What kinds of research must be reviewed by the DHRP and IRBs?

In order to determine whether or not the research proposed meets the criteria of approval set by The University of Toledo and certain sponsoring agencies, all research involving human subjects must be submitted for prior review. Protocols are reviewed by the DHRP or the IRB office staff under the regulations set forth in 45 CFR 46 and placed into one of three categories: convened review, expedited review or exempt. The DHRP may also determine that a certain application is not human subject research under the definitions set forth in 45 CFR 46.102.

It is the prerogative of the DHRP and IRB p roposal is exempt. For additional information regarding categories of review, please access the federal guidance information at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/iuch as (i) research on regular and special educati research on the effectiveness of or the comparison amon classroom management methods. This category may inc

î X Research involving the use of educational tests (c survey

procedures, interview procedures or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employment or reputation. Research which deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol, cannot be exempt from review.

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4. Research involving the collection or study of existing data2, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This category may include children.

5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. This category may include children.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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 the level found to be safe, by the U.S. Food and Drug Administration or approved by the Environmental Protection Agency or the Food and Safety and Inspection Service of the U.S. Department of Agriculture. This category may include children.

1 Harm to subjects means that any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or can be damaging to subjects' financial standing, employability, or reputation.

2 Existing data means the items exist before the research was proposed or was collected prior to the research for a purpose other than the proposed research. (For purposes of a grant, this refers to data collected prior to the time the research was proposed.)