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IRB AND COMMUNITY ENGAGEMENT RESEARCH

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Case example:

A local hospital emergency department submits an application to the IRB for a study. The ED doctors are responding to an increased incidence of trauma admissions of adolescents (15-20 years old) and they believe that alcohol and illegal drugs are a factor.

The study protocol provides a detailed rationale for doing a blood test to screen for alcohol and illegal drugs for member of the target groups at every ED. If the test is positive, they will inform parents and arrange a screening, brief intervention, and referral (SBRIT). The study team requests a waiver of authorization and will insert a sentence in the blanket consent used at admission. All members of the target group will be tested even if they lack capacity or a LAR at admission.

The study team has developed short education program that will be presented at assemblies in high schools located in the immediate geographical region.

What Didn't the IRB Know?

The submission was a research protocol involving a community as participants

- Why didn't they know?
  - The protocol did not adequately describe that the population - or that it was Community Engagement Research
  - Studies submitted for IRB review have **Round Peg - Square Hole** syndrome
    - Use of a Clinical Trial Template
    - Use of a Grant Application Excerpt
    - Or a Hybrid Format
      - strong on background and significance but lacking Human Subject information

Submissions tend to lack information for IRB review under federal regulations

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Community Engagement Research (CEnR)

CEnR is a collaborative process between the researcher and community partner that creates and disseminates knowledge and creative expression with the goal of contributing to the discipline and strengthening the well-being of the community. CEnR identifies the assets of all stakeholders and incorporates them in the design and conduct of the different phases of the research process.

Advocates assert that it promotes better research and translation of findings.

Other benefits of CEnR include development of research that is responsive to community needs, increased capacity built through partnerships, expanded funding opportunities and greater opportunities to translate findings into practice.*

*VCU - Adapted from Carnegie and CDC.

What The IRB Does Know

- Collectively, IRBs are know …A Little about Everything
  - Most IRBs are generalist
  - Made up of scientists, non-scientists and community representatives
    - Membership represents most areas of expertise needed for most research studies
    - Training – initial and ongoing on regulations and special topics
    - Strong commitment to facilitate research
- The community representative member is **not** related to Community Engagement

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Community Engagement Research

Who is Responsible? The IRB or the Researcher?

Can IRB be Positioned to Evaluate Community-Engagement Considerations?

Yes, with help…

- Researchers can provide the IRB with information about the community and the impact of the research
- Protocols can address the IRB required findings: criteria for approval

Are Researchers Equipped to Design IRB Approvable Studies?

Yes, with help…

- IRBs need to provide researchers with appropriate tools
  - Protocol templates
  - Informed Consent guidance and options that are reasonable for the research

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IRB Approval Criteria

1. Risks to subjects are minimized
2. Risks are reasonable in relation to benefits
3. Subject selection is equitable
4. Informed Consent will be obtained and documented
5. Privacy is protected
6. Confidentiality is maintained
7. Data will be monitored for safety
8. Special protection for vulnerable populations

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The ED Protocol Submission

What it did right:

- Heavy on background and significance
- Described procedures
- Provided rationale
- Outlined the aims of the study

What went wrong:

- Lacked rationale for altering the consent process
- Lacked any explanation of consent documentation
- Did not present the participants as a community or describe the subject selection
- Did not indicate how the study would minimize risks to the community
- Listed risks as only the risks to the individuals coming to the ED
- Did not address privacy concerns
- Did not describe how confidentiality would be maintained

IRBs and Community Engagement Research

When designing the protocol, the community perspective needs to be highlighted using the IRB review criteria as a guide

For example:

- **What the ED protocol outlined as risks:**

  Risks to subjects are minimal and include breach of confidentiality

- **What the ED Protocol could have describe the risks as:**

  Participants may be harmed by a breach in confidentiality which could lead to exposure of their behavior and possible criminal charges. Parents raising/protecting children may be impacted by the results of this research and harmed by the stigmatization on a psychological, social and financial level, organization playing a role note directly related to healthcare may be impacted if the serve an adolescent population who may in turn be impacted by exposing children to additional risks beyond the trauma they experienced and the community avoiding ERs knowing they had used drugs/alcohol. EMT may be impacted when they arrive at a scene and due to lack of trust, they are not provided with adequate information.

