerable populations:
- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.
- Research involving decision-impaired persons could be allowed if their inclusion was justified (HHS, 2017).

Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required*
Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable bio specimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8) (HHS, 2017).

Research with vulnerable populations may be approvable with this exemption:
- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

Category 8: Secondary Research for Which Broad Consent Is Required*
Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable bio specimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio specimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d);
(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117;
(iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results (HHS, 2017).

Research with vulnerable populations may be approvable with this exemption:
- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

*Cedar Crest College IRB is not currently reviewing proposals in which broad consent is utilized. These exemptions are listed here for information only.
Research involving prisoners as subjects, survey or interview of children, and the observation of public behavior of children when the researcher participates in the activity MAY NOT BE EXEMPT.

All funded research and certain other types of research, e.g. course related, student-generated, and unfunded faculty research, normally require IRB approval. Certain categories of institutional and internal research about the students, faculty, and staff of Cedar Crest College that involves data collection on the opinions and preferences of the college community or surveys about ways to improve college services would not usually require approval. (i.e. Course Evaluations, Faculty Evaluations – by students, by faculty, by peers) The exception to this would be when disclosure of the responses outside the research context could put individuals at risk of civil or criminal liability or be damaging to their reputation or social and economic standing. Information deemed as sensitive includes that about subjects; drug use, alcohol use, sexual behavior, medical condition, or possible illegal conduct. Research of this nature must receive IRB approval.

COMMON RULE (45 CFR 46) SUBPARTS B, C, AND D

Subpart B: Research Involving Pregnant Women, Fetuses, and Neonates

Additional protection and limitations are placed on research involving pregnant women, fetuses in utero, or neonates. Please contact the Chair of the IRB for additional information.

Subpart C: Research Involving Prisoners

Additional protection and limitations are placed on research on prisoners. Please contact the chair of the IRB for additional information.

Subpart D: Children as Subjects in Research

The range of activities that may be approved by Expedited or Limited review is reduced when children are involved as subjects in research. Specifically, research involving survey or interview procedures and research involving the observation of public behavior where the investigator is a participant in the activities being observed may not receive Expedited or Limited review when these research activities involve persons under the age of 18 (hereinafter, “child” or “children”).

Written permission is required of both parents or the legally appointed guardian(s) for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. The requirement for written permission may be waived by the review committee.
where it is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

**Assent:** In addition to the written permission required of parents, it is necessary to acquire the assent of children, when they are capable of providing assent. “Assent” means a child’s affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 14 years and older, written assent is required. For children under 14, verbal assent may be obtained. The principal investigator must submit to the IRB the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding whether assent must be obtained and how it will be documented.

Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as subjects are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators, or the guardian organization. The advocate must have the background experience to act in the best interests of the children for the duration of their participation in the research. It is suggested that the principal investigator identify a suitable advocate and secure his or her consent to serve prior to review by the IRB. Advocates for child wards are not required for research involving no more than minimal risk or research presenting the prospect of direct benefits to the individual children.

**THE SCOPE OF IRB AUTHORITY**

All research covered by the College’s Human Subjects Research Policy shall be reviewed by the IRB prior to the involvement of the subjects. The IRB shall have authority to approve, require modifications to (to secure approval), or disapprove the research, and to conduct continuing review of the research at intervals appropriate to the degree or risk, but not less than once per year.

The IRB shall have authority to require that information given to subjects as part of informed consent is in accordance with the requirements for informed consent listed below, (see below) and to observe or have a third party observe the consent process and the research.

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with 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 actions and shall be reported promptly to the investigator, appropriate institutional officials, and the appropriate granting agency official.
IRB COMMITTEE MEMBERSHIP

The IRB shall be comprised of at least five standing members: one (1) scientist (may include the social/behavioral sciences; one (1) non-scientist; two (2) faculty members at large, with at least one being from the graduate faculty, and one (1) community member having no affiliation to the College. (HHS, 2017). One member will serve as the committee chair. The committee will be co-chaired by the Associate Provost as a compliance officer for the College. The Associate Provost is a permanent, but non-voting member of the IRB committee. He/She serves in an advisory capacity.

The college representatives are elected for a three-year term. The members are elected by the faculty from a slate of candidates selected by the Faculty Personnel Committee. The community member is appointed by the Provost in consultation with the IRB.

The members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the college. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members’ backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, including fetuses, pregnant women, prisoners, children, handicapped or mentally disabled persons, persons with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects. The IRB may not consist entirely of men, women, or of members of one profession (HHS, 2018).

