A Manual for Human Subjects Review

June 19, 2018
Cochise College acknowledges extensive use of the guidelines for human subjects review published by the University of Arizona, Arizona State University, and Pima College in the development of this manual.

Direct all questions concerning this manual and the human subjects review process to:

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2 GENERAL GUIDELINES

2.1 INTRODUCTION AND OVERVIEW
The Dean of Institutional Research, Effectiveness, and Planning (IREP) and the Human Subjects Review Committee (HSRC) are charged with reviewing and overseeing human subjects research. Anyone proposing to conduct research projects, including surveys and focus groups, at the college must obtain approval by the Dean, IREP prior to the project’s administration. Additionally, college staff who are conducting research in the community must have their research projects reviewed.

The review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed consent, assessing and minimizing risks, and maintaining privacy and confidentiality. Further, the intent of this process is to ensure that Cochise College is in compliance with federal guidelines by assuring that human beings exposed to any research procedures are adequately protected. Compliance is regulated by the Office for Human Subjects Protection (OHRP) at the U.S. Department of Health and Human Services (DHHS). Protection of Human Subjects Regulations can be found under the Code of Federal Regulations, Title 45 (45 CFR Part 46), and on the Web at:


2.2 EXEMPT FROM REVIEW
Research projects are exempt from review if they are conducted by Cochise College instructors or students in their classes or by departmental personnel within their own department and if the data collected do not contain personally identifiable information.

2.3 PROCEDURE
Researchers who are not affiliated with Cochise College are required have their projects reviewed by the Dean, IREP, prior to proceeding. Students and employees of the college are encouraged to contact the Dean, IREP, to determine what human subjects process, if any, is required before conducting the research project.

The process begins with the Dean, IREP, determining the potential risk level, as listed below. If the project is determined to pose no risk then a formal application is not required; however, researchers not affiliated with the college are still required to obtain permission to proceed and subsequently submit a follow-up report for all studies.

If the research project is considered a minimal or greater risk then the researcher must submit an human subjects application. That application is reviewed by the Dean of IREP and a written response is provided to the researcher, including assignment of risk level. If the project is not approved then the response will also include justification for that decision and instructions on how the researcher can appeal that decision.

2.3.1 Step One: Determine the Research Project’s Risk Level
Before any other action is taken, the primary investigator should contact the Cochise College IREP office and ask that the risk level for the research project be determined. If the risk level is “no risk” or “minimal risk” then an expedited approval process can be used which would save the primary investigator significant time and effort. Following are the potential risk levels for research projects.
• **No Risk:** Projects which are perceived to have no risk are not required to undergo a formal review by Dean, IREP. Projects that are determined to have no risk include in-class surveys, student projects that involve no outside subjects, faculty surveys of their own students, and similar projects.

• **Minimal Risk:** Projects are considered minimal risk when they exceed the no risk level but still pose little risk to the subjects. These projects will be approved by the Dean, IREP, and assigned to expedited review by the HSRC. The most common type of minimal risk research include things like surveys, interviews, oral histories, focus groups, or program evaluations where no personally-identifiable information is gathered.

• **Moderate or Substantial Risk:** Projects deemed by the Dean, IREP, to have moderate or substantial risk to human subjects will be assigned to the HSRC for resolution. Categories in this group would include studies with vulnerable populations, studies that employ deception, international studies, and studies where information may be disclosed that could require mandatory legal reporting.

### 2.3.2 Step Two: Submit an Application

When an application is necessary, the following checklist will be used to ensure that researchers have completed and submitted all the required documentation for the Human Subjects Review process:

1. Completed Application for Human Subjects Review
2. Research Proposal
3. Supporting Materials: Research Instruments, Interview Protocols, etc.
4. Consent Form(s)
5. Researcher’s Vita or Biographical Sketch
6. Verification of the researcher’s completion of a Human Subjects Protection Program training
7. Signed IRB Approval from Home Institution or Request for Provisional Approval if required by Home Institution
8. Site Access Approval(s)
9. Confidentiality Statement

All materials must be submitted before evaluation of the research project begins. Applications should be submitted at least one month prior to the anticipated project start date to the Dean, IREP.

Properly completed forms can help prevent delays. The forms are available from the Office of Institutional Research, Effectiveness, and Planning web site:

[https://www.cochise.edu/ie/humansubjectsreview/](https://www.cochise.edu/ie/humansubjectsreview/)

### 2.3.3 Step Three: Response

The Dean, IREP, will formally respond to all requests for human subjects research projects. However, research projects may also be subject to further review by Cochise College senior administration. Moreover, if the project is being performed at a facility not associated with Cochise College, the researcher has the responsibility of also complying with that organization's guidelines.

### 2.4 Human Subjects Protection Program Training

Certain research projects may require the primary investigator to complete formal Human Subjects Protection Program (HSPP) training. An HSPP certificate that is less than four years old from another college or university is acceptable for a research project at Cochise College. Researchers who need HSPP training can complete an online course made available through the University of Arizona without charge. The primary investigator should access [CITI HSPP Training](https://www.cochise.edu/ie/humansubjectsreview/) and select the University of Arizona as the organization affiliation. Then, follow the prompts to create a user name/password through the main
registration page. (Note: there is an option for the University of Arizona Single Sign On (SSO) but Cochise College researchers need to use the “Create Your CITI Program Username/Password” option.) For Step 7 of the process, select “Human Subjects” training and on the next screen select “Undergraduate Level BASIC Course.” The undergraduate course is the most basic of the HSPP training and is normally adequate for research at Cochise College, but the primary investigator may be required to complete a different course, like the Social & Behavioral Research BASIC Course or Native American Course, if that is more appropriate for the research being conducted.

2.5 STUDENTS AS RESEARCH SUBJECTS
Students play an integral role as subjects in research concerning topics like teaching methods; however, it is critical that students’ participation is voluntary. The classroom environment, by its very nature, creates unintentional coercion due to the relationship between the student and instructor. For this reason, instructors must avoid involving their own students as research subjects. Faculty who wish to involve their own students as subjects should be able to provide a good scientific reason, rather than convenience, for selecting those students as research subjects. The research project should be relevant to the topic of the class and participation should be part of the learning experience for the students. In instances where investigators can provide a good reason for involving their own students in their research, someone other than the primary investigator (instructor) should obtain informed consent and collect the data.

2.6 HUMAN SUBJECTS REVIEW COMMITTEE
The Human Subjects Review Committee (HSRC) will maintain fairness and impartiality in its review process and will be comprised of at least five members, diversified by race, gender, cultural background, and profession. The HSRC will be chaired by the Dean, IREP, and will include at least one member from a scientific area, one from a non-scientific area, and one person not affiliated with Cochise College who is knowledgeable about the local community. The committee will be convened as needed and the membership may change to better match the research project being evaluated.

2.7 APPEAL OF REVIEW DECISION
To appeal an initial review decision, the researcher must submit a completed Appeal of Decision Form (see Attachment 2) within 10 business days of receiving the decision. An initial decision that was rendered solely by the Dean, IREP, may be appealed to the HRSC whose decision is final. An initial decision that was rendered by the HRSC may be appealed to the Vice President for Instruction/Provost whose decision is final. After review, the appellant authority will communicate its decision in writing to the researcher.

2.8 SITE AUTHORIZATION(s)
Researchers must receive authorization from all appropriate instructional deans whose students or employees are to be subjects. If the research is to be conducted with students or employees district-wide, then approval must be obtained from the Vice President for Instruction/Provost. If the research includes subjects from organizations outside Cochise College then authorization from those organizations is also required. Authorization granted by the administrator of the area involved in a research project does not provide clearance to begin the research nor does that authorization guarantee the cooperation of faculty, staff, or students in the research project.
2.9 **Termination of the Research Authorization**

Human subjects approval is valid for one year or for a shorter interval determined by the Dean, IREP, based on the risks involved. If the research continues beyond a year, a Periodic Review Form (see Attachment 3) must be submitted to extend approval for the next year.

