



IRB NEW PROTOCOL SUBMISSION

Project Title:	
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Investigator Information:

Principal Investigator:		Secondary Investigator or Project Supervisor*:	
Department:		Department:	
Department Phone:		Department Phone:	
Contact Phone:		Contact Phone:	
Contact Address:		Contact Address:	
City/State/Zip:		City/State/Zip:	
E-Mail Address:		E-Mail Address:	

* Student projects must be submitted with a faculty member listed as Secondary Investigator or Project Supervisor.

Principal Investigator is:

<input type="checkbox"/>	Faculty	<input type="checkbox"/>	Staff	<input type="checkbox"/>	Student
<input type="checkbox"/>	Outside Researcher	<input type="checkbox"/> Other (Please specify:)			

Type of Project:

<input type="checkbox"/>	Research	<input type="checkbox"/>	Grant Activity	<input type="checkbox"/>	Class Project
<input type="checkbox"/>	Other (please specify):				

Does the research involve an outside institution/agency other than SKC? SKC IRB policy requires that written permission be obtained from research sites or from the entities at which research will occur. Documentation of site permission should be attached.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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If yes, please list the institutions/agencies.	Letter of Site Permission Attached (yes/no)

Project Information:

Present/Proposed Source of Funding:			
Anticipated Project Start Date:		Anticipated Project End Date:	

*Please attach a copy of the funding application.

* You may not start this project until IRB approval is received.

Data Collection Methods for Identification of IRB Classification:

Please check your response to each question.

	Yes		No	1. Does the research involve prisoners?
	Yes		No	2. Does the research involve using survey or interview procedures with children (under 18 years of age) that is not conducted in an educational setting utilizing normal educational practices?
	Yes		No	3. Does the research involve the observation of children in settings where the investigator will participate in the activities being observed?
	Yes		No	4. Will videotaping or audio tape recording be used?
	Yes		No	5. Will the participants be asked to perform physical tasks?
	Yes		No	6. Does the research attempt to influence or change participants' behavior, perception, or cognition?
	Yes		No	7. Will data collection include collecting sensitive data (illegal activities, sensitive topics such as sexual orientation or behavior, psychological characteristics, or other data that may be painful or embarrassing to reveal)?
	Yes		No	8. For research using existing or archived data, documents, records or specimens, will any data, documents, records, or specimens be collected from subjects after the submission of this application?
	Yes		No	9. Can subjects be identified, either directly or indirectly, from the data, documents, or records?
	Yes		No	10. Does the research involve potentially culturally sensitive topics pertinent to the Confederated Salish and Kootenai Tribes? Examples but are not limited to include stories, songs, or beliefs about particular topics to be collected from tribal members.
	Yes		No	11. Does the research involve natural resources (e.g. water, plant samples, animal samples) that will be collected on the Flathead Indian Reservation?

Description of Subjects:

Anticipated total number of participants who are minors (less than 18):	
Anticipated total number of participants who are adults:	

What are the participants' characteristics? If study participants are restricted to one gender, one race/ethnicity, or other single demographic characteristics, include the rationale.

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Special Considerations:

Please indicate any special considerations for human subjects protection. Check all appropriate blanks below.

	Audio taping		Videotaping		Archival/Secondary Data Analysis		
	Photography		Web-based research		Biological Samples		Protected Health Information

Explain how the above media or samples will be used and how/when they will be destroyed.

Cultural Considerations:

Please indicate any use of knowledge or materials that may be considered intellectual property of the Confederated Salish and Kootenai Tribes. Check all appropriate blanks below.

	Use or knowledge of traditional plants		Contact with tribal elders
	Inquiry into traditional knowledge, e.g. history, spiritual beliefs		Health and Lifestyle Behaviors specific to tribal members
	Research related to Natural Resources within Reservation Boundaries		

If any of the above boxes are checked, please explain further:

Plans to Involve Community/Stakeholders in Research and Return Results to the Community/Stakeholders

Aligned with Indigenous Research Methods, how will the research include respectful participation by the community/stakeholders and how will research results be returned to the community/stakeholders for their review and use?

Project Personnel List:

Please list the names of all personnel working on this project, starting with the principal investigator and the secondary investigator/project advisor. Research assistants, students, data entry staff and other research project staff should also be included. Note that all personnel must complete human subjects and cultural training. See the SKC IRB site for more information. Note that the SKC IRB does not keep copies of training on file.

