

Research Advocacy Network

Advancing Patient-Focused Research

IRB and the Community Member *How You Can Get Involved*

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&

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How Are Participants Rights Protected?

- Scientific review
- Institutional review boards (IRBs)
- Data safety and monitoring boards
- Informed consent

Scientific Review

All research involving people is overseen by some form of scientific review.

- Clinical trials with new drugs are subject to FDA review and approval
- Clinical trials using approved drugs are subject to funding agency (NIH/NCI) review and approval.
- Almost every point in the development of a protocol, is subject to peer review.

Informed Consent

Before agreeing to take part, patients have the right to understand all that is involved in a clinical trial;

- Purpose
- Procedures and treatments
- Possible risks and benefits
- Individual rights



Unaffiliated Membership Requirement/Recommendation

- “The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also 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.” ... *from the IRB Guidebook*
- In 2001, the National Bioethics Advisory Committee recommended non-affiliated members of each IRB be 20% of its membership

Non-affiliated Member Role

- Provides the voice of the participant to the research process
- Participant can be
 - healthy volunteer
 - person with the disease or condition being studied
- Provides balance
 - excitement over the new treatment and the reality of an unproven regimen
 - benefit versus risk, taking into consideration quality and quantity of life

What does a community member bring?

- Unique viewpoint
- Non-affiliated – not biased by employment
- Non-scientific – not biased toward the interesting question
- Community representative – the neighborhood, the patients, the public, society
- Practical real world concerns

What does a community member bring?

- Evaluate
 - Benefits to the participant
 - Risks to the participant
- Answer the Question: Do the benefits outweigh the risks?

Barriers to Community Participation

- Clear definition of the role of the community member
- Time required
- Complexity and amount of information to be reviewed
- Lack of public recognition of the work
- How to find willing candidates
- How to train potential members – Don't know what a non-scientist needs to know

Focus Group Results

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FOCUS GROUP RESULTS

Background

- The Research Advocacy Network conducted focus groups using a professional market researcher
- We brought together IRB administrators from four major medical centers in Chicago
- We invited the community members from those same four centers to a separate focus group

FOCUS GROUP RESULTS

Value of Community Member

- IRB Administrators
 - Different perspective
 - Independent of pay, promotion or job status
 - Drawback – if they didn't show up and they were needed for quorum the meeting was postponed
- Community Members
 - Counterbalance scientific minds
 - Provide another voice
 - Reflect the human side
 - Protect ALL participants
 - Drawback – might take more meeting time

FOCUS GROUP RESULTS

Biggest Challenge

- IRB Administrators
 - Lack of role definition
 - What community are they representing
 - Patient in general
 - Neighborhood
 - Typical participants
 - Non-affiliation with the institution
- Community Members
 - Not knowing expectations of the IRB – chair, members and staff

FOCUS GROUP RESULTS

Other Challenges

- IRB Administrators
 - Amount of time
 - Complexity of material
 - The Chair
- Community Members
 - Time
 - Intimidation factor
 - The Chair

FOCUS GROUP RESULTS

Training

- IRB Administrators
 - Belmont Report
 - Policies of the institution
 - The regs
 - Conflict of interest
 - Vulnerable populations
- Community Members
 - Observed a meeting
 - Class on how to work with the application
 - Online course for IRB members
 - IRB newsletters

FOCUS GROUP RESULTS

Training

- What the community members would like:
 - How to read a protocol
 - Requirements for informed consent documents
 - History of patient protections
 - Clinical trial process
 - Science
 - Mentoring
 - Glossary of terms and acronyms

FOCUS GROUP RESULTS

Ways to Express Appreciation

- IRB Administrators
 - Appreciation lunch or dinner
 - Letters from President
 - Money
 - Electronic teleconferencing
- Community Members
 - Give feedback and evaluation
 - Appreciation Dinner
 - Gift certificates
 - Credits for continuing ed
 - Say Thank You
 - Money

FOCUS GROUP RESULTS

Bottom Line

- IRB Administrators saw the value of community IRB members and would like to attract more. Retention was less of an issue than recruitment.
- Community members felt there was great value in what they did but they would like to know they were meeting the needs of the IRB.