

EXEMPT CATEGORIES (brief description)

Category 1 104(d)(1)

- A. Commonly established educational setting.
- B. Normal educational procedures.
- C. Unlikely to adversely impact students' opportunity or assessment of educators.

Category 2 104(d)(2) Only test/survey/interview/public observation (data collection only, may include visual or auditory recording, may NOT include intervention/only includes interactions.

- (i) Recorded information cannot readily identify participant(s) OR
Surveys and interviews, no children;
Educational tests/observation, children only if investigators do not participate.
- (ii) Any disclosure will not reasonably place the subject at risk if disclosed.
- (iii) Information is recorded with identifiers or code linked to identifiers and IRB conducts limited review; no children. **REQUIRES LIMITED REVIEW BY THE IRB.**

Category 3 104(d)(3)(i) Involves benign behavioral intervention (BBI) through verbal, written responses, adult subjects, and one of criteria is met (no children and no medical interventions).

- A. Recorded information cannot readily identify participants.
- B. Any outside disclosures would not reasonably place participant at risk.
- C. Information is recorded with identifiers and cannot have deception unless participant prospectively agrees.
REQUIRES LIMITED REVIEW BY THE IRB

Category 4 104(d)(4) Secondary research, consent not required, data collected from another primary activity, retrospective and prospective 2ndry use.

- (i) Specimens/information is publicly available.
- (ii) No identifying information recorded by investigator, no contact or re-identification with participants?
- (iii) Collection and analysis involving use of identifiable health information when regulated by HIPAA (no biospecimens).
- (iv) Information collected by or on behalf of federal government generated or collected information obtained for non-research activities.

Category 5 104(d)(5) Research and demo projects supported by a federal agency/department and designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs or procedures; or possible changes in methods or levels of payment for benefits or services under the programs. **MUST BE POSTED ON A FEDERAL WEBSITE**

Category 6 104(d)(6) Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below level found to be safe by FDA or approved by the EPA or the Food Safety and Inspection Service of USDA. **NO PRISONERS**

Categories 7 and 8 require broad consent. The AU IRB has determined the regulatory requirements for legally effect for legally effect broad consent are not feasible within the current institutional infrastructure. Exempt categories 7 and 8 will not be implemented at this time.