

**AUSTIN COLLEGE
INSTITUTIONAL REVIEW BOARD
STATEMENT FOR RESEARCH ON HUMAN SUBJECTS**

STATEMENT OF PURPOSE AND AUTHORITY

Austin College (hereinafter “the College”) affirms that human research subjects should be treated with dignity, respect, and with due regard for their welfare. To protect human research subjects, the College establishes the Institutional Review Board (hereinafter “IRB”). The IRB shall review all research involving human participants performed under College auspices for compliance with federal guidelines and with commonly accepted ethical standards.¹ “Research” in this context means a systematic investigation designed to develop or contribute to commonly accepted knowledge. Activities that fit this definition will be considered “research” for purposes of this policy irrespective of whether they are supported or funded under a program which may or may not be considered research for other purposes. Research in this instance is usually described in a formal protocol that sets forth a precise objective and a set of procedures designed to reach that objective.

The Institutional Review Board will in most cases assess research proposals only in terms of the ethical implications that each project may suggest for human subjects. We understand "human subjects" to include all individuals and groups from whom researchers anticipate gathering information or data necessary for the successful completion of the research design. We consider the terms “subject” and “participant” to be synonymous and these terms may be used interchangeably in this or other relevant documents. For example, all those who will be asked to subject themselves to interviews, surveys, physical or psychological testing, feats of strength or agility, etc., will be considered human subjects, and the potential risks and hazards that may arise from their participation as research participants will be assessed by the IRB in accordance with

¹ Federal requirements of IRBs are outlined by Title 45 Code of Federal Regulations (CFR), Part 46, Protection of Human Subjects (June 18, 1991), known as the Common Rule. The Office of Human Research Protections (OHRP) in the Department of Health and Human Services of the federal government oversees IRB filings for federal research. OHRP defines the Criteria for IRB approval of research as follows:

- *Risks to participants are minimized;
 - *Risks are reasonable in relation to anticipated benefits;
 - *Selection of participants is equitable;
 - *Informed consent is sought from each subject;
 - *Informed consent is appropriately documented.
- http://137.187.172.201/cbttng_ohrp/cbts/assurance/module3qset1_16.asp

This does not apply to faculty or students who clearly operate outside the contractual relationship to the College and where there is no reasonable perception that the College is involved in the project.

applicable codified rules that may exist, as well as by reference to existing normative standards.

At the same time, the Institutional Review Board will remain vigilant to ensure the protection of "research collaborators" -- here defined as faculty, staff, students, and other employees or agents of Austin College who are, for whatever reason or incentive, engaged in the conduct of the proposed research. Any potential risk, harm, exploitation, or unwarranted discomfort that might befall these research collaborators will trigger an immediate response by the members of the IRB -- a response that will involve three interrelated obligations. First, the IRB will cease any further consideration of the research proposal until after the issues are resolved -- a delay that might jeopardize the timing of the research design. Second, the IRB will offer a written and detailed explanation of its precise concerns for the security and well-being of the research collaborators. Finally, as these issues are typically heard not in the arena of research ethics, but emanate from a concern for ethical professional conduct and a respect for all persons, the IRB will forward its written concerns to the Vice President for Academic Affairs who will respond as he or she sees fit. IRB assessment of the research proposal will continue only after the concerns have been allayed.²

A. STATEMENT OF PRINCIPLES

While other principles may also apply, three general prescriptive judgments relevant to human subject research are identified in this statement. These are comprehensive and are stated at a level of generalization that should assist scientists, participants, reviewers and interested citizens in understanding the ethical issues inherent in research involving human subjects. The objective is to provide an analytical framework that will help guide the resolution of ethical problems arising from research involving human participants.

² Note the first page of JP4 (Judicial Guidelines and Procedures for the Faculty) of the Austin College *Operational Guide*:

The responsibility of a faculty member toward students is grounded in a special professional relationship that respects the dignity of each individual and that values learning and academic freedom. This relationship is many-sided: as teachers, faculty members owe their best effort to encourage the free pursuit of learning in the student; as mentors and teachers, they should be responsive and trustworthy; as professionals, faculty members are obligated to avoid any sort of exploitation arising from the position of authority inherent in the professor's role; finally as those who assess performance, faculty members are obliged to deal in an even-handed manner with students and to judge student performance fairly and impartially. (Emphasis added)

1. **Respect for persons** – Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents and second, that persons with diminished autonomy are entitled to protection. An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.

Each person should be given the respect, time, and opportunity necessary to make his or her own decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. (Such information is especially important when conducting any form of “deceptive research” or other research that depends on the misleading of any human participants). There should be no pressure to participate. When a subject is not of legal age or is deemed incompetent to consent to treatment, it is necessary for a proxy (family member, guardian, or friend) to decide consent.

The principle of autonomy requires that protection be given to potentially vulnerable populations such as children, the elderly, the mentally ill, or prisoners. Individuals in these groups may be incapable of understanding information that would enable them to make an informed decision about study participation. They are considered potentially vulnerable. Consequently, careful consideration of their situation and needs is required and extra care must be exercised to decide who will be given an opportunity to participate and who (and for what reason) will be excluded.

2. **Beneficence** – Persons are treated in an ethical manner by respecting their decisions and protecting them from harm. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do no harm and (2) maximize possible benefits while minimizing possible harms.

3. **Justice** – Justice is a difficult and complex ethical issue. Who ought to receive the benefits of research and bear its burdens is a question of justice in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some burden is unduly imposed or when some benefit to which a person is entitled is denied without good reason. Attempt at all times to distribute the risks and benefits fairly and without bias.

Keep the principles of autonomy, beneficence, and justice in mind when you are selecting participants, obtaining consent, and conducting your study. **The responsibility to protect and inform research participants is ultimately yours (all those engaged with research) and cannot be ignored or delegated.** Although you may delegate various tasks to certain team members, you cannot delegate the responsibility of protecting and informing participants of their rights.

B. RESPONSIBILITIES OF THE RESEARCHERS

1. Informed Consent - To discern the key components of informed consent, one must understand the ethical issues of research involving human participants. Research participants should be made aware of certain information, including:

a. Research Purpose: State the purpose of the research and give a fair explanation of your research procedures.

b. Research Procedures: Explain tasks and procedures from the subject's point of view (what will he or she be expected to do?). Estimate the total amount of time for the person involved in the study. Explain the frequency of procedures and include any additional costs or charges for the research procedures with estimated amounts. State why the individual is eligible to participate or what criteria will be used to determine eligibility.

c. Risks: Describe any foreseeable risks or discomforts the subject will bear. Include all reasonably common risks as well as potentially serious risks and, if possible, indicate the likelihood of occurrence. Risks may range from inconvenience to bodily pain. Do not overlook "soft" risks such as confidentiality and embarrassment. Decisions about invasive procedures will always involve a degree of uncertainty regarding the harmful effects. Calculating the probability that these situations will occur can aid in explaining the risks.

The view of the nature of a risk will vary from subject to subject. Be sensitive to the difficult task of determining if the subject is more of a risk taker, is ignoring the risk(s), or has not adequately understood the probability of the risk(s).

d. Benefits: Describe any benefits to the subject or others that can reasonably be expected. Benefits may range from feeling good about participation to monetary compensation to free access to an experimental drug. Be careful, however, not to oversell any benefits. Calculate the probability that these beneficial effects will occur. This will aid in determining the weight given to the benefits. If there are no benefits, clearly state this. The consent document must describe the terms of any payments used to compensate individuals for their participation. This includes the conditions under which research collaborators or research participants would receive partial payment or no payment at all. Incentives sometimes offered by companies for recruiting participants (finder's fees) are not allowed by the IRB.

e. Alternatives: State alternative procedures or courses of treatment, if any, that might be advantageous and available to the subject. Provide information on what would be considered the standard treatment(s) for the client's diagnosis. What are the subject's other options? (In non-therapeutic studies, the alternative may simply be nonparticipation.)

f. Confidentiality: The informed consent process must describe the level of confidentiality of the research data and the measures that you plan to take to ensure that confidentiality is maintained. Describe the steps that will be taken to protect the subject's privacy. Also describe under what circumstances records will be made available and to whom. Include any techniques you may use for identifying data, such as creation of a numeric code. Participants should be assured that their identity will not be disclosed.

