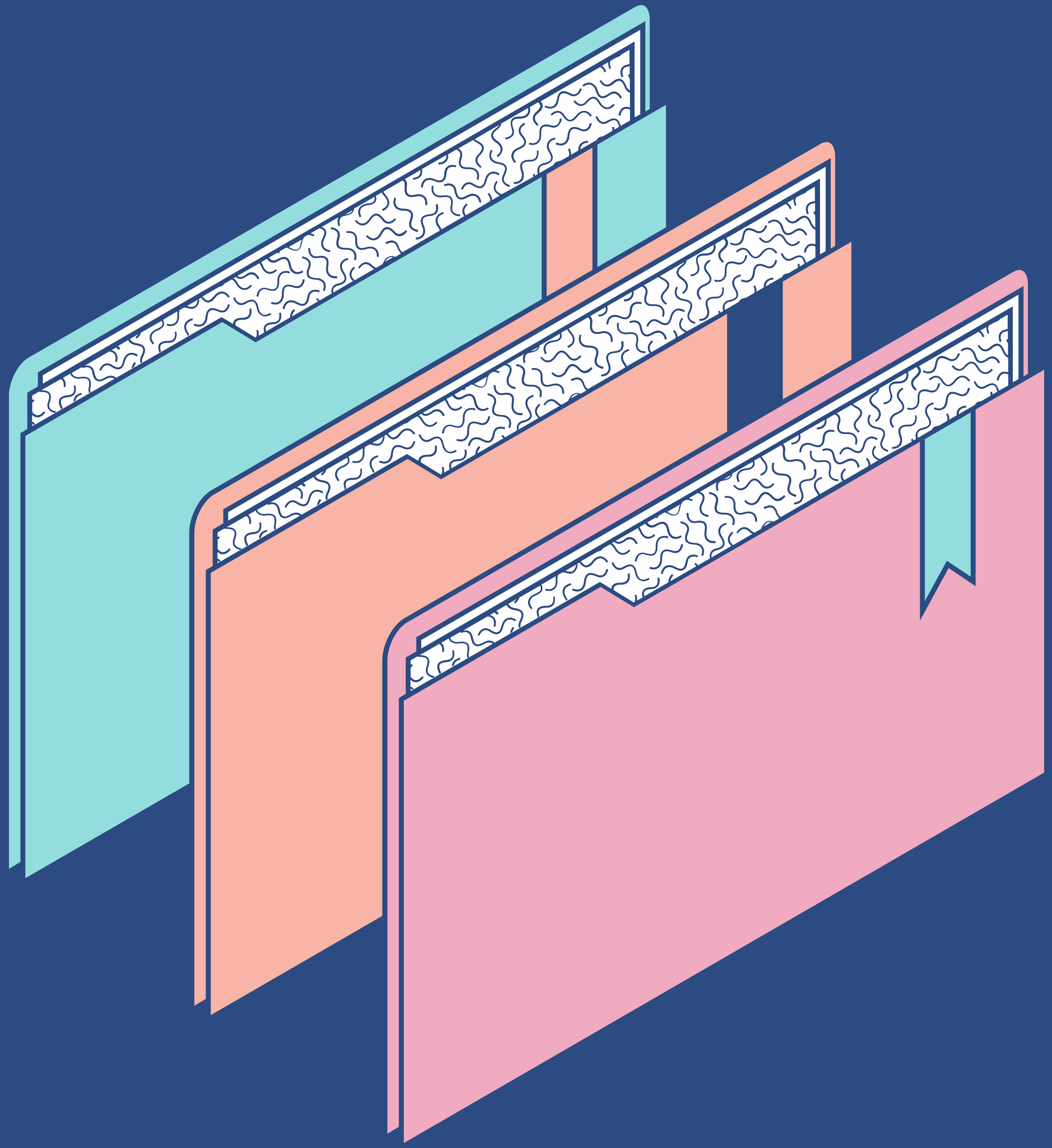
Inviting the Community to the IRB:

