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

Structure, Jurisidiction, and Conflict of Interest

MUSC
Medical University of South Carolina

AAHRPP

- Association for the Accreditation of Human Research Protection Programs, Inc.
- Independent, non-profit accrediting body
- Voluntary, peer-driven process
- The Gold Standard
- MUSC's pursuit of accreditation demonstrates our commitment "to scientifically and ethically sound research and to continuous improvement"
- MUSC was first accredited in September, 2009; reaccreditation in September 2012 and September 2017 and 2022

AAHRPP Site Visit

Facts vs Misconceptions

Test? Audit?

The site visit is not a test, nor is it an audit.

HRPP Growth

AAHRPP recognizes that the MUSC HRPP continues to evolve and grow, and that we are committed to protecting human subjects.

What is AAHRPP looking at?

- Validation of support for the HRPP from the top down.

What is AAHRPP looking at?

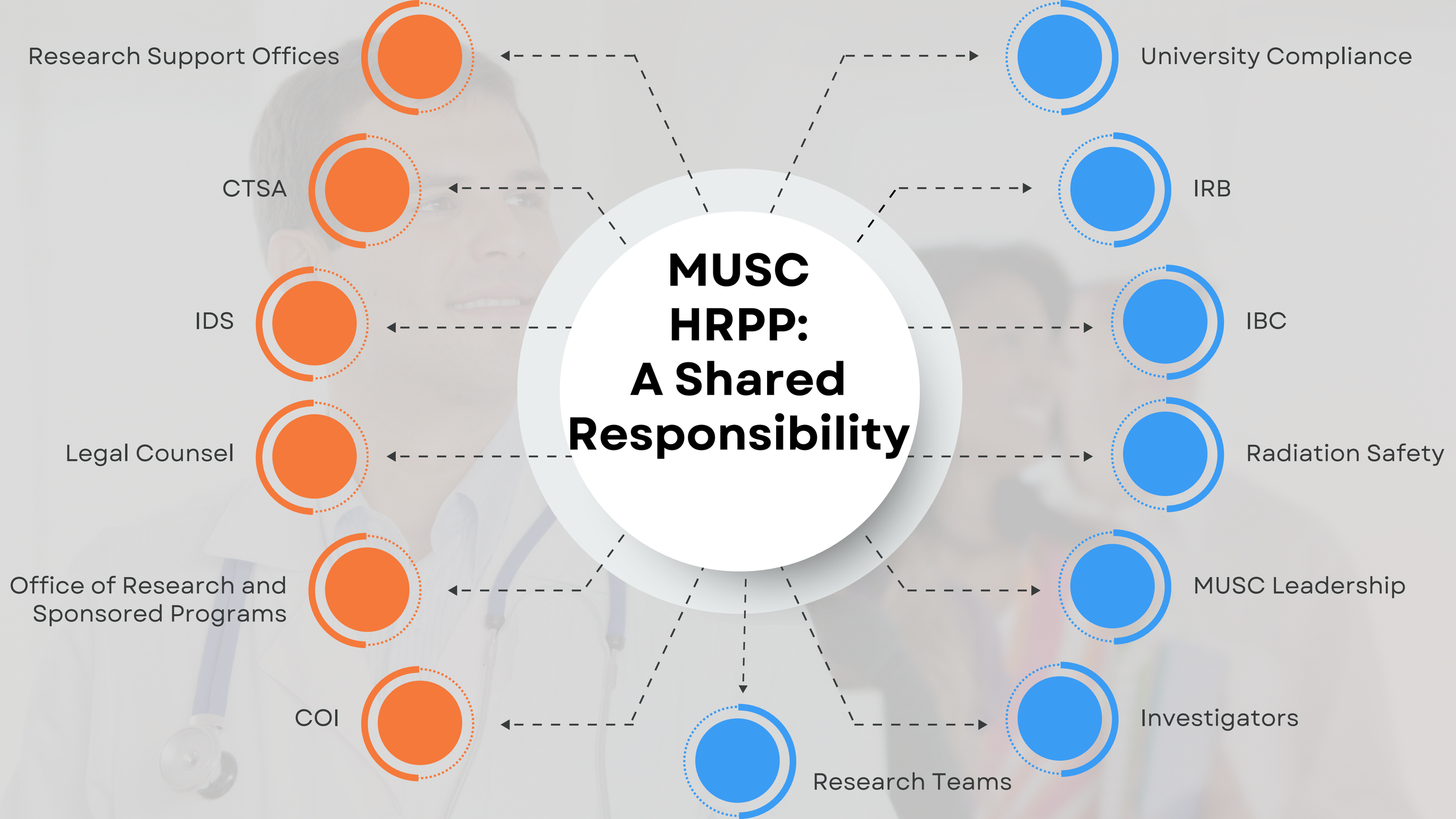
- That ALL people within the HRPP communicate and relate with each other.

