

Ethical Principles and Regulatory Mandate to Protect Human Research Participants	Effective Date	
	Revision Date	9.2.2020

1.0 Purpose: The purpose of this standard operating practice (SOP) is to describe the ethical principles and regulatory mandates surrounding the protection of human research participants.

2.0 Research Protocols Affected:

2.1 Human research activities reviewed and approved by the University and Medical Center Institutional Review Board (UMCIRB).

3.0 SOP: All human research conducted at ECU and those affiliates utilizing UMCIRB for IRB approval must comply with all applicable federal, state, local laws and regulations, institutional policies, and are guided by the ethical principles outlined in [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#).

The US Department of Health and Human Services (DHHS) regulations at 45 CFR Part 46, Subpart A constitute the Federal Policy (Common Rule) for the protection of humans in research. DHHS regulations also include additional protections for pregnant women, human fetuses and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D). These regulations are enforced by the DHHS, Office for Human Research Protections (OHRP) and are applied to all non-Exempt human research reviewed and approved by the UMCIRB.

The Food and Drug Administration (FDA) has codified informed consent (21 CFR Part 50), IRB (21 CFR Part 56), and child protection (21 CFR Part 50, Subpart D) regulations that are almost identical to the DHHS regulations. Additional FDA regulations relevant to the protection of human participants address Investigational New Drug Applications (21 CFR Part 312), Biological Products (21 CFR Part 600), Investigational Device Exemptions (21 CFR Part 812), and Humanitarian Use Devices (21 CFR 814 subpart H). All human research that involves test articles, whether investigational or approved, will be reviewed by the UMCIRB according to these regulations.

4.0 Definitions:

4.1 **The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research** defines the ethical principles and guidelines for the protection of human research participants. The Belmont Report provides important guidance regarding the boundaries between biomedical human research and the practice of medicine. Perhaps the most important contribution of The Belmont Report is its elucidation of three basic ethical principles:

- 4.1.1 Respect for persons (operationalized by obtaining informed consent)
- 4.1.2 Beneficence (operationalized by weighing risks and benefits)
- 4.1.3 Justice (operationalized by the fair selection of participants)

5.0 Responsibilities:

5.1 Principal Investigator (PI) will

5.1.1 Abide by the ethical principles, regulatory requirements, and institutional policies,

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- procedures, and practices for the conduct of human research.
- 5.1.2 Adhere to their professional standards when conducting human research.
 - 5.2 UMCIRB office staff will
 - 5.2.1 Pre-review proposed and on-going human research to identify concerns regarding ethical and regulatory issues prior to IRB review.
 - 5.2.2 Evaluate UMCIRB processes and procedures to ensure they support the ethical and regulatory requirements for conducting human research.
 - 5.3 UMCIRB Committee, Chairperson (or designee) will
 - 5.3.1 Ensure human research has met the criteria set forth in the federal regulations, state and local laws, and institutional policies, procedures, and practices before approving such human research to maximize potential benefits and minimize known or potential risks.

Revision History:

Date	Change	Reference Section(s)
5.18.2016	Pulled information to a stand-alone document.	All
9.2.2020	Updated UMCIRB office name and minor clarifications.	2.0, 3.0, 5.0

References:

FDA. Code of Federal Regulations: http://www.ecfr.gov/cgi-bin/text-idx?SID=d9905f5b97ecf190bef5dc6ea45f2743&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

DHHS, OHRP. Code of Federal Regulations: <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>