Conducting Research WITH People, Not ON Them

Aisha Bradley, Compliance Professional, PACT

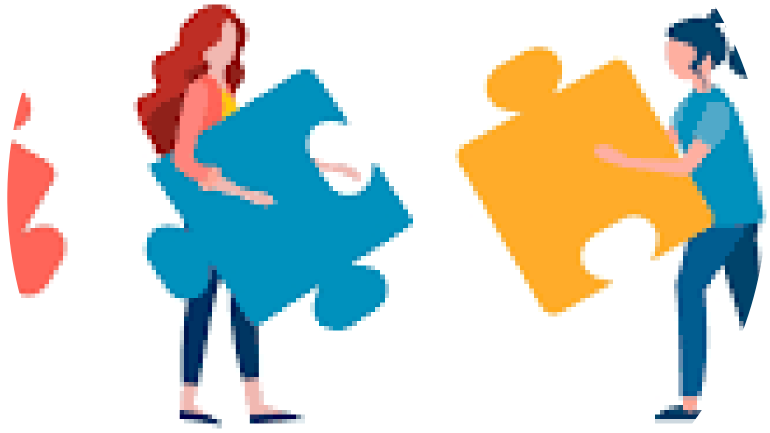


Agenda

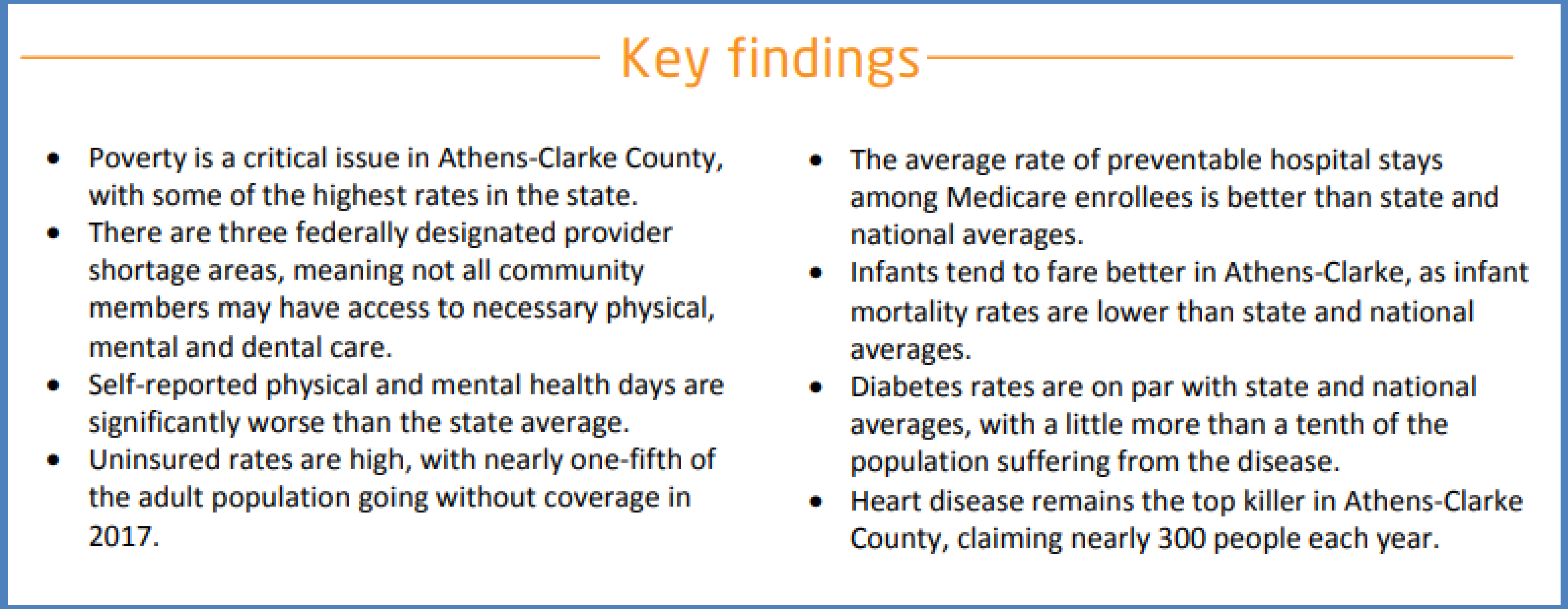
KEY TOPICS DISCUSSED IN
THIS PRESENTATION

1. Principle of Justice 45 CFR, Part 46
2. Define Privilege
3. How do IRB’s and researchers contribute to privilege blindness
4. Solutions


I'M NO EXPERT



Overview of Athens-Clarke County



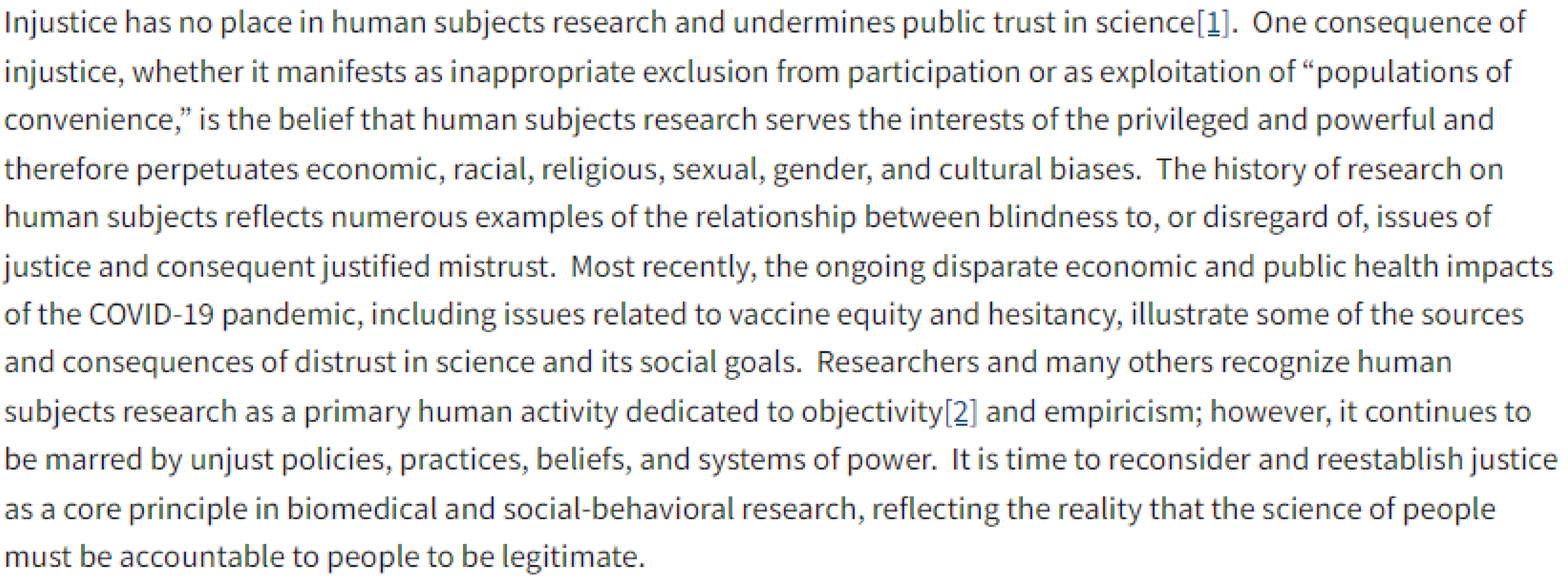
Key findings

- Poverty is a critical issue in Athens-Clarke County, with some of the highest rates in the state.
- There are three federally designated provider shortage areas, meaning not all community members may have access to necessary physical, mental and dental care.
- Self-reported physical and mental health days are significantly worse than the state average.
- Uninsured rates are high, with nearly one-fifth of the adult population going without coverage in 2017.
- The average rate of preventable hospital stays among Medicare enrollees is better than state and national averages.
- Infants tend to fare better in Athens-Clarke, as infant mortality rates are lower than state and national averages.
- Diabetes rates are on par with state and national averages, with a little more than a tenth of the population suffering from the disease.
- Heart disease remains the top killer in Athens-Clarke County, claiming nearly 300 people each year.

- Piedmont Health Community Health Needs Assessment

- Heart Disease was the #1 killer for all races, followed by mental and behavioral health disorders.
- Athens- Clarke County is majority White, but Hispanics and Black communities face the highest unemployment rates, and highest drop-out rates.
- According to the Centers for Disease Control and Prevention, in 2017, the highest percentage of Georgians with diabetes had not graduated high school and earned less than $25,000.
- Poor women have twice as many deaths from cervical cancer than affluent women.
- Black males in Georgia are 8 percent more likely than white males to be diagnosed with cancer, and black males are 25 percent more likely than white males to die from cancer.
- 33 percent of those living in poverty in the county did not graduate high school in the 2015-2016 school year. Minorities were twice as likely to not have a high school diploma.
- 40 percent of children in Clarke County lived in poverty in 2017

Consideration of the Principle of Justice under 45 CFR part 46



Injustice has no place in human subjects research and undermines public trust in science[1]. One consequence of injustice, whether it manifests as inappropriate exclusion from participation or as exploitation of "populations of convenience," is the belief that human subjects research serves the interests of the privileged and powerful and therefore perpetuates economic, racial, religious, sexual, gender, and cultural biases. The history of research on human subjects reflects numerous examples of the relationship between blindness to, or disregard of, issues of justice and consequent justified mistrust. Most recently, the ongoing disparate economic and public health impacts of the COVID-19 pandemic, including issues related to vaccine equity and hesitancy, illustrate some of the sources and consequences of distrust in science and its social goals. Researchers and many others recognize human subjects research as a primary human activity dedicated to objectivity[2] and empiricism; however, it continues to be marred by unjust policies, practices, beliefs, and systems of power. It is time to reconsider and reestablish justice as a core principle in biomedical and social-behavioral research, reflecting the reality that the science of people must be accountable to people to be legitimate.

Defining Privilege

Black L. R., Stone D. (2005). Expanding the definition of privilege: the concept of social privilege

First, privilege is a special advantage; it is neither common nor universal. Second, it is granted, not earned or brought into being by one’s individual effort or talent. Third, privilege is a right or entitlement that is related to a preferred status or rank. Fourth, privilege is exercised for the benefit of the recipient and to the exclusion or detriment of others. Finally, a privileged status is often outside of the awareness of the person possessing it.

The Role of Researchers and IRB’s

Consider the role of researchers and IRBs in privilege, marginalization, and equitable creation of knowledge in the research enterprise

How can privilege blindness gatekeep the community from participating in research?

What are some types of privilege, and how can we combat privilege blindness?

Religion

Ability

Gender Identity

Race

Class

Sexuality

Education

Gender

So... what is privilege?

And what can you do?

"Privilege is the benefits and advantages held by a group in power, or in a majority, that arise because of the oppression and suppression of minority groups." *

Furthermore, "privilege is, by the social justice definition, the advantages people have that they don't often think about because they never have to experience the oppressive side. Understanding it requires an active effort to see things from the perspective of other, underprivileged people." *