TRAINING FOR IRB MEMBERS

The IRB chair is encouraged to complete CITI-IRB training. All IRB members will complete online training and provide the completion certificate to the Associate Provost. Online training will be completed through HHS at: https://ori.hhs.gov/education/products/montana_round1/human.html
Committee members will complete Section Six: Human Participation in Research. Faculty members, especially those serving as research advisors, are encouraged to complete this training also.

IRB CONVENED FULL COMMITTEE MEETINGS

Basic Order of IRB Meetings
Review and approval of the minutes from the previous meeting
Question asked: If any conflict of interest exists from IRB members and studies, recusal will be expected.
Chair/Vice-Chair/IRB member presents amendments to prior studies if any, and votes are taken.
Primary reviewer presents review of new study applications and summarize important issues related to research ethics, safety, and science.
Secondary reviewer comments on the research plan by indicating whether he or she agrees or disagrees with the issues as outlined by the first reviewer or adds further issues. Discussion to make sure every issue and question is addressed, and a call for a vote to approve, accept with contingencies, defer, or disapprove follows (CITI, 2019).

**Quorum Requirements, The Importance of the Community Representative**

In order for the votes to take place, quorum must be established. Generally, quorum is defined as 50% of the members plus 1 being present. Quorum must include at least one non-scientist member. In many IRBs, the community member is also the non-scientist, therefore in the absence of the community member voting cannot take place and the meeting would have to be re-scheduled (CITI, 2019).

**Voting Options at Meeting**
IRB members at a convened IRB meeting vote yes, no, or abstain on a motion to approve, require modification in order to secure approval, or disapprove research activities. The minutes document the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving the research; and a summary of the discussion of controverted issues and their resolution.

If a committee member is listed in a study undergoing review, or has any other conflict of interest (COI), he or she may not participate in the initial or continuing review of the study except to provide information as requested by the IRB. The committee member must leave the room (that is, recuse themselves from the discussion) and must be listed as recused in the vote. It is recommended that the recusal of IRB members because of a conflicting interest also be documented when recording votes on IRB actions (CITI, 2019).

**COMMITTEE RECORD KEEPING**

The following records must be maintained by the IRB for **three years**:

A. Copies of all research proposals reviewed; scientific evaluations, if any, that accompanied the proposal; approved sample consent documents; progress reports and renewals submitted by investigators; and reports of injuries to subjects.

B. Minutes of IRB meetings which should be in sufficient detail to show attendance at the meeting, action taken; the vote on these actions including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a summary of the discussion of disputed issues and their resolution.
C. Records of continuing review activities.

D. Copies of all correspondence between the IRB and the investigators.

E. A list of the IRB members detailing their names, earned degree, representative capacity, indications of experience sufficient to describe each members’ chief anticipated contribution to the IRB, and any employment or other relationship between the member and Cedar Crest College (e.g. full-time employee).

F. A statement of significant new findings provided to subjects, as required by the policy on informed consent, discussed above.

CONFLICT OF INTEREST

A conflict of interest (COI) is any circumstance where personal, professional, financial, or other private interests of a person or institution compromise or have the potential to compromise the exercise of professional judgment or obligations, or may be perceived as doing so (CITI, 2019).

If an IRB member has a COI with a proposal, he/she will recuse themselves from the discussion of the proposal. There are clear regulations (HHS, PHS, NIH) concerning principal investigator(s) COIs, especially financial COIs. Investigators with COIs should communicate with the IRB chair.

DECISION RULE

The Institutional Review Board is designed to protect human subjects of research by making decisions on the ethics of proposed research. It is not to offer an opinion on the merits of a research proposal’s design or execution apart from this narrow question regarding the effect on human subjects. The Board should consider the rights of subjects not to be harmed; therefore, the Board must ensure that participants are notified of all potential risks and that they need not endure risks they are unwilling to accept. Since the decisions of the Institutional Review Board are not to reflect members’ possibly divergent interests or opinions regarding research methods or topics, decisions should normally be made by consensus (Hick, 2017).

