

# IRB/ERB Challenges in Reviewing HIV/Drug Abuse Research

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# Brief Intros

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- Sue
- Elizabeth
- Have you submitted an IRB as the PI?



# The Role of the IRB

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- Revised Common Rule (2019)
  - SIRB
  - Still...articulated through:
    - Respect for Persons (Informed Consent; Privacy, Confidentiality)
    - Beneficence/Nonmaleficence (Risk/Harm)
    - Justice (Equitable participation/equitable distribution of burden/benefit)

# Respect for Persons

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- Privacy/Confidentiality/Anonymity
  - Cultural
  - Legal
  - Generational perspectives
  - Data security and stewardship
- COCs—automatically issued
  - How would you explain these to participants?
  - “The study is supported by National Institutes of Health (NIH) funds. Such studies are automatically covered by a CoC.
  - The study is not NIH funded, but the IRB requires the study team to obtain a CoC because the study collects sensitive data which will remain identifiable.



# Beneficience

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- What are anticipated risks?
  - “Minimal risk:” According to the federal regulations at [§46.102\(i\)](#), *minimal risk* means that the *probability* **and** *magnitude* of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- What are anticipated benefits?
  - Think of different levels, ie, individual, communal, society

# Justice

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- Who is your intended audience and why?
- Enrollment criteria must be scientifically justified
- Do demographics matter?
  - Racial, gender, geographical, SES, orientation, educational
- Recruitment methods—is recruitment getting you to the scientifically valid population you need?



# Are These Adequate?

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- Maybe?
- No?
  - Fiduciary
  - Relational
  - Integrity

# Markham (2018)

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- Three Models of “Doing Ethics”:
  - the *error-avoidance* model, the *concept-driven* model, and the *impact-focused* model
  - Your MRP should provide empirical data for IRB on what the participant-perceived risks and benefits are
  - SCIENTIFICALLY VALID EMPIRICAL DATA ARE CRITICAL!



“

To do the right thing does not always involve doing what common ethics models or regulators consider the right thing.

Figure out what the right thing to do ethically is and see if the  
regs fit?

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*“...reliance on concepts rather than contextual details can lead not just to misdefining the vulnerability of participants, but to mistaking predetermined notions with actual experiences of harm”*

# Case Examples

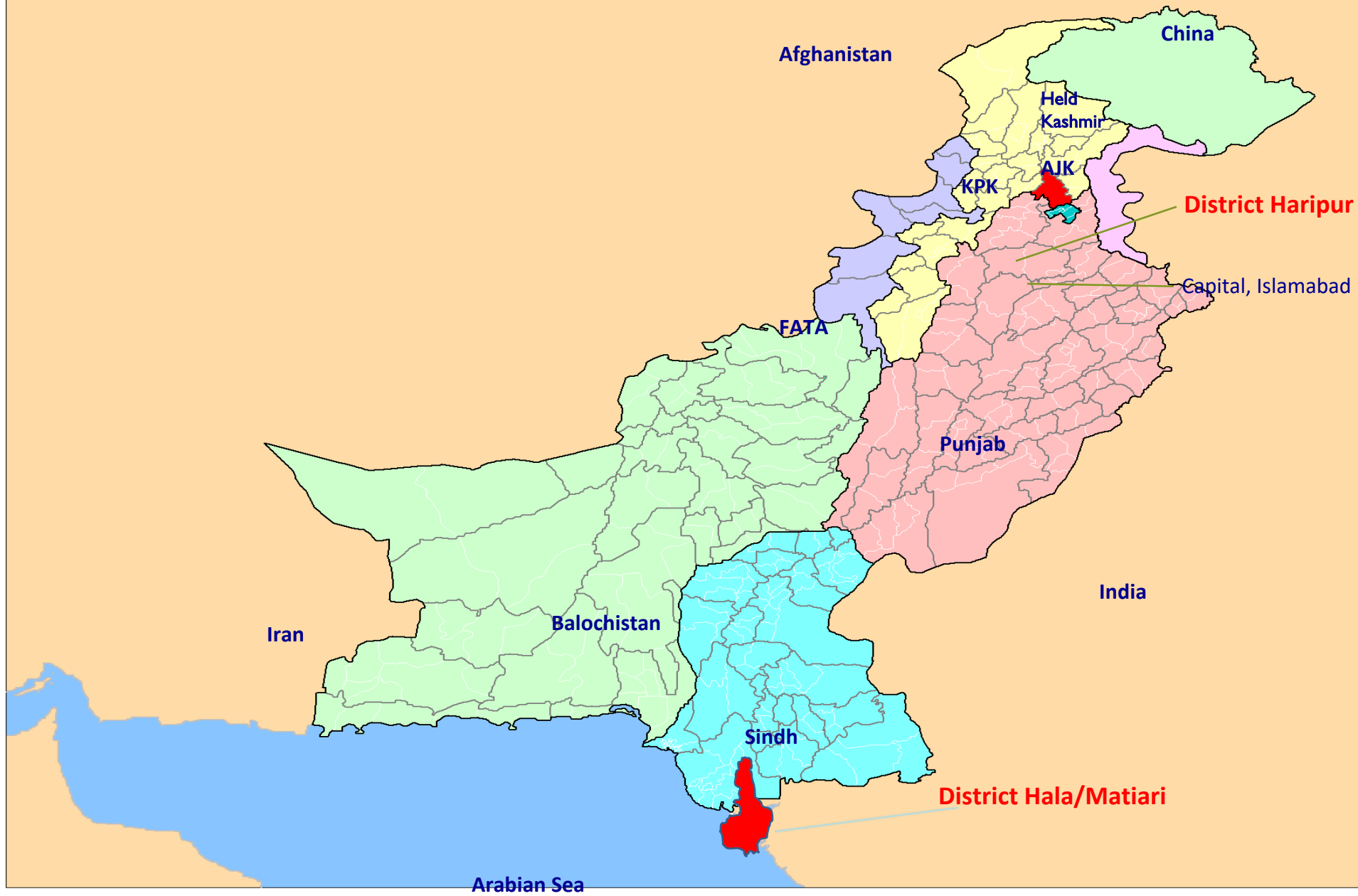
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# Treatment of Pediatric Pneumonia in Developing Countries

