Research Approval Committee Handbook

Acknowledgments

The St. Charles Community College (SCC) Research Approval Committee acknowledges Maricopa Community College for permission to use portions of their Institutional Review Board Handbook (Introduction, Information the Investigator or Project Director Provides, The IRB's Functional Relationships, Management of the IRB, Procedures of the IRB, Basic Principles, Record Requirements, Student Engaged Research, Confidentiality Guidelines, Glossary) as the model for developing guidelines for the SCC Research Approval Committee Handbook. Permission was obtained from Lori Thorpe, Maricopa Community College IRB Coordinator.

The St. Charles Community College (SCC) Research Approval Committee acknowledges Red Rocks Community College for permission to use portions of their Institutional Review Board Handbook (Introduction, Ethical Foundations and Purpose, The IRB's Functional Relationships and Memberships, Management of the IRB, Basic Principles, Record Requirements, Student Engaged Research, Conflict of Interest Guidelines, Confidentiality Guidelines, Glossary) as the model for developing guidelines for the SCC Research Approval Committee Handbook. Permission was obtained from Dr. Tim Griffin, Red Rocks Community College IRB Chair.

The Research Approval Committee has worked diligently to develop a Research Approval Process, standard operating procedures, and supporting documents and forms. This work was made possible by dedicated members including faculty and administration.

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Research Approval Committee

1. Introduction

A. Charge:

To ensure the safety of human subjects of research conducted at St. Charles Community College (SCC). The Research Approval Committee (RAC) encourages and supports the scholarly endeavors of students, faculty and staff and strives to enforce best research practices. The RAC also strives to ensure that research conducted at SCC, or with SCC faculty, staff, and or students; or by SCC faculty, staff, and students adheres to ethical research guidelines.

B. Objective

Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. SCC's RAC will review human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies are protected, that risks are no more than minimal, that all human subjects only volunteer to participate in research after being provided with proper informed consent, and that any research is conducted in an ethical manner and in compliance with established standards. The SCC RAC only has the power to review research considered exempt or expedited, and thus, any research posing a greater than minimal risk to human subjects must be reviewed by a formal, registered, and external, Institutional Review Board (IRB). SCC does not have a formally registered IRB, therefore the researcher must locate and obtain approval from a formal, registered, and external IRB on their own. With that being said, the RAC will review any external IRB approval and accept or decline the external IRB's approval. The SCC RAC does not have the power to override an IRB's disapproval. Those individuals seeking to conduct human subjects research may not solicit subject participation or begin data collection (including pilot testing) until they have obtained approval from the SCC RAC.

Research projects involving human subjects that are considered to be exempt from both SCC RAC and formal IRB review must still go through a review process. The types of research generally given the status of exempt from review include normal educational practices such as work undertaken as part of a course, educational tests when the subjects are not identified, and surveys or interviews in which the subjects volunteer and are not personally identified (however, there are some exceptions to this). **Only the RAC can determine exempt status.**

Note: The RAC can only review human subjects research. It is beyond the scope of the committee to review research involving vertebrates and/or biological hazards.

The RAC does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the RAC is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

2. Higher Learning Commission (HLC) Compliance

The RAC will work to maintain compliance with HLC Criterion Two: Integrity: Ethical and Responsible Conduct: 2.E., Section 1 in that it will see that the "institution provides effective oversight and support services to ensure the integrity of research and scholarly practice conducted by its faculty, staff, and students." The SCC RAC will do so by reviewing research conducted at SCC, or with SCC faculty, staff, and or students; or by SCC faculty, staff, and students through executing exempt and expedited reviews and requiring formal IRB (external to SCC, until SCC formally forms one) review for all other research endeavors.

3. Ethical Foundations and Purpose

The primary purpose of the RAC is to protect the welfare of human subjects used in research. The RAC bases its ethical foundations and purposes on the same federal guidelines that formal IRB's do. This section serves to inform potential investigators of where this framework stems from.

Three major documents provide the basis for the ethical foundations of U.S. federal regulations that govern research on human subjects: The **Nuremberg Code**, the **Declaration of Helsinki**, and the **Belmont Report.** The international codes of conduct (Nuremberg and Helsinki) provide a modern history on the treatment of human subjects in research. The Belmont Report provides the ethical principles and guidelines designed to protect human subjects in U.S. research.

