

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-5.04
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SOP 5.04 – Exempt Determination

1. Objective

To describe procedures for determining whether a human subjects research project qualifies for exempt status under 45 CFR 46.104(d)(1)-(8).

2. General Description

In accordance with federal regulations, institutional policy, and prior to project implementation, UNLV applies the federal Common Rule (45 CFR 46.104(d)) and related guidance regarding the eight categories of research that can be considered “exempt” from the federal regulations. The regulations of the Food and Drug Administration (FDA) about exemption are applied only to FDA-regulated human subjects research.

Definitions

Exempt - Research that is found to be “exempt” is still considered to be human subjects research. However, it is exempt from meeting the requirements of the federal human subjects regulations, including the requirement for initial and annual IRB review.

Minimal risk - UNLV applies the definition of minimal risk provided in federal regulations (45 CFR 46.102): The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Additional requirements

In addition to the federal criteria, research qualifies for exempt status only if it involves no more than minimal risk.

The IRB and ORI-HS retain the right to require oversight and continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations even though it may not be required by federal regulation.

All or nothing

All of the proposed research activities of a federally funded study must fit into one or more of the exemption categories defined by federal regulations. Parts of the research cannot be considered exempt when other parts are not.

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Federal opinion: When different institutions are conducting portions of a single research study: the entire study must meet one or more of the exemptions in order for the exemptions to apply to the portion of the study occurring at a single institution. This applies even when different institutions under subcontracts are conducting the components of the study.

Prospective determination required

The research may not begin until the Principal Investigator (PI) has received notification from ORI-HS that the research qualifies for exemption.

Duration of exempt status

Exempt status is granted for the period until the research is completed. However, if the research will continue past a period of three (3) years, researchers must notify ORI-HS of continuation or the protocol will be closed.

Collaboration and Exempt Determination

When UNLV researchers are collaborating with another institution, it is possible to obtain only one (1) determination for the project. The UNLV researcher should contact ORI-HS prior to application submission to determine the status of the submission. See SOP 3.10 for additional considerations when conducting collaborative research.

When the project involves researchers not affiliated with UNLV, those researchers must complete and sign the Individual Investigator Assurance for Exempt Research Studies.

Exceptions

Research with the following characteristics will not be granted exempt status even if they meet one or more of the above criteria:

- Research involving prisoners as subjects
- Research involving children as subjects when it involves survey or interview procedures
- Observation of public behavior of children when the investigator interacts with the children.

Contact Information for ORI-HS, to respond to complaints or concerns about subject rights

The eight (8) Exemption Categories

Category 1: Educational Practices

45 CFR 46.104(d)(1): 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. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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- Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms. They may also include after-school programs, preschools, vocational schools, alternative education programs, and other sites where educational activities regularly occur.
- Normal educational practices include established or innovative teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher. Normal educational practices are activities that could occur regardless of whether the research is conducted.

Category 2: Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior

45 CFR 46.104(d)(2): 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) if at least one of the following criteria is met:

- (i) 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;
- (ii) 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
- (iii) 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 required by §46.111(a)(7).
 - Interpretation of the “Identifiable” criterion: This criterion means that the data are collected/recorded anonymously – which means that no identifiers can be connected to the data, either directly or through a coding system.
 - Audio/Videotapes and photographs are usually considered to be identifiable. Therefore any data collection that involves audio/video recordings or photographs of subjects would not be considered anonymous.
 - It is also possible that multiple pieces of information, none of which are identifiable on its own, may identify a person when brought together. Under such circumstances, the data would be considered identifiable.

Category 3: Benign Behavioral Interventions

45 CFR 46.104(d)(3): (i) 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 if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (A) 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;

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- (B) 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
- (C) 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 required by §46.111(a)(7).

(ii) 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.

(iii) 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.

- “Brief in duration” speaks to the intervention itself, not the data collection period.
- This exemption can only apply to adult subjects.
- Subjects that need a legally authorized representative to assist in decision making would not qualify for this exemption.
- Subjects in this exemption category must prospectively agree to participate in the study. This prospective agreement is not required to be explicit consent but must understand that their involvement in the research is agreed to. Due to this requirement, research involving deception can only occur for this exemption category if they agree to “be unaware of or misled regarding the nature or purpose of the research.”
- “Intervention” is limited to procedures with the following: “communication or interpersonal contact with the subject, the performance of a cognitive, intellectual, educational or behavioral task, or manipulation of the subject’s physical, sensory, social, or emotional environment. This does not include physical (bodily) tasks or manipulations (e.g., range of motion activities, physical exercise) unless these are minor activities that are incident to the behavioral intervention and do not increase risk. For example, manipulating a keyboard, doing a puzzle, or walking while listening to music would be physical activities that could be considered minor activities that are taking place incident to the benign behavioral intervention. Physical interventions that are physically invasive or those that could be harmful or painful would not meet the exemption.

