

DETERMINATION OF STATUS

Page 13

DETERMINATION OF "EXEMPT" STATUS

INTRODUCTION/DEFINITION

EXEMPT (from further IRB oversight) research is a category of research, defined by Title 45 Code of Federal Regulations Part 46 (aka the Common Rule) that does not require FULL BOARD review and approval. Unless otherwise required by department or agency policies, research activities, which only incorporate human subject involvement as described below, will qualify for one or more of the following EXEMPT categories.

EXEMPT CATEGORIES

These exemptions do NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [*Applies to research with minors.*]
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) [*applies to research with minors*], survey procedures [*does NOT apply to research with minors*], interview procedures [*does NOT apply to research with minors*], or observation of public behavior [*applies to research with minors only when the investigator(s) does(do) NOT participate in the activities observed*] **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, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is NOT already EXEMPT under #2 if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office, **or** (ii) Federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner

DETERMINATION OF STATUS

Page 14

that subjects cannot be identified directly or through identifiers linked to the subjects. [*Applies to research with minors.*]

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 these programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) payment for benefits or services under those programs.

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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

DETERMINATION OF EXPEDITED STATUS

If your project is not classified as EXEMPT and the risk of harm anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, your project may qualify for EXPEDITED review (involves minimal risk).

DETERMINATION OF FULL BOARD REVIEW STATUS

If your project involves more than "minimal risk" to participants as defined previously, your project requires a FULL BOARD review. Protocols involving any of the following will also require FULL BOARD review (unless your project qualifies as EXEMPT as described in that section):

- Including minor subjects (children 17 years of age or younger⁴)
- Targeting special populations (prisoners, pregnant women, individuals with disabilities)
- Using of video- or audiotape to record participants
- Asking questions that may be highly embarrassing or compromising (e.g., sexual behavior, sexual orientation, alcohol consumption, illegal drug use,

⁴ UNLESS your project meets the EXEMPT criteria defined in that section.

DETERMINATION OF STATUS

Page 15

medical conditions, violations of the law, personal finances, problems in the workplace, etc.)

- Exposing participants to graphically violent or pornographic materials
- Inflicting physical pain upon, attaching electrodes to, or injecting any substance into participants
- Creating high levels of stress, fear, discomfort, or tension
- Threatening participants in any way
- Causing participants to violate laws or official university regulations
- Providing some participants with benefits denied to others (this includes payments or rewards for participation, e.g., exclusively offering extra credit to research participants, etc.)
- Causing physical or mental exhaustion or engaging participants in intense (maximal) exercise
- Placing individuals in confining physical settings or attaching other devices
- Exposing participants to extreme conditions (e.g., bright lights, loud noise, intense pressure, strong odors, complete darkness, extreme heat or cold, sudden movement, etc.)
- Leaving participants alone for periods of time longer than 20 minutes
- Taking hair samples or nail clippings from participants
- Taking human tissue samples or sampling any other bodily fluid