

Human Research Protection Programs and Research Operations Partnering for Success



1



Kate Cohen, JD, CHRC, CHC
Chief Compliance Officer
SIU Medicine
kcohen65@siumed.edu



Justin Osborne
Associate Vice President
HRP Consulting
osbornej@thehrpconsultinggroup.com



2

Objectives

- ▶ Examine the roles of the Human Research Protection Program (HRPP) and Research Operations (Ops) and identify overlap
- ▶ Discuss bridging the gap between HRPPs and Ops and establishing a partnership
- ▶ Brainstorm how HRPPs and operations can support each other to ensure long term success



3

Poll- Who is the Room?

- ▶ Research Compliance/HRPP
- ▶ Research Operations
- ▶ Research Administration
- ▶ Industry/CRO/Consultants
- ▶ General compliance here to learn about research



4

Why Are We Talking About This?

- ▶ HRPP and Ops are groups that don't traditionally talk to each other a lot
- ▶ Different reporting lines/structure
- ▶ Every institution's model is different
- ▶ You can't do one without understanding the other



5

Roles and Responsibilities



6

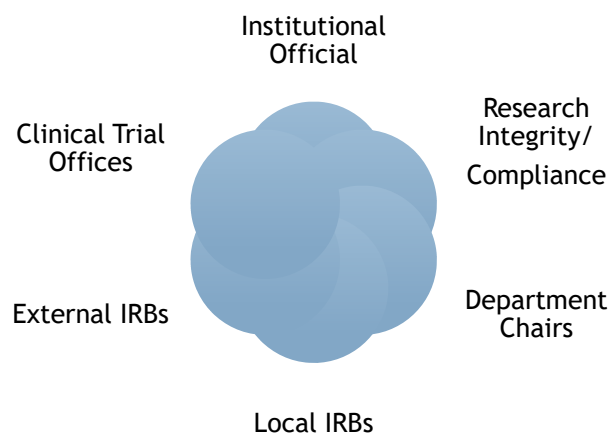
HRPP

- ▶ The HRPP is a comprehensive system to ensure the protection of the rights and welfare of subjects in research
- ▶ It is more than the IRB. It is the collective effort of all who participate in the development, conduct, review, approval and facilitation of research involving human subjects



7

HRPP



8

Role/Responsibilities of the HRPP

- ▶ Helping to ensure the institution is protecting human subjects
- ▶ Helping the institution comply with legal requirements and ethical guidelines
- ▶ Foster a culture of compliance within human subjects research
- ▶ Education and outreach
- ▶ Advance care through excellence in research



9

Research Operations

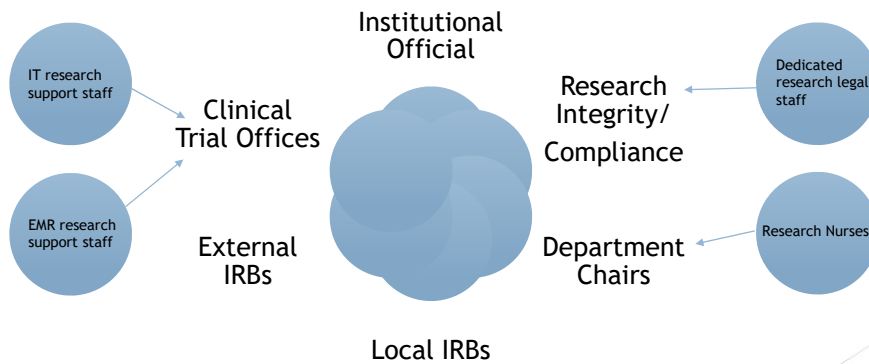
- ▶ What does Ops cover? It Depends!
 - ▶ Will vary by institution
 - ▶ People who operationalize and implement the study



10

Research Operations

- ▶ Ops is often spread out across the organization
- ▶ Centralized and Decentralized models



11

Research Operations

- ▶ Contract
- ▶ Budget
- ▶ Finance
- ▶ Billing
- ▶ Coordinators
- ▶ Marketing
- ▶ Research nurses
- ▶ Investigators
- ▶ Clinical informatics/IT support



12

Role of Research Ops

- ▶ Implement Studies
- ▶ Translate regulations into functional study designs
- ▶ Make Institution/Site more appealing for new studies
 - ▶ Find/Build relationships with industry partners
 - ▶ Identify tools to make site more competitive
- ▶ Discover efficiencies in study activities
- ▶ Enroll participants!



