

## **BUTTE COLLEGE POLICY: HUMAN SUBJECTS PERMISSION AND REVIEW**

**Statement of Policy:** It is considered unethical to conduct research or institution related work with human populations (subjects) without the members of the subject population being informed of the nature and possible impact of such projects on the target populations. “Informed consent” must be willingly given to the person(s) conducting the research/work by members of the subject population before the project can go forward. Therefore, it is the explicit policy of Butte College, as specified by the criteria listed below, that informed consent be obtained by the representative who is organizing the project and that institutional approval be granted by an appropriate review process before that project can begin. The following policies and procedures are designed to be consistent with Title 45, Code of Regulations, Part 46, Protection of Human Subjects; effective August 19, 1991. These policies and procedures are paraphrased below, but are meant to be consistent with Subpart A of the Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects). These policies are not intended to critique or review specific methodological genres.

**Populations and Obligations:** When members of various institutions (e.g. institutions of higher education or grant sponsoring agencies) work with or conduct research on human populations, ethical concerns often arise. It is therefore critically important for the member(s) of the institution to communicate as clearly as possible the nature of the research/work to be conducted and to discuss the potential impact of the research/work on the subject population. The member(s) of the institution should: 1.) communicate in an appropriate manner the nature of the project (The preferred format should be a written document. However, if dealing with an oral population, an oral agreement with witnesses present should be obtained.); 2.) any potential danger(s) or compromising situations that might arise as a result of the research/work must be communicated to the subject population; 3.) when appropriate, equitable compensation should be offered to the subjects as payment for their cooperation; 4.) how the member(s) of the institution might benefit either monetarily or professionally from the project; 5.) intellectual property rights must be observed and respected (e.g. if a profit is generated from creative input stemming from the subject population or a member of that group they must be compensated and have their intellectual property rights recognized). Moreover, a compensation agreement must be made with the member or members of the subject population in either written or oral form. These agreements can be made after the project is underway. 6.) Confidentiality must be maintained to protect human subjects from harm, unless the subjects waive their right to confidentiality. Waving rights to confidentiality can only be done after the subjects are informed of the potential impact of their waiving this right is explained in full. Populations that should be considered for Human Subjects Review are:

- 1. Students in educational settings:** Young students (4<sup>th</sup> grade and below) should be considered “special” and any research or work with such populations must be conducted with extreme care. The approval of parents, legal guardians, teachers, and school administrators must be obtained. Obtaining consent for these subjects

through the above mentioned overseers should be written in the form of “Informed Consent” documentation. If a member of Butte College is only visiting a class for a brief period of time and no systematic research is conducted, only the permission of the teacher and school is necessary.

- 2. Subjects with special needs:** Human subjects with physical or mental disabilities must be given careful consideration to protect their interests and to preserve their wellbeing. If the subjects are not able to comprehend the nature of the project, informed personnel who work with or attend to the subjects must be consulted. The member of Butte College must defer to the judgment of the “experts” in charge to safeguard the rights of these subjects.
- 3. Ethnolinguistic populations:** Members of Butte College who are working with or conducting research on ethnolinguistic populations (e.g. “ethnic minorities” or “language minorities”), should be aware of the potential for miscommunication. This awareness should be based on some knowledge of the structural differences among different languages (e.g. “negative transfer”) and the potential for miscommunication based on cultural differences. Interpreters or “cultural-linguistic brokers” must be used whenever possible.
- 4. Religious populations:** Communities of people with specific beliefs should be informed of the nature of research/work/visitations before actual contact with the community is made. Sometimes short term class projects involve visitations of religious communities and their sacred places of worship. For example, Churches, Mosques, Buddhist Temples, and Synagogues (and other religious settings) are sometimes the topic of student projects. Short terms projects of this nature need not go through a formal Human Subjects Review process. However, students who visit such communities and localities must inform appropriate religious leaders and communicate the goals and objectives of their project. A member of Butte College who is visiting a religious community for reasons or purposes other than their own personal beliefs, must not attend under the guise or the intent of “covert” observation.
- 5. Other considerations:** Any person or member of a population being studied by a Butte College employee must be given the right of confidentiality, to the extent that the law and ethical considerations permit. Butte College retains the right to view research data if needed, but seek to maintain confidentiality with regard to the identity of the research and the research subjects, unless the rights are waived.

**Subject Information Consent Form:**

[We]/I are/am asking you to participate in a research/work project. Therefore information regarding the conditions, potential impact, the nature of the research must be communicated to you. Once you understand the nature of the research/work your “informed consent” must be given to us before the project can begin. Later changes in the protocols must also be included as part of the informed consent process.

1. The study/work project is being conducted by \_\_\_\_\_  
\_\_\_\_\_.

2. The study/work project is being sponsored by (list Butte College first, then department and discipline, or funding agency if appropriate) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

3. Time and place of the study/work project \_\_\_\_\_  
\_\_\_\_\_.

4. Describe the nature of the study/work project (include goals and objectives) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

a. Purpose of the study \_\_\_\_\_.

b. Procedures/Methods \_\_\_\_\_  
\_\_\_\_\_.

c. Potentials Risks \_\_\_\_\_  
\_\_\_\_\_.

d. Potential Benefits \_\_\_\_\_  
\_\_\_\_\_.

e. Compensation (How will subjects be compensated for their participation) \_\_\_\_\_  
\_\_\_\_\_.

5. Confidentiality (How will confidentiality be maintained? How long will data be kept? How will it be stored? If needed, how will the data be disposed of?) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

Additional information and conditions of the proposed project can be attached.

The subject(s) for the project described above understand that their participation is voluntary. Subjects are free to withdraw their consent at any time without penalty or loss of benefits to which they are entitled. Also, if exemption from the Human Subjects Review is requested, use a written narrative to propose a rationale. Criteria for exemption:

1. The project is short term (e.g. several hours or a day) and does not involve any significant impact on the subjects.
2. The project has already undergone a Human Subjects review through another institution (e.g. you have joined an ongoing project that has already been established).
3. Public documents are examined, but will not in any way compromise confidentiality or cause harm to anyone whose name appears in the documents.
4. The project is based on direct observation of ongoing public behavior and no names are used (e.g. observing people in parks, sporting events, and so forth).

Subjects acknowledge, by their signature(s), mark, or witnessed oral agreement, that they understand the conditions stated above, and that the (the subjects) consent to their full or partial participation in the above stated project.

**Consent:**

Signature of Subject \_\_\_\_\_ Date \_\_\_\_\_

Signature of Investigator/Butte College Representative

\_\_\_\_\_ Date \_\_\_\_\_

Revisions may be attached, but must be dated and signed by all previous participants and investigators, unless changes involve specific individuals or highly specific conditions.

Prepared by Michael S. Findlay 2006