Name of Individual:	Project Role:	Indicate whether documentation of Human Subjects Protection Certification is provided

Part B:
PROJECT DESCRIPTION

1. Describe the significance of the project. What is the significance/purpose of the study? (Please provide a brief 1-2 paragraph explanation in lay terms.)

2. Describe the methods and procedures. Describe activities the subjects will perform and how the subjects will be used. Describe the instrumentation and procedures to be used and kinds of data or information to be gathered. **Provide enough detail** so the IRB will be able to evaluate the activities from the subject's perspective (expand box as needed):

3. Describe research tools such as questionnaires, surveys, or testing instruments.

List all questionnaires, surveys, and/or assessment instruments/measures used in the project.
Submit copies of all research instruments, tools, surveys, etc. with the IRB application.

4. Describe recruitment procedures. Describe recruitment procedures, including how the names and contact information for participants will be obtained, how participants will be approached about participating in the study, whether follow-ups or reminders will be used and how those will be sent. ***Submit copies of recruitment flyers, ads, phone scripts, emails, etc. These require IRB approval.**

5. Describe benefits to participants. Discuss the benefits (does not include payment for participation) of the research, if any, to the human subjects and to scientific knowledge (*if the subjects will not benefit from their participation, state this*):

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6. Describe in detail risks to participants. Also provide the methods that will be used to minimize risks.

Discuss risks and discomforts, if any, to which the human subjects will be exposed (*Potential adverse effects may be physical, psychological, professional, financial, legal, spiritual, loss of social standing, or cultural. Researchers can never guarantee that there are no risks – use the term “minimal.”*)

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7. Describe Compensation. Will compensation be provided to participants? *If ‘Yes’, please describe amount and type of compensation, including money, gift certificates, extra course credit, etc.*

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8. Describe Processes for Obtaining Informed Consent. How will informed consent/assent be obtained?
Attach copies of informed consent/assent forms, emails, and/or letters. Please refer to the SKC IRB website for information which must be included in informed consent materials.
* Please note SKC IRB policies concerning assent and parental permission for participants under the age of 18.

9. Describe how confidentiality will be maintained. How will confidentiality of records be maintained?
Will individuals be identified? Who has access to the records/data?

For web-based studies, how will the data be handled? Will the data be sent to a secure server? Will the data be encrypted while in transit? Will you be collecting IP addresses?

If transcriptions are required, how will transcriptions be handled? Who is doing the transcriptions? Please attach a copy of the confidentiality agreement that transcriptionists will sign.

* For studies utilizing Protected Health Information (PHI; e.g., information obtained from a hospital, clinic, or treatment facility), how will this PHI data be obtained and safeguarded? Please provide a copy of the release of authorization that will be used to obtain permission from the participant for the agency/institution to release protected health information for project purposes or a letter from the agency/institution documenting agreement to provide protected health information for project purposes.

10. Plans for dissemination of results. How will the results of this project be reported? For example, will they be published, presented at conferences, sent to other agencies or individuals, or distributed in other ways?

Note that per SKC IRB Policy, the IRB may request a copy of final manuscripts or may request to review manuscripts or presentations prior to dissemination. Notification of this requirement will be provided in the letter of approval from the IRB.

By signing this IRB protocol, the researcher(s) agrees to the following:

- The research project will not be implemented until the researcher receives final approval from the Salish Kootenai College Institutional Review Board. .
- The researcher inform the IRB in writing of any adverse or unanticipated problems. Timelines for required notification are provided on the IRB website.
- Any changes to the approved research protocol must be submitted in writing to the Salish Kootenai College Institutional Review Board prior to implementing the changes.
- All researchers who will collect data or see disaggregated data must complete training in human subjects protection training. Certificates of such training should be submitted with the IRB application.
- Failure to comply with Salish Kootenai College Institutional Review Board policy, including failure to promptly respond to communication from the IRB, constitutes non-compliance. The Salish Kootenai College Institutional Review Board has the authority to
- IRB approval for non-exempt research applications is provided for one year only. After one year, approval for the research ceases and the research must stop unless the researcher submits a request for continuing review is approved. When the research is completed, the researcher must submit a final report to the IRB using the form available on the SKC IRB website.

Required Signatures:

Principal Investigator:		Date:	
Secondary Investigator or Project Advisor:		Date:	