

During the Best of Times and the Worst of Times: Communication Between IRBs and Researchers

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 **2021 Advancing Ethical Research Conference** November 16-19

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Disclosure: Dr. Myra Luna-Lucero, EdD

*I have no relevant personal/professional/financial relationship(s)
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*Teachers College, Columbia University
Research Compliance Director*

Learning Objectives

1. Objective 1

- Share IRB experiences during the pandemic

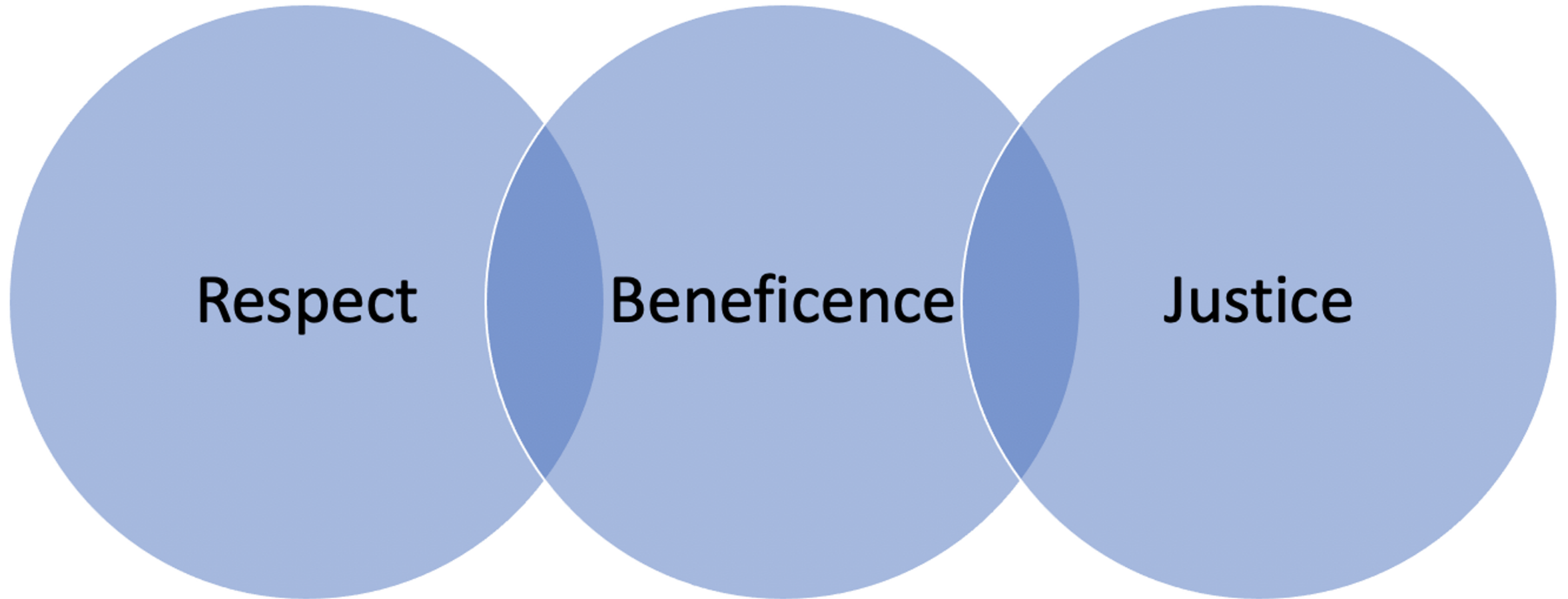
2. Objective 2

- Share researcher experiences during the pandemic

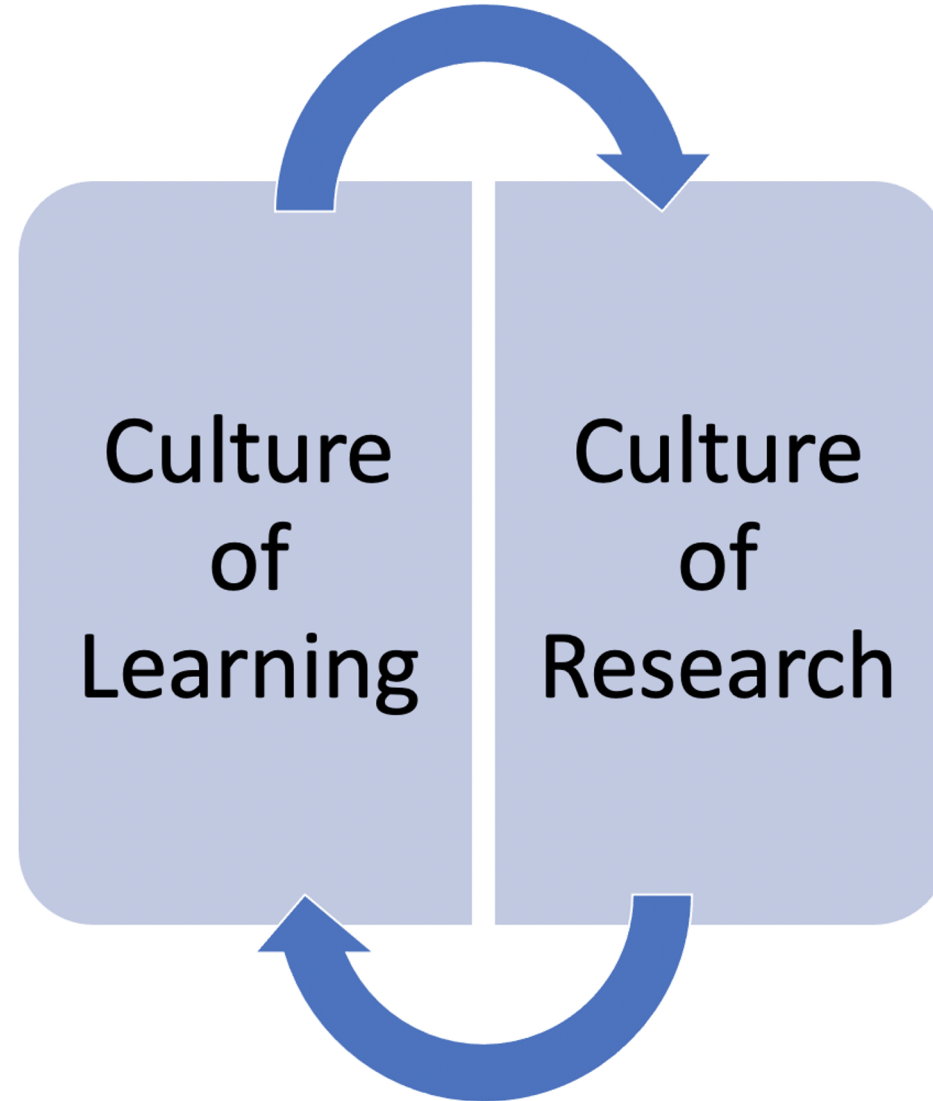
3. Objective 3

- Discuss communication between the IRB and researchers during the pandemic, and lessons learned

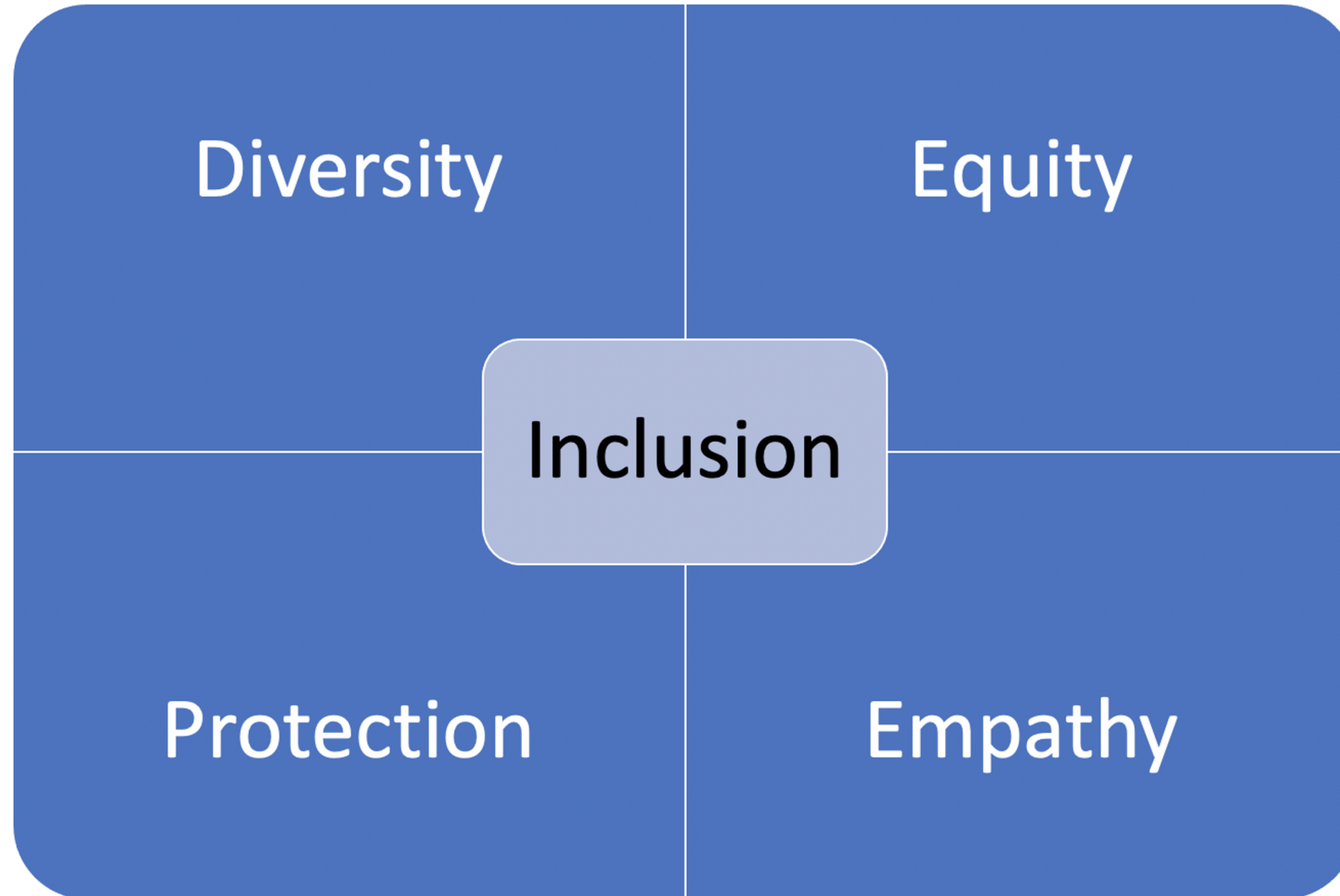
Ethical Principles



What We Support



What We Value



What We Do Everyday

Train

Guide

Review

Support

Evaluate

Educate

What March 5 – 15, 2020 Meant For

1. Ethics and research compliance
2. What we support, value, and do everyday



Pre-COVID

Post-
COVID

Research Compliance & Safety Committee



**Ethics & Safety
Amid Uncertainty
Training Modules**

Pulse of Research During a Pandemic

During natural or unnatural (person-made) disasters and humanitarian crises, researchers must establish extra safeguards to protect participants engaged in research.



Present Day: Ethics Amid Uncertainty

- Identify limitations
- Acknowledge scarce resources, small sample size, and modified methodology
- Seek information to fill any knowledge gaps

**ACKNOWLEDGE
LIMITATIONS**



- Understand your research responsibilities
- Stay informed and vigilant to protect yourself and others
- Decrease chances of harm

**CONTINUALLY
ASSESS RISK**



Present Day: Ethics Amid Uncertainty

- Analyze, adapt, and customize data collection methods
- Explore research and technology resources to help you meet goals

**DEVELOP NEW
STRATEGIES
AND INNOVATE**



- Develop high quality, content-specific plans for engaging participants in research activities
- Remain in compliance with Federal, State, City, and study site guidelines

**MAINTAIN
COMPLIANCE
AND HIGH QUALITY
STANDARDS**



Present Day: Ethics Amid Uncertainty

- Create a supportive space where individuals can make informed decisions about their health and safety
- Provide safeguards for study participants

**INCREASED
DECISION-
MAKING ABILITY**



- Participate in robust training and development programs
- Stay informed
- Expand your background knowledge

**REMAIN
CONSISTENT**



Present Day: Ethics Amid Uncertainty

- Test your knowledge, gauge your understanding
- Collect resources to keep updated on the latest news concerning research with human subjects

**TEST KNOWLEDGE,
SEEK INFORMATION
AND RESOURCES**



Present Day: Ethics Amid Uncertainty

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- Acknowledge scarce resources, small sample size, and modified methodology

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ACKNOWLEDGE LIMITATIONS



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CONTINUALLY ASSESS RISK



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TEST KNOWLEDGE, SEEK INFORMATION AND RESOURCES



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1. Preparing Researchers for In-Person Engagement Information Packet
 - a. Phased Ramp Up
 - b. Return to Campus Requirements
 - c. Steps to Resume In-Person Activities
 - d. Reporting Flow For Research Activities
 - e. Participant Covid Positive
 - f. Participant Unwell Off-Campus
 - g. Participant Unwell On-Campus
 - h. Off-Campus_Access Requirements
 - i. Ramp Down Checklist
 - j. Researcher Short-Term Crisis Management Guide
 - k. Post-Consent Safety Precautions
 - l. Research Lab or Center Safety Monitor Agreement

Questions?

Thank You