

Standard Operating Procedure (SOP)

SOP #: 851.007	Process and Required Elements of Consent for Exempt Research
Executive Owner: VP of Research Operations	Effective Date: 9/25/2020
	Review Date: 9/25/2020

Scope	This standard operating procedure (SOP) applies to the <Research Personnel> and Institutional Review Board (IRB) staff members, chair and committee members at AdventHealth Orlando.
Purpose	The purpose of this SOP is to describe the required process and provide the required elements of informed consent for studies determined by the IRB to meet Exempt criteria.
Qualified Personnel	IRB Chair, IRB Members, IRB Staff Members, Investigators and <Research Personnel>.
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	<ol style="list-style-type: none"> 1. An IRB member determines whether a study meets the criteria of Exempt research and whether consent is required. 2. The consent process must provide sufficient opportunity for the participant to consider whether to participate and minimize the possibility of coercion or undue influence. 3. The consent may not include exculpatory language. Exculpatory language is language through which the participant is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. 4. The consent must disclose sufficient information in understandable language using plain terms when appropriate for the participant to make a decision, to include: <ol style="list-style-type: none"> 4.1. The activity involves research 4.2. The purpose of the research 4.3. The procedures to be followed 4.4. That participation is voluntary 4.5. The expected duration of participation 4.6. The confidentiality of the responses or anonymity of the process 4.7. Whom to contact for questions about the research
Definition(s)	IRB: Institutional Review Board
Reference(s)	45 CFR 46.101(b)(1)-(6) <Pre-2018 Requirements> 45 CFR 46.104(d)(1)-(8) <2018 Requirements> DOD: 32 CFR 219
Related Documents	HRP-423 WORKSHEET: Exemptions

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Keywords

HRP-508 TEMPLATE: Consent for Exempt Research

IRB, exempt, research, consent, AHRI