	Institutional Review Board **Institutional Review Checklist**	Salish Kootenai College Institutional Review Board PO Box 70 Pablo, MT 59855

IRB Protocol # _____

Title of Research: _____

P.I. _____

Co P.I. _____

Determination of Level of Review. Please check category below, and indicate rationale in the appropriate section below. Exempt _____ Full Review _____ Expedited _____ Cultural _____	Reviewer:
Documentation of Human Subjects Protection Training/Cultural Training is complete for all listed investigators and other personnel. Comments:	Yes ____ No ____
Site Permission is included for all research sites as appropriate. Comments:	Yes ____ No ____
Final notice sent (date):	

Reviewer Signature:	Date:
Reviewer Signature:	Date:
_____ Resubmit ____ Approved _____ Approved with Modifications listed below _____ Referred to Full Board _____ Refer to Culture Committee(s)	

Instructions: Please provide your judgment concerning the following criteria. If you check "No" in any area, please provide comments. If you provide comments, please check the "Comment" space provided.

1. **Research Relevance** The use of subjects in this project is relevant and appropriate to answer the questions being asked. The study design is appropriate to answer the questions being asked.	Yes____ No ____ Comment ____
2. **Selection of Subjects** The selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted. Special considerations include vulnerable populations, including children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.	Yes____ No ____ Comment ____
3. Minimization of Risks Procedures are used to minimize physical, emotional, financial, legal, and cultural risks to subjects by using procedures which are consistent with sound research design and do not necessarily expose subjects to risk.	Yes____ No ____ Comment ____
4. Procedures for monitoring safety When appropriate, research design makes adequate provision for monitoring data collected to ensure safety of subjects.	Yes____ No ____ Comment ____
5. Risks to subjects are reasonable in relation to anticipated benefits. Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects and the importance of the knowledge that may reasonably be expected to result.	Yes____ No ____ Comment ____
6. Procedures for protecting privacy and confidentiality Adequate provisions exist to protect the privacy of subjects and maintain confidentiality of data.	Yes____ No ____ Comment ____
7. Recruitment and consent process The recruitment and consent process, including telephone scripts, ads, brochures, compensation) are fully described, appropriate, and non-coercive. Informed consent form contains necessary components including the following as appropriate: Procedures, risks/benefits, additional costs that may result from participation in the research, right to withdraw, consequences of a subject's decision to withdraw, compensation, confidentiality procedures, and researcher contact information.	Yes____ No ____ Comment ____

8. If there is a grant application, does the IRB protocol and informed consent document correspond to the grant application/protocol?	Yes____ No ____ Comment ____
9. Cultural Risks The research involves potentially sensitive areas pertinent to the intellectual property rights of the Confederated Salish and Kootenai Tribes. Review by the appropriate Culture Committee(s) should be required.	Yes____ No ____ Comment ____

Criteria Number	Reviewer Comments:

Research Exempt from Review
Exempt status is granted by the IRB Chair to proposals which do not involve research subjects from statutorily vulnerable populations, or do not involve more than minimal risk. This includes:

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

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

____ 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
  (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

_____ 4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

_____ 5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

_____ 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Use of photography, videotaping, and audiotaping does not fall under Exempt classification as individuals may be identified. However, if the recording is to facilitate accurate record keeping and will be erased following transcription, it may go in the exempt category.

Research that is Expedited:

_____ 1. The subjects are not from certain statutorily vulnerable populations and the research involves easily manageable risk.

_____ 2 Minimal or no-risk projects are those which involve no foreseeable danger to the subjects and may not require written informed consent. Examples of no-risk procedures include: administration of anonymous opinion questionnaires, measurements such as reaction time or hand-eye coordination, and interviews on non-threatening topics.

___ 3. Research on individual or group characteristics or behavior that may involve minor stress, discomfort or embarrassment (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

____ 4. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis or previously collected data that was only used for evaluation purposes).

Research that may need Cultural Review: