Partnering with Patients, Families and Members to Conduct Patient-Centered Research within a Learning Health Organization

Institute for Patient-and Family-Centered Care
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Overview, Tools & Processes
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Director, Research Strategy & Administration
HealthPartners Institute

Experience & Best Practices
Christine Norton, MA
Patient Co-Investigator
Largest Consumer-Governed Non-Profit Healthcare Organization in the Country

- **22,500** employees
- **1.5 million** members
- **1 million** patients

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- 200+ clinician and staff researchers
- 300+ staff
- 450 active research studies at any time
- Clinical Trials and Health Services Research

Cancer
Chronic Disease
Health Economics
Maternal & Child Health
Mental Health

Neuroscience
Oral Health
Research Methodology
Critical Care
Center for Memory & Aging
Patient, Family, Member Engagement in Research

Mission

“We Seek to Improve Health and Well-being in Partnership with our Members, Patients and Community”
## PFM Engagement in Research Experience

<table>
<thead>
<tr>
<th>Study / Initiative</th>
<th>Patient Engagement</th>
</tr>
</thead>
</table>
| PIONEER Study (Solberg - PCORI) | Christine Norton – Patient Co-Investigator  
Patient Advisory Council |
| Hypertension & Thiazides Study (Margolis – NHLBI) | Two Patient Advisors |
| Hyperlink Study (Margolis - PCORI) | Christine Norton – Patient Co-Investigator  
Additional Patient Investigator TBD  
Patient Advisory Council TBD |
| Patient Reported Outcomes - Organizational Initiative | Patient Partners in Development |
| Research Strategy and Planning Council (Institute) | Patient Member |
Patient, Family, Member Engagement in Research

Resources for Building Infrastructure:

• HealthPartners Patient Engagement Team
  o > 30 Active Patient Partnerships
• HealthCare Services Research Network - Special Interest Group
• Institute Stakeholder Group
  o 3 Senior Investigators (Margolis, Solberg, O’Connor)
  o 2 Senior Project Managers (Tillema, Bergdall)
• HealthPartners Legal, Compliance & IRB Teams
• Institute for Patient-and Family-Centered Care
• Patient Centered Outcomes Research Institute (PCORI)
• Patient Advisory Group: PCORI-funded Project (PIONEER – Solberg)
Patient, Family, Member (PFM) Engagement in Research – Toolkit

- Planning Checklist with Available Resources
- Templates:
  - Job Descriptions
  - Recruiting Materials
  - Standard Contracts
- Sample Interview Questions
- Best Practices for Meetings
- Compliance Guide
- IRB Quick Reference
- myLearning Online Training & Onboarding
<table>
<thead>
<tr>
<th>Process Step</th>
<th>Resources/Templates Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine Need for Study</td>
<td></td>
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<tr>
<td>Define Role for PFM Engagement</td>
<td>✓ Job Description Templates</td>
</tr>
<tr>
<td>Structure the Engagement</td>
<td>✓ Contract Agreement (Consultant Agreement)</td>
</tr>
<tr>
<td></td>
<td>✓ Finance: Budget &amp; Payment Mechanism</td>
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<tr>
<td>Determine Privacy / Compliance Training Level</td>
<td>✓ Compliance protocol</td>
</tr>
<tr>
<td>Define Requirements for Recruitment</td>
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<tr>
<td>Review &amp; Select Venues for Recruitment; Review with IRB if Necessary</td>
<td>✓ IRB protocol</td>
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<tr>
<td></td>
<td>✓ Recruitment materials (study summary; flyers, letters, 1-page study summary)</td>
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<tr>
<td></td>
<td>✓ HP/PN PFM Inventory</td>
</tr>
<tr>
<td>Complete Application Process &amp; Screen Volunteers using study appropriate questions. Customize screening questions based on method:</td>
<td>✓ Application Form</td>
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<tr>
<td></td>
<td>✓ Job Description</td>
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<tr>
<td></td>
<td>✓ Interview/Screening Questions</td>
</tr>
<tr>
<td></td>
<td>✓ Guidelines to Screening (avoid bias)</td>
</tr>
<tr>
<td>Select Participants &amp; Finalize Paperwork</td>
<td>✓ Compliance Protocol</td>
</tr>
<tr>
<td></td>
<td>✓ Contract Templates</td>
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<tr>
<td>Onboard Selected Participants &amp; Complete Paperwork</td>
<td>✓ Compliance Protocol</td>
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<tr>
<td></td>
<td>✓ myLearning PFM page</td>
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<tr>
<td>Train in Privacy &amp; Security</td>
<td>✓ Compliance Protocol</td>
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<td></td>
<td>✓ myLearning PFM page</td>
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<tr>
<td></td>
<td>✓ Checklist for Meeting conduct</td>
</tr>
<tr>
<td>Conduct Study</td>
<td>✓ Meeting best practices</td>
</tr>
<tr>
<td>Monitor and Evaluate Participation</td>
<td>o Feedback Form – Patient to PI</td>
</tr>
<tr>
<td></td>
<td>o Feedback Form – PI to Patient</td>
</tr>
<tr>
<td>Project End</td>
<td></td>
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<tr>
<td>Dissemination / Papers / Authors</td>
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</table>
What is the [Study Name] Patient Engagement Council?

