

# Research Classification Worksheet

## Peru State College Institutional Review Board

IRB FORM 1 (April 2010)

**Rationale.** The purpose of the Institutional Review Board (IRB) is to provide oversight for all research conducted at Peru State College and to ensure regulatory compliance and ethical treatment of research subjects, primarily human research subjects. Peru State College must be aware of all research conducted under its aegis and such notification is the responsibility of the individual researcher. The IRB provides both the mechanism for notification and a repository for records of such activity. The IRB conducts protocol reviews as required to ensure regulatory compliance and ethical treatment of research subjects.

**Purpose.** This worksheet will determine the review status of your research project. While all research must be reported to the Institutional Review Board, all research is not subject to protocol review. *Exempt proposals* require IRB notification but not IRB protocol review. *Expedited proposals* require application for IRB protocol review but these proposals are generally limited to review by the IRB chair. *Full Board Review proposals* require application for IRB protocol review and are subject to protocol review by the full IRB.

**Instructions.** Begin with question 1 below and clearly indicate your answer by checking the appropriate response. Continue down the classification worksheet until the review status of your research proposal is clearly indicated and follow the accompanying directions to notify the IRB of your research activity or request a protocol review. Participants refers to human subjects of the research activity.

1.     T ( )     The proposed research does not involve human subjects.  
       F ( )

If true, the research is classified *Exempt from IRB Protocol Review* and the worksheet is complete. Complete IRB Form 2, "Institutional Review Board Notification of Research Activity" and electronically submit both this completed worksheet and your completed Form 2 to the IRB chair.
2.     T ( )     The proposed research is not for publication or dissemination but is a teaching or  
       F ( )     demonstration exercise conducted as part of a regularly scheduled PSC course for  
                  which I am the instructor of record.

If true, the research is classified *Exempt from IRB Protocol Review* and the worksheet is complete. Complete IRB Form 2, "Institutional Review Board Notification of Research Activity" and electronically submit both this completed worksheet and your completed Form 2 to the IRB chair. If this is a recurring course exercise, your notification remains active for 4 years at which time you should re-notify the IRB or your activity.
3.     T ( )     Participants are elected or appointed public officials or candidates for public office and  
       F ( )     the interview or survey concerns the responsibilities of the office.

If true, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

4. T ( ) Research involves the collection or study of existing data, documents, records,  
F ( ) pathological specimens, or diagnostic specimens. These sources are publicly available  
or the information is recorded by the investigator in such a manner that participants  
cannot be identified directly or through identifiers linked to the participants.

If true, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

5. T ( ) Research is conducted by or subject to the approval of a federal department or agency  
F ( ) and is designed to study, evaluate, or examine one or more of the following (please  
select all that apply):

\_\_\_\_\_ public benefit or service programs

\_\_\_\_\_ procedures for obtaining benefits or services under those programs

\_\_\_\_\_ possible changes in, or alternatives to, those programs or procedures

\_\_\_\_\_ possible changes in methods or levels of payment for benefits or  
services under those programs

If true, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

6. T ( ) Research involves observation of public behavior in a non-educational setting and the  
F ( ) researcher does not have contact with the participant(s).

If true, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

7. T ( ) Research involves taste and food quality evaluation and consumer acceptance studies  
F ( ) where (please select those that apply):

\_\_\_\_\_ wholesome foods without additives are consumed

\_\_\_\_\_ A food is consumed that contains a food ingredient for a use and at or  
below a level found to be safe by the Food and Drug Administration  
(FDA), the Environmental Protection Agency (EPA), or the Food Safety  
and Inspection Service of the U.S. Department of Agriculture (FSIS-  
USDA).

\_\_\_\_\_ A food is consumed that contains an agricultural chemical or  
environment contaminant at or below a level found to be safe by the

Food and Drug Administration, the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If true, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

8. T ( ) Research is conducted in established or commonly accepted educational settings,  
F ( ) involving normal educational practices (e.g., research on regular and special education instructional strategies; research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods)

If true, evaluate the following qualifying statement. If false, proceed to question 9.