However, in special circumstances, such as for reportable conditions like child abuse, absolute confidentiality may not be possible. If this or a similar possibility exists, then explain the circumstances under which information must be disclosed and to whom.

g. Disclosure of Potential Conflict of Interest: Researchers must inform the IRB of any conflicts of interest they have in the research, such as a stake in a company that might benefit from the research. The IRB might require that prospective participants be made aware of this information.

h. Contact Information: Give the names of people who can answer questions about the research; include the principal investigator. If the researcher is a student, include the names and phone numbers of the principal investigator and, where applicable, the faculty supervisor for questions. Furnish the contact name of a neutral third party who can explain the rights of research participants if the subject has any questions.

i. Withdrawal: Always stress the fact that participation is voluntary. State that refusing to participate will involve no penalty or decrease in benefits to which the subject is otherwise entitled. Emphasize that the individual may discontinue participation at any time without penalty or loss of benefits. If there are limitations or risks involved in withdrawal, such as a danger to the subject's well being, these must also be clearly explained.

2. Recruitment of Subjects and Collaborators

Recruitment of participants and collaborators needs to be done in a nonbiased, non-power-based manner. Participants must be made aware that they can withdraw from participation without penalty. Convenience should not be the sole factor in the selection of participants. All avenues of recruiting participants should be investigated. The following relationships can be potentially troublesome for informed consent and have important implications to be considered.

a. Teacher-Student

Special care is needed when an instructor wants to include his or her students in a research study – as either subjects or collaborators. If research participation is part of the grade for a course, the instructor must be prepared to create an alternative assignment for

students who refuse to participate. Additionally, researchers might fail to identify the need for informed consent if they perceive that the study poses no physical or psychological risks. Subjects' perceptions of risk may differ from those of researchers, so informed consent is always required. Participants or collaborators, including students, have the right to refuse involvement in a research project even if there is no identified risk.

b. Employees as participants

Colleagues, subordinates, or peers should never be placed in a compromising situation with perceived retribution for not being a research participant. Recruiting through advertisements or a third party is a better strategy for avoiding coercion.

It is the responsibility of the researcher and research assistants to read and understand these policies and procedures.

C. APPLICATION PROCESS

The review of research involving human participants is designed to result in procedures which accomplish research objectives while protecting the rights and welfare of human participants. Any research involving human participants is subject to review and approval by the IRB. To be approved, all conditions listed below must be satisfied. Failure to adequately meet any of these conditions will result in disapproval of the research proposal.

1. Investigators must provide to the IRB formal assurance of compliance with all applicable guidelines and standards by submitting an application for approval together with a copy of all relevant components of the complete research protocol. Copies of all research instruments including survey forms, observation protocols, consent forms, etc., must be attached to the application. This also includes any projected budget, letter of agreement if relevant, and estimated time required for completion.

2. Risks to human participants and research personnel must be minimized by using procedures consistent with sound research design, and risks must be reasonable in relation to anticipated benefits.

3. The selection of research participants must be equitable, and informed consent must be obtained and documented for each subject unless the IRB approves otherwise.

4. Data collection must be monitored by the researcher to ensure the safety and well-being of participants, and adequate provisions must be made to protect the privacy of participants and the confidentiality of the data collected.

The researcher initiates the review process by completing a formal application which is available on the Austin College Intranet or through the IRB. All applications must be signed by a faculty member whose role in the research is clear. All questions in the application form must be answered in detail and in a professional manner.

While it is essential to attend closely to all issues listed here (C. 1– 4), particular attention must be given to informed consent, voluntary participation and confidentiality and/or anonymity of data sources.

The main function of the IRB is judicial rather than educational. Determining ethically sound conduct, obtaining informed consent, completing any forms, and submitting a professional, well-written proposal, etc., is the sole responsibility of the researcher(s).

D. IRB REVIEW CRITERIA

The IRB uses the following criteria to review your research:

1. Risks to the participants are minimized.
2. Risks to the participants are reasonable in relation to anticipated benefits.
3. Selection of participants is equitable.
4. Informed consent is:
 - a. sought from each prospective subject or his or her legally authorized representative and
 - b. properly documented.
5. Adequate preparation is taken to protect the privacy and confidentiality of participants.
6. Adequate provisions are made for the ongoing monitoring of the participants' welfare.