In addition to the routine periodic review, researchers are obligated to keep the Dean, IREP, informed of unexpected findings involving risks and to report any occurrence of serious harm to subjects. Problems of these types must be reported without delay. Failure to comply with periodic review requirements, or to immediately report problems involving risks to human subjects not foreseen in the approved protocol, will be cause for suspension or termination of the study. To the extent that the study is an integral part of any funded research project, the project scope may need to be formally altered should a study be terminated or suspended. This suspension notice will be reported to the researcher, institutional officials, and external funding sources.

2.10 **Changes in Research Design**

Any proposed change, amendment, or addendum to a protocol or consent form must be reviewed and approved by the Dean, IREP, prior to implementation. The researcher will present a letter to the Dean, IREP, describing the change, amendment, or addendum including:

1) a description of current procedures/study design
2) proposed changes in procedures/study design
3) any anticipated change in risk and/or benefit to subjects
4) any/all revisions necessary to the consent form

The Dean, IREP, has the authority to determine whether or not a proposed change, amendment, or addendum will increase risk to the subjects and to approve proposed changes that do not involve increased risk. Changes which are determined by the Dean, IREP, to substantially increase risk must be approved by the HSRC.

2.11 **Data Management**

The researcher is solely responsible to assure privacy and confidentiality to all research subjects and must provide processes to protect all data gathered. The following represents reasonable guidelines for researchers to observe.

- When a computer database with research-related information is kept the privacy and security procedures must be documented on the Application for Human Subjects Review form.
- Procedures should include physical security of the computer and memory devices, specifically designated (and limited) personnel access, and use of software security codes to permit data access and entry only to authorized research personnel.
- Information obtained from computer databases must only be used for research or to ensure subject safety.
- Hard copies containing confidential subject information must be stamped as confidential and access limited to persons with a designated "need to know" authority.
- All documentation gathered during the course of the research project must be destroyed at the end of the applicable retention period. The data may not be used for non-protocol purposes without each subjects’ written permission and may not be shared with non-involved researchers.
- At the conclusion of the research project data stored on a computer shall be removed from the computer and any storage copies kept in a secure locked site as outlined in the original protocol.
These electronically stored data must be destroyed as specified in the original Application for Human Subjects Review.

2.12 Advertising for Subjects
Advertising for prospective volunteer subjects must receive prior approval by the Dean, IREP, and the HSRC as part of the application process. Coercive statements must be avoided and any potential risks must be clearly identified. Compensation may be mentioned but no dollar amount should be indicated in any advertising. The level of compensation must be commensurate with the time and inconvenience involved and must not be in amounts which could be construed as economically coercive. The college’s Vice President for Administration should be consulted for an acceptable processes to disburse and human subject payments.

2.13 Financial Disclosures
Information regarding research funding is relevant to the extent that it may result in “undue inducement” to either the researcher or to the subjects (i.e., unjustifiable subject compensation which could have an adverse effect on the risk-benefit ratio). Consequently, the project application must include both the source and amount (either total or per-capita) of funding. The reviewing entity reserves the right to request a more detailed budget breakdown in order to assess risk-benefit in a particular study. The reviewing entity may request a clearer disclosure of expenses if these are believed to be coercive.

2.14 Liability Statement
Liability for research related injury is a legal issue and is not covered by the policies set out in this document. The contractual relationship between the sponsor, the researcher, and the institution will provide details of liability. The consent form should contain standard information as set out in the sample forms and should contain a statement such as “questions regarding liability are to be discussed with the researcher.”

2.15 Informed Consent
Informed consent is fundamental to research involving human subjects as they must participate willingly after having been informed about the research and how they will be involved. A consent form must be signed by each participant involved in the study. If research data is obtained from human subjects via online surveys, the researcher must include an “accept” or “decline” option in lieu of a signed consent form from each subject participating in the survey.