A. Nuremberg and Helsinki

The Nuremberg Code was developed out of the Nuremberg trials in 1947 where accounts of the horrors of human experimentation during the Nazi Regime were recorded. The Code outlines the basic ethical principles that ought to govern research involving human subjects. The first principle of the Code represents the essential feature of ethical research on humans: "the voluntary consent of the human subject is absolutely essential." In order to achieve this necessary element, the Code details what is implied by this requirement: legal capacity to consent, freedom from coercion, and sufficient knowledge and comprehension of the nature of the research. The Code provides further requirements for the ethical conduct of human research including the minimization of risk and harm to the subject, a favorable risk/benefit assessment, researchers who are both qualified and who employ proper research design, and the ability for the subject to withdraw at any time during the process.

Issued by the World Medical Association in 1964, the Declaration of Helsinki outlines similar recommendations to those found in the Nuremberg Code in order to guide doctors performing biomedical research involving human subjects. Focusing specifically on medical research, this declaration documents the sources of vulnerability and ways to protect vulnerable populations in carrying out such research. It is the duty of the physician researchers "to protect the life, health, privacy, and dignity of the human subject." These international documents provide a framework for the ethical treatment of human subjects in research.

B. Belmont Report

Post-WWII efforts for ethical research in the United States resulted in a number of congressional hearings and policy changes. This culminated in the 1974 National Research Act which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged with identifying the basic ethical principles that should govern research on human subjects and creating guidelines to ensure research would be performed according to such principles. In order to achieve this, the Commission considered: (1) the boundaries between biomedical and behavioral research and medical and behavioral practice, (2) risk-benefit criteria to determine appropriate research involving human subjects, (3) proper guidelines to select human subjects for participation in research, and (4) the nature and criteria of informed consent.

The 1978 Belmont Report provides the basic ethical principles underlying the conduct of research involving human subjects. These principles are: (1) respect for persons, (2) beneficence, and (3) justice. **Respect for persons** requires the acknowledgment of individuals as autonomous agents and protection for those individuals with diminished autonomy. An autonomous person is one who is capable of self-determination in deliberating goals and acting under the direction of those goals. Such self-determination in individuals is developmental, and some individuals may lack this capability due to illness, mental disability, or other circumstances. Respect for persons protects those who are immature and incapacitated.

Application of the ethical principle of respect for persons to the conduct of research demands informed consent. Informed consent consists of three elements: information, comprehension, and voluntariness. Possible research subjects must be given sufficient information about the full nature of the research such as the procedure, the purpose, and anticipated risks and benefits. To ensure comprehension of such information, the information must be adapted to the subject's intellectual and psychological capacities. In those cases in which such capacities are immature or diminished, a third party may be authorized to act in that person's best interest. Consent is only valid when given voluntarily, free of coercion and undue influence.

Beneficence implies an obligation to secure the well-being of individuals and prevent them from harm by maximizing anticipated benefits and minimizing possible harms. Achieving this balance may involve a risk-benefit analysis to determine when it may be justifiable to take risks to seek benefits, and when such benefits do not outweigh the risks undertaken.

Application of the ethical principle of beneficence demands the systematic assessment of the probability and magnitude of risks and benefits to the subjects. It is the responsibility of the investigator to ensure that the proposed research is properly designed. It is the responsibility of the RAC to evaluate whether the risks to the subjects are justified.

4. Special Populations:

According to federal regulations, if an investigator plans to study a special population they must receive formal IRB approval (external to SCC, until SCC formally forms one). Federal regulations require that **IRB's** give special consideration to protecting the welfare of children and other particularly vulnerable subjects (those listed below). For more information visit hhs.gov.

A. Children
B. Vulnerable Populations
   i. Pregnant Women, Neonates, and Fetuses
   ii. Prisoners
C. Native Americans
D. Other Population Groups
   i. Research involving population groups such as the mentally and physically infirm, and others in conditions of dependency, helplessness, or deprivation, may require additional precautions and procedures to assure their protection. Subjects may be paid to encourage their participation. Where subjects are drawn from particularly vulnerable groups, however, compensation may under certain circumstances cast doubt upon the voluntary nature of their consent. In such circumstances, the IRB may either limit or disapprove compensation.

