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 46.101(b)(1)-(6).

2. General Description

In accordance with federal regulations, institutional policy, and prior to project implementation, UNLV applies the federal Common Rule (45 CFR 46.101(b)) and related guidance regarding the six 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.

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.

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 only individuals authorized to determine that research is exempt. Researchers do not have the authority to determine that their own research qualifies for exempt status.

All or nothing

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

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.

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 that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The Six (6) Categories

Category 1: Educational Practices
45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: 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.

- 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 46.101(b)(2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** any disclosure of the human subjects' responses outside of 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.

- 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: Educational Tests, Survey Procedures, Interview Procedures, or Observation of Public Behavior

45 CFR 46.101(b)(3): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2) if: the human subjects are elected or appointed public officials or candidates for public office; or Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Interpretation of the "public officials" criterion: This category is for the same procedures as in category 2, but holds public servants to a different privacy standard by not requiring that the collected data be anonymous and is not concerned with any risks that may result from disclosure of the data. This category does not apply to public employees such as managers and staff in public agencies or offices. Federal guidance provides the following non-inclusive list of examples of public officials:

- Mayors, governors
- School superintendents, school board members
- Police chiefs

Category 4: Existing Data or Specimens

45CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- Definition of "existing": The materials or data to be used in the research must be existing or "on the shelf" at the time the research is proposed to ORI-HS on the Exempt Status Request form. This category does not apply to the prospective collection of data or specimens even if it would be collected outside the research study.
- 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 by or Subject to the Approval of Department or Agency Heads

45 CFR 46.101(b)(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: Public benefit or service programs; 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. The protocol must:

- Be conducted pursuant to specific federal statutory authority;
- Have no statutory requirements for IRB review;
- Not involve significant physical invasions or intrusions upon the privacy interests of participants;
- Have authorization or concurrence by the funding agency.

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 46.101(b)(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.

3. Roles & Responsibilities

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

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.

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. A response 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

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

ORI-HS Procedures

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 review 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 review 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.

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:

- 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 she plans 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 46.101
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".

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.