- T ( ) Participants do **not** include children or minors (< 19 years of age).  
F ( )

If true, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

9. T ( ) Research uses educational tests (cognitive, diagnostic, aptitude, achievement), survey  
F ( ) procedures, interview procedures or observation of public behavior.

If true, evaluate the following qualifying statements. If false, proceed to question 10.

- T ( ) Participants include children or minors (< 19 years of age).  
F ( )

- T ( ) Information obtained is recorded in such a manner that human  
F ( ) subjects can be identified, directly or through identifiers linked to the subjects.

- T ( ) Any disclosure of the human subjects' responses outside the research  
F ( ) could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- T ( ) There is no federal statute requiring, without exception, that the  
F ( ) confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

If all qualifiers are false, the research is classified *Exempt from IRB Protocol Review but Subject to IRB Oversight* and the worksheet is complete. Complete IRB Form 3, "Institutional Review Board Notification of Research Activity Requiring Oversight" and electronically submit both this completed worksheet and your completed Form 3 to the IRB chair. The IRB chair verify the review status of the proposed research and return an endorsed copy of your form 3 before the research start date. (Allow 14 days for processing.)

10. T ( ) Research involves the use of observation, surveys or interviews in a **non-educational**  
F ( ) **setting.**

If true, evaluate the following qualifying statements. If false, proceed to question 11.

T ( ) Participants will be give informed consent.  
F ( )

T ( ) Participants will not be identifiable either directly or through data set  
F ( ) identifiers linked to participants.

T ( ) Disclosure of participant responses will not place the participant at risk  
F ( ) of criminal or civil liability or be damaging to the participant's financial  
standing, employability or reputation.

T ( ) Survey research does not deal with sensitive or highly personal aspects  
F ( ) of the participant's behavior, life experiences or attitudes (e.g.,  
chemical substance use and abuse, sexual activity or attitudes, sexual  
abuse, criminal behavior, sensitive demographic data, and detailed  
health history).

T ( ) Research surveys and/or interviews do **not** involve children (< 19 years  
F ( ) of age).

If all qualifying statements are true, the research is classified as *Expedited* and the worksheet is complete. Complete IRB Form 4, "Institutional Review Board Notification of Research Activity and Application for Human Subjects Protocol Review" and electronically submit both this completed worksheet and your completed Form 4 to the IRB chair. The IRB chair will verify the status of the proposed research, review the human subjects protocol, and return an endorsed copy of your form 4 before the research start date. (Allow 14 days for processing.)

If all qualifying statements are not true, the research is classified as *Full Board Review* and the worksheet is complete. Complete IRB Form 4, "Institutional Review Board Notification of Research Activity and Application for Human Subjects Protocol Review" and electronically submit both this completed worksheet and your completed Form 4 to the IRB chair. The IRB will verify the status of the proposed research, review the human subjects protocol, and return an endorsed copy of your form 4 before the research start date. The IRB chair may request your attendance at the review meeting. (Allow 30 days for processing.)

11. T ( ) Research involves the use of observation, surveys or interviews in an **educational**  
F ( ) **setting.**

If true, evaluate the following qualifying statements. If false, proceed to question 12.

T ( ) Participants will give implied informed consent.  
F ( )

T ( ) Participants will not be identifiable either directly or through data set  
F ( ) identifiers linked to participants.

T ( ) Disclosure of participant responses will not place the participant at  
F ( ) risk of criminal or civil liability or be damaging to the participant's  
financial standing, employability or reputation.

- T ( )                      Survey research does not deal with sensitive or highly personal aspects  
F ( )                      of the participant’s behavior, life experiences or attitudes.(e.g.,  
                                     chemical substance use and abuse, sexual activity or attitudes, sexual  
                                     abuse, criminal behavior, sensitive demographic data, and detailed  
                                     health history.
- T ( )                      Research surveys and/or interviews do **not** involve children (< 19 years  
F ( )                      of age).
- T ( )                      The study procedures do not represent a significant deviation in time  
F ( )                      or effort requirements from those educational practices already  
                                     existing at the study site.
- T ( )                      The study procedures involve no increase in the level of risk or  
F ( )                      discomfort compared to normal routine educational practices.
- T ( )                      Provisions are made to ensure the existence of a non-coercive  
F ( )                      environment for those students who choose not to participate.
- T ( )                      The school or other institution has granted or will be granting written  
F ( )                      approval for the research to be conducted.