The consent form must be written in language easily understood by the subject. Technical terms should be avoided or if needed, explained thoroughly in simple language. The following elements should be addressed in an informed consent form:

1. Nature and purpose of the research
2. Nature of the subject’s involvement - what activities and for how long
3. Potential risks or discomforts for the subject
4. Potential benefits of the research for society and for the subject
5. Indication that subject’s participation is voluntary
6. Indication that subject may withdraw at any time without prejudice
7. Procedures for maintaining confidentiality/anonymity
8. Name and phone number of the person who the subject is to contact with questions or concerns about the research
9. Statement of liability, including indication that the subject does not waive any legal rights by signing the form
10. Signature by subject agreeing to participate in study and by researcher attesting to disclosure requirements and legality of subject’s signature

Sample forms are provided in the pages that follow. Forms One and Two are to be used for research projects deemed to have Moderate to Substantial Risk and Forms Three and Four for projects with no more than Minimal Risk.

2.16 RESEARCH REPORTS AND PUBLICATIONS
At the conclusion of the study, the researcher is required to provide Cochise College with copies of documents such as annual or final reports to granting agencies, papers presented at professional meetings, and publications based on the research conducted through permission of the Dean, IREP, or HSRC at Cochise College. In addition, human subjects involved with the study should be provided with final results or publications should they request them.

3 SAMPLE FORMS
Sample forms used for human subjects research are provided in the pages that follow.
3.1 **INFORMED CONSENT FORM FOR ADULTS**

Read and address each numbered element of this model form in developing an informed consent form for the proposed research study. The consent form must be written in lay language and at an appropriate level to meet the needs of a specific population. Please add additional statements when appropriate.

1. [Researcher’s name], who is [title/position], has requested my participation in a research study at this institution. [Place title of project and page number at top of all pages of consent form.]

2. **I have been informed that the purpose of the research is to...** [Describe the justification for the research. If appropriate, indicate the number of subjects involved and why the subjects are included.]

3. **My participation will involve...** [Describe the subject’s participation and identify those aspects of participation, which are experimental. Indicate the expected duration of the subject’s participation. If the subjects are students, patients, clients or employees, advise that nonparticipation or withdrawal from the study will not affect their grade, treatment, care, employment status, etc., as appropriate.]

4. I understand there are foreseeable risks or discomforts to me if I agree to participate in the study. The possible risks are... Possible discomforts include... [Any foreseeable risks or discomforts are to be explained/described.] OR There are no foreseeable risks or discomforts. [If this sentence is applicable, delete #8.]

5. I understand that there are alternative procedures available. Alternative procedures include... [Describe any alternative procedures to be included in language the subject can understand.] OR There are no feasible alternative procedures available for this study. If the study includes no intervention, you may delete #5 entirely.

6. I understand that the possible benefits of my participation in the research are... [Describe the benefits of participants, or lack of benefits, to the individual subject as well as to society.] OR I understand that although there may be no direct benefits to me, the possible benefits of my participation in the research are...

7. I understand that the results of the research study may be published but that my name or identity will not be revealed. In order to maintain confidentiality of my records, [researcher’s name] will... [Indicate specifically how the researcher will keep the names of the subjects confidential, the use of subject codes, how this information will be secured, and who will have access to the confidential information. “Confidentiality will be maintained” is not acceptable.]

8. I understand that in case of injury I can expect to receive the following treatment or care which will be provided at my expense: [If more than minimal risk of foreseeable injury is anticipated, describe the facilities, medical treatment, or services which will be made available in the event of injury or illness to a subject.] OR If #4 indicated no foreseeable risks or discomforts, delete #8.

9. **I have been informed that I will be compensated for my participation as follows:** [If compensation is to be provided to subject, include amount of compensation, method of payment, and schedule for payment including whether payment will be made in increments or in one lump sum.] OR **I have been informed that I will not be compensated for my participation.**

10. I have been informed that any questions I have concerning the research study or my participation in it, before or after my consent, will be answered by [name of individual, address, and telephone number]. [This refers to the researcher. In the event the researcher is a student, the name of the doctoral or thesis advisor (responsible faculty member, outside institution, or thesis advisor) must be included.]

