Committee for the Protection of Human Subjects
Checklist for Researchers and Reviewers

A. **Abstract**: one paragraph summary of the protocol, including potential risks, benefits, and risk management procedures

B. **Protocol**: included in this order as applicable to the study:

1. Purpose and Background
- ☐ a. Brief references to literature or statement of the problem
- ☐ b. Justification for study involving humans (medical research)
- ☐ c. Specific aims of research
  - 1) Hypotheses, questions to be answered, data to be tested or gathered
  - 2) Relevance to continuing work in the field

2. Subjects
- ☐ a. Number
- ☐ b. Source
- ☐ c. Criteria for inclusion and exclusion
- ☐ d. Rationale for using special groups whose capabilities to provide informed consent may be absent or limited
- ☐ e. Discussion of potential problems and risks involving the subject group

3. Methods
- ☐ a. Recruitment procedures ensuring voluntary participation
- ☐ b. Investigational or experimental procedures involving human subjects
- ☐ c. Special procedures (IND, radioisotopes, electrical equipment, etc.)
- ☐ d. Frequency and duration of each procedure
- ☐ e. Location of study

4. Potential Benefits
- ☐ a. Benefits to the individual subject or patient, if any
- ☐ b. Benefits to the population from which the subject is drawn
- ☐ c. Benefits to science, society, humanity in general

5. Potential Risks
- ☐ a. Psychological/emotional
- ☐ b. Social
- ☐ c. Physical
- ☐ d. Economic
- ☐ e. Legal
- ☐ f. Violations of normal expectations

☐ 6. Precautions Taken to Minimize Risks (If confidentiality is an issue, specify how it will be managed and protected, i.e., coding procedures, storage of and access to identifying data, when data will be destroyed.)

☐ 7. Compensation of Subjects

☐ 8. Academic Background and Experience of Investigator(s)

C. **Evidence of CITI Human Subjects Research Training Completion**: All investigators and collaborators, including student collaborators, must have a current CITI certification. See: https://www.fresnostate.edu/academics/humansubjects/training-modules/index.html

D. **Consent Form**: For studies involving risk, the form should be in language appropriate to subjects and include the following information. See Sample Informed Consent Document: https://www.fresnostate.edu/academics/humansubjects/forms/

- ☐ 1. Purpose of research (including larger social purpose, if appropriate)
- ☐ 2. Procedures (including time required and locale)
- ☐ 3. Potential risks and discomforts
- ☐ 4. Potential benefits
- ☐ 5. Where applicable, alternative treatments, including their risks and benefits
- ☐ 6. Extent of confidentiality
- ☐ 7. Statement regarding voluntariness of participation and freedom to withdraw without jeopardy
- ☐ 8. Investigator's phone number and email for questions
- ☐ 9. If applicable, terms of compensation
- ☐ 10. CPHS Chair phone number and email for reporting injuries and questions of rights
- ☐ 11. If applicable, provision for parent, guardian, or physician consent

If an introductory statement will preface the consent form, both should be submitted. For studies not involving signed written consent, researchers should submit the cover letter or statement that will be used to obtain voluntary participation of subjects.

E. **Study Instruments**: Surveys, interview guides, focus group questions, etc.

F. **Approval Letters from Participating Institutions** (as applicable)

All protocol information and supporting documentation should be submitted through Kuali IRB, which can be accessed here: https://www.fresnostate.edu/academics/humansubjects/index.html.

If you have any questions, pleases call (559) 278-4468 or email cphs@mail.fresnostate.edu.