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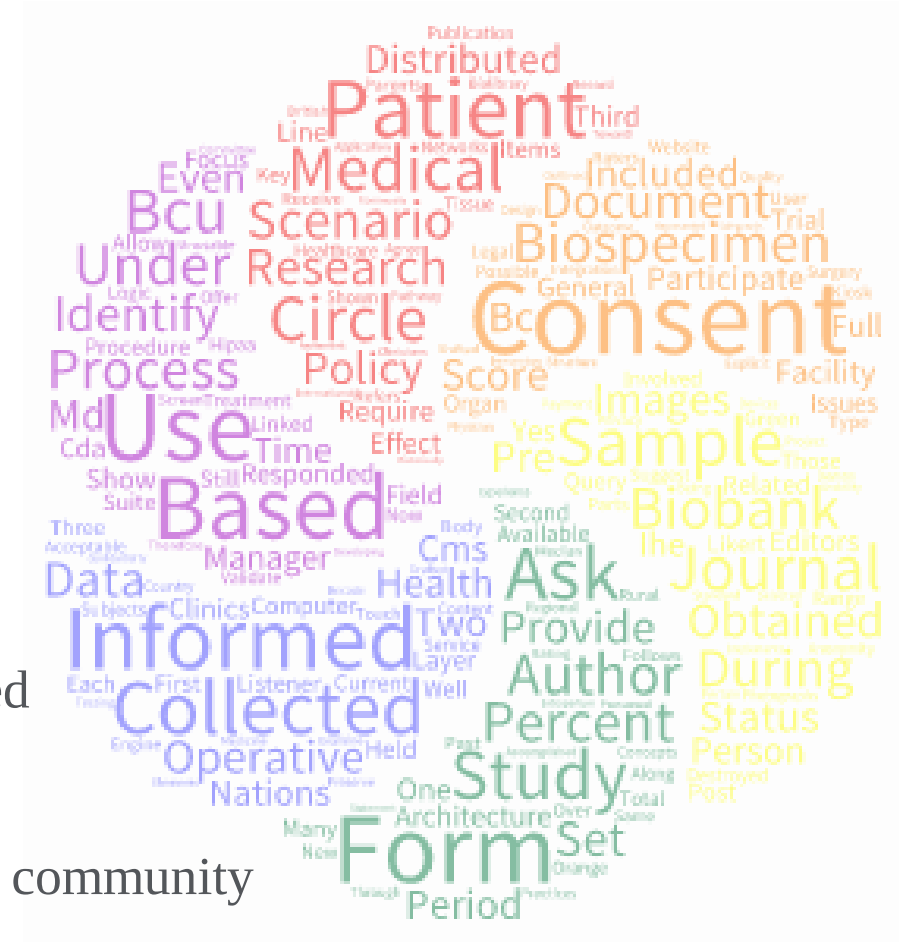
Areas for Improvement

Recruitment and Consent

- How will consent to be obtained
- How are community leaders involved in recruitment
- Is there compensation and how is it allocated
- Is there a conflict of interest (COI) and how will it be managed
- What is the strategy to emphasize voluntariness
- How does the project reflect the cultural characteristics of the community
- How are key community members included in research design and conduct
- Is education and training needed



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Areas for Improvement

Subject selection

- How is ”community” defined in the project
- What is the strategy to identify key community members
- Will community leaders be involved in defining inclusion/exclusion criteria
- How are benefits and burdens distributed
- How are community standards of fairness applied

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Areas for Improvement

IRB Operations

- Staff
  - Lack of experience among IRB staff and members in evaluating CEnR
- Protocol Templates
  - Need to have non-biomedical protocols to assist non-biomedical researchers with necessary information
- Guidance and policies
  - IRB guidelines and policies that do not address community risks
- Process
  - IRBs that lack process for input from community leaders

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Parting Message:

Protocols addressing regulatory criteria for IRB review will likely be approved faster

- Call your IRB and discuss your project
  - Partner with your IRB to make sure they understand what you are submitting and explain the community aspects
- Ask if the IRB has a protocol template for non biomedical research
  - We use Protocol Builder http://www.protocolbuilderpro.com
- Ask for a pre-review of your protocol
  - Be open to the possibility that your protocol may not have addressed the required criteria and will need revisions

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Questions?

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THANK YOU

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References

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