The Institutional Review Board should strive for consensus rather than a simple majority. The board should function as a jury ascertaining facts and applying standards rather than as a legislature representing diverse interests and creating policy. Not all faculty interests can be represented on the review board or in the appeals process. A consensus decision-making rule is therefore important because it both reflects and promotes a unitary community where equal respect obviates the need for equal protection of interests. The decision-making rule is protection of interests. The decision-making process will optimally entail reasoned face-to-face deliberation and consensus regarding the ethics of proposed research (Hick, 2017).
INSTITUTIONAL RESEARCH

Institutional research or internal research is the gathering of data from or about Cedar Crest students, faculty, or staff members by college offices or organizations, with the intent of using the data solely for internal informational purposes or for required data-collection purposes. Examples would include surveys or other data-collection instruments designed to: improve college services or procedures; ascertain the opinions, experiences, or preferences of the college community; or provide necessary information to characterize the college community. This kind of data collection does NOT require review by the IRB except:

a) in instances where the information deals with sensitive aspects of the subject’s own behavior, with the result that disclosure of the responses outside of the context of the research could place the subject at risk of civil or criminal liability or be damaging to the subject’s reputation, employability, or financial standing. Examples would include information on subjects’ drug use, alcohol use, sexual behavior or illegal conduct.

b) in instances where the information is going to be disseminated in any form to any audience for other than internal purposes.

CRITERIA FOR APPROVAL OF RESEARCH

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
   
a. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

   b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, 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 research on public policy) as among those research risks that fall within the purview 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.
4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative (LAR), in accordance with the requirements for informed consent listed below.

**There are TWO possible exceptions to the requirement for informed consent**:  

a. In the instance of ethnographic fieldwork which relies principally on participant observation as a method, it is recognized that the complex, continuing interaction between the researcher and hosts cannot always be reduced to an informed consent form. However, in those cases where the protocol of informed consent might be waived, the researcher should explain why it would not be appropriate to follow this procedure and what steps he or she plans to take to eliminate the possibility of doing any harm to individuals or groups.

b. In the instance of covert observation of non-public behavior in which there are no apparent risks and the research project would be seriously compromised by disclosure of the research in progress, the IRB may waive the informed consent requirement. (For example, if the only risk involved disclosure of information, appropriate safeguards could be established to negate this risk.) Approval for covert research methods would be granted only after full board review and guidelines are established by the board.

*Requires advance notification of the IRB chair.*

5. Informed consent will be appropriately documented, in accordance with the requirements for informed consent listed in another section of this manual.

6. Where appropriate, there are adequate provisions for monitoring the data collected to ensure the safety of subjects.

7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as fetuses, pregnant women, children, prisoners, handicapped or mentally disabled persons, persons with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline, appropriate additional safeguards are required in the study to protect the rights and welfare of these subjects.

**TYPES OF RESEARCH REVIEW**

All research involving human subjects must be submitted to the IRB via mycedarcrest. Specific instructions for application to IRB are found in the section labeled, Procedure for Submitting a Research Project for Review. There are four categories of review: Exempt, Expedited, Limited and Full. Exempt projects do not need
to be reviewed by the IRB, but the instructors may request that students submit for the learning experience with the process of IRB approval. The expedited review determines whether or not the proposed research meets the requirements for being exempt from complete review, or whether the project should be submitted for review under another category. Expedited category does not apply to any research with children. The limited review is applicable in instances of minor changes in previously reviewed research and in special cases of limited human involvement with minimal risk. The full review is required for all new research proposals that do not meet the requirements for expedited review or limited review. Research proposals requesting funding from Health and Human Services agencies are required by the agencies to receive full committee review if they are not eligible for limited review.

According to 45 CFR 46.102, the following activities are NOT considered research: scholarly and journalistic activities (i.e. oral histories, biographies, literary critiques, legal research, historical scholarship, and journalism. These activities do NOT require IRB reviews.

Sections A to D provide further information related to the types of review. Normally, research that is conducted while fulfilling the requirements of a course would be determined as expedited (see A). Research that has already been reviewed by the IRB of another institution is also normally determined to be expedited. Part D provides further information for these cases.

All research proposals involving human subjects must be submitted to the chair of the IRB via mycedarcrest. As an initial evaluation, proposals submitted under the expedited category will be reviewed by the IRB Chair

A. Exempt Review (For research conducted by CCC faculty, staff, and students—only if required by the course instructor*)

Designation given for Categories 1 – 6 Exempt Studies, as defined in the Cedar Crest IRB regulations and by HHS Common Rule (45 CFR Part 46) that have minimal risks for the research subjects. This type of review requires five (5) business days* for processing. Researchers will file a research description supplement through the online IRB section of mycedarcrest.

*If the research is exempt, IRB application is NOT required, but for instructional purposes the professor of record may allow students to submit as a learning experience.

