

MODEL FORMS

1. INFORMED CONSENT FORM--ADULTS:

TITLE OF RESEARCH STUDY INFORMED CONSENT FORM

Read and address each numbered element of this Model Form in developing an informed consent form for the proposed human research study. The items numbered and in bold face are to be included in the consent form. PLEASE NUMBER THE CONSENT FORM FOR SUBMISSION FOR HUMAN SUBJECTS REVIEW. You may request the numbering be waived during data collection. The consent form must be written in lay language and must be typewritten. The language must be further simplified to meet the needs of a specific population. Please add additional statements when appropriate.

1. **Investigator's name, who is title/position, has requested my participation in a Research study at this institution.** [Place title of project 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 subject is 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, 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, name of investigator will...** [Indicate specifically how the investigator 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. Description may include on and off-campus services.]

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 principal investigator. In the event the investigator is a student, the name of the doctoral or thesis advisor (responsible faculty member) 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 Executive Director for Planning and Institutional Research at 206-4934.** [This information must be included in all consent forms. If #4 has indicated "no foreseeable risk, or discomfort"; then first phrase (in parenthesis) 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 Principal Investigator plus his/her degree] at _____ [phone number]). A copy of this consent form will be given (offered) to me.**

(Release statement for videotaping or relinquishing confidentiality must be inserted here if applicable.)

Subject's
Signature _____ Date _____

Other Signature _____ Date _____
(if appropriate)

13. **"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."**

14. **"I have provided (offered) the subject/participant a copy of this signed consent document."**

Signature of Investigator _____
Date _____

2. INFORMED CONSENT FORM--MINORS:

**TITLE OF RESEARCH STUDY
INFORMED CONSENT FORM**

The elements of the Informed Consent Form for Adults are used with the following variations:

1. **Investigator's name, who is title/position, at Pima Community College has requested my minor child's (ward's) participation in a research study at this institution.**
2. [same as adult]
3. **My child's (ward's) participation will involve...**
4. [same as adult]
5. [same as adult]
6. **I understand that the possible benefits of my child's (ward's) participation in the research are...**

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, name of investigator will...**
8. **I understand that in case of injury I can expect the following treatment or care which will be provided at my expense:**

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:** [same as adult]

OR

I have been informed that I will not be compensated for my child's (ward's) participation.

10. [same as adult]

11. [same as adult]

12. [same as adult]

(Release statement for videotaping or relinquishing confidentiality must be inserted here if applicable.)

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

13 [same as adult]

14. [same as adult]

Signature of Investigator _____
Date _____

3. WRITTEN ASSENT FORMS--CHILDREN:

Language must be simplified as appropriate for the age group used as subjects, such as:

I, _____, understand that my parents (mom and dad) have given permission (said it's okay) for me to take part in a project about

_____ under the direction of

_____.

I am taking part because I want to. I know that I can stop at any time I want to and it will be okay if I want to stop.

Name

OR

I, _____, understand that my parents have given permission for me to participate in a study concerning _____

_____ under the direction of _____.

My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time. If I choose to not participate, it will not affect my grade (treatment/care, etc., as appropriate) in any way.

Name

For children unable to understand written assent forms, a verbal script for assent should be submitted in lieu of the above.

4. LETTER CONSENT--ADULTS:

(Typically studies which would not exceed minimal risk)

Dear _____:

I am a faculty member [a student under the direction of Dr./Mr./Ms. _____] in the Department of _____ at Pima Community 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,

* * * * *

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

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 Pima Community College Executive Director for Planning and Institutional Research at (520) 206-4934.

5. LETTER CONSENT--MINORS:

(Typically studies which would 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 Pima Community College. I am conducting a research study entitled _____. The purpose of the research is to _____.

Your child's participation will involve _____ (Include the 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, 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,

* * * * *

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.)

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 Pima Community College, Executive Director for Planning and Institutional Research at (520) 206-4934.

6. 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 Pima Community College. I am conducting a research study entitled _____. The purpose of the research is to_____.

I am requesting your participation, which 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.

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,

7. **SAMPLE VERBAL SCRIPT:**

(Recruitment of subjects from classrooms, telephone surveys, and recruitment by personal contact)

I am a faculty member [a student under the direction of Dr./Mr./Ms. _____] in the Department of _____ at Pima Community 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-_____.

8. CONFIDENTIALITY STATEMENT

(Persons assisting the researcher should complete this document. If the study includes sensitive information, it is also to be utilized by the researcher.)

[TITLE OF STUDY]

CONFIDENTIALITY STATEMENT

As a researcher working on the above research study at Pima Community 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.

Signature of Researcher

Date

Signature of Witness

Date