Reproductive Health Research and Privacy

National Committee on Vital and Health Statistics

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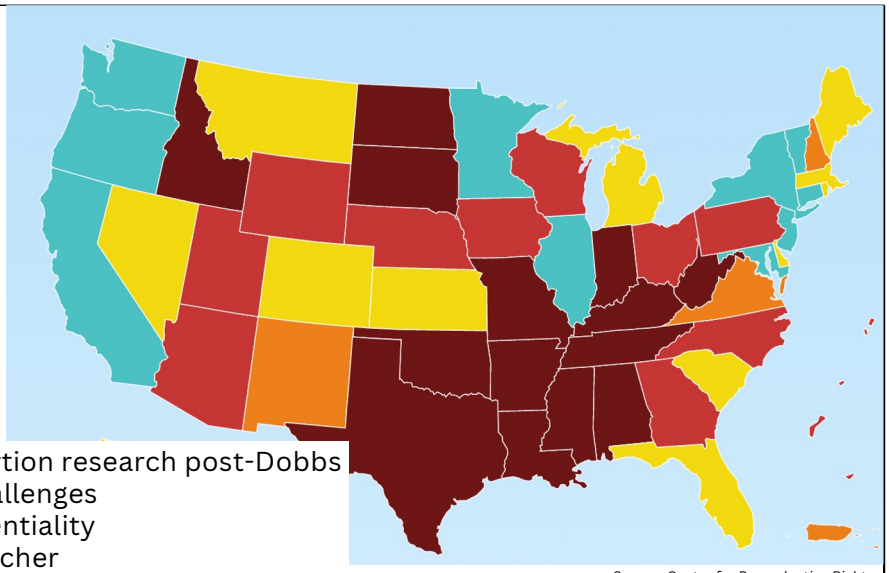
Good afternoon, and thank you for having me on this panel about such an important topic with these incredible co-panelists. My name is Elizabeth Mosley, I use she/her pronouns, and I am an Assistant Professor at the University of Pittsburgh School of Medicine with CONVERGE, the Center for Innovative Research on Gender Health Equity. But I live and work in Atlanta, Georgia where I am affiliate faculty at Emory Rollins School of Public Health with RISE, the Center for Reproductive Health Research in the Southeast. I am a full spectrum doula, and I do community-engaged research with community-based and reproductive justice partners.

Outline of Remarks



Source: Center for Reproductive Rights

- Setting the stage: abortion research post-Dobbs
- IRB and regulatory challenges
- Certificates of Confidentiality
- Precarity of the researcher
- Problem-solving together
- Contact information

Today I want to set the stage by sharing insights about the kind of abortion research needed and how we do that research, sharing some stories about IRB and regulatory challenges we've been facing since Dobbs, illuminating how the gold standard NIH Certificate of Confidentiality might be tested in this new policy landscape, how abortion stigma and illegality leads to uncertainty and risks for researchers, and finally how we as researchers, the NCVHS, and other reproductive health stakeholders can all problem solve and move forward together.

Setting the stage

I want to quickly set the stage for abortion research and data security.

First, abortion research has been and always will be needed to ensure access to high-quality, patient-centered reproductive healthcare and to optimize reproductive health outcomes. However, abortion research is most critical in moments like this following monumental, unprecedented shifts in reproductive health policy when legality of abortion is restricted in over half over US states, where 25 million women of reproductive age live. Restrictive abortion policies are one manifestation of abortion stigma—the social process of assigning negative attributes to and discriminating against those associated with abortion.

Second, abortion research includes patients who reach abortion care, those who face barriers and never reach abortion care, and those who self-manage their abortions outside of the health sector. It often involves longitudinal study designs that allow us to follow patients during pregnancy and after the pregnancy ends. For that reason, abortion research employs not only secondary analysis of patient records and claims data, but also primary data collection through self-report surveys and in-depth interviews.

This landscape—characterized by stigma *and* the need for sensitive, identifiable data—introduces challenges and risks for data privacy, confidentiality, and security.

