

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Broadening Representation on Institutional Research Committees - A Paradigm to Model

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1. Background

As a National Cancer Institute (NCI)-designated cancer center, an institution is mandated to have a Protocol Review & Monitoring System (PRMS) consisting of a Scientific Review Committee (SRC) and an Institutional Review Board/Privacy Board (IRB/PB) to oversee human subject research. The focus of this initiative was to evaluate membership opportunities and to expand representation across its two largest committees responsible for scientific (SRC) and human subject protection (IRB/PB) reviews.

Traditionally, representation on major institutional committees has been by hierarchical selection by senior leadership. Membership criteria were largely subjective and dependent on individual senior leaders' interpretation of a particular faculty member's qualifications and fit. Competing priorities of the service chiefs and/or "free time" of potential members created an additional layer of subjectivity. The same small pool of investigators tended to be nominated for multiple institutional committees, and typically, there was not an opportunity for self-nomination.

2. Goals

To broaden membership opportunities, we implemented a transparent, accessible, inclusive, and formalized process for institutional research committee membership by:

1. Defining responsibilities and qualifications
2. Streamlining application/interview processes
3. Developing outreach strategies, including promotion of the importance of institutional citizenship.

3. Solutions and Methods

- Brainstorming meeting with institutional research leadership to evaluate how best to expand membership, reduce barriers to membership, and ensure inclusivity
- Outreach to internal councils for membership recruitment, including Black Faculty & Scientists Advisory Council (BFSC), Black, Latinx, Asian, Multi-racial Faculty & Fellows Alliance (BLAM FFA), Junior Faculty Council (JFC)
- Published policies and procedures, PRMS#106 (Table 1)
- Demographic survey of committees to establish benchmark data (Table 2)

4. Outcomes

A new standard operating procedure (SOP) was written to reflect the stated goals of the initiative, include applicable qualifications and process to access membership (Table 1).

Outreach for membership resulted in 22 inquiries: 14 from the JFC, 5 from BFSC, and 3 from other sources. Most inquiries came from junior faculty at 82 percent and 18 percent from mid-level and senior faculty. Multiple clinical departments were represented: Anesthesiology/Critical Care (1), Laboratory Medicine (2), Medicine (10), Neurosurgery (1), Surgery (4), Radiation Oncology (2) and Translational Research Laboratories (2).

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Thirteen new members: 5 for SRC and 8 for IRB/PB were invited to join. Two self-nominees were appointed to other committees.

The committee demographics survey results (Table 2) compare the membership to the demographic breakdown of the center's workforce. The outcomes highlighted a positive change in increasing transparency and inclusivity within membership where a higher percentage of Hispanic or Latino and Asian are represented in the committees compared to the center.

5. Lessons Learned and Future Directions

Evaluation will be critical to inform the longer-term success of these initiatives. Specifically, understanding the following:

- Measuring and evaluating whether diverse committee membership effectively ensures diversity and inclusion in clinical trials.
- Evaluating membership retention, engagement, and other intangible effects of greater institutional cross-sectional committee involvement.

Moving forward, these strategies are a template to develop broader institutional representation in the regulatory bodies overseeing human subjects' research. The implemented measures are substantial initial steps which subjectively have been well received and provide a framework for institutional reorganization in one area of major institutional focus.