Interviews

Interviews with each group (PIs, IRB Members, etc) are only a small portion of the overall assessment of the HRPP.

Questions

If you don't know the answer to a question, say so! ***Adding, but here is where I would find information.***


MUSC HRPP: A Shared Responsibility
Research Support Offices
CTSA
IDS
Legal Counsel
Office of Research and Sponsored Programs
COI
University Compliance
IRB
IBC
Radiation Safety
MUSC Leadership
Investigators
Research Teams

What is an Institutional Official (I/O)?

An individual who is legally authorized to act for the institution and can assure the institution will act acccording to the terms of the FWA.

Sufficient authority to allow authorization of necessary administrative or legal action should that be required.

Ensures that the HRPP has the resources and support essential to function in compliance with all requirements of human subject research.

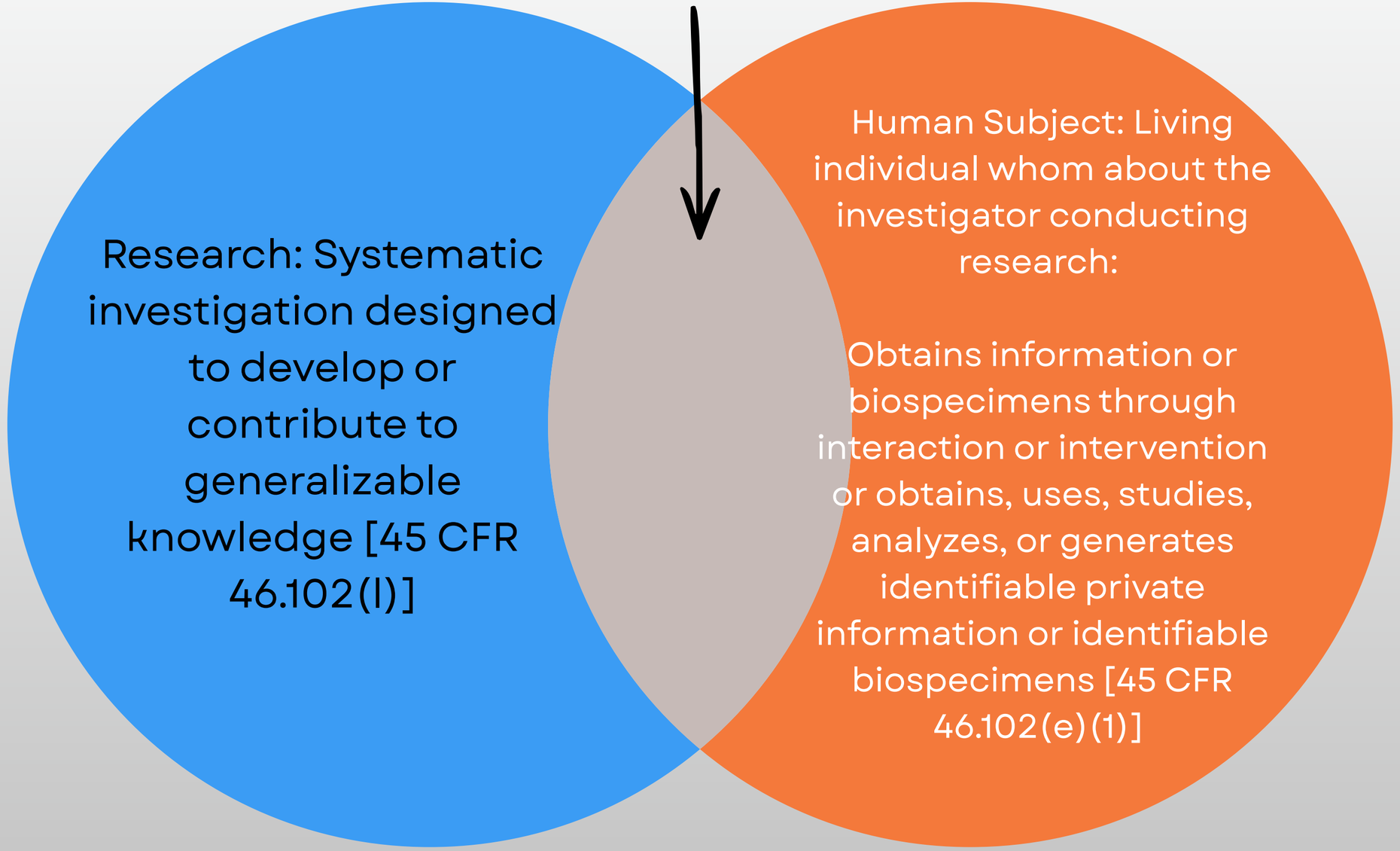
Organizational Chart

What is Federalwide Assurance (FWA)?

