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

Session 2

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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

National Strategy on Gender Equity and Equality

Letter from the President and Vice President

From the Emancipation Proclamation, to the passage of the 19th Amendment, to the Voting Rights Act and the Civil Rights Act, to the fight for reproductive rights and marriage equality—and countless movements and victories before and since—America has been strengthened through the years by our tireless pursuit of greater equity for all.

Impact to IRB's

The Belmont Report

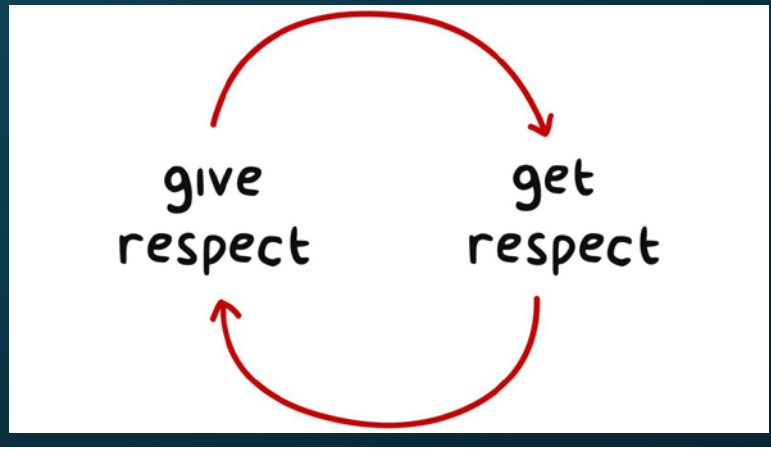
Ethical Principles and Guidelines for the Protection of Human Subjects of Research

✓ *Respect for Persons*

✓*Beneficence*

✓*Justice*

Respect for Persons



Individuals should be treated as autonomous agents, and those with diminished autonomy are entitled to protection.

The **Right** or **Power** to self-government

Undertaken or carried on **without** outside control

Exist, Capable , Respond. React, Develop **independently**

Existing or capable of existing **independently**

Beneficence

Maximize Possible Benefits → Ethical Manner → Person's Well-being → Minimize Possible Harms → Acts of Kindness

Obligation → Do No Harm → Use Best Judgement → Give Forethought → Consider Long Term Impact

Justice

"Fairness and Distribution" or "What is Deserved"

To Each Person According to Societal Contribution

To Each Person According to Individual Effort

To Each Person According to Individual Need

To Each Person According to Merit

To Each Person an Equal Share

Criteria for IRB Approval of Research (excluding limited review)

To approve research, the following requirements must be satisfied

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of knowledge that may reasonably be expected to result
3. Selection of subjects is equitable
4. Informed consent will be obtained and documented (unless waived) accordingly
5. There are adequate provisions for data monitoring to ensure safety of subjects if appropriate
6. There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data if appropriate
7. There are additional safeguards to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence

Risks To Subjects are Minimized

When examining risks, IRBs think critically and consider more than just physical harm. IRBs may consider psychological, social, economic, legal, risks to dignity and respect.

Key points to remember:

- Risks may be less obvious and hard to identify
- Risks can be both time and situation specific
- Risks can be subjective and relevant to specific populations, or even individuals
- Requires considering the specific features of a study; context matters
- Lack of empirical data may complicate risks assessment

Things to consider

Unfortunately, Black/Brown people, LGBTQ+ individuals, and Women are not widely represented in Research Studies, which is why entities such as the NIH created a Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research.

When investigators use procedures which are consistent with a sound research design are we placing subjects at unnecessary risk by removing certain elements of the research studies.

Ex; the use of validation tools that assess belonging, discrimination, inclusivity, equity, etc.,

Risks/Benefits

When examining whether risks to subjects are reasonable in relation to anticipated benefits, IRBs may consider the likelihood and magnitude. They may weigh and/or forecast benefits in relation to direct or indirect benefit, the importance of knowledge, and significance gained from the research.

For example, there is a risk of being identified as doing something illegal or that is inconsistent with state law as a result of participating in research.

Things to consider

Should IRBs be concerned with removal of equity terms, identity language, and diversity statements in study related procedures such as those used in surveys, questionnaires, behavioral, and/or observational studies?

Furthermore, if the knowledge gained is important and cannot be obtained otherwise, it is justifiable to include subjects that may identify in the categories under the new legislation?

Selection of Subjects is Equitable

- ❑ Who is the target population?
- ❑ Is the target population appropriate for answering the questions the protocol addresses?
- ❑ Is the inclusion criteria sufficiently inclusive?
- ❑ Are the reasons for exclusion scientifically valid?
- ❑ Are there adequate additional safeguards for potentially vulnerable subjects?