If all qualifying statements are true, the research is classified as *Expedited* and the worksheet is complete. Complete IRB Form 4, “Institutional Review Board Notification of Research Activity and Application for Human Subjects Protocol Review” and electronically submit both this completed worksheet and your completed Form 4 to the IRB chair. The IRB chair will verify the status of the proposed research, review the human subjects protocol, and return an endorsed copy of your form 4 before the research start date. (Allow 14 days for processing.)

If all qualifying statements are not true, the research is classified as *Full Board Review* and the worksheet is complete. Complete IRB Form 4, “Institutional Review Board Notification of Research Activity and Application for Human Subjects Protocol Review” and electronically submit both this completed worksheet and your completed Form 4 to the IRB chair. The IRB will verify the status of the proposed research, review the human subjects protocol, and return an endorsed copy of your form 4 before the research start date. The IRB chair may request your attendance at the review meeting. (Allow 30 days for processing.)

*Continued, next page*

12. T ( ) Research involves human subjects that will be exposed to more than minimal risk,  
F ( ) which means: “the probability and magnitude of harm or discomfort anticipated in the  
research are greater in and of themselves than those ordinarily encountered in daily  
life or during the performance of routine physical or psychological examinations or  
tests”.

If true, the research is classified as *Full Board Review* and the worksheet is complete. Complete IRB Form 4, “Institutional Review Board Notification of Research Activity and Application for Human Subjects Protocol Review” and electronically submit both this completed worksheet and your completed Form 4 to the IRB chair. The IRB will verify the status of the proposed research, review the human subjects protocol, and return an endorsed copy of your form 4 before the research start date. The IRB chair may request your attendance at the review meeting. (Allow 30 days for processing.)

13. T ( ) Research involves invasive collection of human tissue or samples.  
F ( )

If true, the research is classified as *Full Board Review* and the worksheet is complete. Complete IRB Form 4, “Institutional Review Board Notification of Research Activity and Application for Human Subjects Protocol Review” and electronically submit both this completed worksheet and your completed Form 4 to the IRB chair. The IRB will verify the status of the proposed research, review the human subjects protocol, and return an endorsed copy of your form 4 before the research start date. The IRB chair may request your attendance at the review meeting. (Allow 30 days for processing.)

If you are unable to classify the review status of your proposed research activity, please contact the IRB chair directly for assistance.

**Notification of Research Activity**  
**Peru State College Institutional Review Board**

IRB FORM 2 (April 2010)

**Principal Investigator**

Name:

Email:

Phone number:

If PI is student, name of Project Advisor:

List other primary researchers and affiliations

Will undergraduate students participate as researchers?

Yes ( )

No ( )

**Anticipated starting and completion dates**

Starting Date:

Completion Date:

**Funding Agency (if any)**

**This research is classified (select one and attach completed IRB Form 1):**

( ) *Exempt*

## Title of Research Project

## Project Summary

### Certification Statement

In providing this notification, I certify that I have read and understand the principles of the Responsible and Ethical Conduct of Research as outlined in *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition*. 2009. Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, Published by The National Academies Press ([http://www.nap.edu/catalog.php?record\\_id=12192](http://www.nap.edu/catalog.php?record_id=12192)). If my research includes undergraduate research students, I understand that it is my responsibility to instruct them in the Responsible and Ethical Conduct of Research. Federal, State, and Local Departments and Agencies may have their own standards for conducting research and it is my responsibility to familiarize myself with and comply with any such applicable standards. I understand the definition of Research Misconduct (intentional, knowing, or reckless fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, honest error or difference of opinion withstanding) as defined by the United States Public Health Service (Department of Health and Human Services) regulations at 42 Code of Federal Regulations (CFR) Part 93 ([http://ori.dhhs.gov/documents/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf)) and I acknowledge my responsibility to report such misconduct to the VPAA for inquiry and investigation.

