

# ST. CLOUD STATE UNIVERSITY – IRB PROTOCOL REVIEW CHECKLIST

Investigator (PI): \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Type: \_\_\_\_\_

Other Investigator(s): \_\_\_\_\_

Training Date(s): \_\_\_\_\_

Training Type(s): \_\_\_\_\_

**Is the activity research?**

- |  |     |    |
|--|-----|----|
| A) The activity is a systematic investigation, including research development and testing. | Yes | No |
| B) The activity is designed to develop or contribute to generalizable knowledge.           | Yes | No |
- If you answered YES to both questions, continue with checklist.*

**Does the activity involve human subjects? If yes, continue.**

- |   |     |    |
|---|-----|----|
| A) The activity obtains data through intervention or interaction with the participant                                 | Yes | No |
| B) The activity obtains identifiable private information (participant identity is or may be readily determined by PI) | Yes | No |
- \*\*If you answered yes to one of the above questions, continue with checklist.**

	<u>Reviewer 1</u>	<u>Reviewer 2</u>		
	N/A	YES	NO Disagree	Comments

1. **Funded research?**  
 A) Funding source provides no conflict  
 \_\_\_\_\_  
 \_\_\_\_\_
  
2. **Was research design and the procedures adequately described?**  
 \_\_\_\_\_  
 \_\_\_\_\_
  
3. **Were procedures to identify/recruit participants adequately described?**  
 A) Parents/guardian consent, if participants are under age 18  
 B) Limited participant population is necessary/justified for research design  
 C) Written agreement to collaborate with outside agency obtained  
 D) Alternative class activity specified  
 E) Permission given freely, without duress/coercion  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
  
5. **Confidentiality or anonymity?**  
 A) Participant anonymity/confidentiality assured  
 B) Data stored securely  
 C) Results data reported in a confidential manner  
 D) Raw data destroyed within appropriate timeline  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
  
6. **Description of risk adequate?**  
 A) Were potential risks identified as minimal risk  
 B) Adequate precautions outlined  
 C) Given risks, are benefits sufficient to outweigh risk  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
  
7. **Informed consent/consent form (or intro/cover page for questionnaires or surveys)**  
 A) Clear  
 B) Provide enough information  
 C) Answer participant questions  
 D) Permission to withdraw at any time  
 E) Name and contact info of researcher and/or advisor  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
  
8. **Sharing results and debriefing**  
 A) Explanation how to obtain study results/summary (encouraged)  
 B) Debriefing (if deception involved)  
 \_\_\_\_\_  
 \_\_\_\_\_

Reviewer Initial      \_\_\_\_\_      \_\_\_\_\_

**Project is Minimal Risk\***      Yes      No

Comments: \_\_\_\_\_

### PROTOCOL REVIEW & APPROVAL INFORMATION

Reviewers: \_\_\_\_\_ SCSU IRB#: \_\_\_\_\_

Category Approved: \_\_\_\_\_ Exempt      \_\_\_\_\_ Expedited 1      \_\_\_\_\_ Expedited 2      \_\_\_\_\_ Full      Approval Date: \_\_\_\_\_

Expiration Date:      N/A        \_\_\_\_\_      \_\_\_\_\_      \_\_\_\_\_

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**IRB Protocol Review Checklist**

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	<u>Reviewer 1</u>		<u>Reviewer 2</u>		Comments
	N/A	YES	NO	Disagree	
<b>9. Research which is <u>Externally Funded</u> by federal department or agency</b>					
A) Review grant narrative for alignment of research activity					_____
<b>10. Possible Expedited Review – 1 Process</b> (only requires one reviewer)					
A) Limited participation – children under 18 in educational setting					_____
B) Limited participation – non-English speaking					_____
C) Limited participation – employees of specific/targeted organization					_____
D) Minimal risk – undesired or unexpected psychological changes					_____
E) Minimal risk – sensitive information category (anonymous)					_____
F) Minimal risk - deceptive techniques (minor)					_____
G) Collection of audio/video/digital/ image for research purposes					_____
<b>11. Possible Expedited Review - 2 Process</b> (at least two reviewers)					
A) Limited participation - children under 18 outside educational setting					_____
B) Limited participation - prisoners					_____
C) Limited participation – economically/educationally disadvantaged					_____
D) Limited participation – persons with cognitive impairments					_____
E) Minimal risk – physical pain/discomfort/injury from procedures/drugs					_____
F) Minimal risk – invasion of privacy/ <u>absence of informed consent</u>					_____
G) Minimal risk – sensitive information (confidential)					_____
H) Minimal risk – deception (more than minor)					_____
<b>12. Full Board Review Process</b>					
A) Research will presents more than minimal risk to participants					_____
B) Risk where ID of participants/responses place at risk for criminal or civil liability or damaging to financial standing, etc.					_____
C) Classified research involving human subjects					_____
D) Umbrella protocol outlining standard dept/center processes					_____
<b>13. Student Class Project</b>					_____