Colorado College Institutional Review Board Policies and Procedures Manual

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The Colorado College IRB has drawn this policy manual in part from the Kenyon College IRB Policies and Procedures Manual and from the Bucknell University IRB Policies and Procedures Manual, in both cases with their express permission. We are grateful to both institutions for generously offering their manuals for Colorado College's use.

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Note: Federal regulations are cited and quoted directly in most cases, though a few terms have been modified. The Colorado College IRB uses the term "participants" instead of "subjects," the term "application" instead of "proposal," and the term "researchers" instead of "investigators," "principal investigators," or "PIs" in most cases; these changes are reflected in this document.

1. Introduction, Purpose and Ethical Principles

This manual has been written to assemble and make readily available the policies and procedures guiding the Colorado College Institutional Review Board (hereafter IRB), the college committee that ensures research carried out with human participants is ethically and legally sound. ("Research" is defined, along with many other relevant terms, in Appendix 2.) Researchers (faculty, staff, and students) and IRB members are the intended users of this manual. The manual describes and explains various aspects of the review process and regulatory requirements.

The purpose of the Colorado College IRB is to foster ethical treatment of human research participants and to oversee all research (broadly defined) involving human participants conducted under the auspices of Colorado College. The IRB acts with the full support of Colorado College leadership, which is committed to safeguarding the welfare, rights, and privacy of all people who participate in research projects carried out by members of the Colorado College community.

The National Research Act of 1974 established the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research. This commission published *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research* (1979), which articulates the ethical principles that guide the conduct of research with human participants. This report serves as the foundation of *Title 45 Code of Federal Regulations Part 46* (hereafter 45 CFR 46), whose regulations are the basis of most CC IRB policies and procedures (http://www.hhs.gov/ohrp/humanparticipants/guidance/45cfr46.html). In the design, conduct, approval and review of research, Colorado College officials, IRB members, and researchers adhere to the basic principles set forth in *The Belmont Report* (respect for persons, beneficence, and justice) and to the regulations set forth in 45 CFR 46.

To demonstrate respect for persons, Colorado College researchers must seek and obtain voluntary informed consent from potential research participants. Informed consent means that participants are given explicit assurances of the voluntary nature of their involvement in terms that are easy to understand, and that they are not under duress or pressured to serve as participants. The consent process also includes information about the research project that will assist participants in deciding whether to participate in the study or not. In addition, respect means honoring the privacy of individuals with regard to the information they provide to the researcher; respect also means maintaining confidentiality with regard to the participant's identity unless an agreement with the participant has been made that their identity may become public.

The principle of beneficence requires that researchers maximize the potential benefits to participants and/or to society, while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research. All participants should be treated in an ethical manner. Benefits to participants, or benefits in the form of generalized knowledge gained from the research, should always outweigh the risks. If there are any risks resulting from participation in the research then there must be benefits, to the participants, to society, or to both.

Justice means that participants must be selected fairly and that both the risks and benefits of research are distributed evenly. To the greatest extent possible, researchers should resist the temptation to select participants simply because of convenient availability, manipulability, situations that invite coercion on the part of researchers, or because of social, racial, sexual, economic, cultural, or other biases institutionalized in society.

Colorado College is especially concerned with and committed to safeguarding the welfare, rights, and privacy of all persons who participate in research projects conducted under its auspices, and to ensuring that participants in such research are aware of their rights and the protections available to them. Moreover, the College is legally required to assure the federal government that such safeguards are being provided and enforced for federally funded research involving human participants. Many U.S. government departments and private funding agencies have their own research policies regarding human participants. Researchers carrying out federally-funded research should check to see whether a funding agency has policies and procedures that go beyond Colorado College IRB policies.

All research involving human participants carried out by Colorado College faculty, staff, and students must be carried out in accordance with federal laws and Colorado College IRB policies, whether the research is funded or unfunded and regardless of the source of funding.

All research projects involving human participants, regardless of funding status and source of funding, must be approved or receive exemption from the IRB prior to the researcher(s) gathering any data or information from participants.

2. The Colorado College IRB: Role, Jurisdiction, and Authority

Colorado College requires that researchers must protect the rights, privacy and welfare of individuals recruited for participation in research. The Colorado College IRB holds the primary responsibility of protecting human participants involved in scientific, social, behavioral and educational research conducted by departments, programs, and all administrative divisions and organizations affiliated with the college.

The jurisdiction of the IRB includes the authority to:

- review, approve, require modifications of, or disapprove research protocol applications submitted by faculty, staff and student researchers;
- suspend or terminate approval of research not being conducted in accordance with requirements or that has been associated with unexpected serious harm to participants;
- observe or have a third party observe the consent process and the conduct of the human research;
- ensure that voluntary informed consent will be obtained by researchers in a manner that meets the requirements of 45 CFR 46 by requiring documentation of informed consent (with the option to waive the requirement for such documentation in certain circumstances);
- determine whether an activity falls within the legal parameters of human research;
- determine whether financial interests related to the research have implications for approval of the research;
- carry out limited IRB review in circumstances that warrant it according to 45 CFR 46; and

- to ensure that research conducted by outside researchers involving Colorado College community members has been approved or exempted by the outside researcher's home IRB before supporting the research moving forward.

The IRB is charged with two main responsibilities:

- Determining and certifying that all research protocols conform to the regulations and policies set forth by the Department of Health and Human Services regarding the health, welfare, safety, rights, and privileges of human research participants; and
- Assisting researchers in conducting ethical research that complies with federal and other regulations in a way that permits the accomplishment of the research activity; this is done via training, education, and guidance to individual researchers and through educational sessions in courses where human participants research will be carried out.

The IRB meets these responsibilities through a review of applications and exemption requests submitted by researchers, negotiations between the IRB and researchers for approval of research, and IRB outreach to the research community. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human participants. The dignity and welfare of individuals who participate in research must be a central concern of everyone involved in the research. The college, and all faculty, staff and student researchers, share in the collective responsibility for the ethical conduct of research.

The research community must operate and collaborate in a culture of trust, mutual assurance, and integrity by upholding the highest ethical principles in the conduct of research and the pursuit of knowledge.

Our Federal-Wide Assurance with the Office for Human Research Protections (part of the Department of Health and Human Services) details the relationship of Colorado College and the Office for Human Research Protections within DHHS. This agreement and other DHHS policies empower the IRB with the authority to review, approve, require modification to, or disapprove research activities conducted by Colorado College researchers, including jurisdiction over proposed changes in previously approved research and determination of which approved research projects require continuing review more frequently than the maximum interval of twelve months.

IRB decisions and requirements for revisions, if any, are conveyed to researchers in writing via email, with an opportunity for appeal to the IRB by the researcher in the case of disapproval. Although research may receive IRB approval, a department chair or other administrative officials may conclude that the research project does not meet the policies and goals of the college and may disapprove, suspend, or terminate a project. However, IRB decisions to require modifications in, disapprove as submitted, suspend or terminate a project are final. Further, no college committee or official can approve a researcher's conduct of any human participants research that the IRB has not approved or exempted.

IRB approval means that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements. IRB

exemption means that the research falls into a category designated by the federal government as eligible for an abbreviated review based on a limited set of criteria.

The Colorado College IRB operates largely through the work of its permanent Chair. More information on the role of the Chair and on IRB workings in general is available in Appendix 3 at the end of the document.

3. The Nature and Practice of Research

3A. Research Subject to Review

Virtually all federally funded research with human participants is governed by federal regulations described at 45 CFR 46. This federal code defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Research that does not include testing or evaluation (qualitative social science, for example) can still count as research under this regulation. Another way to put it would be to say that systematic investigations are studies that are intended and designed to collect data about human participants with the purpose of drawing conclusions and reporting research findings.

As covered throughout this document, any discussion of research potentially subject to IRB review begins with this definition. Many activities that might commonly be understood as research are not defined as research by the federal government; those activities do not fall under IRB purview.

The most important elements of the above definition for CC IRB purposes are as follows:

- The data collection must be *designed* (and thus *intended*) to contribute to a body of knowledge; data collection intended (for example) to answer questions of personal interest but not intended to contribute to academic knowledge does not count as research.
- The knowledge being contributed to must be *generalizable* and not merely information with no connection to an academic discipline or interdisciplinary area. This does not mean that small-scale qualitative research cannot contribute to generalizable knowledge in an academic area, only that the point of such research must be to contribute in this way.

At Colorado College, all faculty and staff research that conforms to these definitions must be submitted for review by the IRB *regardless of funding source* (federal, state, local, private or unsponsored), with the only exceptions being cases of exempt research as discussed later in this document. The Colorado College IRB reviews protocol applications from all disciplines. In accordance with the Federal-Wide Assurance (FWA No. 00009502) issued to Colorado College by the Office for Human Research Protections, all human participants research funded by the federal government must be performed in accordance with the regulations laid out in this document. In addition, the actions of Colorado College officials, researchers, and staff must conform to all applicable federal, state and local laws and regulations.

Student research involving human participants and intended to result in generalizable knowledge must also be submitted for review. Such research includes all senior theses along with any other

undergraduate research intended for publication or wide dissemination such as a web page or presentation outside of the classroom such as at a conference or poster session. Student research involving human participants must be supervised by a Colorado College faculty advisor who will assume the responsibility for ensuring that all research procedures comply with federal, state and college policies designed to protect human participants; the one exception involves Venture Grants, discussed below, for which faculty advisors may not have social science research methods training. Classroom projects and independent studies that are exclusively for instructional or mentorship purposes need not undergo review by the IRB if the risks are not greater than minimal (a definition of which is provided below). All student research that poses greater than minimal risk must be submitted for IRB review.

3B. Social/Behavioral/Educational vs. Biomedical Research

Most research carried out at Colorado College is social/behavioral/educational research, meaning that it focuses on how people make sense of the world – their perceptions, experiences, and values – along with the kinds of actions they take in response to their understandings. A small amount of physiological research is carried out at CC; at this time such research is only pursued by the Department of Human Biology and Kinesiology. Colorado College does not carry out medical research, strictly defined.

The Colorado College IRB reviews both social/behavioral/educational and physiological research applications. In general, the IRB has different concerns about the two kinds of research. Physiological research is more likely to generate risk of physical harm, whereas social/behavioral/educational research is more likely to generate risk of social, emotional, financial, and other kinds of non-physical harm. The two kinds of research receive equal scrutiny by the IRB, which strives to work closely with professors in both types of fields to understand and minimize potential harm to participants.

3C. Determining when Research Begins and Ends

There are two general types of IRB concern for the well-being of participants. One type involves the earlier stage during which people participate in the research; the other involves the period after their participation when it remains important to keep their information private and their identity confidential or anonymous (both of which issues are discussed in detail below).

From the perspective of the IRB, research begins after the IRB application has been approved and the researcher begins recruiting participants. Research continues through the last data collection-related interaction with the final participant. While the research process obviously continues after researchers are done interacting with participants, the IRB does not remain engaged with the process after that time as long as the initial application made a compelling case that participant privacy and confidentiality or anonymity would be managed effectively. During the period of engagement, the IRB may continue to interact with the researcher if questions or concerns arise, or if changes are made to the research protocol. More information on the nature of these interactions is provided below.

3D. Cross-Institutional Research and Reliance on External IRBs

Colorado College researchers (generally faculty or staff, though students may also work on such projects) planning to carry out research at other institutions must work with the institution of study to determine what that institution requires in order for the CC researcher to receive permission to carry out research there. The Colorado College IRB will provide formal letters for third parties indicating that a CC researcher has received CC IRB approval; the CC IRB can also work with CC researchers to provide other assistance upon request.

Researchers from other institutions may carry out research involving Colorado College students, faculty, and staff under certain circumstances. Specifically, such a researcher needs to provide the Colorado College IRB Chair with the researcher's contact information, a copy of the research protocol they submitted to their home institution (along with all attachments), and a copy of the approval or exemption letter from the IRB at their home institution. The contact email must also include anticipated start and end dates for the research, along with a summary paragraph about the nature of the research. If, in the CC IRB Chair's estimation, the research can be carried out with good protection of CC participants, the researcher will be invited to pursue his or her research among CC participants. Under no circumstances are external researchers permitted to carry out research on Colorado College students without documented IRB approval from their own institutions. The CC IRB does not provide any support in recruiting students or otherwise managing such research projects. If an external researcher needs to work with CC faculty or staff, the researcher is responsible for establishing the necessary relationships.

Multi-institution research, in which there at least one researcher at two or more institutions working on the same research project, is referred to as cooperative research by the federal government. Each institution is responsible for safeguarding the rights and welfare of human participants and for complying with relevant policies. Institutions engaged in cooperative research must obtain approval from a single IRB for any portion of the research conducted in the United States unless multiple IRB review is required by law (as is the case with some tribal law passed by the official governing body of an American Indian or Alaska Native tribe). The "Single IRB" law means that one institution's IRB must take primary responsibility for overseeing the legal and ethical aspects of the research. The Colorado College IRB is committed to working with other IRBs in cooperative research situations to determine the most appropriate single IRB to oversee the project, to developing the necessary paperwork to make legal arrangements, and to provide other necessary support for such projects.

3E. College Participation in National Surveys

Colorado College previously participated in large-scale national surveys such as the National Survey of Student Engagement (NSSE), the HERI CIRP Freshman Survey, the HERI CIRP College Senior Survey and the HERI Faculty Survey. The information in this section is included in case the college should return to such participation in the near future.

While Colorado College does not use college-specific findings in the context of research as defined by the federal government, the organizations that oversee these surveys (the Indiana University at Bloomington Center for Postsecondary Research (NSSE), the Higher Education

Research Institute (the other three surveys)) do use overall findings in the service of research and have a clear intention to contribute to generalizable knowledge. Under these circumstances the CC IRB must treat these surveys as research. However, the Colorado College IRB is released from any specific approval obligations because the universities where these educational institutes are located require the survey overseers to go through a local IRB approval process and Colorado College's position regarding research originating elsewhere is that CC IRB approval is not necessary as long as the originating institution can demonstrate proof of local IRB approval. Therefore, the CC IRB's only concern regarding these surveys is that the originators include an appropriate consent form that survey takers review before taking the survey and that potential participants are aware that their participation is voluntary.

3F. Researcher Responsibilities

Federal regulations, policies, and guidance documents describe the role of researchers, illustrating further the principles of mutual trust, collective responsibilities and the nature of decentralized accountability in human participants research. Researchers must acknowledge and accept their own responsibilities for protecting the rights, privacy and welfare of the human participants.

Researchers hold the following responsibilities in all human participants research contexts:

- Obtaining training in the ethics of human participants research;
- Acknowledging and accepting the ethical and legal responsibilities for protecting the rights and welfare of research participants;
- Understanding and complying with all applicable policies, procedures, guidance, and determinations of the IRB;
- Providing oversight and appropriate training for all research team members;
- Ensuring that all research team members comply with IRB decisions and requirements;
- Conducting research as agreed to in IRB application or as implied in an exemption request;
- Promptly reporting unanticipated problems involving risks to participants or others to the IRB;
- Promptly reporting any serious or continuing noncompliance with IRB requirements, regulations, or determinations to the IRB;
- Promptly acknowledging and abiding by any suspension or termination of IRB approval;
- Keeping records relating to the research, including statements of significant findings and consent documents, for at least three years after completion of the research;
- Maintaining updated records to include the initial application or exemption request, approval or exemption emails (and letters where relevant) from the IRB, modifications requested and approved, continuation or re-approval progress reports, consent forms administered and signed, correspondence related to the study, adverse events reports if any, and other relevant materials. These records must be maintained for review or audit by the IRB for a minimum period of three years after official closure of the study. (In the case of student researchers the sponsoring faculty member, department or program should maintain the records.)

In addition, researchers hold the following responsibilities in cases where research has required (and received) approval rather than exemption:

- Obtaining and documenting informed consent of participants or their legally authorized representatives prior to participation in the research, unless those requirements have been waived by the IRB;
- Obtaining prior IRB approval for any modifications of previously approved research;
- Completing requests for continuing review as requested by the IRB; and
- Ceasing all research activities involving human participants if approval of a study expires before the IRB is able to carry out continuing review and grant approval, and only resuming such activities upon IRB approval.

Prior to submitting applications to the IRB for review, student researchers must present the complete application including all attachments to their advisor to verify that the proposed study has undergone rigorous scientific merit review. The advisor must read the IRB application and contact the IRB Chair with an email of approval, using language included in the application form. This email is not required for exemption requests or for Venture Grant-related applications in which the Venture Grant advisor does not have social science research methods training.

4. IRB Criteria for Approval: Protecting Human Participants

The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human participants in an atmosphere of mutual trust and scientific integrity in the pursuit of knowledge. The IRB review process applies to research conducted by faculty, students, staff, visiting scholars and others whether conducted on Colorado College premises, at off-campus sites, or under subcontracts to other entities. The review requirement applies to all research on human participants that is conducted under the auspices of Colorado College, regardless of funding source or sponsorship status by a government entity or some other organization.

The IRB is responsible for ensuring that all approved research complies with the letter and spirit of the human participant protection regulations as well as the ethical principles stated in The Belmont Report and discussed above: respect for individuals, beneficence, and justice. Additionally, the IRB is responsible for ensuring that any applicable state or local laws are followed.

45 CFR 46 describes IRB criteria for approval as follows (this language is exact with the exception of the use of the term “participants” for “subjects”):

“In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
(1) Risks to participants are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
(2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, 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 participants 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 (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
(3) Selection of participants 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. The IRB = should be particularly cognizant of the special problems of research that involves a category of participants who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
(4) Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by the federal regulations.
(5) Informed consent will be appropriately documented or appropriately waived in accordance with the federal regulations.
(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
(7) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
(8) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

In practice, this means that for a research application to receive IRB approval, the researcher must demonstrate the following in the application:

- Risks of harm to participants are minimized
- The risk/benefit ratio is acceptable
- The selection of participants is fair
- Recruitment methods and advertising material are appropriate
- Vulnerable participants are only included if necessary/appropriate
- Incentives to participate are appropriate and non-coercive
- Informed consent process and documentation are appropriate
- Deception and incomplete disclosure are managed appropriately
- Privacy and confidentiality are protected
- Additional protections are in place for vulnerable participants
- Potential researcher conflicts of interest are avoided

Each of these categories of protection is discussed further below.

4A. Risks of Harm to Participants are Minimized

Risk refers to the probability of harm, whether physical, psychological, social, legal, economic, criminal, or some other type. Both the probability and the magnitude of harm may vary from minimal risk to greater than minimal. Risks include immediate risks of study participation, risks related to breach of confidentiality or inadvertent disclosures, and risks of long-term effects. Risks should be minimized by screening out prospective participants at undue risk, carrying out

proper monitoring of procedures, and protecting individual privacy and confidentiality adequately.

In the federal regulations, 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."

The IRB defines minimal risk studies as those in which the activities and experiences of participants can reasonably be understood as comparable to the following examples:

- For surveys: most online consumer preference and consumer experience surveys; personality inventories; most political surveys
- For interviews: journalistic interviews focused on someone's area of expertise; life stories as might be collected by an oral historian; some topics that might arise in a therapeutic setting (as long as the consent process gives adequate warning of the potential for emotional responses)
- For experiments or other types of research involving more direct intervention: activities that do not cause physical pain, emotional discomfort, humiliation, or other negative physical or psychological effects.

Greater than minimal risk studies include the gathering of personal information that is particularly sensitive, especially in cases where illegal activities (illicit drug use, criminal acts) are the subject of study since failure to protect privacy or confidentiality/anonymity in such a case could have severe negative consequences for the participant. Other topics that could result in embarrassment or other personal harms if privacy/confidentiality measures fail (including, for example, the use of protected health information) may also fall in this category.

Studies that involve the infliction of pain or physical discomfort are likely to be considered greater than minimal risk though even here context matters; a physiological exercise study involving athletes may be minimal risk if the physical discomfort they experience in exercising during the research is no more intense than the physical discomfort they experience during a routine exercise program or while playing their sport.

Greater than minimal risk studies may also include research procedures that employ deception, covert observations in settings where privacy is expected, or other nontransparent methods. When possible, research should be overt and fully transparent; when such transparency would render the research impracticable the research may still be minimal risk when the consent process is as transparent as it reasonably can be and when a rigorous debriefing process (more on which below) is in place.

The IRB Chair should be consulted ahead of time regarding whether a particular topic, participant group, or research method can be considered minimal risk, as well as in situations where the relationship between the probability and magnitude of harm is complex or unclear.

Further information about harm as it is understood by IRBs can be found at https://www.coloradocollege.edu/other/irb/irb-concerns/irb-concerns-harm.html.

4B. Risk/Benefit Ratio is Acceptable

A benefit is a valued or desired outcome, an advantage. Benefits of research may accrue directly to the individual participating in the research or may benefit society as a whole, as is often the case in social/behavioral/educational research. In the latter case, the benefit may come primarily or solely from the contribution to academic literature or it may include a more direct benefit to people or groups outside of the research.

The IRB will assess whether the risks to participants are reasonable in relation to the anticipated benefits to the participants or to society. The IRB reviews proposed studies to ensure that the risks are minimized to the greatest extent possible and that the benefits of research participation are maximized.

To a limited extent, the IRB will consider the scientific merit of the study design, since it would be unethical to place human participants at risk with a study where methodological procedures are so flawed that little or no reliable information will be obtained. Primary responsibility for the review of scientific merit rests with the researcher and, if relevant, their advisor.

Federal regulations also require the IRB to review any possible benefits a participant may derive from participation in research as well as the benefits of new knowledge that may justify asking a person to undertake the risks of the study. Payments for participation in research or other incentives are not considered benefits, and should not be described as such.

4C. Selection of Participants is Fair

Distributive justice, the third principle of *The Belmont Report,* requires the fair selection of participants and the equitable distribution of the risks and benefits of research. This also means that participants are free to refuse participation in the research; the IRB is especially attentive to any signs of potential coercion.

The systematic selection of participants because of their convenient availability may result in an uneven distribution of the benefits and the burdens of research; the same is true when participants are selected because they belong to one or more groups that face social/political inequality and therefore may be unusually subject to coercion or manipulation. Students, patients, clients, or employees are problematic research participants in situations where the researcher also has control or influence over their grades, their access to health care and other services, or their jobs, because true, non-coerced consent is difficult if not impossible in such circumstances. The research application should clearly articulate how recruitment activities will avoid even the appearance of coercion when selecting participants who are in a dependent relationship to the researchers.