11. I understand that in case of injury, if I have questions about my rights as a subject/participant in this research, or if I feel I have been placed at risk, I can contact the Dean, Office of Institutional Research, Effectiveness, and Planning. [This information must be included on all consent forms. If
#4 has indicated “no foreseeable risk, or discomfort,” then first phrase (I understand that in case of injury) should be omitted.

12. I have read the above informed consent. The nature, demands, benefits and any risk of the project have been explained to me. I knowingly assume any risks involved. I understand that I may withdraw my consent and discontinue participation at any time without penalty or loss of benefit to myself. In signing this consent form, I am not waiving any legal claims, rights, or remedies. (I can obtain further information from [name of Researcher plus his/her degree] at [address and phone number]). A copy of this consent form will be given to me.

13. [Release statement for videotaping or relinquishing confidentiality inserted here if applicable.]

________________________________________________________   ________________
Subject’s Signature     Date

14. “I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature.”

15. “I have provided the subject/participant a copy of this signed consent document.”

________________________________________________________   ________________
Researcher’s Signature     Date
3.2 INFORMED CONSENT FORM FOR MINORS

Read and address each numbered element of this model form in developing an informed consent form for the proposed research study. The consent form must be written in lay language and at an appropriate level to meet the needs of a specific population. Please add additional statements when appropriate.

1. [Researcher's name], who is [title/position], at Cochise College has requested my minor child’s (ward’s) participation in a research study at this institution.
2. I have been informed that the purpose of the research is to... [Describe the justification for the research. If appropriate, indicate the number of subjects involved and why the subjects are included.]
3. My child’s (ward’s) participation will involve... [Describe the subject’s participation and identify those aspects of participation, which are experimental. Indicate the expected duration of the subject’s participation. If the subjects are students, patients, clients or employees, advise that nonparticipation or withdrawal from the study will not affect their grade, treatment, care, employment status, etc., as appropriate.]
4. I understand there are foreseeable risks or discomforts to my child (ward) if he/she agrees to participate in the study. The possible risks are... Possible discomforts include... [Any foreseeable risks or discomforts are to be explained/described.] OR There are no foreseeable risks or discomforts. [If this sentence is applicable, delete #8.]
5. I understand that there are alternative procedures available. Alternative procedures include... [Describe any alternative procedures to be included in language the subject can understand.] OR There are no feasible alternative procedures available for this study. If the study includes no intervention, you may delete #5 entirely.
6. I understand that the possible benefits of my child’s (ward’s) participation in the research are... [Describe the benefits of participants, or lack of benefits, to the individual subject as well as to society.] OR I understand that although there may be no direct benefits to my child (ward), the possible benefits of my child’s (ward’s) participation in the research are...
7. I understand that the results of the research study may be published but that my child’s (ward’s) name or identity will not be revealed. In order to maintain confidentiality of my child’s (ward’s) records, [researcher’s name] will... [Indicate specifically how the researcher will keep the names of the subjects confidential, the use of subject codes, how this information will be secured, and who will have access to the confidential information. “Confidentiality will be maintained” is not acceptable.]
8. I understand that in case of injury my child (ward) can expect to receive the following treatment or care which will be provided at my expense: [If more than minimal risk of foreseeable injury is anticipated, describe the facilities, medical treatment or services which will be made available in the event of injury or illness to a subject.] OR If #4 indicated no foreseeable risks or discomforts, delete #8.
9. I have been informed that compensation for my child’s (ward’s) participation is as follows: [If compensation is to be provided to subject, include amount of compensation, method of payment, and schedule for payment including whether payment will be made in increments or in one lump sum.] OR I have been informed that I will not be compensated for my child’s (ward’s) participation.
10. I have been informed that any questions I have concerning the research study or my child’s (ward’s) participation in it, will be answered by [name of individual, address, and telephone number]. [This refers to the researcher. In the event the researcher is a student, the name of the doctoral or thesis advisor (responsible faculty member, outside institution, or thesis advisor) must be included.]
11. I understand that in case of injury, if I have questions about my child’s (ward’s) rights as a subject/participant in this research, or if I feel he/she has been placed at risk, I can contact the Dean, Office of Institutional Research, Effectiveness, and Planning. [This information must be included on all consent forms. If #4 has indicated “no foreseeable risk, or discomfort,” then first phrase (I understand that in case of injury) should be omitted.]