Each institution engaged in federally funded research must provide written assurance that it will comply with human subject protections regulations (45 CFR 46):

When is IRB Review Needed?

Human Subjects Research



The IRB has the authority to approve, require modifications to (in order to approve), or disapprove all research activities involving human subjects when:

- MUSC faculty, staff, or students are engaged in human subject research
- It is conducted at MUSC facilities
- It is conducted using MUSC private records

Regulatory Adherence

The University subscribes with the ethical principles and complies with the following regulations as appropriate for the research being conducted.

The Belmont Report

Identifies the basic ethical principals underlying the conduct of human subject research:

Regulatory Adherence

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

Establishes regulations that govern FDA materials in research.

- 21 CFR 50
- 21 CFR 56
- Other parts of 21 CFR depending on the research

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

- 45 CFR 46 (Common Rule)

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

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

Regulatory Adherence

International Conference on Harmonization (ICH) Good Clinical Practice

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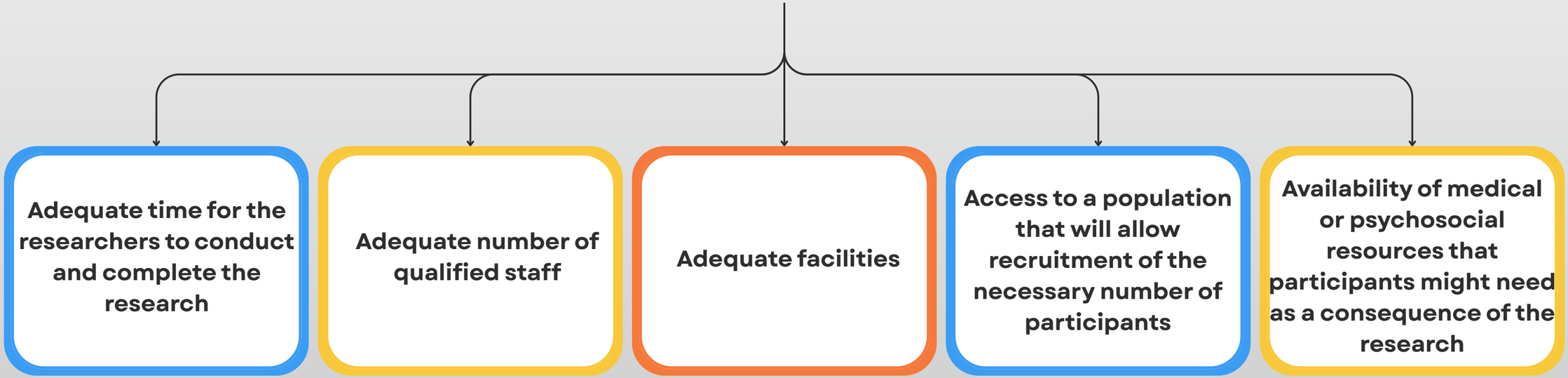
MUSC does not apply ICH/GCP requirements to all human research. The IRB is compliant with FDA regulations and ICH guidelines related to GCP, except where ICH GCP conflicts with FDA or DHHS.

Who is involved in conducting scientific review at MUSC?

Each department chairman or center director is ultimately responsible for the review and scientific integrity of any proposal that will be sent to the IRB.
This includes:

