Chadron State College Human participant Research:
Characteristics of
Expedited Review Status

Research that provides no more than minimal risk to participants but does not meet the administratively-reviewed exempt category will require either expedited or full-board review. The specific circumstances of the proposed research will be reviewed to determine the level of risk to the human participants. Select activities that may fall under the expedited IRB Review category includes the following (listed below). Please note that these listed activities are not deemed to be of minimal risk simply because of their inclusion on the list; inclusion merely means that the activity is *eligible* for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

Research Categories that may be Eligible for Expedited Review:

Category	*Conditions*
1. Research on existing data or specimens	Participant confidentiality must be appropriately maintained, and risk to the individual must be minimized.
2. Clinical studies of drugs and medical devices when the following conditions are met:	a. Research on drugs for which investigational new drug application is not required (as defined in Title 45 Federal Code of Regulations 54), AND b. Research on medical devices for which an investigational device exemption application is not required OR the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling.
3. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:	a. From healthy, nonpregnant adults who weigh at least 100 pounds (amount drawn may not exceed 550 ml in an 8 week period, and may not occur more frequently than 2 times per week). OR b. From other adults or children (amount drawn may not exceded 50 ml or 3 ml/kg body weight in an 8 week period and may not occur more frequently than 2 times per week).
4. Prospective collection of biological specimens for research purposes by noninvasive means.	May include (a) hair and nail clippings collected in a nondisfiguring manner, (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

5. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be appropriately cleared/approved for marketing and use.	May include (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imagining; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.	
7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	Characteristics and behaviors may include, but are not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
8. Research on moderate exercise by healthy volunteers	
9. Continue review of research previously approved by the convened (full-board reviewed) IRB as follows:	a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants, OR b. where no participants have been enrolled and no additional risks have been identified; OR c. where the remaining research activities are limited to data analysis.

Additional Notes:

- Research involving 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 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 research project application falls into the Expedited Review category, the primary reviewer for that application will be the Chair of the IRB. The Chair will determine that participant rights and welfare are appropriately considered, and no more than minimal risk exists for participants.

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 the Chair will notify the researcher in writing regarding the status of the application once the modifications are submitted and approved.