5. Information Principle Investigators (PIs) must provide to the RAC

A. Appropriate certification of training in Human Subjects Research.

B. Research Proposal Form

i. A Research Proposal Form must be submitted for new research and research approved by an external, formal IRB.

ii. This includes the full study description which addresses:

a. Abstract Describing Project and Purpose:

Briefly describe (a) the project or study, and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests, or other instruments are to be used, include a brief description and <u>one copy</u> of the instrument(s).

b. Methodology:

Specify who the project participants or research subjects will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State <u>how much time</u> will be required of each participant or subject. Describe procedures to which individuals will be subjected. Use additional pages if necessary.

c. Voluntary Participation:

Specify the steps that will be taken to ensure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

d. Confidentiality of Data and Privacy Protection:

Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape, and audio materials.

Note: PI's must keep all research materials for a minimum of five years after **completion** of the study.

e. Informed Consent:

Attach a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to participants.

Note: When using a student subject pool, it is imperative that students know that they are not required in any way to participate in the research taking place.

1. Principles of Informed Consent:

A. When an activity does not involve therapy, diagnosis, or management, and a professional/ subject relationship exists (e.g., participation in a research project), the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be given to the person signing the form, and a copy must be kept on file with the PI.

B. Some research may not impose the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the RAC may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

i. That the only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality, or

ii. **That the research presents no more than minimal risk of harm to subjects and involved no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the RAC may require the PI to**

provide subjects with a written statement regarding the research (e.g., a cover letter).

f. Risks to Participants:

(a) Describe any potential risks to participating individuals – physical, psychological, social, legal or other; (b) include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and (c) in research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.

g. Benefits:

(a) Describe the benefits and/or any compensation that the participating individuals can expect, and (b) describe the gains in knowledge that may results from the project or research study.

C. Any future changes to the research project must be submitted to the RAC for review and approval prior to implementation, as these may alter the status of the project. Further, any new findings that develop during the course of this study must be promptly reported to the RAC. Finally, within 30 days of the stated project completion date, a Research Status Form must be submitted to the RAC.

6. Change of Intent

A. If an instructor collects data within the classroom, solely for use in the classroom, in most cases, this does not require RAC review or formal informed consent. However, if at any time the intent of the instructor changes in such a way that they decide to use this data for publication or presentation purposes, they are required to submit a proposal to the RAC and to obtain proper informed consent. If it is not possible to obtain informed consent, this data will be deemed pilot data, and the instructor will have to obtain RAC approval and the appropriate informed consent from a new group of students. Data that has been obtained under RAC approval and within proper informed consent guidelines is the only data that can be published or presented on.

7. The RAC's Functional Relationships and Membership

B. The RAC functions administratively through the SCC Division of Academic and Student Affairs. This Division provides administrative coordination for the RAC with the various academic and administrative units within SCC.

C. The RAC advises and makes recommendations to the President and Vice Presidents, to policy and administrative bodies, and to faculty and staff on all matters related to the use of human subjects in research.

D. The RAC is composed of at least five members. Alternates and non-voting members may also be appointed, with alternates authorized to vote only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one RAC member, each alternate may represent only one regular member.

E. The RAC is composed of college representatives with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee

members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of SCC regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

F. The RAC must include both men and women, at least one member whose primary concerns are in science areas, and one whose primary concerns are in nonscientific areas.

G. No person shall be excluded from serving on the RAC based on sex, race, color, or national origin.

Membership Category	Employee	Title	Department	Phone ext:	Email
Chair	Dr. Chris Hubbard Jackson	Director	Institutional Research	8271	chubbard@stchas.edu
Vice Chair	Christina Cox	Associate Director	Institutional Research	8337	cusher@stchas.edu
Vice Chair	Dr. Felicia Emery	Biology Instructor	Bus, Sci, Ed, Math, and Comp Sci	8281	femery@stchas.edu
	Amanda Turner	Instructor of Nursin	Nursing and Allied Health	8640	aturner@stchas.edu
	Lindy McGuire	Director of Operations – Center for Healthy Living	Nursing and Allied Health	8631	lmcguire@stchas.edu
	Marvin Tobias	Professor of Psychology	Arts, Humanities, and Social Sciences	8552	mtobias@stchas.edu
	Dr. Vaidehi (Vi) Rajagopalan	Professor of Psychology	Arts, Humanities, and Social Sciences	8624	vrajagopalan@stchas.edu
	Dr. Garrett Foster	Instructor of Engineering	Bus, Sci, Ed, Math, and Comp Sci	8645	gfoster@stchas.edu