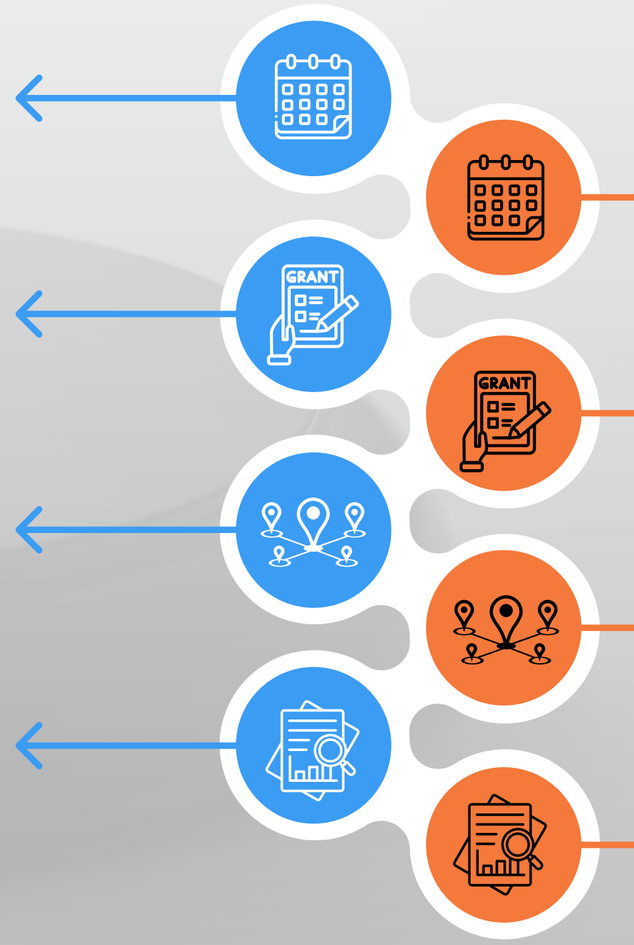


- ***The research that occurs at MUHA and the RHNs is reviewed for scientific integrity in the RHN governance committee.***

Single IRB Review (sIRB)

Legal arrangement that allows one IRB to review the research on behalf of other engaged institutions.

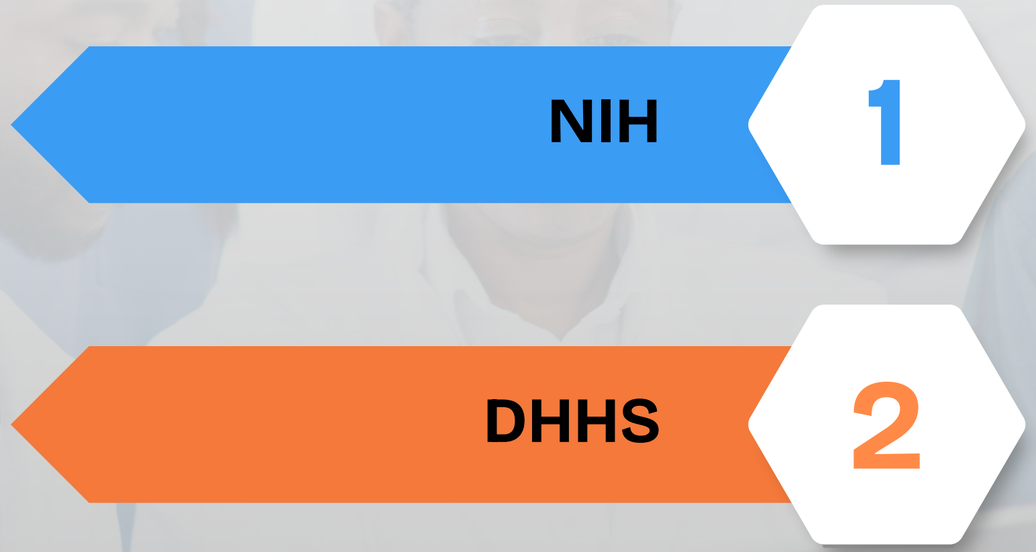
NIH Policy		DHHS Policy
Effective January 25, 2019		Effective January 18, 2020
Applies to NIH funded new grant, renewal, revision, or resubmission		Applies to ANY federally funded new grant, renewal, revision, or resubmission
Multi-site		Multi-site
Non-exempt		Non-exempt



When is Reliance Appropriate?

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research.

Required



Conflict of Interest

The Conflict of Interest committee plays an important role in assisting the MUSC community with understanding federal regulations and implementing best practices for managing potential conflicts arising from interactions with industry partners and engagement in entrepreneurial activities.

Conflicts of interest, particularly financial conflicts, have the potential to adversely affect professional judgment and compromise the integrity of the institution’s research, scholarship, teaching, evaluation, and administrative operations.

Conflict of Interest Management

1
Forwarded to COI office
Sent via eIRB.

2
COI office
Initiate review, coordinates the necessary documents between the researchers and the Research COI Committee Chair.

3
Review Determination
Administrative Review vs Full Committee Review

4
Decision
COI office communicates decision to IRB. Approval issued in eIRB. Committee Approval plan provided to IRB.

5
IRB
The IRB has the final authority to decide whether the approved management plan for any disclosed COI allows research protocols involving human subjects to be approved.

Questions?

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

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