What is the purpose of the [Study] Patient Engagement Council?

Who is an ideal PEC Member?

Other valuable skills include:

What do PEC Members do?

Will PEC members be paid?

Additional Benefits of Participating:

Funding information:
[STUDY NAME] is a research project being conducted by HealthPartners Research Institute. Our research will focus on improving patient care based on information we receive from patients like you who have [specific condition or experience in something]. This is an opportunity for you to help us understand your experience and improve healthcare.

The [Study Name] project is working to help patients, caregivers, and their healthcare providers make informed decisions. To do this, we need patients to share their perspectives about living with this condition and their priorities for health research. We are looking for patients to help us by:

[Describe the position(s) briefly]
Participating as a member of our Patient Engagement Council who will participate in formal meetings with other patients and researchers in person and by conference call (paid position).

If you are interested in becoming a member of our Patient Engagement team, please contact Project Manager to learn more:

Phone:  
Email:
PFM Engagement – Interviews

• Prior Volunteer Experiences?
• Any experience in the health field? In other Boards or community groups?
• Do you have any prior experience with research?
• Do you have any particular concerns or special interests about health care? (Probe: Such as?)
• Do you feel have experience or feel comfortable speaking in meetings (sharing your story)?
• Please share an experience when you had a different view point or opinion on an issue in a professional or public setting. How did you handle that situation?
• What is your availability for these specific meeting times/frequency?
• Are you comfortable with email / conference calls /computers?
• Do you have any transportation restrictions or issues?
• Additional Study-specific Questions: Topic, Interests, etc.
## Patient, Family, Member Engagement in Research - Compliance

<table>
<thead>
<tr>
<th>Role of PFM in Research</th>
<th>Duties</th>
<th>Compliance Considerations</th>
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</table>
| **Advisory Panel**      | Grant Development Activities  
                          | Project Meetings           |  • Practices tied to Federal Funding? |
|                         | No PHI (Confirm)              |  • Volunteer Orientation / Onboarding practices? |
|                         | Potential Co-Author (?)       |  • Organizational employee legal requirements (codes, confidentiality, etc.) |
|                         |                                |  • Signed volunteer or employment agreement required? |
| **Co-Investigator**     | Grant Development Activities  
                          | Project Meetings           |  • HR requirements for screening new employees? |
|                         | Data Review or Discussions    |  • Practices tied to Federal Funding? |
|                         | Co-Author                     |  • Volunteer Orientation / Onboarding practices? |
|                         |                                |  • Organizational employee legal requirements (codes, confidentiality, etc.) |
|                         |                                |  • Signed volunteer or employment agreement required? |
|                         |                                |  • Research Privacy & Security / Code of Conduct Training(s) required? |
| **Consultant**          | Grant Development Activities  
                          | Project Meetings           |  • Practices tied to Federal Funding? |
|                         | Data Review or Discussions    |  • Volunteer Orientation / Onboarding practices? |
|                         | (Confirm)                     |  • Organizational employee legal requirements (codes, confidentiality, etc.) |
|                         | Co-Author                     |  • Signed agreement required? |
|                         |                                |  • Research Privacy & Security / Code of Conduct Training(s) required? |
| **Focus Group Member**  | Occasional Meetings to provide |  • Practices tied to Federal Funding? |
|                         | feedback                       |  • Volunteer Orientation / Onboarding practices? |
|                         | No PHI                         |  • Organizational employee legal requirements (codes, confidentiality, etc.) |
|                         |                                |  • Signed volunteer or employment agreement required? |
### Role of PFM in Research

