

**A Discussion About How New
Legislation May Impact Institutional
Review Boards (IRBs): *Anti-DEI, Anti-
LGBTQ+, and Anti-Reproductive Rights***
The Single IRB Series

Session 3
Tuesday, June 4, 2024
1:00 PM (EST)



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Disclosure: ALL SPEAKERS

We all have no relevant personal/professional/financial relationship(s) with respect to this educational activity

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Discussion Topics



New Legislations



The Current Impact



How IRBs May Be Impacted?



sIRB Review and multisite Studies



Next Steps

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- Since our first presentation on May 7th the state of Kansas has signed into law prohibiting public colleges from requiring students or employees to submit diversity statements for admission, hiring, or promotion. This will take effect on July 1, 2024.
- In addition, the state of Iowa has signed into law also barring public colleges from requiring diversity statements and giving preferential treatment to anyone based on such statements. This will take effect on July 1, 2025.
- On May 23, 2024, the Board of Governors at University of North Carolina “UNC” reversed a policy removing the requirement to submit diversity and inclusion reports to the Board of Trustees every year. It also mandates that all UNC schools comply with a series of amendments passed by North Carolina General Assembly to limit what can be discussed or taught about race, racism, and sex in government institutions. This policy passed with two black board members voting “no”. Earlier in the month, they passed a separate proposal to divert 2.3 million from DEI Programs to public safety. What is not outlined is how many DEI jobs might be impacted.
- There are now 515 anti-LGBTQ bills in the U.S. During my first presentation there were 275. As a reminder these bills criminalize and ban access to gender affirming care. In addition to several states passing these bills into law, there are several bills advancing in states like Alaska, Arizona, Florida, Hawaii, Illinois, Louisiana, and other states.
- As you all know there are abortion bans and restrictions across our country. However, now there is increased discussion at the federal level about the possible restrictions on a person’s right to birth control, and other contraceptives.
- Lastly, Tennessee’s governor has approved legislation designed to block adults from helping minors get an abortion or receive gender-affirming care without parental consent. This will take effect on July 1, 2024.

Legislative Updates

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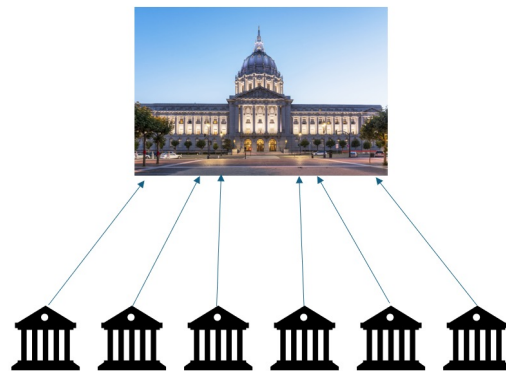
Single IRB Basics

- Request state, local laws, and institutional policies
 - Affect the IRB review and approval
 - If this is not asked for, it should be provided regardless
- Consent form requirements – Any specific language for an ICF
 - Birth control methods that maybe required by an institution
 - Use of gender-neutral language for pregnancy testing and birth control
- Assent form language
 - Withdrawing participants from research if they become pregnant
 - Limits on who can receive lab results (based on state emancipation laws)
 - Parents may figure out their child became pregnant if they are withdrawn, even if they cannot receive lab results
- Responsibilities and communications
- Who does what? (Relying vs. Reviewing)

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Legislation & Interpretation of laws

- Are we protecting participants when we are trying to understand what the law?
- The legal teams have to figure out how to interpret legislation
- If the legal team is even interested in interpreting the legislation, that will impact research as well
- The IRB is not the interpreter of the laws; this is done by external departments



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Anti-Abortion Law Impact

- Generalizability of research to a population
 - Excluded most of the childbearing population – excluding women from research.
- Exclusion of pregnant participants
 - Sponsored studies, clinical trials drug or device studies
- Female of childbearing age two forms of birth control

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Legally Authorized Representatives

- Enrollment of adults not competent to consent
 - Definition: Cognitive or a condition that would not allow them to consent for themselves
- From the CA State Perspective – There are positives and negatives – if another state excluded these participants
- Respect for persons, we don't want to enroll anyone unless there is a serious condition.
- The opportunity to consent an individual after they become capable to consent

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LBTQIA+ & special populations

- How are populations reported?
- Maybe eliminating a large portion of the population?
- Should systems capture special populations?
- What if states are requiring certain populations from not identifying accurately?

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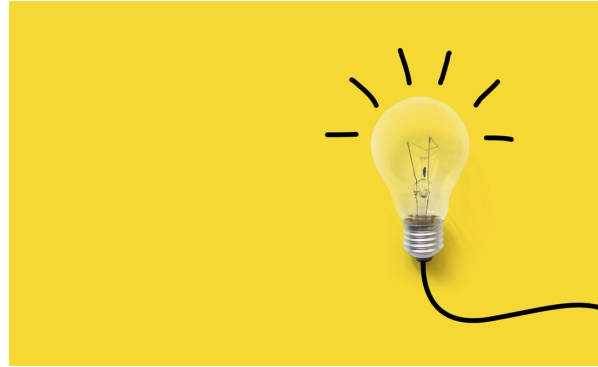
HIPAA Protections

- Even though the Civil Rights Office has strengthened HIPAA Protections, this is being challenged in courts
 - E.g., A research repository could reveal PHI/PII
 - If HIPAA is challenged successfully the organization holding the research repository could be mandated to provide PHI to the attorney general that could reveal things about you that are against the law,
 - E.g., you had an abortion in another state, or were taking illegal drugs.

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Next Steps

- Know where your state stands with new legislation
- Take Inventory of research that may be impacted by new legislation
- Communicate with key stakeholders
- Appoint a liaison or group dedicated to maintain communication and/or project manage
- Ask questions



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Questions

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