Category 4: Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

45CFR 46.104(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available;

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(ii) 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;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) 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.*

- Research can qualify for this category of exemption if the investigators initially have access to identifiable private information, but de-identify the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include direct identifiers (names, social security numbers, addresses, phone numbers, etc.) or indirect identifiers (codes or pseudonyms that are linked to the subject’s identity).

Category 5: Research and Demonstration Projects Conducted or Supported by or Subject to the Approval of Department or Agency Heads

45 CFR 46.104(d)(5): Research and demonstration projects that 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.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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.

Such projects include, but are not limited to:

- Internal studies by Federal employees
- Studies under contracts or consulting arrangements, cooperative agreements, or grants.

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- These projects also include also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

This category applies only to federally supported projects examining federal public benefits programs. It is extremely rare for research to meet the criteria of this category.

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

45 CFR 46.104(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 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.

- The research may not involve the consumption of any type of food, or volume of food, that would present any risk to the subjects. The research must involve what the subject would consider reasonable eating behaviors.
- Definition of “wholesome”: means that the investigator has not manipulated the food ingredients, and that the content of the food will not be detrimental to the health of the subjects. If the research involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA.
- Studies involving the consumption of alcohol, vitamins, and nutritional supplements do not qualify for exempt status.

Category 7: Storage or Maintenance for Secondary Research for which Broad Consent is Required

45 CFR 46.104(d)(7): 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 if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

Under the limited IRB review, the IRB must determine that:

- Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the applicable informed consent and broad consent requirements;
- Broad consent is appropriately documented or waiver of documentation is appropriate; and
- 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.

Category 8: Secondary Research for which Broad Consent is Required

45 CFR 46.104(d)(8): 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:

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(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) 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.

Category 7 and 8 considerations:

- To implement fully a broad consent program, institutions would be required to install a system to track biospecimens and data for which individuals provide their broad consent, as well as the terms of the broad consent to determine which future research uses remain within scope.
- Extensive and seamless IT system capacity will be necessary for any institution or health system to implement fully a broad consent tracking system, as both broad consents as well as refusals to consent (unless the materials are destroyed) must be tracked over the lifetimes of persons who give broad consent and persons who refuse to give such consent. Due to these systems requirements for electronic tracking processes, SACHRP expects that, practically speaking, institutions or systems without interconnected, interfacing and fully interoperable medical records systems will not be able to implement and benefit from the broad consent regimen established in the Final Rule. A “confederated,” non-IT-unified health system will simply not be able, without significant error, to track these consents and refusals to consent. These logistical barriers will greatly limit the utility of the broad consent option.
- The practical utility of the broad consent will probably include (1) an identified biorepository or databank study, whose defined purpose is to collect biospecimens and associated data from a well-defined set of individuals and for which the broad consent elements can be included in the study consent, thus giving researchers downstream access to the related exemptions, and (2) primary research studies in which the researchers seek to use an “add-on” or integrated broad consent to facilitate future research uses of the identified data and biospecimens collected as part of that primary study. In each of these cases, however, the use of broad consent would be specifically targeted to well-defined subject groups, rather than to a broad swath of all newly-admitted patients or all newly-enrolled clients.
- A subject’s refusal to give broad consent also does not prevent the unconsented uses of their identifiable data and biospecimens for purposes that are not considered “research” under the revised Common Rule. For these reasons, if a person who is offered a broad consent refuses to give that consent, institutions have three basic options. First, if allowed by other law, they may simply destroy that person’s identifiable information and biospecimens. Second, they may de-identify the person’s information and biospecimens and use them for future research without restraint. Third, they may decide to retain the identifiable information and biospecimens, but allow their future use only for non-research purposes, such as quality improvement. In this third option, however, the institution must track that person’s information and biospecimens to ensure they are not used for future research purposes.

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3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/ Study Personnel (SP), Office of Research Integrity – Human Subjects (ORI-HS) Staff, IRB Members

Who determines exempt status?

The CIP certified staff of the UNLV Office of Research Integrity – Human Subjects (ORI-HS) (and in some cases members of the IRB) are the individuals authorized to determine that research is exempt. Researchers and/or others who might have a conflict of interest regarding a study do not have the authority to determine that their own research qualifies for exempt status.