B. Expedited Review

If the research is found to meet the requirements for expedited review, the investigators must still ensure confidentiality, inform the participants of the requirements of the research, and inform participants that participation is voluntary and that they may withdraw from the study without penalty. Subjects must be exposed to no more than minimal risk, which is defined as risk of harm no greater than those encountered in daily life or during performance of routine physical or psychological tests. Proposals are
exempt from more detailed review (i.e., limited category or full review) if the research described poses minimal risks to subjects and proper procedures are used to implement ethical principles for the protection of human subjects. The following types of research (conducted by both faculty and/or students) may fall into the expedited review category:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

   (b) 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 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects’ privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

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

(c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

B. Limited Review

Limited review may be appropriate for certain types of research involving no more than minimal risk and for minor changes in approved research. The review may be carried out by the IRB Chair and/or by one or more experienced reviewers designated by the chair from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the full review procedure set forth below. Reviewers may refer the proposal to full committee. The principal investigator will be informed in writing whether the proposed research has been approved or referred for full committee review. All members of the IRB will receive written notification from the chair of research activities that have been approved by limited review.

There are four exemptions that may require limited IRB review: Exemptions 2, 3, 7, and 8 (See the Exemption Categories on pages 5-9 of this document).

C. Full Committee Review

Any research which poses more than a minimal risk to the participants will be subject to full committee review. Any research not covered under the expedited or limited review categories is referred to the IRB for full committee review. The research is either approved, approved pending modifications which must be verified by committee members, or not approved. Investigators will be notified in writing about the committee’s decision.

D. Certification by Another Institution’s IRB

If a Cedar Crest student, faculty member, or staff member is conducting research in another institutional setting, Cedar Crest’s requirement for research ethics review will be met by a certification, signed by the principal investigator of the other institution, verifying that the research project has been reviewed and approved. That certification and a copy of the letter notifying the IRB that the research has received institutional approval must be submitted to the IRB Chair. Review of research funded by or conducted at Cedar Crest, or for which a member of the Cedar Crest academic community has primary responsibility, must follow the procedures outlined in other sections of this document.
INFORMED CONSENT

A. General Requirements for Informed Consent*

Informed consent is a written agreement made between an investigator and a freely participating subject, that describes in easily understandable language: (a) the subject’s role in the investigation, (b) the potential risks and benefits associated with study participation, (c) the confidential nature of all information obtained in the investigation, and (d) the provision for voluntary withdrawal without necessity for explanation by the participant. Additionally, no informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

In the case of online survey research, informed consent will be included in the email containing the link to the online survey. The survey will begin with an initial question which indicated that the survey completer has read the description of the study, the potential risks and benefits, and understands that they have the right to withdraw (not complete) from the study. Checking the box at the end of this initial question indicates informed consent by the participant**.

*Note: See pages 11 and 12 for Informed Consent and Assent rules for participants under the age of 18.

**Note children 18 years old or younger may not participate in online research. It is not possible to verify their assent.

The basic elements of informed consent include:

1. a description of the proposed study that includes the purpose, the procedure, and the expected duration of the subject’s participation;

2. a description of foreseeable risks (i.e., physical, psychological, social, legal) that could be associated with study participation;

3. a description of benefits that could be associated with study participation;

4. a disclosure of any appropriate alternative procedures that might be advantageous for subject;

5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. a related explanation for research involving more than minimal risk that describes whether any compensation and/or medical treatment will be available if injury occurs and, if necessary, a description of the compensation and/or medical treatment and information about the associated availability;
an explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject;

a statement that describes participation as voluntary and assures that refusal to participate will not involve penalty or loss of benefits to which the subject is otherwise entitled; and,

a statement that discontinuation of participation at any time will not involve penalty or loss of benefits to which the subject is otherwise entitled;

When appropriate, any of the following additional elements of informed consent should be included:

a statement that the treatment or procedure to be used may involve risks which are currently unforeseeable;

anticipated circumstances under which the subject’s participation may be terminated by the investigator without the subject’s consent;

any additional costs to the subject that may result from participation in the research;

the consequences of the subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

a statement that if 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,

the approximate number of subjects involved in the study.

The Institutional Review Board (IRB) may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

the research involves no more than minimal risk to the subjects;

the waiver or alternation will not adversely affect the rights and welfare of the subject;

the research could not practically be carried out without the waiver or alteration; and
(4) the subjects will be provided with additional pertinent information after participation, whenever appropriate.

