COLUMBUS STATE
INSTITUTIONAL REVIEW BOARD

Helpful Hints on What Qualifies as an Exempt IRB Protocol

Submitting a research project for evaluation by Columbus State's IRB can be a daunting task filled with new terminology and foreign processes. We, at Columbus State's IRB, would like to make this as straightforward as possible. A good place to begin for anyone considering submission of a protocol are the different levels that a protocol can be designated – any project submitted to our IRB can be considered Not Research (NR), Exempt, Expedited, or Full. Since Columbus State requires all surveys to be seen by the IRB, even those considered Not Research (e.g., In-service Satisfaction Surveys) must provide notification. Of the protocols considered "research," the most convenient from the standpoint of the submitting principal investigator is the *Exempt* protocol designation. This category is defined by the Office of Human Research Protection (OHRP) to encompass research that poses no more than minimal harm to research participants. Exempt protocols need only to be reviewed by the IRB Chair and since they don't require full committee approval, turnaround time can be much shorter. The following is a summary based on the criteria in OHRP's *Revised Common Rule* §46.104 Exempt research[i].

In order to facilitate the process of helping your research meet the criteria for *Exempt* research, listed below are some recommendations that would allow research to be considered *Exempt* rather than *Expedited* or *Full*.

1. If it's research done in typical educational settings to explore "normal educational practices" that don't impact student-participants' opportunity to learn, including taking significant time and attention away from standard educational content that may have a detrimental effect on student achievement.
2. Research on adults using educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior as long as **at least one** of the following criteria is met:
    a. The information is recorded so as to be anonymous (individuals can't be traced back through the data, meaning no identifiers are paired with the data).
    b. Any disclosure of the information would not place the subject at risk for criminal or civil liability, or be damaging to subjects' financial standing, employability, educational advancement, or reputation.
    c. The information is non-anonymous but the IRB conducted a limited IRB review and made a determination that the qualities for meeting exemption are still met.
3. If the study uses benign behavioral interventions on adults (e.g., an early alert 'nudge' or an email reminder to register for the next semester; the intervention is brief, harmless, not likely to have a significant adverse lasting impact), the study will be exempt if **at least one** of the following criteria is met:
    a. The information is recorded so as to be anonymous (individuals can't be traced back through the data, meaning no identifiers are paired with the data).
    b. Any disclosure of the information would not place the subject at risk for criminal or civil liability, or be damaging to subjects' financial standing, employability, educational advancement, or reputation.

    c. The information is non-anonymous but the IRB conducted a limited IRB review and made a determination that the qualities for meeting exemption are still met.
4. Secondary research for which consent is not required. Secondary research uses of identifiable private information that has been collected for non-research purposes or from research studies other than the proposed study (as long as the use of the information aligns with what subjects were told during the informed consent process of the original study) if **at least one** of the following criteria is met:
    a. The identifiable private information or biospecimens are publicly available.
    b. Participants are anonymous, the researcher doesn't try to contact the participants, and the investigator will not re-identify participants.
    c. The research is conducted by, or on behalf of, a Federal department or agency.
5. Research funded and/or conducted by a Federal agency meant to study, evaluate, improve, or examine a public benefit.
6. Taste and food quality evaluations and consumer acceptance studies.

We at Columbus State's IRB are here to help. Don't hesitate to reach out to the IRB Administrator (irb@cscc.edu), should you have any further questions.

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[i] The 2018 Common Rule specifies two additional exemptions, 7 and 8, related to use of information under what is called "broad consent". Exemptions 7 and 8 will not be implemented at Columbus State at this time.