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Principal Investigator

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Date

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Project Advisor  
*Project Advisor signature required for student applications*

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Date



**Notification of Research Activity**  
**Peru State College Institutional Review Board**  
IRB FORM 3 (April 2010)

**Principal Investigator**

Name:  
Email:  
Phone number:

If PI is student, name of Project Advisor:

List other primary researchers and affiliations

Will undergraduate students participate as researchers?

Yes ( )                  No ( )

**Anticipated starting and completion dates**

Starting Date:

Completion Date:

**Funding Agency (if any)**

**This research is classified (select one and attach completed IRB Form 1):**

( ) *Exempt*

( ) *Exempt from IRB Protocol Review but Subject to IRB Oversight*

Does the research involve human subjects? Yes ( ) No ( )

*Human subjects are involved in a project if it uses data from human responses, observations of human beings or human materials, whether such data are obtained directly from human sources or from secondary sources.*

## Title of Research Project

## Project Summary

### Certification Statement

In providing this notification, I certify that I have read and understand the principles of the Responsible and Ethical Conduct of Research as outlined in *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition*. 2009. Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, Published by The National Academies Press ([http://www.nap.edu/catalog.php?record\\_id=12192](http://www.nap.edu/catalog.php?record_id=12192)). If my research includes undergraduate research students, I understand that it is my responsibility to instruct them in the Responsible and Ethical Conduct of Research. Federal, State, and Local Departments and Agencies may have their own standards for conducting research and it is my responsibility to familiarize myself with and comply with any such applicable standards.

I understand the definition of Research Misconduct (intentional, knowing, or reckless fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, honest error or difference of opinion withstanding) as defined by the United States Public Health Service (Department of Health and Human Services) regulations at 42 Code of Federal Regulations (CFR) Part 93 ([http://ori.dhhs.gov/documents/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf)) and I acknowledge my responsibility to report such misconduct to the VPAA for inquiry and investigation.

If human subjects are involved, I certify that I have read, understand, and acknowledge my conduct obligations under 45 CFR Part 690: Federal Policy for the Protection of Human Subjects (Same as 45 CFR Part 46, which pertains to HHS): THE COMMON RULE FOR THE PROTECTION OF HUMAN SUBJECTS (<http://www.nsf.gov/bfa/dias/policy/docs/45cfr690.pdf>). If children are involved as subjects, I certify that I have read, understand, and acknowledge my conduct obligations under 45 CFR Part 46: Federal Policy for the Protection of Human Subjects, SUBPART D-Additional Protections for Children Involved as Subjects in Research (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

I acknowledge my obligation to obtain written approval for any significant deviations from the originally approved protocol before making those deviations and to report immediately all adverse participant effects to the Chair of the IRB. I certify that the rights and welfare of the participating subjects are adequately protected and that informed consent of subjects will be obtained by methods that are adequate and appropriate.

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Principal Investigator

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Date

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Project Advisor

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Date

*Project Advisor signature required for student applications*

**Notification of Research Activity and  
Application for Human Subjects Protocol Review**

**Peru State College Institutional Review Board**

IRB FORM 4 (April 2010)

**Principal Investigator**

Name:

Email:

Phone number:

If PI is student, name of Project Advisor:

List other primary researchers and affiliations

Will undergraduate students participate as researchers?

Yes ( )

No ( )

**Anticipated starting and completion dates**

Starting Date:

Completion Date:

**Funding Agency (if any)**

**This research is classified (select one and attach completed IRB Form 1):**

( ) *Exempt from IRB Protocol Review but Subject to IRB Oversight*

( ) *Expedited*

( ) *Full Board Review*

Does the research involve human subjects? Yes ( ) No ( )

*Human subjects are involved in a project if it uses data from human responses, observations of human beings or human materials, whether such data are obtained directly from human sources or from secondary sources.*

## Section A: Research Protocol Detail

**Title of Research Project**

**Project Summary**

**Project Justification**

### **Participants**

Description of participants:

Number of participants:

Age(s) of the participants:

Describe how potential participants will be selected:

Please describe how participants will be recruited once they are identified. If you are working with outside individuals or organizations to recruit individuals, provide documentation regarding recruitment of subjects.