8. Management of the RAC

A. The RAC Chair has authority to sign all RAC action items.

B. The RAC Vice Chair is a voting member of the RAC and presides over the RAC in the absence of the Chair. The Vice Chair is appointed by the Chair with the concurrence of the RAC, and has authority to sign all RAC action items in the absence of the Chair. Further, the responsibilities of the Vice Chair are as follows: preparing RAC meeting agendas and minutes, preparing email correspondence, assisting PI's in submitting applications, communicating the RAC determinations to the PI as well as communicating as needed with various parties, and keeping apprised of current human subject's research developments working with the RAC chair to orient new RAC members.

C. Members and alternates of the RAC shall be appointed by the Chair of the RAC for a tenure of two to three years. However, the term of appointment may be terminated by

notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to participate for an extended period, as a consequence of unavoidable conflicting activities, the RAC Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the RAC before their term is completed for reasons of poor participation for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the RAC may be extended by mutual agreement between the member and the Chair.

D. All RAC members are required to undergo human subjects' research training at the time of their initial appointment.

E. RAC members do not receive compensation for their service

F. Consultants with competence in special areas may be used when deemed appropriate.

1. **Procedures of the RAC**
    - **A. RAC Meetings**
        - i. RAC will meet physically at least once a year.
        - ii. All other correspondence will take place via email, conference call, or other electronic means.
    - **B. Reviews**
        - i. All members of the RAC will review proposals. An external, qualified consultant may be contacted for their expertise if necessary. In order for research to be approved, a minimum of two-thirds of RAC members must vote and the proposal must receive the approval of a majority of voting members.
        - ii. RAC members involved in the research being proposed must abstain from review.
    - **C. Research Proposal Form**
        - i. Prospective PIs must submit one original with signatures and one electronic version of the "Research Proposal Form" to the Chair of the RAC. Copies of the form are available on the web site.
        - ii. Applications will be treated as Exempt or Non Exempt. Non Exempt protocols can be either Expedited or will require a full, IRB (external to SCC, until SCC formally forms one) review. These categories are further detailed below:
    - **D. Exempt Protocols**

The RAC Chair, Vice Chair, or Designee will review the Research Proposal Form to determine if the project is eligible for exempt status or expedited review, or if significant risk is inherent of the study and therefore needs a full (external) IRB review. **The investigator cannot make this decision.**

Exempt types of research typically include (adapted from IRB guidelines):

- i. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

ii. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

iii. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) of this section, if: (1) the human subjects are elected or appointed public officials or candidates for public office; or (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

v. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; (4) possible changes in methods or levels of payment for benefits or services under those programs.

vi. Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed, or (2) if a food is consumed that contains a food ingredient at or below the level found to be safe or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency for the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The RAC Chair, Vice Chair, or Designee, not the PI, shall make the determination as to whether a project is Exempt or Non Exempt.

E. Expedited protocols

This research will (1) present no more than minimal risk to human subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Categories that can be reviewed through an expedited review (adapted from IRB guidelines):

i. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

ii. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than two times per week.

iii. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    a. Hair and nail clippings in a non-disfiguring manner
    b. Deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction
    c. Permanent teeth if routine patient care indicated a need for extraction
    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
    g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during delivery
    h. Supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
    i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

j. Sputum collected after saline mist nebulization

iv. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
    a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion if the subjects privacy
    b. Weighing or testing sensory acuity
    c. Magnetic resonance imaging
    d. Electrocardiography, electroencephalography, thermography, detection or 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

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

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

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

viii. Continuing review of research previously approved by the convened RAC as follows:
    a. Where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up or subjects
    b. Where no subjects have been enrolled and no additional risks have been identified
    c. Where the remaining research activities are limited to data analysis

ix. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories

two (2) through eight (8) do not apply but the RAC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

F. Full Board Review

Required when the research is defined as (a) systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; (b) that involves human subjects (i.e. a living person about whom a researcher collects either identifiable private information OR data through an intervention or interaction); (c) **involves greater risk than minimal risk to those human subjects.**

In addition, if an investigator is seeking a federally funded grant for their research, they must submit to a formal IRB.