Certain groups of potential participants have been defined as “vulnerable,” usually meaning that they are unable to freely refuse to participate in research. These participants must receive special protections, which are discussed in a later section of this document. More information about

vulnerable participants is available at https://www.coloradocollege.edu/other/irb/irb-concerns/irb-concerns-vulnerable-participants.html.

4D. Recruitment Methods and Advertising Material are Appropriate

With all potential research participants, the process of recruitment begins at the first point of contact prior to the initiation of the procedures for obtaining informed consent. In many ways, recruitment is the introduction to the consent process, and may take the form of a flyer, an email or list-serve announcement, a newspaper advertisement, or a verbal exchange between the researcher and the potential participant. Recruitment techniques must respect the rights of all individuals to decide whether or not they will participate voluntarily. They should not feel coerced; nor should they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, for example, a teacher recruiting students, should take special precautions to ensure that a decision to participate is not based on subtle pressures such as grades or a fear of loss in benefits such as counseling services. All flyers, posters, advertisements, letters, email announcements, internet postings or any other recruitment materials should be attached to the research protocol for examination by the IRB and must be approved prior to their use. Templates for recruitment emails and letters are on the IRB homepage (https://www.coloradocollege.edu/other/irb/index.html), which also includes a description of the information needed for recruitment posters.

4E. Vulnerable Participants are Only Included if Necessary/Appropriate

The IRB will consider the research setting and study purposes, including whether the proposed study intends to involve vulnerable classes of participant populations such as children (including 17-year-old college students), students, prisoners, participants with cognitive disorders, or economically or politically disadvantaged people.

To ensure that certain populations are not recruited solely because of their availability, such as prisoners or patients in mental health institutions, the National Commission for the Protection of Human Participants recommends a hierarchy of preference in the selection of participants for research: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons.

The Colorado College IRB ensures that the researcher's rationale for the use of vulnerable participants is clear and convincing. For example, researchers carrying out an experiment that involves college students for participants can easily exclude 17-year-old students (who are legally considered children) without compromising the integrity of the experiment. However, an Education Department study focused on the classroom experiences of high school students requires the participation of legally defined children, and as such can receive IRB approval as long as some additional consent matters are handled appropriately.

4F. Incentives to Participate are Appropriate and Non-Coercive

Researchers planning to use incentives in research involving Colorado College students must review the CC IRB incentives page (https://www.coloradocollege.edu/other/irb/using-

incentives.html) before finalizing research planning or beginning the research, as this page includes mandatory legal information.

Incentives are not considered benefits to participants and should not be described as such.

It is permissible to pay participants for participation and to offer non-guaranteed incentives for participation (such as entry into a raffle for a gift card), but neither payment nor non-guaranteed incentive may be large enough to serve as coercion to participate.

The amount of money or other benefit that is large enough to be considered potentially coercive or to raise the issue of undue influence varies by situation and participant characteristics. The IRB will evaluate a $5 incentive for a Colorado College student participant differently than it will evaluate the same $5 incentive for a homeless person in Colorado Springs, for whom the $5 may be worth a lot more. Payments must be especially carefully thought through when participants are economically disadvantaged people who may be able to be coerced more readily to participate if they are guaranteed money for doing so.

Colorado College students recruited for participation in research may be given the opportunity to earn research course credits or extra credit points for grades. However, the researcher must demonstrate to the IRB that the students in the participant pool are not being coerced and that their consent will be freely given. Care should be taken to eliminate any undue influence of faculty so that participation is not a course requirement without the possibility of other alternatives.

In all cases there must be an educational value or benefit to students explicitly described in the protocol and in the consent form along with measures to protect student autonomy and confidentiality. Students must be provided with choices and options in order to obtain the equivalent course credits or grade incentives. Examples of such alternatives might include attendance at a research seminar, writing a brief report, or other assignments with educational value. Alternative activities should be comparable to research participation in terms of time, effort and convenience. Researchers should avoid any inference that volunteering to join a study will place students in good favor with the faculty in the course in terms of grading, recommendations, or future employment.

4G. Informed Consent Process and Documentation are Appropriate

Informed consent is fundamental to ensuring the continuous and adequate disclosure of research risks and benefits. Informed consent is an educational process between the researcher and the participant. The process begins with the initial presentation of a research activity to a prospective participant by the researcher or a member of the research team and continues through the end of the research activity and the closing of the research study. The IRB will review the process described by the researcher for obtaining informed consent including when, where and how consent is obtained and any provisions for the ongoing consent of participants. The IRB will be particularly concerned that all consent processes are voluntary (not coerced), that they provide sufficient information about the research to the participant, and that the participant understands the information. Except as discussed elsewhere in this section no researcher may involve a

person as a research participant unless the researcher has obtained the legally effective informed consent of the participant or the participant's legally authorized representative.

Most participants make their decision regarding whether to participate in research during the initial contact. The researcher should avoid the potential for any misunderstandings and provide the participants with sufficient time to reflect on the nature of their proposed participation.

The second step in the consent process is the presentation of a written consent form to individuals who express an interest in participating in the study, unless the research qualifies for a waiver or alteration of documented informed consent. Written informed consent is not always necessary or appropriate in some educational, social and behavioral science research; these cases are described below. When written informed consent is appropriate, a member of the study team should ensure that the participant reads and understands the consent form. Federal regulations require that all consent form statements describe the nature of the research and the request for participation in language that is understandable to each potential participant. Consent forms should avoid technical jargon or terminology that is not defined; the forms should also adjust for educational backgrounds, mental abilities and ages of the intended participants.
All participants who agree to participate in a study should be provided their own copy of the signed consent form. Signatures of both the participant and the researcher (or study team member) are required.

The consent process does not end with the signing of the informed consent form.
Research is an on-going process, which involves the constant re-evaluation of current information and procedures. Therefore, researchers are ethically obligated to keep participants apprised of issues related to their participation in the study as appropriate. Any new information or changes in procedures that affect the participants should be presented to them in writing; in most cases this will involve the signing of a new consent form or a revision of the original form.

The consent form provides potential research participants sufficient written information to decide whether to participate in a research study or not based on an explanation of the proposed research and the nature of the participation that is requested of them.

The form should be easily identified in bold text as "Consent to Participate in Research" (or the equivalent) at the top of the first page. The title of the research should be descriptive and not overly technical. Section headings should be used to identify the basic and any additional elements of informed consent.

Once approved, the consent form reviewed by the IRB is the only one that can be copied and administered to research participants. Any changes to approved consent forms must be submitted to the IRB as proposed modifications prior to their use.

Please be aware that the informed consent requirements in this policy do not preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Informed consent processes and documentation receive extensive coverage in 45 CFR 46. This section of the manual begins with excerpts of the law that are relevant to Colorado College; the term "investigator" has been changed to "researcher." All elements of the regulation presented here are in effect for all research reviewed by the IRB unless a waiver or alteration of consent or documentation has been approved.

45 CFR 46 states:
(1) Before involving a human participant in research covered by this policy, a researcher shall obtain the legally effective informed consent of the participant or the participant's legally authorized representative.
(2) A researcher shall seek informed consent only under circumstances that provide the prospective participant or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
(3) The information that is given to the participant or the legally authorized representative shall be in language understandable to the participant or the legally authorized representative.
(4) The prospective participant or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
(5) (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
(6) No informed consent may include any exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the sponsor, the institution, or its agents from liability for negligence.

Basic elements of informed consent: [With certain exceptions specified elsewhere], the following information shall be provided to each participant or the legally authorized representative:
(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the participant;
(3) A description of any benefits to the participant or to others that may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
(5) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant;
(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and
(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another researcher for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or
(ii) A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional elements of informed consent: [With certain exceptions specified elsewhere], one or more of the following elements of information, when appropriate, shall also be provided to each participant or the legally authorized representative:
(1) A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
(2) Anticipated circumstances under which the participant's participation may be terminated by the researcher without regard to the participant's or the legally authorized representative's consent;
(3) Any additional costs to the participant that may result from participation in the research;
(4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
(5) A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant;
(6) The approximate number of participants involved in the study;
(7) A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;
(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and
(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Please note that items 7-9 immediately above will rarely be relevant for Colorado College research.

The federal government, in its 2019 revision of the regulations, offered new "broad consent" categories that institutions are free to adopt or not as they wish. The Colorado College IRB has elected not to adopt the broad consent options and therefore does not include information about that option in this document.

Under certain circumstances, the IRB may legally waive the requirement for participant consent or may approval alterations to the consent process. Federal regulations describing the conditions for such waivers and alterations are as follows:
(1) An IRB may waive the requirement to obtain informed consent for research.
(2) An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent. An IRB may not omit or alter any of the requirements described in items (1)-(6) on page 18 above.
(3) In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
(i) The research involves no more than minimal risk to the participants;
(ii) The research could not practicably be carried out without the requested waiver or alteration;
(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
(iv) The waiver or alteration will not adversely affect the rights and welfare of the participants; and
(v) Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

An IRB may approve a research application in which a researcher will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant or the participant's legally authorized representative, if either of the following conditions are met:
(1) The researcher will obtain information through oral or written communication with the prospective participant or legally authorized representative, or
(2) The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The informed consent requirements [listed above] are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

The following paragraphs cover federal regulations regarding documentation of informed consent.

(a) [Unless waived by the IRB], informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by

the participant or the participant's legally authorized representative. A written copy shall be given to the person signing the informed consent form.
(b) [Unless waived by the IRB], the informed consent form may be either of the following:
(1) A written informed consent form that meets the consent requirements given above. The researcher shall give either the participant or the participant's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the participant or the participant's legally authorized representative.
(2) A short form written informed consent form stating that the elements of informed consent given above have been presented orally to the participant or the participant's legally authorized representative, and that the key information required was presented first to the participant, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the participant or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the participant or the participant's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the participant's legally authorized representative, in addition to a copy of the short form.

An IRB may waive the requirement for the researcher to obtain a signed informed consent form for some or all participants if it finds any of the following:
(i) That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern;
(ii) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or
(iii) If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
In cases in which the documentation requirement is waived, the IRB may require the researcher to provide participants or legally authorized representatives with a written statement regarding the research.

The federal regulatory coverage of consent, as shown above, does not cover issues of assent (consent as it involves participants who are children). Colorado law states that children may not legally sign contracts; a consent form for research participation counts as a contract in this instance. If a participant in Colorado is under eighteen years of age (even if they are a college student), parental permission is required, unless the research participant is married or emancipated by court order. Parental permission must be documented in writing through the use of a parental permission form. For most kinds of research, it is easier for researchers to commit to working only with adults as long as this strategy will not compromise the integrity of the research.

If the research involves minimal risk, the permission of one parent is sufficient. If the research involves greater than minimal risk, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child. Parental consent may be waived by the IRB if it is not a reasonable requirement to protect the participants (for example, neglected or abused children). In such cases, the researcher requesting the waiver must propose an alternative mechanism for protecting the children who will be participating in the study.

As noted above, children are not legally able to consent to participating in research, but children can legally assent to such participation. The distinction between the terms is important and must be followed scrupulously in research involving children. Assent describes a child's affirmative agreement to participate in research. In all instances where children are capable of providing assent, the researcher will develop a separate assent form written in language appropriate to the educational level of the child or, in the case of younger children, will develop an assent script.

