

TCU/Tribal IRB Checklist for "Exempt" Review 07/04/05

Date: / / **ID #:** **Title:**

Primary IRB: **Concurring IRBs:**

PI: **PI's Institution:**

Primary Reviewer: **Co-Chair Reviewer:**

Purpose [brief outline]:

Methods [e.g., survey, chart review] **& study population:**

To be "exempt" from further IRB review, the protocol must include ONLY 1 or more of the following categories. Check within which category[ies] the protocol fits.

- A. Use only existing, anonymous or publicly available, data. _____
- B. Research or demonstration service or care program: approved by funding Agency Director; involves only administrative issues; evaluation methods are also exempt. _____
- C. Interviews, surveys, educational tests, or observations with non-vulnerable people. _____
- D. Research or evaluation of normal educational practices. _____
- E. Food research to evaluate quality, taste, or consumer acceptance. _____

To be "exempt," the protocol must also meet all of these 5 criteria.

- 1. It is not greater than minimal risk to individuals & communities; and _____
- 2. If exempt because participants cannot be identified, it indeed protects anonymity; and _____
- 3. Any disclosure of info about others is no more than minimal risk to them; and _____
- 4. If done in a tribal, TCU, or health facility, the disclaimer is accurate; and _____
- 5. If education or health data: FERPA, PPRA, Privacy Act, & HIPAA are met. _____

NOTE: This form may be used/modified by tribal/TCU IRBs, without permission by author.

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