MEDICAL UNIVERSITY OF SOUTH CAROLINA HUMAN RESEARCH PROTECTIONS PROGRAM (HRPP)

Ethical Conduct of Research & Federal Regulations Governing Research

MUSC
Medical University of South Carolina

Ethical Principles and Regulatory Adherence

MUSC complies with the following regulations as appropriate for the research being conducted:

Identifies the base ethical principles underlying the conduct of human subject research:

- Respect for Persons
- Beneficence
- Justice

Regulates research involving human subjects in order to protect the rights and safety of subjects:

- 45 CFR 46 - Protection of Human Subjects (The Common Rule)

Establishes regulations that govern FDA materials in research:

- 21 CFR 50 - Protection of Human Subjects
- 21 CFR 56 - Insitutional Review Boards
- Other parts of 21 CFR dependent on the research

Enforces HIPAA: Provides data privacy and security for medical information:

- 45 CFR 160
- 45 CFR 164 (A)(E)

Ethics: The Belmont Report

Cornerstone of ethical principles and foundation of federal regulation

Belmont Principles

Respect for Persons

- Autonomy
- Vulnerable Protection
- Voluntary
- Informed
- Right to Withdraw
- Privacy and Confidentiality

Beneficence

- Maximize Benefits
- Minimize Harm
- Justify Benefits to Individual or Society

Justice

- Equitable Selection
- Who is Included?
- Who is Excluded?

45 CFR 46: Protection of Human Subjects

The Common Rule: Published in 1991 and adopted by 15 Federal departments and agencies.

Administered by the Office for Human Research Protections (OHRP), 45 CFR 46 are the regulations guiding the conduct of federally funded human subject research (Subpart A: The Common Rule) and contain:

45 CFR 46: Protection of Human Subjects

Includes The Common Rule as well as regulatory protections for the noted special populations. Researchers adhere to each subpart based on the subject population.

Subpart A:
The Common Rule – Basic Protections

Subpart B:
Pregnant Women, Fetuses & Neonates

Subpart C:
Prisoners

Subpart D:
Children

What is a Human Subject? 45 CRF 46.102(e)

01 A living individual about whom an investigator is conducting research:

02 Obtains information or biospecimens through intervention/interaction with the individual.

03 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research:

(per the Common Rule)

Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge.**

***Generalizable knowledge** is where information can be applied to populations or situations beyond what is being studied.

Food and Drug Administration

21 CFR 50: Protection of Human Subjects
21 CFR 56: Institutional Review Boards

Applies to review of human research involving FDA regulated products (e.g. food, dietary supplements, drugs, medical devices, some medical apps).

Applies when the investigation intendes to ‘treat, cure, mitigate, diagnose, or prevent disease in humans’.

Contains:

- Applicability
- Definitions
- Membership Requirements
- Criteria for IRB approval, 21 CFR 56.111
- Requirements for informed consent

Other FDA regulations may apply based on research being conducted (e.g. 21 CFR 812: Investigational Device Exemptions, 21 CFR 312: Investigational New Drug Application).

Definition Differences

FDA Regulations

Clinical Investigation:
Any experiment that involves a test article and one or more human subjects

Human Subject:
An individual who is or becomes a participant in research either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

The Common Rule

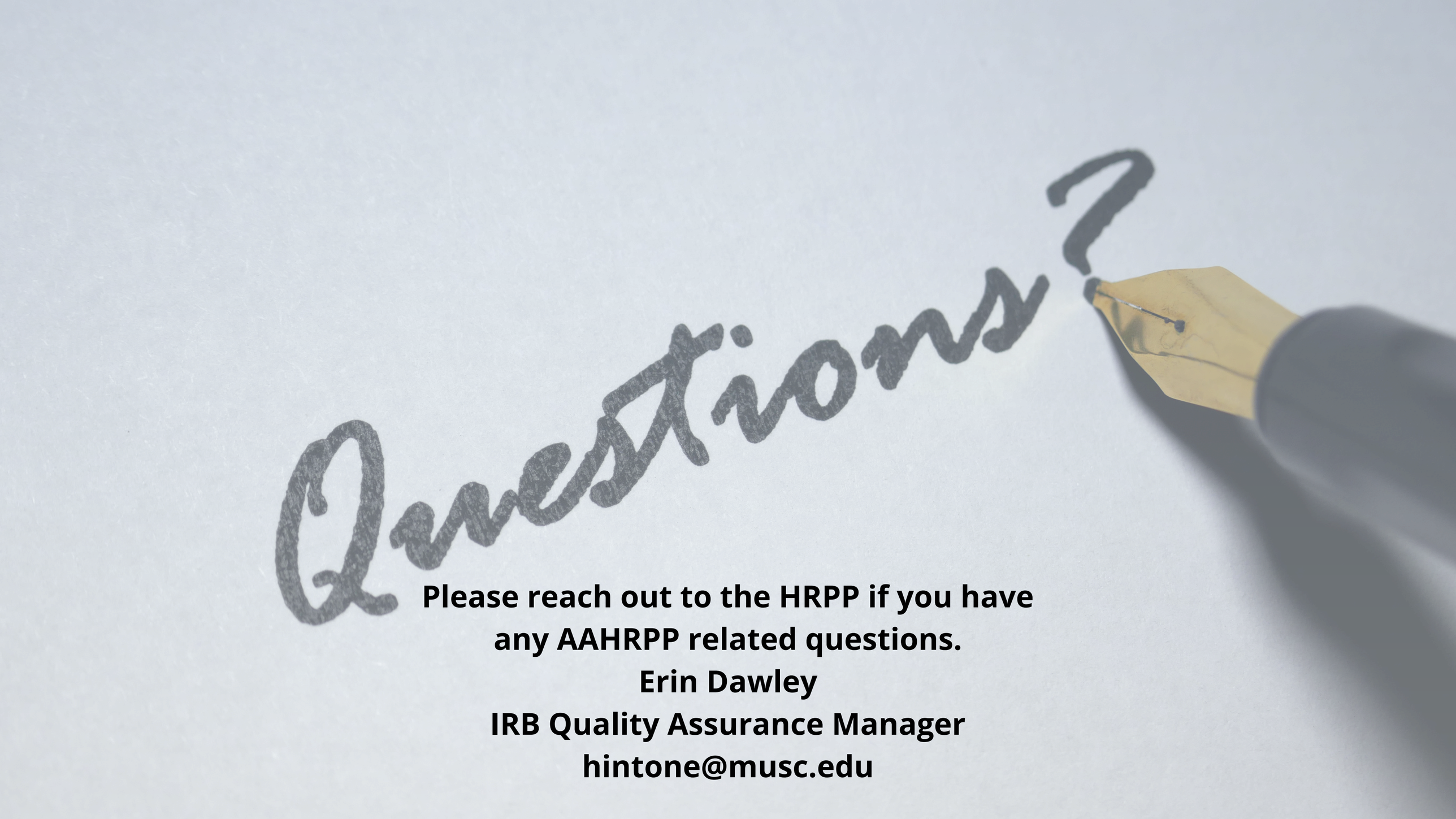
Research:
A systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge.

Human Subject:
A living individual about whom an investigator conducting research obtains:

- information or biospecimens through interaction or intervention

OR

- obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.



Please reach out to the HRPP if you have any AAHRPP related questions.

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