4. Procedures

Principal Investigators' Procedures

Requesting an exempt determination

PIs request an exempt status determination from ORI-HS by submitting a completed Exempt Research Application. Before applying for exempt status, PIs should confirm that their study is, in fact, considered research with human subjects.

- In addition to the application, the PI is responsible for submitting all research related materials. This may include documents such as the informed consent/parent permission/assent/information sheet, surveys, interview questions, data collection sheets, recruitment materials, facility authorization, etc.
- CITI training must be current (completed within the last five (5) years) for all research team members. If there are researchers not affiliated with UNLV, a copy of their equivalent human subjects research ethics training will need to be submitted. In the event they do not have human subjects research ethics training, they will need to complete the UNLV CITI Training. See SOP 4.05 for additional information about Researcher education requirements.

Requesting a continuation of exempt status

When the exempt research will continue beyond three years, the PI must notify the ORI-HS of its continuation or the protocol will be closed.

Modifications to the research

Minimal changes to exempt studies may not need to be reviewed; a modification request would not typically be required for the following types of modifications to an approved study:

- Personnel changes (e.g. change in members of the research team; however, change in PI requires a modification request)
- Change in the number of subjects to be enrolled
- Change of Status (e.g. continuing to enroll additional subjects)
- Non-substantive editing of associated documents (e.g., recruiting announcements, consent/assent documents)
- Change in tool used in the protocol that is unrelated to human subject risk (e.g. substitution or minor revision of instrumentation used in the study).

It is the responsibility of the PI to document minor changes to the approved exempt study. In the event of an audit, these documented changes must be provided to ORI-HS.

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Any substantive change to the exempt research may invalidate the exempt determination. The researcher is responsible for consulting with ORI-HS when changes are planned, to ascertain whether a new exempt determination, IRB review, or no action is required. PIs may contact ORI-HS via phone or email detailing the changes. If contacted by phone, the researcher will be asked to provide a written summary through IRBNet. A determination/acknowledgement will be sent back acknowledging the changes and notifying the PI if any further action needs to be taken.

If a minor modification is implemented by the researcher and is subsequently determined to be inconsistent with exempt status of a study, the researcher(s) could be subject to UNLV noncompliance procedures (see SOP 11.02).

Standards of conduct

Although research that qualifies for exempt status is not governed by federal regulations, investigators remain responsible for protecting the rights and welfare of their subjects by conducting the research in accordance with: The ethical principles of Respect for Persons, Beneficence, and Justice as described in the Belmont Report; Other applicable federal and state laws; UNLV policies; and Relevant professional standards and codes of conduct as generally accepted in the investigator's academic and/or professional discipline.

- The investigator is responsible for making every effort to ensure soundness of research design.
- Ethical requirements also extend to incidental findings arising in the course of research. Researchers should be prepared to respond to any issues that arise in the course of exempt research to ensure the protection of research participants.

Voluntary participation

The Belmont principle of Respect for Persons states that subjects should be given the opportunity to choose whether to participate in research. For this reason, ORI-HS expects that investigators will generally obtain some type of consent from subjects for any exempt research where the investigator will collect data through interaction (in-person or otherwise) with the subjects. This consent(s), whether presented as a document or as an online format, should be submitted with the application.

- If the research involves children, it is almost always appropriate to inform parents of their child's participation in the research. The signature of one parent is commonly accepted in exempt studies (Note that there may be other federal regulations that require parental permission, such as the COPPA regulation from the federal Department of Commerce about collecting identifiable information through a website from children under the age of 13).
- The consent process need not include all of the federally required consent elements. ORI-HS encourages investigators to provide subjects with, at a minimum, the information listed below in the consent process and before any data collection begins. Additional information may be appropriate in some cases.
 - The identity/affiliation and contact information of the investigator
 - A statement that indicates that the activity is research and that participation is voluntary
 - A brief description of the study procedures
- The information sheet template may be used in these instances where researchers need an example to use.

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ORI-HS Procedures

Ethical Considerations

Although most exempt research requires no further oversight to be conducted ethically, some exempt research raises ethical concerns or requires measures to protect participants. The following will be considered when reviewing research that may be exempt:

- Selection of participants is equitable.
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data if necessary.
- If there are interactions with participants, there will be a consent process that will disclose such information as:
 - The activity involves research.
 - A description of the procedures.
 - Participation is voluntary
 - Name and contact information for the PI.
- There are adequate provisions to maintain the privacy interests of participants.

Overall process

ORI-HS staff assesses the materials provided by the PI. They apply the criteria and guidance described in this document to determine whether a human subjects research project qualifies for exempt status.

Prior to determination decision, the staff member may contact the PI for clarification about procedures in the protocol and/or to obtain copies of additional materials needed to make the determination.

