

 Office of Research Integrity - Human Subjects		SOP #:	ORI(HS)-5.04
		Revision #:	3.0
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Approved By: ORI Executive Director	*[Redacted]	Date	Date First Effective: May 25, 2014
Approved by: Biomedical Chair	*[Redacted]	Date	
Approved by: Social Behavioral Chair	*[Redacted]	Date	Revision Date: January 21, 2019

SOP 5.04 – Exempt Determination

1. Objective

To determine if research falls under 45 CFR 46.104(d)(1)-(8).

2. General Description

UNLV Institutional Review Board (IRB) determines if research falls under 45 CFR 46.104(d) and (e) (FDA) and (F) (FDA).

Definitions

Exempt Research: Research that is exempt from IRB review.

Minimal risk: UNLV Institutional Review Board (IRB) determines if research falls under 45 CFR 46.102): The probability and magnitude of harm or discomfort anticipated by the subjects are minimal.

Additional requirements

IRB must determine if research falls under 45 CFR 46.104(d) and (e) (FDA) and (F) (FDA).

IRB and ORI-HS will determine if research falls under 45 CFR 46.104(d) and (e) (FDA) and (F) (FDA).

All or nothing

All research falls under 45 CFR 46.104(d) and (e) (FDA) and (F) (FDA).

(i) If the information is not in the public domain, the information is not to be disclosed.

public information is not to be disclosed.

(i) The information is not to be disclosed if it is a trade secret, confidential information, or information that is exempt from disclosure under 5 CFR 164.501.

information is not to be disclosed if it is a trade secret, confidential information, or information that is exempt from disclosure under 5 CFR 164.501.

5 CFR 164.512(b); or

(v) The information is not to be disclosed if it is a trade secret, confidential information, or information that is exempt from disclosure under 5 CFR 164.501.

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UNLV Office of Research Integrity - Human Subjects and Instit

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As a condition of the
 IRB review process, the
 HS investigator must
 obtain IRB approval
 before conducting any

ORI-HS Exempt Determination

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If a study is
 exempt from UNLV
 SOP 11.02).

Standards of conduct

As a condition of the
 IRB review process, the
 HS investigator must
 obtain IRB approval
 before conducting any

IRB; Other UNLV

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- The
- Ethical
- Research

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Voluntary participation

As a condition of the
 IRB review process, the
 HS investigator must
 obtain IRB approval
 before conducting any

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- If a study is
 exempt from UNLV
 SOP 11.02, the
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Involvement of third party subjects
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