The IRB may consult with the college attorney about the legal requirements for informed consent, and should consider doing so in complex cases and cases where substantial risk exists, and must do so in cases where physical touch (i.e., potential battery, e.g., surgery) is involved.

B. Documentation of Informed Consent
Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally appointed representative. A copy shall be given to the person signing the form.

An IRB can waive the requirement for the investigator to obtain a signed consent form for some or all subjects if any of the following apply:

(1) that 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern;

(2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;

(3) that, as the case of ethnographic fieldwork, the researcher can, by virtue of the probability of his or her long term presence and participation in the lives of people, achieve a personal rapport with people that would be disrupted by the use of a consent form;

(4) that, in case of covert research, there are no apparent risks and the research project would be seriously compromised by disclosure of the research in progress.

C. Waiver of Signed Informed Consent
In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

PROCEDURES FOR SUBMITTING A RESEARCH PROJECT FOR REVIEW

A. All research involving living, human subjects must be submitted to the IRB.

B. There are three categories of review: expedited, limited and full. The expedited review determines whether or not the proposed research meets the requirements
for expedited status previously written in this manual, or whether the project should be submitted for review under another category. The limited review is applicable in instances of renewal, minor changes in previously reviewed research, and in special cases of limited human involvement with minimal risk. The full review is required for all new research proposals that do not meet the requirements for expedited or limited review. Research proposals requesting funding from Health and Human Services agencies are required by the agencies to receive full committee review if they are not eligible for expedited or limited review.

C. Faculty who allow or require research projects by their students (when such projects involve the use of human subjects) should submit an application under the expedited or limited category, depending on the nature of the research. If the research is found to be eligible for expedited review, and the same project will be carried out on a regular basis (e.g., similar project every time a particular class is taught), the researcher should submit a written request to the IRB with the original IRB approval number and date, to ask for subsequent review at the beginning of every fall semester, or as needed, provided the research objectives and methodology are not changed. Include a description of what progress has been made thus far in the research study (i.e. a Progress Report).

D. Templates for the Research Description Supplement, Informed Consent, and Consent Record Slip are found on mycedarcrest under the Campus Connect tab and Institutional Review Board. The following information should be submitted to the IRB on mycedarcrest:

- Online IRB application
- Research Description Supplement
- Informed Consent Form
- Consent Record Slip (if applicable)
- Instruments (survey, interview/observation protocol, etc.)
- Permissions from offsite agencies (if applicable)
- Grant Proposal (if applicable)

The IRB is interested in the protection of human participants only. Emphasis will be placed on the description of the research procedures, qualifications of the investigators, the informed consent of the participants as previously described in this document, the confidentiality and anonymity of the participants, and the secure storage of data. Rulings will be based on these aspects of the research proposal.

E. The committee’s actions, comments, and recommendations will be sent to the principal investigator. If a proposal is disapproved, the principal investigator may request a convened committee meeting.
F. Any changes in a proposal or consent form must be promptly reported to the IRB Chair. Minor changes will be expedited and approved by the IRB chair. Major revisions must be approved by the full committee.

G. **All adverse reactions and unexpected side effects must be reported immediately, in writing to the IRB chair.**

H. Interim progress reports should be submitted if requested by the IRB to insure that the rights and well being of subjects are protected.

I. **Annual renewals are mandatory.**

**APPEALS**

Investigators may request that the IRB reconsider the decision made. A rationale must accompany that request. The principal investigator will receive written notification of the committee’s decision.

**ANNUAL RENEWAL PROCEDURES**

Thirty days before the anniversary of the last approval date, the following should be submitted (two of each for expedited, six of each for full review):

A. A written request to the IRB including the original IRB approval number and date of approval, in which the researcher(s) request an extension of the research project for a subsequent year. (If the project is over three years old, submit the entire original proposal, also.) Include a progress report.

B. If any changes have been made, submit instruments, with any changes noted, and the consent form(s) and written explanation of study, with changes highlighted.

**COMPLETION OF RESEARCH AND DATA DESTRUCTION**

_When a project is completed, withdrawn, or past the phase involving human subjects, the principal investigator will inform the IRB Chair immediately in writing._

All documentation associated with the research (including research proposals, write-ups, completed informed consent forms, and data) must be kept in a secure place by the researcher(s) for a period of **three years** after the date of the project’s completion and then must be safely destroyed. This minimum period of data preservation and destruction may be modified in accordance with the academic field’s own code of rules, regulations, and ethics.
References