12. I have read the above informed consent. The nature, demands, benefits and any risk of the project have been explained to me. I knowingly assume any risks involved. I understand that I may withdraw my consent and discontinue participation of my child (ward) at any time without penalty or loss of benefit to myself. In signing this consent form, I am not waiving any legal claims, rights, or remedies. (I can obtain further information from [name of Researcher plus his/her degree] at [address and phone number]). A copy of this consent form will be given to me.

13. [Release statement for videotaping or relinquishing confidentiality inserted here if applicable.]

__________________________________________  ____________________
Signature (Father, Mother, Legal Guardian, or Legally Authorized Official)  Date

__________________________________________  ____________________
Other signature (if appropriate)  Date
3.3  LETTER CONSENT FOR ADULTS
(Typically for studies which will not exceed minimal risk)

Dear _________________________:

I am a faculty member [a student under the direction of Dr./Mr./Ms. ______________________] in the
Department of __________________________ at Cochise College. I am conducting a research study entitled
______________________________________.

The purpose of the research is to _______________________________________________. Your
participation will involve ______________________________________ (Include the expected duration of
the subject's participation). Your participation in this study is voluntary. If you choose not to participate or
to withdraw from the study at any time, it will not affect your grade (treatment/care, etc.). The results of
the research study may be published, but your name will not be used. Although there may be no direct
benefit to you, the possible benefit of your participation is _________________________________.

If you have any questions concerning the research study, please call me [or Dr./Mr./Ms.
_______________________________] at (520) ___________ - _____________________.

Sincerely,

[Insert Name]

I give consent to participate in the above study. (Release statement for videotaping or relinquishing
confidentiality must be inserted here if applicable.)

________________________________________________________   ________________
Subject’s Signature     Date

If you have any questions about your rights as a subject/participant in this research, or if you feel you have
been placed at risk, you can contact the Dean, Office of Institutional Research, Effectiveness, and Planning,
Cochise College at (520) 515-5313.
3.4 LETTER CONSENT FOR MINORS
(Typically for studies which will not exceed minimal risk)

Dear Parent:

I am a faculty member [a student under the direction of Dr./Mr./Ms. _______________________] in the Department of ________________________________ at Cochise College. I am conducting a research study entitled ________________________________.

The purpose of the research is to _________________________________. Your child’s participation will involve ________________________________ (expected duration of the subject’s participation). Your and your child’s participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, it will not affect your child’s grade (treatment/care, etc.). The results of the research study may be published, but your name will not be used. Although there may be no direct benefit to you or your child, the possible benefit of your child’s participation is ________________________________.

If you have any questions concerning the research study, please call me [or Dr./Mr./Ms. _______________________] at (520) ___________ - ___________.

Sincerely,

[Insert Name]

I give consent for my child ________________________________ to participate in the above study. (Release statement for videotaping or relinquishing confidentiality must be inserted here if applicable.)

________________________________________________________   ________________
Subject’s Signature     Date

If you have any questions about your or your child's rights as a subject/participant in this research, or if you feel you or your child have been placed at risk, you can contact the Dean, Office of Institutional Research, Effectiveness, and Planning, Cochise College at (520) 515-5313.
3.5 COVER LETTER
(Typically accompanies a questionnaire)

Dear ________________________________________:

I am a faculty member [a student under the direction of Dr./Mr./Ms. ______________________________] in the Department of ____________________________________________ at Cochise College. I am conducting a research study entitled ______________________________________. The purpose of the research is to ______________________________________. I am requesting your participation, which will involve _________________________________ (expected duration of the subject’s participation). Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, it will not affect your grade (treatment/care, etc.). The results of the research study may be published, but your name will not be used.