E. IRB APPROVAL PROCESS

IRB review of research proposals follows one of three review processes: exemption, expedited or full review. The IRB will determine which of the three is appropriate when considering each appropriately submitted proposal. In any case approval of a proposal by the IRB must be unanimous.

1. An exemption review usually takes one to two days and is appropriate for proposals which meet federally mandated standards for exemption from further IRB review. Exemption reviews may be carried out by the chair of the IRB or by a duly designated representative. In any case, it is the responsibility of the IRB to determine whether a project is exempt, not that of the researcher.

Projects may be exempted from further review for the following reasons:

(a). The research will be conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b). Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior is exempt unless:

- (i) information is recorded in such a way that human subjects can be identified directly or through identifiers linked to the subjects; and
- (ii) disclosure of the subjects' responses could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

(c). The research involves the use of educational tests, survey procedures, interview procedures or observation of public behavior which involves only subjects who are elected or appointed public officials or candidates for public office.

(d). The research involves collection or study of existing data, documents, records pathological specimens or diagnostic specimens, if these sources are publicly available, or if the researcher records information in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects.

(e). The research evaluates or otherwise studies public benefit programs, procedures for obtaining benefits or services of such programs, or changes to such programs.

(f). the research involves taste and food quality evaluation if foods provided are wholesome, or contain ingredients at levels found to be safe by the FDA, EPA or USDA.

2. An expedited review usually takes one to two days to complete and is appropriate for proposals which meet **all** the conditions below.

(a). Risks to participants are minimal or nonexistent, and appropriate procedures are in place to safeguard the participants.

(b). Any use of data collected pertaining to participants will not reasonably cause harm or hardship to the participants, and no members of a vulnerable population are research participants.

(c). The research does not deal with sensitive aspects of the subject's own being such as illegal conduct, drug or alcohol use, sexual behavior, sexual orientation, etc.

(d). There is no deception by the researcher to the participants regarding the intended outcome of the research, and there will be no psychological, physiological, or medical tests made on the participants.

(e). Information linking a subject to data will not be kept.

3. A full review requires more time for approval and is necessary when one or more conditions for an expedited review are not met.

(a). The research could put the participants at more than minimal risk.

(b). The release of data could cause harm or hardship to participants, or participants are members of a vulnerable population.

(c). The research investigates sensitive aspects of a subject's being.

(d). The participants are deceived by the researcher in some manner, or psychological, physiological, or medical tests are made on the participants.

(e). Responses are recorded in such a manner that the participants can be identified directly or through identifiers.

4. Merit Review. Ordinarily the IRB will not review research proposals for scientific merit.

5. Research reviewed and approved elsewhere shall be presented to the IRB which may waive review requirements that ordinarily would apply to a project when the researcher has already secured approval for the particular project from an IRB at another institution that operates according to the guidelines set forth in the Austin College IRB

requirements as well as federal guidelines.³ Research reviewed elsewhere by another IRB may be subject to further appropriate review and approval or disapproval by the AC IRB. This provision also applies to collaborative research with another institution.

6. Termination or suspension of IRB approval of research. An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Such action shall include a statement of the reasons for the IRB's action.

7. Appellate Process – Negative decisions by the IRB may be appealed to the vice president for academic affairs on the grounds of a failure by the IRB to carry out a thorough and complete review in accordance with its stated procedures or on the grounds of a possible violation of the academic freedom of the investigator.

F. IRB COMPOSITION

Persons serving on the AC IRB must know current standards of professional conduct and ethical practice. Membership shall be diverse with regard to race and gender. A minimum of two from social sciences, one from humanities, and one from the clinical and/or biomedical fields shall constitute on-campus membership. An off-campus professional shall serve as a member for full reviews.

The Vice President for Academic Affairs shall appoint a chair and vice chair to serve at the pleasure of the Vice President for Academic Affairs.

The Chair of the Austin College IRB will be responsible for keeping and maintaining an accurate written log of all applications, the nature of the application, and its disposition.

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³ 45 CFR 46