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- Standard of care: initial antibiotic dose in village by LHW and refer to MD
- Intervention: antibiotic treatment in village by LHW
- Outcome measure: relapse rate
- Review by US and Pakistani IRB/REB





# Training



Standard Case ARI Case  
Management  
Training of Private MDs



LHWs in Training

# RESULTS

## Hala

	Intervention clusters	Control clusters	Risk Difference (95% CI)
Therapy Failure Adjusted for clustering	8.0% (187/2341)	13.0% (273/2069)	-5.2% (-13.7 to 3.3)

## Haripur

	Intervention clusters	Control clusters	Risk Difference (95% CI)
Therapy Failure Adjusted for clustering	8.9% (165/1857)	17.8% (241/1354)	-8.9% (-12.4 to -5.4)

Bari et al. *Lancet* 2011; 378: 1796–803.

Soofi et al *Lancet* 2012; 379: 729–37.



# Issues?

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- Beneficence: benefit to subject vs study design.
- What research question was answered?
- What is the appropriate control group?
- IRB: protection of human subjects –to what end?

## Case Study 2

- Investigator buys a data set from (FB, Twitter, Geofeedia, etc)
- Geofeedia is an aggregator and constantly mines “public” social media and Internet sites
- “Location-based Intelligence”
- RQ: How well do social media-derived clusters serve as a proxy for real time surveillance of the opioid epidemic?
  - We want to determine how well the social media-identified clusters overlap with those found in the city’s crime data.
- Data used for this analysis will come from multiple social media sources and delivered through the social media platform Geofeedia. Social media data from Twitter, Instagram, Facebook, YouTube, Flickr, Picasa, Sina Weibo, and VK will be **mined for opioid- and heroin-related themes**. Geofeedia provides a comprehensive collection of social media data that allows a user to **search by location for a set of defined keywords, hashtags, and emoji’s**, etc. It also provides the ability to look backwards through time, as well as identify social networks by looking at how users interact and influence others in the social network. **All posts are location-explicit and allow for easy mapping. Although all of the data used are publicly available, we will have the data deidentified (usernames anonymized and replaced with digital alpha/numeric code) and the locations will be slightly offset by rounding the latitude/longitude coordinates by two significant digits.**



- Once the recordings have been initiated, we will geocode the crime data for the city of REDACTED. This will convert address-level data to latitude/longitude coordinates to be used for the spatial modeling. Geocoding the addresses and spatial modeling will be performed using ArcGIS 10.3. Local spatial clustering statistics such as Local Moran's I and Getis-Ord  $G_i^*$ , will be used to detect clustering within the defined study sites. Once this is complete, social media-identified clusters will be mapped onto clusters of opioid and heroin-related arrests. These crime-related clusters will serve as a baseline and will be used for comparison with those clusters identified through social media.

# Exercise

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- As part of your consent process, complete the following sections:
  - You are being asked to be in this study because you...(Purpose and population)
  - In this study, you will...(procedures)
  - In this study, you may experience... (Risks)
  - As a result of being in this study, you may... (Benefits/direct/indirect)



# Ethics and Methods in HIV/Drug Abuse Research: Themes

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- Privacy
  - HIPPA Considerations (US)
  - GDPR (EU)
- Risk/benefit
- Vulnerabilities
  - Prejudices?
- Impact of IRB/Regulations can affect:
  - Research questions
  - Data integrity/scientific validity
- Changes to protocols and procedures
- Data sharing/reporting