Things to consider

In recent years, Congress passed new requirements to improve clinical trial enrollment practices by operationalizing diversity plans to include historically marginalized populations, such as certain racial and ethnic groups and women. As recent as last month, the FDA published guidance on Enhancing the Diversity of Clinical Research Populations.

Is this a direct conflict with new legislation?

If new legislation aims to remove the very things that provide access, resources, and opportunities to potential study participants who otherwise would not have them, IRBs will have to consider whether an adverse effect is occurring.

In other words, are we creating an unnecessary burden to specific groups… that does not just appear in the "commonly known risk" category, but may include effort, intentionality, and other less tangible burdens.

Informed Consent

It is the responsibility of an IRB to examine the Informed Consent Form (ICF) as it relates to documentation and processing for research purposes.

- The Informed Consent Form should include what is needed for an informed decision about participation.
- The Informed Consent Form should be in language understandable to the potential participant.
- The Informed Consent Form should under circumstances promote voluntariness.

Things to consider

Should IRBs be concerned about any potential removal of language that is considered "prohibited" diversity statements, gender identity, inclusive terminology, and/or words that under new legislation may be deemed divisive topics.

This may include some of the following:

- One race or sex, gender, reproductive status is inherently superior to another
- The United States is fundamentally racist or sexist
- One race or sex, gender, reproductive status is consciously or unconsciously oppressive to another
- An individual bears responsibility for actions committed in the past by other members of the same race or sex
- Any individual should feel discomfort, guilt, anguish, or any other form of psychological distress on account of race or sex

Data Safety and Monitoring

When Appropriate, Adequate Provisions for Data Monitoring to Ensure Safety of Subjects.

"Is the monitoring plan appropriate and adequate?"

- Study Design, Inclusion/Exclusion Criteria
- Roles and Responsibilities
- Study Safety
- Reportable Events
- Data Management, Analysis and Quality Assurance

Things to consider

1. As it relates to new legislation things for IRBs to consider, specifically on Investigator-Initiated Trials is how the study is designed and whether peer/scientific review was conducted in a diverse manner. For ex; is the study designed in a way that is inclusive i.e. inclusion/exclusion criteria.
2. If a study is seeking to examine data on Women and Minority groups, is the study team diverse?
3. Will the DMP outline measures to protect participants against foreseeable and unforeseeable risks. Including “incidental findings”.
4. Quality assurance measures for subject recruitment, enrollment targets, and for the validity and integrity of the data.
5. Monitor data for social and legal risks.

Confidentiality and Privacy

Adequate Provisions to Protect Privacy and Maintain Confidentiality

“Certificate of Confidentiality from the NIH”

A CoC is issued by the NIH to safeguard the privacy of research study participants by protecting identifiable research information forced disclosure. A CoC allows investigators and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative or other proceeding, whether at the federal, state, or local level.

Things to consider

We use the term “privacy” in reference to individuals and their right to control what other people know about them and their interactions with others.

Likewise, the term “confidentiality” refers in particular to the security of records and information about individuals.

1. Will personally-identifiable research data be protected to the extent possible from unauthorized access or use?
2. Are any special privacy and confidentiality issues properly addressed, e.g., use of genetic information, HIV status, Gender Identity and/or Sexual Orientation, etc.
3. How to protect against compelled or rewarded and/or encouraged disclosures. For example, if a person is participating in a study with ongoing pregnancy testing and the results are positive and then negative, more information is typically collected in order to assess relatedness. Abortion-related complications may also be identified as an adverse event. In some states, will study staff feel that they are obligated to report this information? **some state laws include reporting requirements, and some have civil liability actions that can be taken by citizens.*

Additional Safeguards for Vulnerable Populations

Income and social protection

Food Insecurity

Education

Unemployment and Job Insecurity

These are subjects vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

Social inclusion and non-discrimination

Housing, basic amenities and the environment

Access to affordable health services

Things to consider

While the Common rule requirement ties this provision to subjects who are likely to be vulnerable to coercion or undue influence, do we have an ethical obligation under the Belmont Report to ensure that populations who are now at risk due to legislation have additional safeguards to help protect against these risks?

- What kind of vulnerabilities are involved?
  - Are they intrinsic vulnerabilities, e.g., limitation in mental capacity because of age or illness?
  - Are the vulnerabilities by reason of extrinsic factors, e.g., socio-economic structures or other social determinants.
- Are the vulnerabilities amendable to measure that can reverse the situation or lessen their impact.

Questions

sIRB Review and Multisite Studies