Eligibility for exempt status may be sent forward for review by the IRB Chair, Co-Chair or member.

- When an IRB Chair, Co-Chair, or Member confirms an exempt application eligible for exempt status, they will document this review on a reviewer sheet and forward to ORI-HS for record keeping and notifications to the PI.
- When an exempt application is deemed not eligible for exempt status, the IRB Chair, Co-Chair or Member will document this review on a reviewer sheet and forward to ORI-HS. ORI-HS will then request the PI to submit an application on the Protocol Proposal Form. The exempt application will be closed.

ORI-HS staff makes the determination for all of the following items as part of the pre-review process, whether or not the PI has explicitly requested it: Initial Protocol Proposal Form applications; any formal request for Excluded; and Exempt Research Applications.

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Documentation

The determination (including the category(s) of exemption) is documented on a review sheet and in any communication to investigators. Determinations are considered ORI-HS records and are appropriately tracked and filed. ORI-HS communicates the determination in writing to the researcher.

Food and Drug Administration (FDA)

Research regulated by the FDA qualifies for exempt status only if it meets the criteria described for Category 6. Moreover, FDA-regulated research does not qualify for exempt status under Category 6 if there have been food or color additives incorporated into the food product and those additives are used in research with the intent to apply to the FDA for marketing of the additive(s).

Involvement of third party subjects

Third party subjects are individuals about whom the researcher is obtaining private identifiable information from someone else. For example, an individual might be asked to provide private identifiable information about the medical history of a relative. The relative would be considered a third party subject. Involvement of third party subjects does not disqualify a project from exempt status.

- Federal regulations do not allow research involving surveys and interviews with children subjects to qualify for exempt Category 2 (surveys, etc.) This means that research involving children as third party subjects and surveys/interviews does not qualify for exempt Cat. 2.

Deception and incomplete disclosure

Deception means deliberately misleading subjects about some aspect of the research. The omission of minor factors is not equivalent to deception. Examples of deception include:

- Misinforming participants about the research
- The use of fake or rigged instruments or procedures
- Misleading play-acting in experimental design
- The use of covert procedures

Incomplete disclosure means deliberately withholding certain information regarding certain aspects of the study. Examples include:

- Withholding specific information about the true purpose of a study. See SOP 6.03 for additional considerations.

Studies using deception or concealment may qualify for exempt status when all applicable exempt criteria are met and when:

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- The deception or incomplete disclosure is necessary to ensure valid results. For example, withholding or misinforming subjects about the true purpose of a study may be important to reduce biased responses (i.e., “demand” characteristics). Research findings suggest that such deception is not harmful to subjects.
- The deception or incomplete disclosure is not being used to get subjects to do something that the majority of them would not do if the information was fully disclosed to them; and
- The conditions of the deception pose no more than minimal risk of physical or emotional distress. “Conditions” include: the nature of the deception or concealment; how likely it is that subjects will learn of the deception or concealment; the nature of any de-briefing; how likely it is that anyone besides the research team and the subject would learn results about a subject that would be distressing to the subject.
- A debriefing of subjects after they complete the procedures may be appropriate and may be required (but is not necessary) to obtain exempt status. The need for a de-briefing does not necessarily exclude a project from exempt status; the key issue is whether the project overall (including the de-briefing) involves no more than minimal risk to subjects.
- An example of survey research involving deception that would qualify for exempt status is when a researcher does not tell the subjects that they plan to see if their answers to demographic questions (e.g., gender, age, socio-economic status, family size, etc.) predict their responses to questions about the value of a college education.

5. References

45 CFR 46.104

45 CFR 46.401 (Subpart D)

21 CFR 56.104

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Office of the Secretary of Health and Human Services; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979.

OHRP, “Guidance on 45 CFR 46.101(b)(5) Exemption for Research and Demonstration Projects on Public Benefit and Service Programs”, March 1983.

Secretary’s Advisory Committee on Human Research Protections (SACHRP), Meeting Minutes, from meeting held on March 8-9, 2011; Attachment E, “The Use of Deception in Research”.

Secretary’s Advisory Committee on Human Research Protections (SACHRP), Recommendations approved July 26, 2017; Attachment B, “Recommendations on Benign Behavioral Intervention”.

Secretary’s Advisory Committee on Human Research Protections (SACHRP), Recommendations approved July 26, 2017; Attachment C, “Recommendations for Broad Consent Guidance”.

Department of Health and Human Services, Advance Notice of Proposed Rulemaking, “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators”. Federal Register volume 76, number 143, July 26, 2011. Re exempt category 2, see page the top of page 44519.