All Colorado College IRB consent form templates are available on the IRB homepage. More information about consent concerns is available at https://www.coloradocollege.edu/other/irb/irb-concerns/irb-concerns-consent.html.

4H. Deception and Incomplete Disclosure are Managed Appropriately

Some types of research necessarily involve deception, particularly social psychological and market research studies. In deception research, participants respond to a situation either in the absence of complete information about the situation (incomplete disclosure) or having been provided actual misinformation about the situation (deception). Having complete information could lead to participants subconsciously modifying their responses to provide the response the participant perceives the researcher to be seeking; psychology refers to this experimental artifact as demand characteristics. Given the potential of demand characteristics to interfere with accurate findings, it is in the interests of researchers to avoid such an outcome; deception is generally the most appropriate way to do so.

Deception and incomplete disclosure pose a problem for the consent process, since they require a situation in which participants are not fully informed about the research in which they are participating. Deception studies that do not raise any additional IRB concerns (that, for example, are minimal risk for harm) can sometimes be reviewed on an expedited basis; deception studies with any additional IRB concerns are reviewed by the convened IRB at a "full Board" meeting.

Deception studies must provide as much information as possible during the consent process, and must include a robust debriefing process at the end of each participant's participation in the research. The debriefing process must include an explanation of why the deception or incomplete disclosure was necessary, must include the offer to withdraw the participant's data without penalty, and must allow participants the opportunity to ask questions and address any confusion or concerns that they have. A debriefing form template is included on the IRB home page.

More information about IRB approaches to deception is available at https://www.coloradocollege.edu/other/irb/irb-concerns/irb-concerns-deception.html.

4I. Privacy and Confidentiality are Protected

Other than research based on the observation of behavior in public places (places where no one would assume they had a right to privacy), all human participants research requires that researchers keep participant identities confidential (or carry out anonymous research where such identities are never captured at all) and keep the information they provide private. The IRB reviews applications and exemption requests to ensure that privacy and confidentiality will be protected.

In general, any information obtained in connection with research that identifies particular participants must remain confidential and may be disclosed only with written permission from the participant(s) or as required by law. Consent forms should detail the extent to which confidentiality will be protected and how specific records identifying the participant(s) will be maintained and kept secure as well as how and when they will be destroyed, if applicable. The more sensitive the research material, the greater the care required in obtaining, handling, coding, storing and securing the data.

Depending on the subject matter of the research, there may be limits to the researcher's promise of confidentiality to the participants. For example, most states require persons who know or have a reasonable suspicion that a child or older person is being abused or neglected to report such suspicion to local law enforcement personnel. Therefore, if the research might reveal child or elder abuse, the consent form should include a statement that under Colorado (or other state) law, the privilege of confidentiality does not extend to such information and the researcher is required to report known or suspected child or elder abuse to the appropriate authorities.

Federal law allows researchers to apply for an advance grant of confidentiality called a "Certificate of Confidentiality." If granted by a federal agency, these certificates provide protection against compulsory disclosure, such as a subpoena, for research data about sensitive issues such as illegal conduct, alcohol or drug use, mental health, or sexual practices or preferences. For information concerning certificates of confidentiality, Colorado College researchers should contact the IRB Chair.

Please see the IRB application form (linked on the IRB homepage) for specific strategies researchers can use to maximize confidentiality and privacy, as well as the confidentiality and privacy sub-page of the website (https://www.coloradocollege.edu/other/irb/irb-concerns/irb-concerns-confidentiality-privacy.html).

4J. Additional Protections are in Place for Vulnerable Participants

Participants who are not completely free and able to refuse participation in research (for intellectual, social, economic, or other reasons) are considered "vulnerable" and need extra care taken to make sure their participation is fully voluntary. Vulnerable participant groups include:

- Children (under 18 in the US and many other countries, and including 17-year-old Colorado College students)

- People with developmental disabilities or who are cognitively impaired
- Members of economically/educationally/politically disadvantaged groups
- Pregnant women, fetuses, and neonates
- Students (in contexts where their professors are carrying out the research)
- Prisoners, and
- Anyone else who might not be completely free or able to refuse participation in the research.

Vulnerability is often discussed in terms of membership in a social group or of a condition affecting an individual, but vulnerability may also involve particular circumstances; someone who is vulnerable in one context may not be vulnerable in a different context. A person who does not speak English would be vulnerable in a context in which the consent process is not carried out in a language in which the person is fluent. A member of a Colorado College athletic team would be vulnerable in a context in which the captain of their team sought to recruit them for a research project.

When a project does not specifically require vulnerable participants, the IRB will request that the researcher remove them from the potential research population.

When vulnerable participants must be included in a project, the IRB will determine whether any additional safeguards are appropriate to protect their rights and welfare, and if so, whether these procedures have been included. The IRB will not approve student research on prisoners unless the research is carried out as part of a project overseen by a faculty or staff member.

Subparts of the federal regulations in 45 CFR 46 require additional protections for pregnant women, human fetuses and neonates Involved in research (Subpart B); prisoners (Subpart C); and children (Subpart D). Researchers should consult Subparts B (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html), C (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html), and D (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) for a description of these special requirements.

Children in particular are in a dependent relationship to adults and can be easily manipulated in a school or clinical setting. Researchers should take every precaution to ensure that a child's decision to participate in research is both voluntary and free from coercion. Refusal to participate must not be met with a negative response or any form of punishment. In an educational setting, school officials or teachers do not have the authority to give consent for the participation of children. Only a parent or legal guardian may permit a child, with the child's assent, to participate in a research study. The IRB will not approve research involving children that has not successfully addressed the regulations in Subpart D, a link to which is included above.

4K. Potential Researcher Conflicts of Interest are Avoided

Conflicts of interest may occur when a researcher's research responsibilities compete with their private interests, such as financial interests, raising concerns of objectivity. Conflicts of interest may exist despite the highest standards of conduct and candor. Researchers are responsible for

informing the IRB of any potential conflicts of interest, finding ways to address those conflicts of interest in order to carry out legally and ethically acceptable research, and providing the IRB with an explanation of how conflicts of interests will be avoided. Research for which there are potential conflicts of interest will not be approved by the IRB until the IRB is convinced that researchers have an appropriate mechanism or process for avoiding conflicts of interest in the research process.

5. The Colorado College IRB Review Process

The IRB will not, under any circumstances, approve or exempt a project for which the research has already been carried out. Applications must be approved or exemptions received before research can begin.

5A. Rolling IRB Application Calendar

Applications are reviewed on a rolling basis by the IRB throughout the calendar year. If the IRB Chair is on vacation for a week or more at any time, this information is announced and posted on the IRB website.

5B. Research that Does Not Require IRB Review: Definitions and Process

Certain kinds of information-gathering projects involving human participants are not considered research by the federal government and thus do not come under IRB purview. (Research that does not involve interacting with living people does not fall under the federal definition of research for IRB purposes.)

A student carrying out a class project that will not be presented or published beyond the class generally does not need to interact with the IRB. However, if the student believes that the project has the potential to become a thesis project or to otherwise contribute to generalizable knowledge, the student should contact the IRB Chair to discuss the most appropriate approach to interacting with the IRB.

The federal government has specified that "scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected" do not count as human subjects research and do not require interaction with the IRB.

For more information, see the IRB webpage sub-page on research not requiring IRB review (https://www.coloradocollege.edu/other/irb/research-types/non-irb-research.html) and the information form on such projects on the IRB homepage.

Researchers are responsible for contacting the IRB Chair if they have any questions about whether their research might require formal interaction with the IRB and, if in doubt, should err on the side of caution.

5C. Application Preparation and Submission Process and Materials

Researchers apply for IRB approval by completing the CCIRB application form and emailing the completed application to the Permanent Chair of the IRB (currently Amanda Udis-Kessler; audiskessler@coloradocollege.edu), along with all necessary supporting materials and (if the researcher is a student) an email of support from the student's advisor with very specific phrasing which is provided on the application form. The application is a Word document that can be saved and modified by the researcher.

A researcher seeking an exemption from the regular application review process should submit the appropriate exemption determination form (Educational Research, Interaction Research, Benign Behavioral Intervention Research, or Secondary Research) by email along with all necessary attachments. All exemption determination forms are on the IRB homepage.

Applications and exemption requests are not reviewed until all necessary materials have been received. Incomplete applications or exemption requests will not be reviewed, nor will application forms or exemption requests with missing attachments (consent forms, debriefing forms, etc.).

Researchers should allow at least one week for appropriate review and at least two weeks during the summer (between the end of Block 8 in a calendar year and the beginning of the following Block 1 in the same calendar year. If the IRB Chair determines that an application requires full Board review, the review process may take up to two blocks from the initial date of submission.

5D. Exempt Research

Studies that are minimal risk and meet the criteria of one or more exemption research categories as stated in 45 CFR 46.104 are considered exempt from the regulations and do not require an IRB review once exemption has been confirmed. The use of the term "exemption" for this category does not mean that the researcher is "exempt" from having to interact with the IRB; it means that the researcher can interact with the IRB using a simpler, streamlined, and usually faster process. Projects designed as exempt based on federal regulations must still conform to all applicable federal, state, and local laws and must be ethically sound.

The federal government allows institutions to decide who is responsible for determining that a given research project is exempt. At Colorado College, only the IRB may determine whether a research project qualifies for exemption; researchers are not permitted to make this determination for themselves.

Several exempt categories are not relevant to Colorado College researchers. For the categories that are relevant, excerpts of 45 CFR 46 appear below:

1) 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.

(2) 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 researcher in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; (ii) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the researcher in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by the federal regulations.

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(A) The information obtained is recorded by the researcher in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;
(B) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or
(C) The information obtained is recorded by the researcher in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review [of confidentiality].
(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the researcher has no reason to think the participants will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the

researcher in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the researcher does not contact the participants, and the researcher will not re-identify participants.

The IRB homepage has exemption determination forms for each of these exemption categories.

Above, the language describing the benign behavioral intervention exemption specifies that it only covers research with adults. Elsewhere in the regulations, it is clarified that research involving members of certain vulnerable groups or communities does not qualify for exemption. Specifically, research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observations of public behavior when the researcher does not participate in the activities being observed. Research involving prisoners can never receive an exemption unless the research is aimed at a broader population that only incidentally includes prisoners.

Most studies involving more than minimal deception cannot receive exemption and must be reviewed using the regular IRB application.

In some cases, a study that has been designated exempt will undergo changes after the exemption that render it no longer exempt according to the federal regulations. If an exempted study has changes in the funding source, a new potential for a conflict of interest, or certain other changes (the risk level becoming greater than minimal, a change in the participant population, a change in the nature of the project, or a change in how information is recorded), the researcher must contact the IRB chair to determine whether the project is now subject to a full-application review based on the changes. This contact must occur within 14 calendar days from the relevant change taking effect.

5E. Expedited Research

Certain non-exempt research can be carried out on an expedited basis, meaning that a single IRB member (generally the Chair) can review the application alone and can either approve the application or can request modifications in order for the application to be approved. (Only the full Board can disapprove a research project.) An expedited review must include documentation of the IRB's determination that the project poses no greater than minimal risk of harm, and IRB members must be informed of research applications approved by expedited review.

The federal government has designated certain types of research reviewable on an expedited basis when the proposed research has no or minimal risk of harm to participants. The expedited process cannot be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, or reputation, or where such identification would be stigmatizing.

