Disclosure of Sponsors

In any public communication the content of which is based on the results of sponsored research, a faculty member or other employee or appointee of an institution of higher education, including a college district, who conducted or participated in conducting the research shall conspicuously disclose the identity of each sponsor of the research. *Education Code 51.954(a)*

Definitions

"Public Communication"

"Public communication" means oral or written communication intended for public consumption or distribution, including:

1. Testimony in a public administrative, legislative, regulatory, or judicial proceeding;
2. Printed matter including a magazine, journal, newsletter, newspaper, pamphlet, or report; or
3. Posting of information on a website or similar internet host for information.

Education Code 51.954(b)(2)

"Sponsor"

"Sponsor" means an entity that contracts for or provides money or materials for research. *Education Code 51.954(b)(3)*

"Sponsored Research"

"Sponsored research" means research:

1. That is conducted under a contract with, or that is conducted under a grant awarded by and pursuant to a written agreement with, an individual or entity other than the institution conducting the research; and
2. In which payments received or the value of materials received under that contract or grant, or under a combination of more than one such contract or grant, constitutes at least 50 percent of the cost of conducting the research.

Education Code 51.954(b)(4)

Restriction on State Agency Contracts

A state agency that expends appropriated funds may not enter into a research contract with an institution of higher education, including a college district, if that contract contains a provision precluding public disclosure of any final data generated or produced in the course of executing the contract unless the agency reasonably determines that the premature disclosure of such data would adversely affect public safety, the protection of intellectual property rights of the institution of higher education, publication rights in professional scientific publications, or valuable confidential information of the institution of higher education or a third party. This prohibition does not apply to a research contract between an institution of higher education and the Cancer Prevention and Research Institute of Texas. *Education Code 51.955(b)–(c)*

Research Involving Human Subjects – Institutional Review Board Common Rule

The Common Rule applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to the Common Rule must comply with the Common Rule.

6 C.F.R. Part 46 (Department of Homeland Security); 7 C.F.R. Part 1c (Department of Agriculture); 10 C.F.R. Part 745 (Department of Energy); 14 C.F.R. Part 1230 (NASA); 15 C.F.R. Part 27 (Department of Commerce); 20 C.F.R. Part 431 (Social Security Administration); 22 C.F.R. Part 225 (Agency for International Development); 24 C.F.R. Part 60 (Department of Housing and Urban Development); 29 C.F.R. Part 21 (Department of Labor); 32 C.F.R. Part 219 (Department of Defense); 34 C.F.R. Part 97 (Department of Education); 38 C.F.R. Part 16 (Department of Veterans Affairs); 40 C.F.R. Part 26 (Environmental Protection Agency); 45 C.F.R. Part 46 (Department of Health and Human Services); 45 C.F.R. Part 690 (National Science Foundation); 49 C.F.R. Part 11 (Department of Transportation)

Exceptions

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories below are exempt from the requirements of the Common Rule, except that such activities must comply with the requirements of this section and as specified in each category.

6 C.F.R. 46.104(a); 7 C.F.R. 1c.104(a); 10 C.F.R. 745.104(a); 14 C.F.R. 1230.104(a); 15 C.F.R. 27.104(a); 20 C.F.R. 431.104(a); 22 C.F.R. 225.104(a); 24 C.F.R. 60.104(a); 29 C.F.R. 21.104(a); 32 C.F.R. 219.104(a); 34 C.F.R. 97.104(a); 38 C.F.R. 16.104(a); 40 C.F.R. 26.104(a); 45 C.F.R. 46.104(a), 690.104(a); 49 C.F.R. 11.104(a)

Research That Does Not Adversely Impact Education

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction is exempt. This includes most research on regular and special education instructional strategies, or research

on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Research Involving Tests, Surveys, Interviews, or Observation of Public Behavior

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) is exempt if at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

2. 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, educational advancement, or reputation; or

3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Benign Behavioral Interventions

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording is exempt if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Secondary Research for Which Consent is not Required

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens is exempt if at least one of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available;

2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 C.F.R. Parts 160 and 164, Subparts A and E, for the purposes of "health-care operations" or "research" as those terms are defined at 45 C.F.R. 164.501 or for "public health activities and purposes" as described under 45 C.F.R. 164.512(b); or

4. The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with Section 208(b) of the E–Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Public Benefit or Service Programs

Research and demonstration projects which are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for

benefits or services under those programs are exempt. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as Sections 1615 and 1615A of the Social Security Act, as amended. Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Taste and Food Quality Studies

Taste and food quality evaluation and consumer acceptance studies are exempt 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 contaminants at or below the level found to be safe, by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Storage or Maintenance for Secondary Research for Which Consent is Required

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use is exempt if an IRB conducts a limited IRB review and makes the following determinations:

1. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of the Common Rule;

2. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with the Common Rule; and

3. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

6 C.F.R. 46.104(d); 7 C.F.R. 1c.104(d); 10 C.F.R. 745.104(d); 14 C.F.R. 1230.104(d); 15 C.F.R. 27.104(d); 20 C.F.R. 431.104(d); 22 C.F.R. 225.104(d); 24 C.F.R. 60.104(d); 29 C.F.R. 21.104(d); 32 C.F.R. 219.104(d); 34 C.F.R. 97.104(d); 38 C.F.R. 16.104(d); 40 C.F.R. 26.104(d); 45 C.F.R. 46.104(d), 690.104(d); 49 C.F.R. 11.104(d)

Secondary Research for Which Broad Consent is Required

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the Common Rule;

2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the Common Rule;

3. An IRB conducts a limited IRB review and makes the determination that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data and makes the determination that the research to be conducted is within the scope of the broad consent referenced at Storage or Maintenance for Secondary Research for Which Consent is Required, above; and

4. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

6 C.F.R. 46.104(a), (d); 7 C.F.R. 1c.104(a), (d); 10 C.F.R. 745.104(a), (d); 14 C.F.R. 1230.104(a), (d); 15 C.F.R. 27.104(a), (d); 20 C.F.R. 431.104(a), (d); 22 C.F.R. 225.104(a), (d); 24 C.F.R. 60.104(a), (d); 29 C.F.R. 21.104(a), (d); 32 C.F.R. 219.104(a), (d); 34 C.F.R. 97.104(a), (d); 38 C.F.R. 16.104(a), (d); 40 C.F.R. 26.104(a), (d); 45 C.F.R. 46.104(a), (d), 690.104(a), (d); 49 C.F.R. 11.104(a), (d)