If participants are under 19 years of age, will parental permission be obtained?

Yes ( )                      No ( )

If no, please explain:

Will subjects be told that participation is voluntary and they are free to withdraw from the project at any time?

Yes ( )

No ( )

If no, please explain:

**Materials and Apparatus**

Attach to this document copies of all written materials to which subjects will be exposed including questionnaires, instructions, cover letters, etc. If applicable, attach Human Performance Lab protocols.

**Procedures**

From the point-of-view of the participants (human subjects), briefly describe or list research protocol.

**Debriefing Statement/Process**

Debriefing should be a part of this procedure. Debriefing generally includes a statement of appreciation to participants, an explanation of the overall purpose of the research, a way to learn about the results, and sometimes information resources to access assistance if subjects would benefit from a service related to the research problem. Elements of debriefing might appear in a cover page to a survey, be done orally, or through a written debriefing statement distributed or read to subjects. ***If the research involves deception, a written debriefing statement is required.***

## Section B: Participant Risk Evaluation

### Risk Criteria

A research participant is considered to be at risk if s/he may be exposed through the procedures of the proposed research to the possibility of physical or mental harm, coercion, deceit, or invasion of privacy. Examples of placing subjects at risk of harm include administration of drugs, requiring unusual physical exertion, deception, or public embarrassment and humiliation. Coercion is a potential risk when subjects are not able to exercise their right to decline to participate. There is a special concern where the principal investigator or his/her mentor is in a relationship of greater power over the participants (e.g. professor-student relationships). Additionally, risks arise when subjects could potentially experience discomfort, anxiety, invasion or privacy or loss of dignity. Risks also arise from the use of stored data or information that was initially obtained for other purposes.

Students will be used as subjects	Yes ( )	No ( )
Experimental drugs will be used	Yes ( )	No ( )
Potential for medical problems exist	Yes ( )	No ( )
Non-English speakers will participate	Yes ( )	No ( )
Minors (less than 19 years of age) will participate	Yes ( )	No ( )
Mentally challenged subjects will participate	Yes ( )	No ( )
Incarcerated subjects will participate	Yes ( )	No ( )
Participants may experience physical discomfort	Yes ( )	No ( )
Participants may experience mental discomfort	Yes ( )	No ( )
Electrical equipment will be used	Yes ( )	No ( )
Mechanical equipment will be used	Yes ( )	No ( )
Deception will be used	Yes ( )	No ( )
Participants will be audio or video recorded or photographed	Yes ( )	No ( )

State your rationale for using special groups (e.g. minors, mentally challenged, incarcerated individuals or any other group whose ability to give voluntary consent may be in question).

Describe and assess any potential risks (physical, mental or other). Consider this from the perspective of the participant. Could s/he feel frightened, intimidated, embarrassed, become ill, etc.? If another research method which would reduce potential risks was not chosen for use, please provide a rationale.

Describe procedures for recording and storing data and the final location of raw data or coding identifiers. The American Psychological Association protocol calls for raw data to be kept for three years after completion of the study. Destroy raw as soon as feasible. Be sure to address any confidentiality issues.

If deception is used, provide a rationale for its use.

Describe procedures of the proposed research designed to protect against or minimize the potential risks. Assess the effectiveness of these procedures.

Describe the benefits to the subjects and contributions to the general knowledge in the field of inquiry.



### **Section C: Implied/Informed Consent to Participate in Research Study**

Whenever possible, obtain informed consent (a signed form) from all participants. Always use plain language and avoid technical terms or discipline jargon. Provide each participant with the name and telephone number of the principal investigator and advisor (if needed) on the consent form or cover letter.