Research categories eligible for expedited review are approved by the Secretary of the Department of Health and Human Services and are published in the Federal Register. The IRB

uses the most current list of these categories of research. The categories in this list apply regardless of the age of participants, except as noted.

Research categories eligible for expedited review that are in use at Colorado College include the following:

1) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, 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 from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

2) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner;…(d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery;…(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

3) 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. 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 participant or an invasion of the participant=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

4) 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).

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

6) 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.

In addition to the above categories, certain other kinds of IRB work can be carried out on an expedited basis, such as:

- The limited IRB review required for certain exempt research,
- Review of minor changes to approved applications, and
- Continuing review of research previously approved by the full Board (1) where the research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or (2) where no participants have been enrolled and no additional risks have been identified; or (3) where the remaining research activities are limited to data analysis

5F. Full Board Review

Most applications submitted to the CC IRB qualify for either exemption or expedited review. Research that does not qualify for exemption or expedited review must undergo a full IRB review by a quorum of IRB members at a convened meeting facilitated by the IRB Chair or a designated substitute from the IRB. (A quorum consists of a majority of the members of the IRB, including at least one member whose primary concerns are in nonscientific areas. If the quorum is lost during the meeting, the IRB does not take further protocol actions that require a vote unless quorum is restored.) Meetings may take place in person or online.

In a full-Board review, the IRB performs a detailed examination of the review application including the proposed informed consent form, and all supporting documentation, including any recruitment materials, questionnaires, or survey instruments.

Researchers whose applications are being discussed are invited to attend part of the meeting to answer questions. If additional expertise is needed to conduct a full-Board review, the IRB Chair appoints a consultant with appropriate expertise in the discipline, population, or location after confirming that the consultant does not have a conflict of interest. The consultant is then sent the same materials as the Board and is expected to attend the meeting; if the consultant has a conflict of interest, they only attend a brief portion of the meeting where their expertise is drawn upon.

No later than one week prior to the Board meeting, an agenda for the meeting and all study materials are made available electronically to all Board members. If a consultant is involved, they provide comments in writing to the Chair no later than a week before the meeting in order to have their comments shared with the Board. All Board members review all materials and seek out any additional relevant information (reviewing HHS laws or additional national, state, or other laws).

IRB members with a potential conflict of interest must recuse themselves from voting and participation in the review, except to provide relevant information requested by the IRB.

After a full discussion of the complete application, the IRB Chair or designated substitute calls for a vote. Results of IRB decisions are then communicated by email to the researcher within three calendar days. The communication justifies any conditions required for final approval,

requests any additional desired information or revisions, and indicates any next steps in the review process where relevant. For revisions, the IRB will set a deadline to receive the revision, which, if missed, will cause the application to be withdrawn. Upon receipt of the email, the researcher may also request a hardcopy letter from the Chair, which will be provided within 14 calendar days.

5G. Review Outcomes: Approval, Revision, Denial

For non-exempt projects, the IRB notifies researchers in writing of its decision to approve or deny approval of the proposed research activity, or to require modifications that would permit IRB approval of the research activity. This notification is provided by email with a follow-up hardcopy letter upon request.

Approval means that the application was approved as submitted without questions or the need for clarification because it met all of the criteria discussed on pages 11-12 above. In such cases, research can begin immediately upon the researcher's receipt of the approval. The approval email (and, where requested, letter) will include the effective date of approval and the date by which a continuing review must be carried out if relevant; if the continuing review date is sooner than a year from the date of approval, the email and letter will explain the reasoning.

Revision functions as a form of approval with stipulations. The researcher will be informed of any clarifications and/or minor revisions that must be submitted to the IRB Chair or a designated substitute, who will review the clarifications and/or revisions on an expedited basis. Research may not begin until the Chair or substitute has reviewed the clarifications and/or revisions and approved the project on behalf of the IRB.

Denial refers to the denial of approval or, put differently, the disapproval of the research application; research may not be carried out if a project is denied approval. Only the full IRB can deny approval of a research project; this may not legally be done on an expedited basis. If the IRB votes to disapprove a research activity, it must include in its written notification a statement of the reasons for its decision and give the researcher an opportunity to respond in person or in writing with an appeal. Ultimately, the IRB retains final authority for approval of proposed research involving human participants.

5H. Researcher Responsibilities upon IRB Exemption or Approval

Once research is approved by the IRB, researchers must obtain documented and legal informed consent from all research participants involved in each protocol, unless the IRB has granted a waiver, exception or alteration as provided for in the federal regulations and described elsewhere in this manual. Researchers must also promptly report any injuries, unanticipated problems or adverse events to the IRB.

A complete list of researcher responsibilities is provided in section 3F above.

5I. Expiration of Approval Periods

When continuing review of research that requires such review does not occur prior to the end of the approval period specified by the IRB, the IRB approval expires automatically. Failure to either close a study or apply for re-approval prior to the expiration date constitutes non-compliance.

If the ending date expires prior to submission of the re-approval application, the researcher must suspend participant contact and all data collection until the re-approval is obtained from the IRB. No new participants may be contacted, recruited, or enrolled during the interim period, and if data has been collected, the data cannot be used in the study.

5J. Continuing Review

For research that is greater than minimal risk and reviewed by the full Board, the IRB conducts substantive continuing review at intervals appropriate to the degree of risk and at least once a year. Minimal-risk research may or may not require continuing review. All projects must satisfy the criteria set forth in 45 CFR 46.111 for the IRB to approve the protocol for continuation. Projects reviewed by the full Board may undergo expedited continuing review procedures if no new participants have enrolled and no additional risks have been identified and/or if the project is limited to data analysis at this point.

Continuing review may involve determining whether the proposed research requires verification from sources other than the researcher that no material changes have occurred since the last IRB review. This may occur in cases of complex projects, researchers with previous compliance issues, information in a continuing review report indicating changes not previously reported, or for randomly selected projects

The IRB will maintain a database of projects that require continuing review and will contact researchers three months, two months, and one month prior to the expiration date to remind them to contact the IRB about the need for continuing review.

To apply for continuation of the research, the researcher requests re-approval by email. The researcher should use the email to inform the IRB of the status of the research project:

- progress toward completion, including status of participant enrollments;
- difficulties encountered, if any;
- adverse events summary, if applicable;
- unanticipated problems involving risks to participants or the withdrawal of participants;
- a copy of the informed consent document currently in use for the study; and
- updated conflict of interest forms for researchers.

In the email, the researcher must certify that the study will continue to be carried out as described in the original application (or with specified changes) and in accordance with the research ethics, norms and standards in the respective discipline. In the case of student or visiting faculty research, the responsible faculty member must send the email.

5K. Reporting Research Modifications to the IRB

All amendments and modifications to a study need IRB approval before they are implemented. If the researcher wants to change anything in the research that would impact the participants, such as recruitment procedures, co-researchers, inclusion/exclusion criteria, research procedures, the informed consent document/process, or data elements collected, the researcher must obtain IRB review and approval prior to implementation of the changes. The only exceptions are changes necessary to immediately protect participants' safety, which may be reported after the fact. If a researcher is unsure about reporting changes to the IRB, they should email the IRB Chair and ask for guidance. There is a form to report modifications on the IRB homepage. Modified consent forms or any other documents or information that participants will see that has been modified must be submitted along with the form.

Modifications to currently approved protocols, research instruments, or to the informed consent process must be submitted to the IRB for review and approval prior to implementation.

The date of approval of the modification does not change the date by which the regularly scheduled re-approval review of the project is to be completed, if applicable.

5L. Procedure for Addressing Complaints from Research Participants

The IRB website includes a subpage with information about contacting the Chair with questions or concerns (https://www.coloradocollege.edu/other/irb/participant-questions-concerns.html). If a participant contacts the Chair with complaints or concerns, the Chair will open a formal complaint process, collect information, and convene the full IRB to determine how best to respond to the complaint. Options range from taking no action to requiring changes in the research protocol to terminating the research, depending on the nature of the complaint and evidence of its veracity.

5M. Reporting Adverse Events

Unanticipated problems involving risks to participants or others, may include:

- Adverse events or injuries that are serious, unexpected, and related
- Breaches of confidentiality involving risks
- New information indicating an unexpected change in risks or potential benefits
- Protocol deviations, violations, or other accidental or unintentional changes to the protocol or procedures involving either risks to participants or others, a likelihood of recurrence, or an alternation in the risk/benefit profile
- Participant complaints indicating an unanticipated risk
- Unapproved changes made to the research to eliminate an apparent immediate hazard to a participant
- Events requiring prompt reporting according to the protocol, sponsor, or funding agency

Researchers must report any unanticipated problems, complications, or complaints to the IRB in a timely fashion using the form on the IRB homepage. Researchers must report to the IRB the nature of the problem within seven calendar days of the occurrence. A separate report must be

filed for each incident summarizing the problem or difficulty encountered along with a statement by the researcher indicating whether a change in the protocol and/or consent form is warranted and whether, in the researcher's opinion, the adverse effect was related to the research activity.

Following receipt of an adverse event report, the IRB will review the information to determine whether any further actions, beyond any changes or amendments to the protocol that are proposed by the researcher, are warranted. The IRB reserves the right to review and approve all proposed changes and to determine whether the study should be continued as originally approved, modified, or discontinued. The IRB is also required to report to any sponsoring federal agency all adverse events that caused injury to participants or other major effects that involved unanticipated risks or problems. Researchers must also comply with any reporting requirements in the protocol itself or as stipulated by the sponsoring agency in grant documents are agency regulations as relevant.

IRB response to notification of such reports may include modification of the research protocol, modification of the consent process or form, approval of continued research without changes, the requirement that additional information be provided to current and/or past research participants, reconfirming consent of current participants, requiring additional follow-up or monitoring for current and/or past research participants, other monitoring of the research, education or mentoring for the PI or staff, additional reporting, requiring additional resources to support the research, placing limitations on the activities or use of data, suspending or terminating the research, suspending enrollment of new participants, and/or referral to other appropriate institutional processes (such as a misconduct review)

5N. Compensation for Injuries Sustained by Participants in the Course of Research

Researchers are expected to provide financial compensation to participants physically injured in the course of their participation in research unless prior agreement has been made with the IRB that no such compensation will be provided. Researchers are expected to work with the IRB during the application process to determine the nature and process of such compensation should it become necessary.

5O. Noncompliance Inquiries and Reporting of Findings

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to research involving human participants. Noncompliance may be minor, serious, and/or continuing; see Appendix 2 for definitions.

Examples of non-compliance include:

- serious violations discovered after completion of a protocol audit;
- instances where non-exempt research was conducted without IRB review and approval or
- without appropriate informed consent procedures;
- implementation of significant modifications without IRB prior approval; and
- instances of repeated or multiple problems with noncompliance by protocol researchers even after IRB warnings.

Anyone may submit allegations of noncompliance involving human participants research to the IRB Chair in writing. The IRB Chair will protect the confidentiality of the person submitting the allegation (the complainant) to the fullest extent possible.

The Chair conducts a preliminary review to determine whether the allegation involves a current IRB-approved study or a historical study.

