Chadron State College Human Participant Research: Characteristics of Administratively-reviewed Exempt Status

Research activities involving human participants in which there <u>is minimal or no risk</u> may be exempt from further IRB review, although initial project review by the IRB is required prior to initiation of the research and subsequently upon any modification of the project. *The research must fully and completely meet the conditions described below to qualify for exempt certification*. Studies designed to assess program/unit effectiveness, use, or quality <u>may</u> qualify for exempt certification under (5) below. Note that ongoing studies need to be annually reviewed by the IRB to ensure continued compliance with IRB policies.

Category	Conditions
1. Research conducted in established	(a) Research on regular and special educational strategies OR
or commonly accepted educational	(b) Research on the effectiveness of or the comparison among
settings, involving normal educational	instructional techniques, curricula, or classroom management methods.
practices.	
2. Research involving the use of	(a) Information is obtained and recorded in such a way that human
educational tests (cognitive,	participants cannot be identified, AND
diagnostic, aptitude, achievement),	(b) Any disclosure of the participants' responses outside the research
survey procedures, interview	cannot place the subject at risk of criminal or civil liability or be
procedures or observation of public	damaging to the participants' financial standing, employability, or
behavior, if <u>all five conditions</u> are fully	reputation, AND
met:	(c) Does not deal with sensitive aspects of the participant's own
	behavior, such as illegal conduct, drug use, sexual behavior, or use of
	alcohol, AND
	(d) Does not use materials, procedures or settings likely to be
	embarrassing, upsetting or intrusive to the participants, AND
	(e) Participants are not in a vulnerable or protected class (including
	under the age of 19).
3. Research involving the use of	The research participant <i>must</i> be a public official or a candidate for a
survey procedures, interview	public office.
procedures when the participant is an	
elected or appointed official or a	
candidate for public office.	
4. Research on the collection or study	(a) The data sources are publicly available, OR
of existing data, documents, records,	(b) The information is recorded by the investigator in such a manner
pathological specimens, or diagnostic	that participants cannot be identified either directly or through
specimens, if:	identifiers linked to the subjects.
5. Research and demonstration	 (a) Public benefit or service programs, OR (b) Press down for alterizing benefit and antibacture of the service program.
projects which are conducted by or	(b) Procedures for obtaining benefits or service under these programs, <i>OR</i>
subject to the approval of School	
Deans or equivalent, and which are designed to study, evaluate, or	(c) Possible changes in or alternatives to those procedures or programs, <i>OR</i>
otherwise examine:	(d) Possible changes in methods or levels of benefits or services under
	(d) Possible changes in methods of levels of benefits of services under these programs
6. Taste and food quality evaluation	(a) Wholesome foods without additives are consumed, <i>OR</i>
and consumer acceptance studies.	(b) Consumed food contains a food additive below the level AND for a
and consumer acceptance studies.	use determined safe by the Food and Drug Administration or
	approved by the Environmental Protection Agency or the USDA
	Food Safety and Inspection Service
	Tool Survey and hispochon Service

Administratively-Reviewed Exempt Research

Additional Notes:

- Research involving participant deception (where the researcher does not fully disclose the purpose of the research or the consequences of a participant's action), sensitive behavioral research, or research involving vulnerable populations (such as pregnant women, prisoners, mentally disordered individuals, children, institutionalized individuals) does <u>not</u> fit the required criteria for this category of review and must receive the full IRB review.
- Observational research that either involves sensitive aspects of participants' behaviors or when done in locations where the participant has a reasonable expectation for privacy, is <u>not</u> eligible for administratively-reviewed exempt certification from the IRB and must receive full IRB review. Similarly, sensitive survey research that may include questions about illegal activities, highly personal behavioral aspects, life experiences, or attitudes, sensitive demographic data, detailed health history, or any other aspect that would have the potential for provoking a negative emotional reaction from the participant do not quality for exempt certification.
- For research with participants under the age of 19 (minors in Nebraska), consult Appendix IV for additional conditions that must be met.

Review Process:

The researcher should complete the Human Participants in Research Training (as described in Principal investigator's Responsibilities) and the IRB Expedited Review Form. The completed form and the training certificate should be submitted to the administrative chair of the CSC IRB.

If the CSC IRB Chair determines that a project application falls into the Administrativelyreviewed exempt category, the Chair will serve as primary reviewer for that application. The Chair will determine that participant's rights and welfare area appropriately considered and that the project qualifies for administratively-reviewed exempt certification.

Two weeks should be allowed for thorough review of a completed application. Once the review has been completed, the Chair will notify the researcher of any required modifications, and will notify the researcher in writing regarding the status of the application once the modifications are submitted and approved.