NOTE: The SCC RAC only has the power to review research considered exempt or expedited, and thus, any research posing a greater than minimal risk to human subjects must be reviewed by a formal, registered, and external, Institutional Review Board (IRB). **SCC does not have a formally registered IRB, therefore the researcher must locate and obtain approval from a formal, registered, and external IRB on their own.** With that being said, the RAC will review any external IRB approval and accept or decline the external IRB's approval. The SCC RAC does not have the power to override an IRB's disapproval.

If a PI must obtain SCC RAC approval before an external IRB submission, the PI must also provide the external IRB approval, once obtained, to the RAC before research can begin.

G. Actions of the RAC

The RAC may take one of the following four actions in regard to the proposed project and consent form: ***Approved, Approved Subject to Revisions, Approved Pending external IRB Approval, Tabled, or Disapproved***

i. Approved

When a project has been approved, the Chair completes the appropriate section of the Research Proposal form, signs and dates it, and distributes one copy of the form to the PI, the RAC files (original), and if appropriate, the performance site. This form constitutes certification of approval when certifications are requested from various sources (e.g., institutions, funding sources, journals, conferences).

Approval will be based on the following:

a. The extent to which the project makes explicit in design and procedures the protection of subjects' rights.

b. Sufficient justification that the potential benefits to the subject, or the importance of the knowledge to be gained, outweighs any potential risks that may be present as a result of any such deception should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative
c. Assurances of acceptable debriefing, if appropriate. It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if such information could adversely affect subsequent data collection in the same study according to the judgment of the RAC, the full explanation may be delayed for a reasonable period of time.
d. There is an explanation to this delay. In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.
e. The adequacy of facilities and other resources necessary for completion of the study and protection of the subjects' rights.
f. Anticipated benefits, if any.
g. The personal risk to the subject in relation to expected benefits.
h. The adequacy of procedures for securing informed consent from the subject.
i. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.
j. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

ii. Approval Subject to Revisions

If the project is approved subject to revisions, the Chair completes the appropriate section of the Research Proposal form, signs and dates it, and distributes it to the PI as a project approved with revisions. The PI then must respond to the restrictions as indicated by the RAC. Upon receipt and approval of the responses, the restrictions are removed and the project is then processed as an approved project and distributed as described above.

iii. Approval Pending external IRB Approval

If the project is subject to full IRB approval, but the external IRB requires SCC's RAC approval before it will review the project, then the RAC can deem the project approved pending external IRB approval. If the project is approved pending external IRB approval, the Chair completes the appropriate section of the Research Proposal form, signs and dates it, and distributes it to the PI as

approved, pending external IRB approval. Once the project is approved by the external IRB, the PI must send the RAC Chair proof of external IRB approval before they may begin research. Once the RAC is notified of external IRB approval, the RAC will update their decision to approved.

iv. Tabled

Tabled action means that the project was not sufficiently complete for the RAC to reach a final decision. In this case, the PI is notified by the Chair of the RAC and the additional information necessary for completion of the RAC review is requested. In the case of a tabled project, the PI may be invited to attend an RAC meeting to present/clarify the project for the Committee.

v. Disapproved

If the project is disapproved, the Chair completes the appropriate section of the Research Proposal form and notifies the PI in writing of the reasons for disapproval. The PI may revise and resubmit his/her project for another review.

10. Basic Principles

As previously mentioned, the basic principles that govern the RAC in assuring that the rights and welfare of the subjects are protected is based on the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report.

A. Therefore, the following principles apply to all research, **including student projects**, involving human subjects at SCC to ensure that adequate safeguards are provided:

i) Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
ii) Risks to subjects must be no larger than minimal for SCC RAC review. All other research must be sent to a formal IRB to be reviewed.
iii) Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
iv) Adequate provisions should be made for recruiting a subject population that is representative of the general population in terms of gender and minority representation, unless scientifically justified.
v) Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
vi) Participation of human subjects in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
vii) All research programs (including pilot tests) that involve human subjects must be reviewed by the SCC RAC and must receive approval ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol.

B. Minimal Risk

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. The risk to which research subjects may be exposed have been classified as physical, psychological, social, and economic.