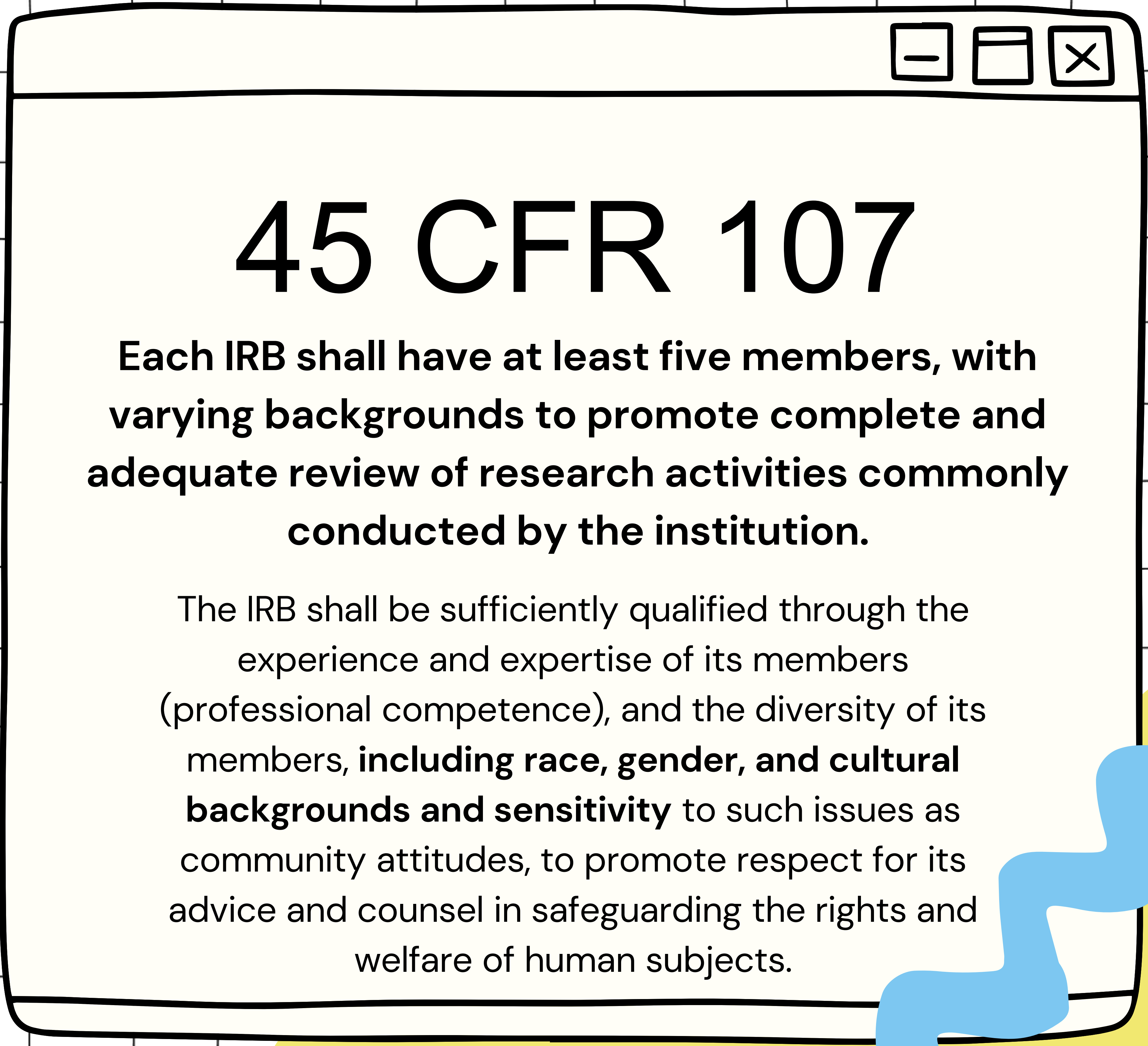
"While you cannot get rid of your privilege, you can acknowledge it. When we force privilege into view and discuss it openly we engage in solidarity with those who do not share in certain privileges with us. Don't be afraid to make a statement, write a letter, post a blog, get into a discussion, or create dialogue and criticism in some way to comment on instances of privilege." **

These are just a few types of privilege. Can you think of others?

Ways that Research have excluded participants....