IRB and regulatory challenges

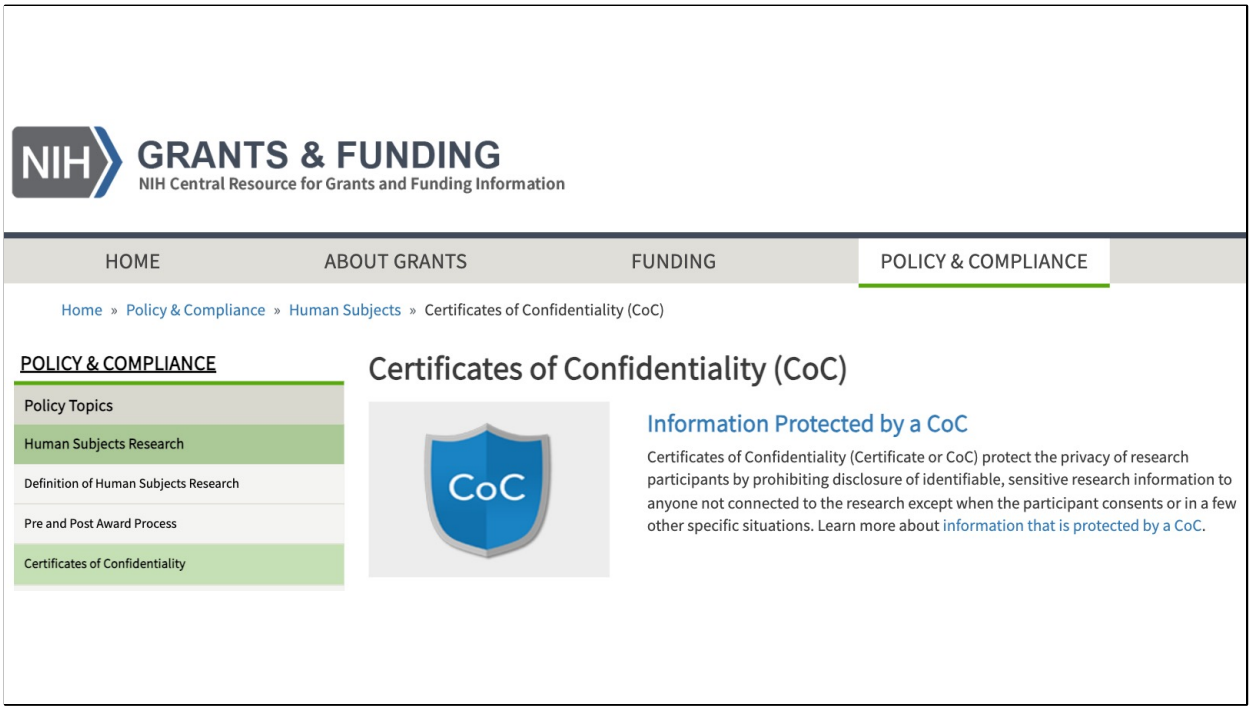
Researchers work closely with institutional review boards (IRBs) for ethical and regulatory oversight of human subjects research. However, the *Dobbs* Supreme Court decision has injected confusion and concern into the IRB review process.

For example, at the University of Pittsburgh we are conducting a study on pregnancy acceptability involving in-depth interviews and longitudinal surveys. Two of our study sites are in Texas and Tennessee, where abortion is completely outlawed. When seeking IRB approval to conduct in-depth interviews with pregnant people who were seeking abortion care in neighboring states, our IRB raised questions including:
-“what are the risk mitigation strategies for interviews in restricted states and how is the team articulating those protections to subjects?”
-“Will audio files remain identifiable?” and
-“There may be risk to subjects not involved in this research study. For instance, if an abortion was completed out of state for someone who resides in these restrictive states, then the practitioner or others who may have assisted the individual in seeking the abortion may be at risk for civil or criminal penalties. Add additional information on how you will minimize the risks to others outside of the subject.”

In other scenarios, some institutional review boards-–even those in restricted

states—do not seem as concerned about the potential risks to human subjects in abortion survey research. For example, at Emory University I co-lead a community engaged full spectrum doula study in Georgia, where abortion is now outlawed after 6 weeks since last menstrual period. This involves in-depth interviews and surveys with doulas who provide abortion information and support including for patients who are seeking care out of state after 6 weeks' gestation. Yet Emory IRB deemed the study exempt—even after repeated requests for review and oversight—because it was evaluated as "low risk" to the doulas involved.

All of the IRB and regulatory challenges are amplified when researching adolescents, who do experience pregnancy and who face disproportionate barriers to abortion care. While pregnant minors are able to consent to research without parental involvement, they might face additional risks if there is a breech in confidentiality.



To date, the NIH Certificate of Confidentiality has been the Gold Standard in data security. This Certificate is a form of protection permitting researchers and their institutions under subpoena *not* to disclosure of any research participant data.

However, there are limits to the Certificate of Confidentiality including: child abuse and threat of harm to self or others. Meaning, if a researcher learns of child abuse or imminent risk of self-harm or harm to others, they might report that incident to the appropriate authorities.

CoC has been challenged in court only a few times thus far, but has so far been upheld. One case involved a defendant, who was being tried for statutory rape. One of the prosecution witnesses was a member of a longitudinal drug use study. The defense requested all study data related to the research participant, but this was ultimately denied due to the CoC.

People often point to substance abuse research as another example of sensitive data about a criminalized and stigmatized behavior. However, this is a false parallel without appreciation for the severe stigma against abortion that equates this health service to murder.

Researchers and regulatory bodies, alike, wonder what *Dobbs* could mean for Certificates of Confidentiality and abortion data. For example, could fetal personhood laws, like the one here in Georgia, be used to seize research data on abortion patients, providers, and supporters under the claim that abortion after 6 weeks is "child abuse"?"

Precarity of the researcher

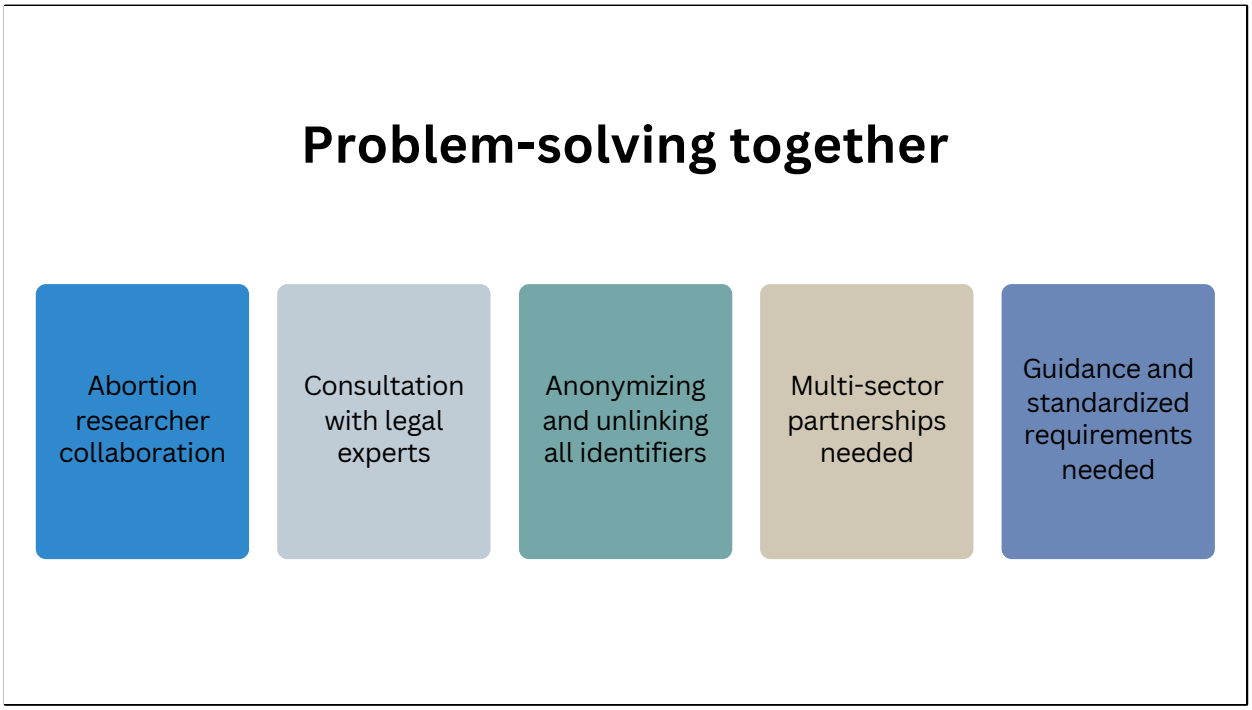
These unprecedented reproductive health policy changes have created a lot of uncertainty and, potentially, legal risks for abortion researchers.

For example, it is standard practice to offer research participants a resource sheet at the end of an interview or survey. In reproductive health research, this often means resources for pregnancy support, abortion care, and adoption. However, new state laws like SB 8 in Texas, which outlaws "aiding and abetting" abortion, could be interpreted to outlaw the provision of educational resources about abortion. It penalizes anyone who knowingly engages in conduct that aids or abets the performance or inducement of an abortion, including paying for or reimbursing the costs of an abortion with a $10,000 fine.

As the University of Pittsburgh IRB asked our team,
Is an interviewer, who gives pregnant women in Texas the phone number for funding support to access abortion out of state, violating any laws or putting participant data at risk?

Similarly, in Georgia, I co-lead a medication abortion study with reproductive justice organization SisterLove. We were funded by Society of Family Planning to create an

educational video about medication abortion. After *Dobbs*, we needed to update our video and secured funding from a local university. However, the university's legal department raised concerns about the video and whether it violated Georgia's 6-week abortion limit. In Georgia, only the provision of abortion care is outlawed not the sharing of information about abortion. However, because of stigma and lack of legal clarity we nearly lost that supplemental funding.



As we move through this precarity and toward solutions, our abortion research community has been meeting regularly to discuss challenges and novel approaches to deal with them. We've been working closely and consulting with reproductive rights and justice attorneys including at the Women's Health Law Project, at If/When/How, and at the Digital Defense Fund. We are implementing new standards of research practice including anonymizing our data completely whenever possible—for example, collecting contact information on surveys completely un-linked from study data; using participant ID codes rather than a file that links people's study ID with their identifiers--for example, asking people at the start of every study "What is the first letter of the city/town where you were born?" "What is first number of the street you lived on when you first enrolled in this study?" Etcetera.

However, we know we need help especially from sectors outside of abortion research. For example, we need research partnerships with IT, legal, regulatory, and the health sectors.

And perhaps most importantly for this Committee, we need guidance and standardized requirements set forth from the federal government to steer researchers and IRBs on the ground. For example, we have clear HIPAA policies for

protection of health data but this does not extend to research data.

I hope this is the start of a continuing partnership to build and implement the safeguards we need to ensure urgent and important abortion research can continue with integrity and adequate protections for human subjects and researchers, alike.

Thank you

Contact me or our research centers with questions and for continuing partnership

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Thank you again for this opportunity and for your attention. We look forward to this continuing partnership together. Please contact me with any questions at this email, and you can follow UPitt CONVERGE and Emory RISE on social media.