If any allegation involves exempt research, the Chair will review the initial findings to determine whether to conduct further inquiry and will inform the complainant. If the allegation involves non-exempt research, the Chair will inform the current membership of the IRB within seven calendar days and convene a full Board meeting. The convened IRB reviews allegation and either requests a formal inquiry into the allegation or dismisses the allegation as unjustified and elects to take no action. The IRB Chair communicates the IRB's decisions to the complainant (if known) and to the researcher against whom the allegation was raised (respondent). If the IRB believes there is a potential immediate risk to participants, it may immediately suspend IRB approval and/or sequester research records, in which case the IRB Chair notifies the respondent immediately.

If any inquiry is carried out, it may include the review of research data (published, unpublished, or both), consent/assent forms, inclusion/exclusion criteria, the applicable approved or exempted IRB protocol, and any other relevant information. Separate interviews are carried out with the complainant (if known) and with the respondent. The respondent is given an opportunity to comment on the allegation and provide information. The interviewer prepares summaries of all interviews and allows all parties to submit commentaries on and rebuttals to the summaries. Others may also be interviewed. The Chair prepares a summary report for the convened IRB which may include any information gathered as part of the inquiry as appendices to the summary report. The IRB Chair confers with college administration and legal counsel as appropriate to provide additional guidance to the convened IRB. The convened IRB determines whether the allegation is substantiated and, if so, whether the noncompliance is minor, serious, or continuing based on the materials compiled during the inquiry. In the case of sponsored research, the incident and findings are reported to the applicable agency/sponsor.

Depending on the outcome of the review, the convened IRB may take a variety of actions, include, but not limited to, the following:

- Approve continuation of research without changes
- Request formal educational intervention
- Request minor or major changes in the research procedures and/or consent documents
- Modify the continuing review schedule
- Require monitoring of research
- Require monitoring of the consent process
- Suspend or terminate IRB approval/disapprove continuation of the study
- Require post-approval monitoring of other active research projects of the researcher
- Suspend the researcher's right to request initial IRB review of research for some period of time

- Disqualify the researcher from conducting human participants research at Colorado College
- Determine that the researcher may not use data already collected for publication
- Require that the researcher contact participants previously enrolled in the study and provide them with additional information and/or re-consent them

The IRB Chair informs the appropriate parties of the allegation, the review process, and the findings of the review, including, but not limited to the respondent, college academic leadership, the complainant, the research sponsor, and other college personnel.

The PI can appeal the determinations of the IRB by responding in writing within 10 calendar days of the date the IRB issues the final decision. Appeals must describe the nature of any claimed procedural error in the review. The IRB can choose to re-open the inquiry or to reject the appeal. The IRB Chair informs the respondent of the decision.

5P. Notice of Terminated Study

The IRB may issue a Notice of Terminated Study under a number of circumstances such as:
- the study approval period has expired without an application from the researcher for re-approval or to close the study;
- serious violations of IRB or federal compliance rules for the protection of human participants;
- unauthorized use of consent forms without notification to the IRB; or
- audit findings that warrant termination of a study.

Upon receiving a Notice of Terminated Study, the researcher is legally required to cease the research project entirely and to communicate with the IRB Chair about potential future options.

5Q. Appeals Policy

Any decision, review outcome, or audit finding may be appealed to the IRB. Researchers must submit their appeal in a letter to the IRB Chair outlining the reasons for the appeal and why the IRB decision, review or audit outcome should be reconsidered. If the appeal involves a relatively minor request, the Chair or a subcommittee of the IRB may consider the issue and reach an equitable determination. However, appeals of expedited and full review outcomes must be reviewed and decided by the full IRB at a convened meeting. The researcher may request to be present at the meeting or may be invited to attend by the IRB to clarify any issues pertinent to the written appeal. After presentation of the information and review of the documents, the full IRB will vote to approve or not approve the appeal. The decision of the IRB will be final.

6. Research Requiring Special Attention

This section covers international research, primary/secondary classroom research, other research involving children, research with prisoners, internet/social media research, research on illegal activities, and CC-specific student research. This section is intended to provide additional information to researchers and IRB members and to point researchers and IRB members to additional online resources.

6A. International Research

Students, faculty members and staff carrying out research as previously defined while abroad have two sets of obligations: first, to the local social structure and people in it, and second, to the CC IRB.

Regarding the first obligation, CC students, staff, and faculty may not carry out human participants research abroad without having gone through whatever official channels have been established at the study site and having been approved for research there. It is the researcher's responsibility to determine what the local obligations are in order to meet them. This means that it is the researcher's responsibility to know the key organizations, legislation, regulations, and guidelines relevant to the particular country in which research is taking place. Much of this information has been compiled in a document, the International Compilation of Human Research Standards, which is updated regularly (https://www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf). In addition, researchers may need to work with a consultant with expertise in legal, cultural, or other issues specific to the region being researched.

Researchers should begin the above preparations before leaving CC, if possible, by communicating with whoever can provide appropriate background information, and by reviewing the relevant links at the International Compilation. Once at the study site, researchers must continue the process of finding out the local specifics of human participants research permission. This must be done proactively; it is not an excuse if the proper channels are not immediately made available to researchers or the proper information provided. Student researchers with questions or concerns can contact Heather Browne (heather.browne@coloradocollege.edu) at the CC Off-Campus Study Office.

The second obligation is met by going through a normal CC IRB application process and receiving either approval or exemption for the research project. Students carrying out research abroad must either go through the CC IRB process before leaving or must have good access to email and a printer (for consent forms) at the research site. The CC IRB recommends printing information from the CC IRB webpage before traveling and bringing the information along. Students' program directors or faculty members off campus should review the IRB application and write the required email of support unless an on-campus advisor has already done so. Students planning to use international research for a thesis project require the same email of support from their thesis advisor as do all students carrying out human participants research for a thesis; this email of support is discussed more fully below.

Student researchers studying under the auspices of programs with their own IRB process (such as the SIT program) go through that IRB process instead of the CC IRB process. Colorado College is committed to making sure that the IRB process in such cases is sound.

More information is available at https://www.coloradocollege.edu/other/irb/research-types/the-irb-and-international-research.html.

6B. Primary/Secondary Classroom Research

Information about educational research is available at https://www.coloradocollege.edu/other/irb/research-types/educational-research.html. While the educational exemption may be appropriate for certain kinds of educational research (see the form on the IRB homepage), educational research involving children is subject to various restrictions as discussed elsewhere in this document.

6C. Other Research with Children

Children are considered vulnerable participants and require special protections; see pages 23-24 above. Children cannot legally consent to participate in research and must go through an assent process instead, one in which parental permission is also required unless it has been waived.

For more information, see https://www.coloradocollege.edu/other/irb/research-types/research-with-children.html and (for further federal government guidance) https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html.

6D. Research with Prisoners

Prisoners are also considered vulnerable participants; at Colorado College, students may only carry out research involving prisoners as part of a larger research team headed by a faculty or staff member. For more federal guidance on research with prisoners, see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-approving-research-involving-prisoners/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html.

6E. Internet/Social Media Research

In certain regards research that uses the internet or social media to either recruit participants or collect information is similar to face-to-face research. However, there are several important differences that fall under categories addressed earlier in this document:

- Risk/benefit ratio: because it is harder to verify that participants are who they claim to be in online research, a research project may turn out to have very little benefit to academia or society, and thus fail to fall on the "benefit" side of the risk/benefit ratio
- Recruitment methods and advertising material: the internet may be used to advertise both internet and other types of research in a wide range of ways; the IRB must review all types of recruitment material as part of a research application
- Informed consent process and documentation: online consent processes may need modification, both to address internet research-specific potential confidentiality and privacy issues and to make the consent process easy enough to keep potential participants from dropping out during the consent process; also, studying online communities raises unique consent issues

- Deception and incomplete disclosure: it can be difficult to guarantee a good debriefing process in internet research
- Privacy and confidentiality: issues of privacy are complicated in research involving online communities, and confidentiality may be more difficult due to data security challenges
- Vulnerable participants: children in particular are problematic as internet research participants and the Colorado College IRB will generally recommend against CC students carrying out internet research involving children

These points are elaborated on in a separate document available on the IRB internet/social media research webpage (https://www.coloradocollege.edu/other/irb/research-types/internet-social-media-research.html). Researchers carrying out internet/social media research are expected to read that webpage and this new supplemental document before applying for IRB approval.

One additional issue involves the fact that survey platforms, internet websites and social media have their own terms of service (TOS) and/or end user license agreements (EULA) including privacy policies; research protocols and consent processes must not in any way contradict any of the TOS or EULAs of the platforms, social media, etc., used in the research. As an example, it is important to be sure the platform in question allows researchers to use the platform to conduct research in the first place. FaceBook has a Statement of Rights and Responsibilities which says, in part, "If you collect information from users, you will: obtain their consent, make it clear you (and not Facebook) are the one collecting their information, and post a privacy policy explaining what information you collect and how you will use it." Researchers should provide information about the TOS and EULA of any platform or website they are using in their protocol in order to demonstrate to the IRB that there are no conflicts or contrasts between the protocol (including the consent process) and the TOS and EULA. (Qualtrics is known to have successfully addressed a number of these issues, and as it is the survey platform licensed by Colorado College, the CC IRB strongly recommends that all CC researchers carry out survey research using Qualtrics.)

6F. Research on Illegal Activities

Please see the CC website subpage on this topic:
https://www.coloradocollege.edu/other/irb/illegal-and-illicit-behavior.html.

6G. CC-Specific Student Research: Venture Grants, Sheffer Grants, Gaylord Grants

Venture grants count as a special type of research (and are treated as such on the IRB application form) because they involve going through a larger process in which the Vice Provost's Advisory Committee (DAC) must be notified that an application has either been approved or exempted by the IRB or does not require IRB approval before the VPAC can approve the venture grant.

Despite this distinctive issue the IRB submission process for venture grant-related applications is identical to the submission process for other types of research regardless of research location. The only practical difference is that the Permanent Chair of the IRB informs the VPAC as well as the researcher when the application has been approved or exempted from the need for approval, using the electronic Summit system.

The IRB does not review venture grant applications or answer venture-grant-related questions under any circumstances. These should be directed only to the VPAC. Venture grant submissions to the IRB will not be reviewed and will delay the IRB approval process.

For Sheffer and Gaylord grants, the student researcher is responsible for informing the IRB that a project is seeking the relevant form of funding and for providing the name of the faculty member overseeing the grant to the IRB Chair.

Appendix 1: Additional Safeguards

The IRB will assess whether a project requires reviewing more frequently than on an annual basis, as well as whether a project needs any additional monitoring procedures to ensure the safety of the participants. Both of these determinations generally will be based on the degree of risk in the study. Appropriate safeguards could include monitoring of the consent process, observation of the research procedures, or review of research related results.

A1A. Data Storage and Security

Data must legally be retained for three years. For more information, see the CC IRB data security page at https://www.coloradocollege.edu/other/irb/data-security.html.

A1B. HIPPA

HIPAA stands for the Health Insurance Portability and Accountability Act. DHHS issued HIPAA regulations to protect the confidentiality of personal health care information effective April 14, 2003. Protected health information is defined as individually identifiable health information maintained or transmitted by a covered entity in any form or medium and includes: demographic information; medical history; information relating to the past, present or future physical or mental health or condition of an individual that is identifiable; the provision of health care to an individual or the payment for the provision of health care; physical examinations, blood tests, x-rays; and other diagnostic and medical procedures.