1. research staff did not ensure that the reading level is appropriate for the target population
2. individuals or groups were selected solely because they are readily available or convenient to reach.
3. Study Procedures only occurred during traditional working hours.
4. Not using data collectors who reflect the study population or culturally sensitive recruitment methods.
5. school principals offered larger gift cards than other adult participants, such as parents

Research With Hard To Reach Populations



45 CFR 107

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, **including race, gender, and cultural backgrounds and sensitivity** to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

45 CFR 107

Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

Community Member

AKA Unaffiliated Member

What do other universities say about community members?

Harvard University

Unaffiliated community members play an important role on the IRB. They bring fresh insight and perspective to board decisions about how best to protect research participants.

Iowa University

They bring fresh insight and perspective to board decisions about how best to protect research participants. The Community Member has the particular responsibility of bringing the perspective of the volunteer research participant to the review of protocols.

University of Kentucky

This member's role is to represent the public's concerns – to serve the public community's interests rather than the university's.

"WHY DOES HAVING ONLY ONE COMMUNITY MEMBER ON THE INSTITUTIONAL REVIEW BOARD (IRB) POSE SIGNIFICANT RISKS TO THE INTEGRITY AND FAIRNESS OF RESEARCH ETHICS OVERSIGHT?

- Lack of Diverse Perspectives
- Potential Biases
- Limited Accountability
- Inadequate community engagement:

Community Engagement (CDC)

The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people

Bringing the IRB to the People

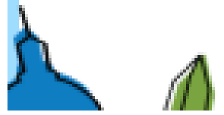
Reaching out to your local communities to let them know about what HRPPs/IRBs do, guidelines and principles in place to protect research participants; listen to their concerns about research and answer their questions, address privilege, creative recruitment strategies, Incentives, Participants as Study Team Members, Community Outreach (K-12)

Bringing the People to the IRB

ENGAGE LOCAL COMMUNITY PARTNERS TO TEACH IRB MEMBERS ABOUT LOCAL COMMUNITIES AND THEIR VIEWS/EXPERIENCES WITH RESEARCH; SEEK INPUT ON PRACTICES, TEMPLATES, AND PROTOCOLS

Ideas for engaging community and patient perspectives

- Build relationships with institutional CE research offices/programs and local community organizations
  - (Be more intentional about identifying, training, facilitating input form, compensating MORE NA/NS members)
  - Ask community member experts for outside review/consultation on individual protocols
- Get broader input on informed consent templates, guidance, and policies
  - Conduct research (surveys, focus groups) with community research partners and/or previous research participants
  - Seek input from institutional community advisory board members (as well as CE, DEI, and plain language experts
- Educate IRB members with
  - Finding from published empirical research on participant experience/views of research
  - Systematically collected data from your own institution
  - Research participant and community organization panels
- Go out into your local communities
  - Present to community research partners and other community groups on the role of the IRB and human research protections
  - Implement a community-based promotional campaign to let the general public know that IRBs exist to protect research participants.
  - HRPP staff attend or collaborate with local health/science-related community events
- Create a community advisory board specifically for your HRPP!



University of Utah Panel C:
A Community Advisory IRB Panel

RESPONSIBILITIES

Advance the University's IRB, Human Research Protection Program, and research community policies and practices to ensure respect for diverse Utah communities and research participants.

Evaluate research projects and make determinations for studies with unique community-based concerns.

Review participant study materials, such as consent forms and recruitment materials, to recommend improvements to literacy.

THE UNIVERSITY OF UTAH

HAS ADVISED THE UNIVERSITY ON A SPANISH INCLUSION POLICY AND ITS IMPLEMENTATION FOR RESEARCH.

HAS PERFORMED USUAL REVIEWS FOR THE IRB.

HAS ADVISED ON STUDY-SPECIFIC RISK LANGUAGE FOR CONSENT FORMS FOR STUDIES WITH A CONTROVERSIAL RISKBENEFIT ASSESSMENT

Remaining ?'s

- SHOULD THE IRB ASK HOW RESEARCHERS ARE NOT ONLY CREATING, BUT ALSO DISSEMINATING KNOWLEDGE?
- How does our current review system and procedures create justice for participants?
- Are IRBs part of gatekeeping mechanisms?
- Who owns the research?