Maximizing IRB Contributions from Non-Scientist and Non-affiliated Members

Stephen Poppel and Nathalia Henry
Content Copyright

All content included in this session is the property of the presenter(s), and is protected by United States and international copyright laws. Certain materials are used by permission of their respective owners. The course content may not be reproduced, transmitted, or shared in any way without the prior written permission of the presenter(s). Access to this presentation should not be construed as a license or right under any copyright, patent, trademark or other proprietary interest of PRIM&R or third parties.
Conflict-of-Interest Disclosure

Nathalia Henry and Stephen Poppel:

We have no relevant personal/professional/financial relationships with respect to this educational activity
Learning Objectives

1. Identify strategies for the effective framing of IRB members’ roles and responsibilities

2. Discuss approaches for non-scientist and nonaffiliated members to communicate more effectively within their IRBs

3. Explore opportunities to overcome structural and cultural challenges that may impact the non-scientist/nonaffiliated members’ positions
## Who We Are; Why We’re Here

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Roles/Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entity/Institution/HRPP</td>
<td>Oversee Human Research Protection Program (HRPP) in accordance with Federalwide Assurance (FWA) and a statement of principles such as the Belmont Report</td>
</tr>
<tr>
<td>Non-Scientific IRB Members</td>
<td>Serve on IRB*</td>
</tr>
<tr>
<td>Unaffiliated IRB Members</td>
<td>Serve on IRB*</td>
</tr>
<tr>
<td>IRB Office Staff</td>
<td>Provide administrative, operational and regulatory support to the IRB. Serve on IRB**</td>
</tr>
<tr>
<td>IRB Chairs and Vice Chairs</td>
<td>Serve on IRB</td>
</tr>
<tr>
<td>Other IRB Panel Members</td>
<td>Serve on IRB*</td>
</tr>
</tbody>
</table>

*As a voting member, alternate and/or designated reviewer
**At some institutions the IRB operational/administrative support staff also serve as IRB members
Regulatory Requirements for IRB Membership

- “Each IRB shall have **at least five members**, with varying backgrounds to promote complete and adequate review of research activities…..”

- “The IRB shall be sufficiently qualified through the **experience and expertise** of its members, and the **diversity** of its members including consideration of race, gender and cultural backgrounds and sensitivity to such issues such as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects”. 45 CFR 46.107 (a)
Regulatory Requirements for IRB Membership (continued)

- “Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.” 45 CFR 46.107(b)

- “Each IRB shall 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.” 45 CFR 46.107(c)
Why do IRBs have Community Members?

“SACHRP believes the scientist/non-scientist distinction was designed to ensure a range of intellectual and philosophical perspectives among IRB members. By use of the term “primary concerns”, both OHRP and FDA regulations acknowledge that the concerns of an IRB member are unlikely to lie solely in scientific, or solely in non-scientific, areas.”

Common Characteristics of IRB Members

- Why do individuals generally desire to serve on the IRB?
- How do non-scientific and unaffiliated IRB members often view themselves?
  - Personal/professional intentions
  - Desired contributions

All Stakeholders have a role in contributing to the effective engagement of non-scientific and unaffiliated IRB members
What is a “non”?

Non-Scientist = ?
Non-Affiliated = ?
= What?
Community Representative?

What community?
What representation?
“Non” vs “Non-Non”

- Non-Non
  - Information + Enthusiasm

- Non (the opposite)
  - Lack of Information + Uncertainty
Focus on Informed Consent
Potential Challenges to Nonscientist or Unaffiliated IRB Member Engagement

- Varying degrees of expertise (That non-scientists aren't experts is a misconception and a misunderstanding of their role as IRB members)
- Language (IRB lingo/regulatory jargon)
- Unclear/undefined expectations

- Structural issues
- Cultural issues
- The framing of IRB roles [The tone from the top (IRB Chairs)]

These challenges can be also viewed as opportunities
Setting Expectations for IRB Review and Approval

- **Belmont Principles** *(Respect for persons. Beneficence. Justice.)*

- **45 CFR 46.111 Criteria for IRB Approval**

- **Elements of Informed Consent (Basic and Additional Elements)**

- **Non-scientist/Unaffiliated member “gut check”**
  *(Risk to benefit, Costs, Participant community perspective (lay point of view), Consent form readability…etc.)*
## Communication and engagement strategies

- **Define roles & responsibilities**
- **Ongoing support:**
  - Education/Training
  - Resources and tools
  - Coaching and mentorship (the “human touch” and a sense of belonging)
- **IRB member evaluation and feedback processes (360 feedback; “performance review”)**

- **All parties establish clear expectations**
- **Refine IRB submission assignment process**
- **Refine meeting conduct/management**
- **Allow the non-scientist to remain a non-scientist**
Com mun i ca tion

kəˈmyoʊnəˌkäSH(ə)n/
Noun

1. the imparting or exchanging of information or news.

2. means of connection between people or places, in particular.

synonyms: transmission, conveyance, divulgence, disclosure
Respect

rəˈспект/

noun
1. a feeling of deep admiration for someone or something elicited by their abilities, qualities, or achievements.

verb
1. admire (someone or something) deeply, as a result of their abilities, qualities, or achievements.

synonyms: esteem, admire, think highly of, have a high opinion of, hold in high regard, hold in (high) esteem, look up to, revere, reverence, honor
Strategy: Quality Control

- ... a good thing!
- Shared Goals
- Long-term Benefit
- Constructive, not Adversarial
Tactics

Collaborate
Prepare
Respect
Contribute
Assert
Befriend
Remember
References/Additional Reading Material

Thank You