


Title: Waiver of Informed Consent or Documentation

Effective Date:	4/1/2021	Document Number:	IRB-SOP-21-0.1
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Approval/Date:

 <hr style="width: 100%;"/> Jamie Peno Assistant Vice President, Research Integrity and Compliance	4/1/2021 Date
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REVISION HISTORY

Date	Section	Author

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the procedures for researchers to obtain a waiver of informed consent in human subjects research, and for the review and approval of waivers of informed consent from the Institutional Review Board.

SCOPE

This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and University of North Texas (UNT) requirements for the management, coordination, and operation of the Institutional Review Board (IRB) program. It applies to all UNT researchers performing human subjects research.

DEFINITIONS/ ABBREVIATIONS
1. Definitions

- 1.1 *Principal Investigator:* The individual who is actively leading and/or supervising the initiation, execution, and completion of a research project in compliance with applicable laws, regulations, and institutional policy governing the conduct of research. It is ultimately the PI's responsibility to ensure that all personnel actively working on the project and interacting with human subjects are following the guidelines of the approved protocol and are treating subjects in a manner befitting ethical use of human subjects. The PI should be the party responsible for submitting the research protocol, providing the RIC or the IRB with requested changes in order to garner approval, and for following the guidelines stipulated for annual review of the protocol and submission of any modification requests.

- 1.2 *Researcher*: Any individual performing various tasks related to the conduct of human subjects research activities, including but not limited to obtaining informed consent from subjects, collecting and analyzing data, interacting with subjects, and communicating with the IRB.
- 1.3 *Waiver of Informed Consent Request*: A request to waive or alter some or all of the elements of informed consent, the requirements to obtain informed consent, or the requirements to document informed consent as required under 45 CFR 46.116 and 45 CFR 46.117.

2. Abbreviations

- 2.1 IRB: Institutional Review Board
- 2.2 OHRP: Office for Human Research Protections
- 2.3 PI: Principal Investigator
- 2.4 RIC: Research Integrity and Compliance
- 2.5 SOP/SOPs: Standard Operating Procedure(s)

RESPONSIBILITIES

This SOP is applicable to all members of Research Integrity and Compliance and Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies for the Institutional Review Board program. This SOP is also applicable to all UNT Principal Investigators and Researchers performing human subjects research.

PROCEDURE

1. Principal Investigator Responsibilities

- 1.1 The Principal Investigator must assess the proposed research to determine if the study meets the regulatory requirements for a Waiver of Informed Consent Request.
- 1.2 The Principal Investigator must complete and submit the “Request for Waiver or Alteration” document and provide protocol specific justification for the request.
 - 1.2.1 The Principal Investigator requesting a waiver for documentation of consent must submit a script of what will be said and/or given to participants.
 - 1.2.1.1 Principal Investigators and Researchers must still provide participants with a consent document disclosing all the required elements necessary for informed consent. The Principal Investigators and Researchers must utilize the consent templates as available on the UNT IRB website.
 - 1.2.2 The Principal Investigator or Researcher performing the informed consent procedures must document participants’ consent in a log or other written form. Such documentation of consent shall be available to the IRB review if requested.

2. IRB Committee Responsibilities

- 2.1 Upon receipt of the Waiver of Informed Consent Request:
 - 2.1.1 The IRB Committee, or designee, will consider the request for a waiver of informed consent and the Principal Investigator’s justification verifying and documenting that regulatory conditions are applicable to the proposed research activity.
 - 2.1.2 The IRB Committee, or designee, will review the written description of the consent that the Principal Investigator will give the study participants.
 - 2.1.3 The IRB Committee, or designee, will make a determination if the Waiver of Informed Consent Request is appropriate.

- 2.1.3.1 If changes are needed, the IRB Committee, or designee, will communicate the requested changes to the Principal Investigator.
- 2.1.3.2 If the Waiver of Informed Consent Request is not appropriate, the Principal Investigator will be notified.
- 2.1.3.3 If the Waiver of Informed Consent Request is appropriate, the IRB Committee, or designee, will place a stamp on each page of the IRB approved Informed Consent document, written description, or Informed Consent Electronic Notice. The approved Informed Consent document, written description, or Informed Consent Electronic Notice will be posted to the electronic submission portal for use by the Researchers.

REFERENCES

- 1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)

APPENDICES

- 1. Waiver of Informed Consent Request