For further details and examples: http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm

11. Record Requirements

The RAC prepares and maintains adequate documentation of RAC activities, including the following:

- **A.** Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by the PI.
- **B.** Detailed minutes of RAC reviews, showing:
    - i. Members present (any consultants/ guests/ other shown separately)
    - ii. Results of discussions on debated issues and record of RAC decisions
    - iii. Record of voting (showing votes for, against, and abstentions)
- **C.** Copies of all correspondence between RAC members including
    - i. Results of discussions on debated issues and record of RAC decisions
    - ii. Record of voting (showing votes for, against, and abstentions)
- **D.** Copies of all correspondence between RAC and the PI
- **E.** Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.
- **F.** Adverse reactions reports and documentation that the RAC reviews.
- **G.** General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least five years after **completion** of the research.

In addition, the RAC maintains a permanent record for the list of current RAC members and written procedures for the RAC.

All forms submitted or retained as evidence of informed consent must be preserved by the PI indefinitely. Should the PI leave SCC, signed consent forms are to be transferred to the RAC Chair.

12. Student Engaged Research

- **A.** Undergraduate research is to be encouraged. Learning the human subject's process is an important part of a college education. Undergraduates are to be strongly discouraged from engaging in research that poses more than minimal risk to subjects, as they are unlikely to have received sufficient training or experience to safely conduct such research. Faculty members can encourage course research activities such that students become familiar with developing research proposals that can fall into the exempt or expedited categories.

B. Procedures

i. Classroom projects that involve systematic collection of data and for which the research objective or design is to develop or contribute to generalizable knowledge are considered research. If the student or instructor plans to use the data outside of the educational setting, then the project is considered research. Such projects should be reviewed by the RAC.
ii. Classroom projects that are designed with the objective of providing students with training about and experience with research methods are not considered research. In these cases, students will not use the data outside of the educational setting. Such projects do not require RAC review.

C. Responsibility of Faculty as Course Instructors

i. Faculty are responsible for overseeing their student's conduct of a research project. They have the primary responsibility for ensuring that human subjects are treated ethically in research.
ii. Faculty will inform students of the ethical principles for the protection of human subjects in research. This includes providing students with training about human subject's research through the previously defined training course.
iii. Sponsoring faculty are responsible for student research and thus must serve as the PI and provide his/her signature on the application. The student can be identified as the Co-PI.

13. Conflict of Interest Guidelines

A. A RAC member is said to have a conflicting interest whenever that RAC member, or spouse, or dependent child of the member:

i. Is a PI or Co-PI on the project;
ii. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the RAC; or
iii. Has identified him or herself for any other reason as having a conflicting interest.

B. It is the responsibility of each RAC member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before the RAC of which they are a member. If the RAC member feels that he or she may have a conflict of interest, the RAC member must notify the RAC Chair immediately so the RAC member may be excused from that review.

If the Chair of the RAC or another RAC member should perceive a conflict of interest, they have a responsibility to bring this matter to the attention of the RAC Chair and the RAC.

C. Typically, there are three phases of an RAC's consideration of a matter: discussion, deliberation and actions (including vote). In general, RAC member(s) who have a real or perceived conflict of interest may remain in the meeting room at the discretion of the RAC Chair during the discussion of the matter in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. RAC review minutes will reflect the absence of a member (by name) when he or she abstains from deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

14. Confidentiality Guidelines

A. Research proposals often include confidential, sensitive or competitive data and information. Examples include personally identifiable information which is outside the scope of what is considered "directory information" provided on SCC students and employees, financial information about students or programs, and innovative programmatic activities.

B. Members will keep confidential and refrain from discussing any such data or information outside of the RAC review. This information will remain confined to the RAC review. Detailed minutes will be recorded and stored in a confidential manner.

APPENDIX 1: Glossary

Adverse Event: An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

Autonomy: Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects.

Beneficence: An ethical principle discussed in the *Belmont Report* that entails an obligation to protect persons 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.

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

Confidentiality: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Debriefing: Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

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

Full IRB Review: Research that is reviewed at a convened meeting at which a majority of the membership of the IRB are present, including at least 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.

Human Subjects: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Informed Consent: A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Institutional Review Board: A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Justice: An ethical principle discussed in the *Belmont Report* requiring fairness in distribution of burdens and benefits; it is often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

Privacy: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Protocol: The formal design or plan of an experiment or research activity: specifically, the plan submitted to an RAC 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 subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Research: A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

Respect for Persons: An ethical principle discussed in the *Belmont Report* requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Risk: The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk”. (See also: *Minimal Risk*).

Voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subjects decision to participate (or to continue to participate) in a research activity.