If you have any questions concerning the research study, please call me [or Dr./Mr./Ms.________________________] at (520) ___________ - ____________.

[If anonymous questionnaire is completed, include statement that “The questionnaire is anonymous, thereby ensuring confidentiality of responses. Return of the questionnaire will be considered your consent to participate.”]

Sincerely,

[Insert Name]
3.6 **SCRIPT FOR SUBJECT RECRUITMENT**
(For recruitment of subjects from classrooms, telephone surveys, and by personal contact)

I am a faculty member [a student under the direction of Dr./Mr./Ms. _______________________] in the Department of ____________________________ at Cochise College. I am conducting a research study entitled ____________________________. The purpose of the research is to ____________________________. I am recruiting subjects to ____________________________ which will take approximately ____________________________. Your participation in this study is voluntary. If you choose not to participate, it will not affect your grade (treatment/care, etc.). The results of the research may be published, but your name will not be used. If you have any questions concerning the research study, please call me at (520) ___________ - _____________________.
3.7 CONFIDENTIALITY STATEMENT

[TITLE OF STUDY]

CONFIDENTIALITY STATEMENT

As a researcher working on the above research study at Cochise College, I understand that I must maintain the confidentiality of all information concerning research participants. This information includes, but is not limited to, all identifying information and research data of participants and all information accruing from any direct or indirect contact I may have with said participants. In order to maintain confidentiality I hereby agree to refrain from discussing or disclosing any information regarding research participants, including information described without identifying information, to any individual who is not part of the above research study and in need of the information for the expressed purposes of the research program.

___________________________________________________________  _________________
Researcher’s Signature     Date

___________________________________________________________  _________________
Witness or Attorney Signature    Date
4 ATTACHMENTS

4.1 APPLICATION FOR HUMAN SUBJECTS REVIEW

*THIS FORM CANNOT BE HAND-WRITTEN*

<table>
<thead>
<tr>
<th>Researcher:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dept. /Office:</td>
<td>Organization:</td>
</tr>
<tr>
<td>Address:</td>
<td>City:</td>
</tr>
<tr>
<td>Phone:</td>
<td>E-mail:</td>
</tr>
</tbody>
</table>

Names and Affiliation(s) of Co-Researcher(s) (If Applicable):

Type of Review:  [ ] New  [ ] Renewal
If Renewal, are there any substantive changes?  [ ] Yes  [ ] No

Project Title:

Location of Study:

Data Collection Period: From:  [ ] (mo/yr)  To:  [ ] (mo/yr)

Site Authorization from Research Site:  [ ] Yes  [ ] No  [ ] Not Applicable
If Yes, Date:  (Attach Authorization(s) to Application)

Supported by Research Grant(s)? Please indicate funding source. Federal regulations require Human Subjects Committee to review the complete grant application

[ ] Unfunded  [ ] Funded  [ ] Seeking funding from _____ source
If Yes, Funding Source(s): _____ Amount(s) (Total or Per-capita): _____

1. **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, design and program activities. 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 one copy of the instruments.

2. **Methodology**: Specify who the project participants or research subjects will be, giving age, race/ethnicity, and general details. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which individuals will be subjected. Use additional pages if necessary.
3. **Voluntary Participation**: Specify the steps that will be taken to insure that each individual’s participation is voluntary. State what, if any, inducements will be offered for their participation.

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

5. **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 the participant.

6. **Risks to Participants**: Describe (a) - 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.

7. **Benefits**: (a) - Describe the benefits/or any compensation that the participating individuals can expect, and (b) - Describe the gains in knowledge that may result from the project or research study.