Privacy standards within HIPAA limit the use and disclosure of health information; restrict most disclosures to the minimum intended purpose; establish new requirements for access to records by researchers; and protect the confidentiality and integrity of health information.

Research protocols submitted by these components to the IRB, and which include the gathering of health or mental health information, must develop and submit a HIPAA Authorization form that contains core elements in the HIPAA Privacy Rule: description of the information to be used or disclosed; identification of the persons or class of persons authorized to make the use or disclosure of the protected health information; identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure; and expiration date or event; the individual's signature and date; and, if signed by a personal representative, a description of his or her authority to act for the individual.

Contact the IRB Chair if you need additional information about HIPAA; it will not be relevant to most IRB research at Colorado College.

A1C. Student Records: FERPA

FERPA is a federal regulation involving student records. If you are carrying out educational research for which student records will be used, please see the IRB FERPA page at https://www.coloradocollege.edu/other/irb/ferpa.html and contact the Registrar as appropriate.

A1D. Audits of Approved Protocols

Federal rules require that IRBs conduct self-monitoring activities in order to insure that researchers comply with regulations and carry out protocols as approved by the IRB. Verification can take place by observing research in progress, especially the enrollment and consenting of participants, auditing of research records on a random basis, and by establishing procedures for the receipt and proper review of complaints from participants in the research. The Colorado College IRB adheres to these methods of verification and also conducts periodic reviews to determine whether protocols are implemented as approved. Data reviewed at the time of audits may include:

- the currently approved protocol;
- recruitment procedures as implemented;
- status of participant enrollments;
- individual participant records;
- consent and assent forms as implemented and filed;
- modifications to protocols; and
- reporting of adverse events, if any.

All adverse events that are attributable to study procedures will require an audit of the respective protocol to determine compliance and to evaluate whether changes in procedures or in the consent form are warranted or if the study should be suspended until further inquiry can be conducted.

Appendix 2: Definitions of Terms

Adverse effect: An undesirable and unintended, although not necessarily unexpected, result of interventions, interactions, or collection of identifiable private information in research.

Anonymity: A research condition in which no one, including the researcher, knows the identities of research participants and cannot connect their data or information with their identities.

Approval: The IRB has indicated that the researcher may begin their collection of information from participants upon receipt of the approval of the project.

Assent: Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research. In the language of 45 CFR 46,

assent means "a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent."

Assurance: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human participants and stipulates the procedures through which compliance will be achieved.

Autonomy: The personal capacity participants should possess in research conditions to consider alternatives, make choices, and act without undue influence or the interference of others.

Belmont Report: A statement of basic ethical principles governing research involving human participants issued by the national Commission for the Protection of Human Participants in 1979.

Beneficence: An ethical principle that requires an obligation to protect research participants from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

Benefit: A valued or desired outcome; an advantage.

Children: Persons who have not yet attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

Coercion: The use of social, political, economic, institutional, emotional, physical, or some other kind of pressure to make someone do something they might not choose to do if acting only out of their own desires.

Cognitively Impaired: Having either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder or delay that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Capacity for autonomy and voluntary participation is thus impaired. Others, including people under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

Compensation: Payment or medical care provided to participants injured in research; does not refer to payment for participation in research (see Remuneration).

Competence: Used as a legal term to indicate a person's capacity to act on one's own behalf; a person's ability to understand information presented, to realize the consequences of acting (or not acting) on that information, and to make a choice (see Incompetence and Incapacity).

Comprehension: Understanding of a research project in which one may choose or not choose to participate; comprehension is one of three elements of consent (along with voluntariness and information) that make up an ethically sound consent process.

Confidentiality: A research condition in which no one except the researcher(s) knows the identities of the research participants. The treatment of information that a participant has disclosed to the researcher in a relationship of trust and with the expectation that it will not be revealed to others in ways that violate the original agreement, unless permission is granted by the participant. Confidentiality is a practical way of guaranteeing participant privacy.

Conflict of interest: A situation in which an IRB member (or their immediate family member) stands to benefit in some way from the project under review, rendering them non-objective with regard to the project review. This could include a financial stake or interest, a proprietary interest (including copyrights, patents, or trademarks), or some other kind of interest. Researchers can also have conflicts of interests which may imperil their objectivity with regard to a research project.

Continuing noncompliance: A persistent pattern of noncompliance that is likely to continue without intervention or failure to work with the IRB on a resolution.

Cooperative research: Research carried out across multiple institutions with at least one researcher at each of the cooperating institutions.

Debriefing: After running a study, explaining to a participant what happened and what the study is for, explaining any deception used in the study, asking for any remaining comments or concerns, and ensuring that the participant is left with no adverse consequences from the experience. This sometimes involves providing contact information for groups that can provide support regarding a difficult issue.

Deception: The intentional withholding of information from participants, or deception about the study's purpose and exact nature, that is deemed necessary by the researcher in order to meet the study's goals. Deception should only be used when the researcher feels that participant knowledge about the study would alter participants' behavior or responses in the study. Deception should not cause any adverse consequences to the participants, and participants should be debriefed after running the study. IRB guidelines on the use of deception should be reviewed. A study that cannot justify the use of deception may not receive IRB approval.

Demand characteristics: A bias that results when participants display characteristics because they are aware that they are being observed.

Denial of IRB approval: The convened IRB has determined that the proposed research is too harmful, has too great a risk-benefit ratio, does not have an adequate consent process, does not sufficiently protect vulnerable participants, or otherwise does not fall within the regulations and/or ethical guidelines that would permit the IRB to approve the research project. A project denied IRB approval must be substantially reconceived before it is resubmitted.

Emancipated minor: A legal status given to those individuals who have not yet attained the age of legal competency as defined by state law, but who are entitled to adult treatment because of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or

procreation. Colorado law does not permit treating 17-year-old college students as emancipated minors.

Equitable: Fair or just; used in the context of selection of participants to indicate that the benefits and burdens of research are fairly distributed (see Justice).

Ethical research: Research that follows widely held guidelines about what is ethical, moral and responsible in research settings (e.g. not plagiarizing others' work, not misreporting sources, not submitting questionable data, not destroying or concealing sources, etc.), that considers its role in the broader community and the effect of its findings on the community, and that otherwise adheres to the Belmont principles and successfully addresses IRB research concerns.

Exempt research: Human participants research activities which are minimal risk in nature and fall into one or more of the federally defined exempt research categories.

Expedited Review: Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk, for minor changes in approved research, and for selected other types of reviews.

Full Board review: Review of proposed research at a convened meeting at which the majority of the IRB members are present, including one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Guardian: An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care. In the IRB context, this includes authorization to give permission on behalf of a child for the child to participate in a research project.

Human Participant: See Participant.

Human Subject: See Participant.

Identifiable biospecimen: A biospecimen for which the identity of the participant is or may readily be ascertained by the researcher or associated with the biospecimen.

Identifiable private information: Private information for which the identity of the participant is or may readily be ascertained by the researcher or associated with the information.

Incapacity: Refers to a person's mental status and means the inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and/or to make a choice (see Incompetence).

Incentive: Payment or non-monetary reward provided in order to encourage potential participants to participate in a research project.

Incompetence: Used as a legal term to indicate the inability to manage one's own affairs.

Informed consent: The principle that potential participants are given adequate and accurate information about a study before they are asked to agree to participate, and that they do in fact agree (consent) to participate. In giving informed consent, participants many not waive or appear to waive any of their legal rights, or release or appear to release the researcher, the sponsor, the institution or agents thereof from liability for negligence. A complete informed consent process includes information about the project, comprehension by the potential participant, and voluntariness (the freedom of the potential participant to choose either to participate in the research or to choose not to do so.

Institutional Review Board (IRB): A specially constituted review body established or designated by an entity to protect the welfare of human participants recruited to participate in biomedical or behavioral research. Responsible for the ethical oversight of all research involving human participants conducted by faculty, students or staff, as well as such research conducted by outside researchers.

Institutional Review Board (IRB) approval: 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.

Institutional Review Board (IRB) exemption: The determination by the IRB that a project is of no greater than minimal risk of harm and that it falls within one or more of the federally designated exemption categories.

Institutionalized: Confined, either voluntarily or involuntarily (for example, in a hospital, prison, or nursing home).

Intervention: Physical procedures by which information or biospecimens are gathered and/or manipulations of the participant or the participant's environment that are performed for research purposes.

Interaction: Communication or interpersonal contact between researcher and participant.

Justice: An ethical principle that requires fairness in the distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly (see Equitable).

Legally authorized representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective participant to the participant's participation in the procedure(s) involved in the research.

Minimal risk: A risk is minimal where 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.

Minor noncompliance: Minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures which do not pose risk to participants and/or that do not violate participants' rights and welfare.

Monitoring: The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and participant protections.

Non-affiliated member: Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community and may be a minister, business person, attorney, or teacher, or have some other role.

Noncompliance: Failure to follow the federal regulations, the requirements or the determinations of the IRB.

Outside researcher: A researcher from a different institution carrying out research involving members of the Colorado College community.

Participant observation: Observation performed by an observer who takes part in the activities they observe.

Non-participant observation: Observation performed by an observer who does not take part in the activities they observe.

Parent: A child's biological or adoptive parent.

Participant: Living individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human participants are defined as: living individual(s) about whom an researcher (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Permission: The agreement of parent(s) or guardians to the participation of their child or ward in research.

Prisoner: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities.

Privacy: A person's capacity to control the extent, timing, and circumstances of sharing information about themselves with others.

Private information: 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (such as a medical record).

Protected health information: Individually identifiable health information maintained or transmitted by a covered entity in any form or medium and includes demographic information, medical history, information to the past, present, or future physical or mental health condition of an individual that is identifiable, the provision of health care to an individual or the payment for the provision of health care, physical examinations, blood tests, x-rays, and other diagnostic and medical procedures.

Protocol: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Related adverse event: An adverse event associated with or having a timely relationship with some aspects of the research in question. Related events may be definitely, probably, or possibly related.

Remuneration: Payment for participation in research; this is different from compensation, which typically refers to payment for research-related injuries (see Compensation).

Research: A systematic investigation (the gathering and analysis of information) designed to develop or contribute to generalizable knowledge, meaning to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. Activities that constitute this definition constitute research for the purpose of this policy whether or not they are conducted or supported under a program that is considered research for other purposes, and whether or not they are published or presented formally.

Researcher: Sometimes called investigator or principal investigator (PI), the lead person who is responsible for the design, conduct, and reporting of a research project. The researcher is responsible for initiation of an IRB review, completing all required training, completing the IRB application form or exemption request form, and gathering all required documentation and signatures. The researcher is also responsible for requesting IRB approval for any protocol changes after IRB approval and for reporting any adverse events taking place during the research.

Respect for persons: An ethical principle requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Review (of research): The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

Revision of IRB Application: The IRB Chair or another member carrying out an expedited review, or the full Board, has determined that an application does not yet meet the federal criteria for approval but that with one or more revisions it would meet those criteria. The IRB assumes that any application receiving a revision request will be revised and resubmitted.

Risk: The probability of harm or injury (physical, psychological, social, economic, or other forms) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant (see Minimal risk).

Serious adverse event: an adverse event that is fatal or life-threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability; or an event which based upon appropriate medical judgment may jeopardize the participant's health and requires medical or surgical intervention to prevent one of the outcomes listed above in this definition.