13

Overlap Between HRPP and Operations



14

Where is the Overlap?

- ▶ Operations is part of the HRPP - it is a fundamental part of the comprehensive system to ensure the protection of the rights and welfare of subjects in research
 - ▶ Consent issues
 - ▶ Documentation standards/practices
 - ▶ Noncompliance
 - ▶ Audits
 - ▶ Finance



15

Real Examples of Overlap

- ▶ Grant submissions involving human subjects- HRPP considerations for grant
- ▶ Budgeting/invoicing for IRB review
- ▶ Institutional approvals
 - ▶ Is your HRPP the gatekeeper for study initiation approval?
- ▶ Data and record keeping
 - ▶ Do you use HRPP data to understand your research universe?
 - ▶ Does the HRPP software work for operations and collect the data that operations and others need?



16

Real Examples of Overlap

- ▶ Software design and implementation
 - ▶ Electronic medical record research modules
 - ▶ Part 11 and SOP restrictions for electronic signatures
 - ▶ Participant stipend/reimbursement software
 - ▶ E-consent software
 - ▶ Source documentation software



17

Establishing the Partnership



18

Risks Posed by the Disconnect

- ▶ Competing standards for investigators
 - ▶ Example- IRB consent SOP vs. operations consent SOP
- ▶ Lack of trust
- ▶ Inconsistent research vision/mission
- ▶ Subpar performance - not meeting enrollment goals



19

Bridging the Gap and Overcoming the Disconnect

- ▶ Understanding roles and boundaries is key
 - ▶ The HRPP can't function without understanding how research is operationalized
 - ▶ Research cannot be successfully executed without understanding requirements related to human research protections (ethical standards, reporting obligations, etc.)
- ▶ Invite each other to the table
 - ▶ Decisions about policies, software, educational approaches, etc.



20

Bridging the Gap and Overcoming the Disconnect

- ▶ Establishing a common approach to research, including stances on outsourcing certain functions, establishing external partnerships, engaging in innovative studies
 - ▶ New emerging topics, technology- psychedelics, AI, GDPR- is everyone on the same page about how to proceed? Is your HRPP prepared and/or have the requisite expertise to consider regulatory implications of these new emerging issues that ops may be ready to jump head first into?



21

Real World Examples

- ▶ Institution wants to double their clinical trials AND cut the HRPP staff
- ▶ PI wants to bring a new study involving cannabis use, but hospital has policies prohibiting cannabis being on-site
- ▶ Electronic Medical Record research ops specialist identifies tool for eConsent in EMR and makes it available for all researchers, unbeknownst that the tool is not part 11 compliant and their IRB has policies against the use



22

Long Term Support and Success



23

Innovation vs Tradition

- ▶ Ops is focused on innovation - research is like any other business and depends on staying up with industry trends
- ▶ HRPP is focused on regulatory/policy requirements
- ▶ They seem incompatible when viewed separately
- ▶ They should be seen as a yin and yang
 - ▶ Together, these opposing forces can build a stronger program
 - ▶ But how?...



24

Setting up Long Term Success

- ▶ Establish a common mission
 - ▶ If everyone is working towards the same goal and expectations are tied to accomplishing that goal, all challenges and conflicts can be resolved
- ▶ Acknowledge the different roles and respect each other for engaging in those roles
- ▶ Open the lines of communication
 - ▶ Institutional risk tolerance vs. HRPP's charge under regulations to protect subjects



25

Setting up Long Term Success

- ▶ The Ronald Gladden Approach
 - ▶ Breaking down walls
 - ▶ Share true intentions
 - ▶ Job shadowing



26

Setting up Long Term Success

- ▶ It's a small, small world
 - ▶ Phone a friend- find someone on the other side who can help you out
 - ▶ Engage expertise outside of your organization



27

Real Examples

- ▶ Research Committee comprised of HRPP and Ops people meeting regularly to discuss topics on both sides
- ▶ Onboarding a new CTMS system (or any research tool), requiring HRPP staff be present for onboarding meetings and implementation discussions
- ▶ Retreats with HRPP and Ops that clearly outlines research mission for whole organization



28

Questions?



29

Kate Cohen, JD, CHRC, CHC
Chief Compliance Officer
SIU Medicine
kcohen65@siumed.edu

Justin Osborne
Associate Vice President
HRP Consulting Group
osbornej@thehrpconsultinggroup.com



30