**Attachments**: Please indicate which items will be included with your application:

- [ ] Cover Letter
- [ ] Research Proposal
- [ ] Curriculum Vitae
- [ ] Informed Consent Forms
- [ ] Site Authorization
- [ ] Questionnaire Interview Outline
- [ ] Verbal Script
- [ ] Confidentiality Statement

In making this application, I certify that I have read and understand the Manual for Human Subjects Review Applicants, and that I intend to comply with the Cochise College Policy. Significant changes in the protocol will be submitted to Cochise College for written approval prior to these changes being put into practice. Further, I understand that, as Researcher, I am responsible for the collection and retention of all informed consent forms and additional documents pertaining to this research study.

**SIGNATURES:**

__________________________________________________________________________  _______________
Researcher  Date

__________________________________________________________________________  _______________
Department Chairperson (if Cochise College Faculty Member)  Date

__________________________________________________________________________  _______________
Faculty Advisor (if thesis or dissertation research)  Date
This application has been reviewed by:

☐ Dean, Office of Institutional Research, Effectiveness, and Planning  ☐ Human Subjects Review Committee

This application is:

☐ Approved with No Substantive Changes  ☐ Approved with Changes Attached
☐ Project requires review in ______ months  ☐ Disapproved

Comments or modifications/conditions for approval, or reason for disapproval:

SIGNATURE: ________________________________  __________________
Dean, Office of Institutional Research, Effectiveness, and Planning  Date

SIGNATURE: ________________________________  __________________
Instructional Dean (when applicable)  Date

SIGNATURE: ________________________________  __________________
Departmental Dean (when applicable)  Date

SIGNATURE: ________________________________  __________________
VP for Instruction (when applicable)  Date
Please return to:

Dean, Office of Institutional Research, Effectiveness, and Planning
Cochise College
901 North Colombo Ave.
Sierra Vista, AZ 85635-2317
### APPEAL OF DECISION FORM/HUMAN SUBJECTS REVIEW

*THIS FORM CANNOT BE HAND-WRITTEN*

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date:</th>
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<tr>
<td>Title of Proposal:</td>
<td>Original Decision:</td>
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**Original Decision Date:**

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<tr>
<th>Approved with Changes</th>
<th>Disapproved</th>
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I am appealing the human subjects review decision rendered on the proposal described above on the date noted above. I am requesting that the decision be changed from:

Disapproved to Approved  
Approved with Changes to Approved without Changes

Indicate below why you are requesting this change:

---

**SIGNATURES:**

- **Researcher**
  - Date

- **Department Chair (if Cochise College faculty member)**
  - Date

- **Faculty Advisor (if thesis or dissertation research)**
  - Date

Do not write below this line.
This appeal is:

Accepted

Decision is changed to: Approved without Changes

Denied

SIGNATURE:

Vice President for Instruction

Date

Please return to:

Dean, Office of Institutional Research, Effectiveness, and Planning
Cochise College
901 North Colombo Ave.
Sierra Vista, AZ 85635-2317
# Periodic Review Form/Human Subjects Review

*This form cannot be hand-written*

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<th>Original Approval Date:</th>
<th>Continuation Date:</th>
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1. **What is the present status of this project?**
   - Continuing [ ]
   - Concluded [ ]

   *If continuing, have there been any substantive changes?*  
   - Yes [ ]  No [ ]

2. **Is the consent form as approved by the HSRC still being used?**  
   - Yes [ ]  No [ ]

   *If no, has a new form been approved?*  
   - Yes [ ]  No [ ]

3. **Have any problems arisen in regard to the participation and safety of the people used as subjects in this project?**  
   - Yes [ ]  No [ ]

   *If yes, was it reported to Cochise College?*  
   - Yes [ ]  No [ ]

   If yes, please list the problems:

   ![Problem List](#)

4. **Has there been any psychological or physical injury to any subject?**  
   - Yes [ ]  No [ ]

5. **Where are the signed consent forms presently being filed?**
   - Building: ________
   - Room: ________

   *Person maintaining them?*
   - Researcher [ ]  Other [ ]

   *Specify Other:*
   - ________

**Signatures:**

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