#### **Elements of informed consent include:**

1. Explanation of the purpose of the study, description of procedures to be followed
2. Identification of individuals performing the procedures and their credentials
3. Description of possible immediate and long-term discomforts, hazards, and risks
4. Description of any benefits to participants or potential benefits to society
5. Offer to answer any questions concerning the procedures at any time
6. A statement that participants are free to withdraw consent and to discontinue participation at any time without prejudice to their future relations with PSC, their professors, or the principal investigator
7. Assurance that the identities of the participants will not be disclosed without the participant's consent
8. Notification that if the participants are minors (less than 19 years of age), one parent or legal guardian must sign the consent form

Please attach a copy of your implied/informed consent document. (See attachment 1 for an implied/informed consent form template).

## Section D: Certification

### Certification Statement

In providing this notification, I certify that I have read and understand the principles of the Responsible and Ethical Conduct of Research as outlined in *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition*. 2009. Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, Published by The National Academies Press ([http://www.nap.edu/catalog.php?record\\_id=12192](http://www.nap.edu/catalog.php?record_id=12192)). If my research includes undergraduate research students, I understand that it is my responsibility to instruct them in the Responsible and Ethical Conduct of Research. Federal, State, and Local Departments and Agencies may have their own standards for conducting research and it is my responsibility to familiarize myself with and comply with any such applicable standards.

I understand the definition of Research Misconduct (intentional, knowing, or reckless fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, honest error or difference of opinion withstanding) as defined by the United States Public Health Service (Department of Health and Human Services) regulations at 42 Code of Federal Regulations (CFR) Part 93 ([http://ori.dhhs.gov/documents/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf)) and I acknowledge my responsibility to report such misconduct to the VPAA for inquiry and investigation.

If human subjects are involved, I certify that I have read, understand, and acknowledge my conduct obligations under 45 CFR Part 690: Federal Policy for the Protection of Human Subjects (Same as 45 CFR Part 46, which pertains to HHS): THE COMMON RULE FOR THE PROTECTION OF HUMAN SUBJECTS (<http://www.nsf.gov/bfa/dias/policy/docs/45cfr690.pdf>). If children are involved as subjects, I certify that I have read, understand, and acknowledge my conduct obligations under 45 CFR Part 46: Federal Policy for the Protection of Human Subjects, SUBPART D-Additional Protections for Children Involved as Subjects in Research (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

I acknowledge my obligation to obtain written approval for any significant deviations from the originally approved protocol before making those deviations and to report immediately all adverse participant effects to the Chair of the IRB. I acknowledge my responsibility to obtain implied/informed consent from all participants. I certify that the rights and welfare of the participating subjects are adequately protected and that informed consent of subjects will be obtained by methods that are adequate and appropriate.

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Principal Investigator

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Date

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Project Advisor

*Project Advisor signature required for student applications*

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Date

## Attachment 1: Consent Form Template

You are invited to participate in a study of *(State what is being studied)*. We hope to learn *(State what the study is designed to discover or measure)*. You were selected as a possible participant in this study because *(State why and how the participant was selected)*.

If you decide to participate, the researcher and his/her associates will *(Describe the procedures to be followed, how long they will take, and their frequency, if applicable. Describe any discomforts and inconveniences that can reasonably be expected. Estimate the total time required. Describe the risks and benefits reasonable to be expected)*.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. *(If research will release information to anyone for any reason, state the persons or agencies to which the information will be furnished, the nature of the information that will be furnished and the purpose of the disclosure.)*

*(If participants will receive compensation or any other benefits, describe the amount or nature. Disclose any alternate ways that the benefits may be obtained. If participants may incur costs because of participation, disclose an estimate of the amount.)*

Your decision whether or not to participate will not prejudice your future relations with Peru State College, *(name of principal investigator and advisor)*. If you decide to participate, you are free to discontinue participation at any time without prejudice.

If you have any questions, please ask us. If questions arise later, *(State name of principal investigator and advisor with telephone numbers and email addresses)* will be happy to answer them.

Your signature indicates that you have read and understand the information provided above and have decided to participate. You may withdraw at any time without prejudice after signing this form should you choose to discontinue participation in this study.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

*(The last line should not appear on forms that will be given to legally competent participants.)*