Serious noncompliance: Noncompliance that adversely affects participants. It may involve substantive harm or a genuine risk of substantive harm to the safety, rights, or welfare of participants and/or may substantively compromise the effectiveness of Colorado College's human research protection program.

Social/behavioral/educational research: Research that is focused on social, behavioral, or educational topics rather than on biomedical topics. Almost all social science research falls into this category.

Suspension of IRB approval: Temporary or permanent withdrawal of IRB approval for some or all research procedures short of termination of IRB approval.

Systematic investigations: Studies that are intended and designed to collect information about human participants with the purpose of drawing conclusions and reporting research findings.

Termination of IRB approval: Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study.

Unexpected adverse event: an adverse event that has not been previously observed or is not consistent in nature, severity, or frequency with existing risk information, such as in the researcher's brochure, research protocol, consent form, or other available information.

Undue influence: A situation in which someone other than the potential research participant has formal authority, political power, or some other kind of power over the potential research participant and uses that power (the "undue influence") to coerce or force the potential research participant to participate in the research against their wishes or their own sense of what would be best for them.

Voluntariness: Freedom from coercion, duress, or undue influence or inducement.

Voluntary participation: The principle that study participants choose to participate or not participate in a research project of their own free will, rather than being coerced or forced to participate.

Vulnerable populations/participants: Any person or population that may be relatively or absolutely incapable of refusing to participate in research. Such populations/participants include, but are not limited to, children/minors, developmentally delayed adults, prisoners, pregnant women, and economically or educationally disadvantaged individuals.

Appendix 3: Additional Information about the IRB

A3A. IRB Registration/Federal-Wide Assurance

The Colorado College IRB is registered with the federal government as IRB00005077 Colorado College IRB #1. The IRB's Federal-Wide Assurance number is FWA00009502.

A3B. IRB Chair

The Permanent Chair of the IRB currently holds this position as part of a larger set of duties associated with assessment and program review. As noted by the title, the position is permanent and does not rotate; all other positions on the IRB rotate regularly.

The duties of the Permanent Chair of the IRB are as follows:

- Review all IRB applications and exemption requests
- Determine whether applications require approval or whether they fall outside the purview of IRB approval (not human participants research as federally defined; exempt from review under one of the federal exemption definitions)
- Work with each applicant to address any issues until the application is ready for approval
- Determine whether a particular application requires full-Board review or advice from others with expertise the Permanent Chair does not have, and follow up to receive input from others as appropriate
- Inform the applicant of approval and inform others where appropriate (the Vice Provost's Advisory Committee for Venture Grant-related IRB applications; Sheffer faculty advisor for Sheffer Fund IRB applications; Gaylord faculty advisor for Gaylord Fund IRB applications)
- Carry out campus education through classroom visits and through the development of other types of materials for students and faculty
- Monitor changes in federal regulations and institutional policy for the protection of research participants
- Engage in continued professional development through reading, organizational membership as appropriate, and attending conferences and workshops
- Respond to IRB-related questions
- Keep documentation of all IRB-related activities
- Serve as convener for the IRB, including scheduling meetings as necessary
- Maintain and regularly improve the IRB website

A3C. IRB Membership

Members shall be appointed to the IRB such that requirements of 45 CFR 46 paragraph 107 are met:

- Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of the members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of participants that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of participants.
- The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

The Colorado College IRB consists of the Chair and, as required by the federal regulations, at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Colorado College.

Faculty members of the IRB are appointed by the Colorado College Faculty Executive Committee and staff members by Staff Council. Members other than the chair and the external member serve two-year terms. The external member is recruited by the Chair.

Where the IRB membership is lacking in expertise in an area relevant to a research project, the IRB is authorized to work with expert consultants in the relevant area. The CCIRB will make use of consultants in cases where an application involves research on a particular group of vulnerable participants (such as prisoners) and the committee has no member with particular expertise in this vulnerable population. Consultants will generally come from the population under study (e.g., a former prisoner), or be an advocate-expert for the population (a prisoners' rights attorney), and may be both.

A3D. Training of IRB Chair and Members

The Permanent Chair of the IRB must have completed the Human Research Protection Training offered online by the Office of Human Research Protections (https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html) and must be committed to continuing education through reading, online trainings such as webinars, and attendance at conferences, workshops and seminars. The CCIRB maintains a small library with which the Permanent Chair must be familiar.

New IRB members must complete the training described above and must provide a copy of their certificate to the Permanent Chair by the second block of their first year of service.

A3E. Training of Student Researchers

Students carrying out research involving people as participants are expected to receive the appropriate training from their professors or advisors, or to complete the Collaborative Institutional Training Initiative (CITI) online courses in the case of summer research.

A3F. IRB Meetings

The Colorado College IRB will meet on an as-needed basis only. Because virtually all of the projects carried out at Colorado College do not fit the legal definition of research, are legally exempt, or fall into the expedited category, the IRB only needs to meet as a convened body in cases where a project would qualify for full-Board review.

If a meeting is needed, the IRB will be contacted at least two weeks before the earliest possible meeting date with all relevant information including any applications and supplementary material.

The IRB Chair is responsible for calling the meeting to order and leading it, assigning an IRB member to take minutes, ascertaining that no one present has a conflict of interest (and of making sure they recuse themselves from the relevant vote if there is a conflict of interest), ensuring that IRB members are free to participate in discussions, leading the discussions, ensuring that IRB members attending virtually can equally and actively participate in all discussions and vote, for making sure that any applications under review either receive a vote or that any move to table the application is appropriate, and for recording the results of all votes.

IRB meetings require a quorum to conduct business. An IRB quorum consists of one half of the regular membership plus one person. If a quorum is present and a nonscientific member is in attendance as part of the quorum, a meeting is considered properly constituted. If the quorum is lost, no votes may be taken until the quorum is regained.

All meetings of the IRB are documented in written minutes to include an agenda of topics, attendance, protocols reviewed, actions taken, voting results, reasons for requiring changes in a project, or reasons for disapproving, suspending, or terminating a project. These minutes are available for review and action by IRB members at subsequent meetings.

A3G. IRB Member Conflicts of Interest

Faculty IRB members are routinely drawn from the community of social science researchers at Colorado College. As such, it is not uncommon for an IRB member to be working on a research project for which they themselves need IRB approval. No conflict of interest is posed if the application is for a project that can be reviewed by the Permanent Chair alone. However, in the case of an application that requires full-Board review, the IRB member who has submitted the application must recuse themselves from deliberations and voting about the application at the meeting where the application is discussed. The IRB member should be present for discussion of all other applications during the meeting.

A3H. Campus Education about Legal and Ethical Human Participants Research

The IRB Chair is responsible for carrying out campus education about legal and ethical human participants research, including visiting classes and department meetings and carrying out individual meetings with any faculty member, staff member, or student who has questions about the IRB process or about general ethical research principles. The IRB website is also used for campus education. The Chair will carry out such educational processes and maintain and update the website as possible, and will use situations such as federal regulations changes or new information gained from professional development training to generate new trainings or website materials.

A3I. Communications from the IRB

The IRB normally begins interacting with a researcher when the researcher's application or exemption request arrives. However, in some cases a researcher may call or email with questions before submitting a application. The IRB must make a good-faith effort to respond to such questions as quickly as possible in order not to delay preparation of the application or exemption request.

Once an application has been received and reviewed, the IRB Chair may contact the researcher for a variety of reasons:

- To obtain more information if an attachment to the application (for example, a consent form) is missing or if some questions on the application form were not answered;
- To request modifications to the application or supporting materials necessary for IRB approval; and/or
- To convey approval of the application or exemption from the need for further review

The IRB Chair will also, at the request of approved faculty researchers, contact grant sponsors or other external bodies with a formal letter indicating approval of the application. In such a circumstance, the Permanent Chair will work with the faculty member to develop a letter appropriate for the particular situation.

A3J. Documentation and Record-Keeping

According to 45 CFR 46:
(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:
(1) Copies of all research applications reviewed, scientific evaluations, if any, that accompany the applications, approved sample consent forms, progress reports submitted by researchers, and reports of injuries to participants.
(2) Minutes of IRB meetings which 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, including the rationale for conducting continuing review of research that otherwise would not require continuing review;
(4) Copies of all correspondence between the IRB and the researchers.
(5) A list of IRB members in the same detail as described elsewhere
(6) Written procedures for the IRB in detail
(7) Statements of significant new findings provided to participants
8) The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk
9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy
(b) 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. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

The IRB maintains all legally mandated documentation in electronic form.

A3K. Periodic Review of IRB Policies and Procedures

The Colorado College IRB Standard Operating Procedures will be reviewed at least every five years for determination of whether new federal regulations, local cultural practices, or other situations call for changes in the operating procedures. The operating procedures may also be reviewed more frequently if the IRB Chair has undergone training (for example at a workshop or conference) which indicates that a review would be beneficial.

The five-year review will address the entire set of operating procedures. Training-related reviews may focus more specifically on the topic or topics covered in the training.

A3L. Posting of this Document

The IRB Chair is responsible for creation, modification, and posting of this document on the IRB website on a page dedicated to it

Appendix 4: Information about IRB Website and Forms

The Colorado College IRB has a website located at http://www.coloradocollege.edu/other/irb/. This website provides information needed to complete an IRB application or exemption request and is a repository of a wide range of additional information about IRB laws and ethical research. As a courtesy to applicants, all IRB forms and templates are kept on the IRB homepage. The webpage will be updated on an as-needed basis based on new information that the IRB Chair deems necessary for researchers and for faculty or staff serving as IRB advisors.

As of September 2021, the subpages of the IRB website include the following:

- Basic Information
- IRB Concerns: Harm
- IRB Concerns: Consent
- IRB Concerns: Vulnerable Participants
- IRB Concerns: Deception
- IRB Concerns: Confidentiality/Privacy
- Types of Research: IRB Review Categories
- Types of Research: Qualitative Research
- Types of Research: Research with Children
- Types of Research: Educational Research
- Types of Research: Internet/Social Media Research
- Types of Research: Venture Grants
- Types of Research: International Research
- Types of Research: Research Not Requiring IRB Review
- Diversity, Equity and Inclusion
- Public and Private Behavior
- Using Incentives
- FERPA and Education Research
- Illegal and Illicit Behavior
- Data Security
- Changes in the IRB Laws
- Conflicts of Interest
- Participant Questions and Concerns
- How the IRB is Staffed
- Glossary
- Professional Association Statements of Ethical Principles

As of September 2021, forms found on the homepage include the following:

- Projects Not Defined as Research Information Form
- Educational Research Exemption Determination Form
- Interaction Research Exemption Determination Form
- Benign Behavioral Intervention Research Exemption Determination Form
- Secondary Research Exemption Determination Form

- IRB Application Form
- Standard Consent Form Template
- Benign Behavioral Intervention Research Consent Form Template
- Paper Survey Consent Form Template
- Online Survey Consent Form Template
- Assent Form Template for Children Ages 14-17
- Assent Form Template for Children through Age 13
- Parent/Guardian Permission Form Template
- Release Form for Use of Photography/Video Recording
- Deception Debriefing Statement Template
- Request for Waiver or Alteration of Informed Consent Process
- Recruitment Email Template
- Recruitment Letter Template
- Modification Application for Approved Projects
- Adverse Event Reporting Form for Approved Projects