<table>
<thead>
<tr>
<th>Role of PFM in Research</th>
<th>Recruitment Methods (examples)</th>
<th>IRB Requirements</th>
</tr>
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<tbody>
<tr>
<td>All Roles</td>
<td>EXAMPLE: Investigators aware of a specific patient advisory group supported by the organization can approach the group staff/contact to determine the best way to engage with prospective individuals to inform about the need for a patient advisor on the study team.</td>
<td>• Check with your IRB officials</td>
</tr>
<tr>
<td>All Roles</td>
<td>EXAMPLE: Investigator or PM approaches a provider(s) at a clinic to suggest appropriate patients to serve in an advisory capacity on a specific study. Provider supplies names of suggested patients and recruitment materials are passed along.</td>
<td>• Check with your IRB officials</td>
</tr>
<tr>
<td>All Roles</td>
<td>EXAMPLE: Subjects currently active in an approved study are approached by the investigator to inquire as to whether the subject might agree to serve in an advisory capacity for a new study.</td>
<td>• Check with your IRB officials</td>
</tr>
<tr>
<td>All Roles</td>
<td>EXAMPLE: Lacking specific patient advisory resources, there may be a need to engage a programmer to evaluate patient medical records to find an individual or individuals that may meet the criteria sought for a patient advisor on the study team. Access to charts for this purpose may need IRB review to grant at minimum a partial waiver of consent according to HIPAA to allow access to their chart, and develop a method of contact to make connection with the patient requesting consideration in joining the study team.</td>
<td>• Check with your IRB officials&lt;br&gt;• Do you need to run opt out lists?</td>
</tr>
</tbody>
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Patient, Family, Member Engagement in Research - Communication
Patient Partner Perspective

The PIONEER Study
Measuring Patient Outcomes from High Tech Diagnostic Imaging Studies

Funded by PCORI (Patient Centered Outcomes Research Institute)

Investigator: Leif Solberg, MD
Co-Investigator: Christine Norton, MA
Patient Partner Perspective

- Selecting a Patient Partner
- Preparing Your Patient Partner
- Supporting Through the Project
- General Tips
Selecting Your Patient Partner

Sources for recruiting patient partners

- Existing Patient Advisory Councils
- Healthcare related nonprofit organizations
- College classes for Adults
- Clinicians – by Specialty
- Researchers – prior studies; outside committees
Selecting Your Patient Partner

Helpful Qualities in a Patient Partner:

- Ability to go beyond anecdotal experience and see the big picture
- Curiosity & willingness to learn
- Ability to work well in a group of diverse stakeholders
- Available for research team meetings – often in person
- Available for the duration of the research project
- Confidence to speak out during meetings
- Comfortable with computers: email, webinars, & editing documents
- Phone access
Preparing Your Patient Partner

**Partner** with Compliance and HR to Determine Agreements & Training Requirements

**Meet** with the PI & Project Manager & other appropriate co-investigators

**Communicate** logistics:

- Primary point of contact
- Team member names
- Contact information
- Affiliations
- Roles in the project / Duties of PP
- Financial Compensation

**Educate** on Specific Research Study:

- Basic explanation of how this type of research works
- Time commitment to participate
- Understandable background articles
- Glossary with acronyms & terminology – this should be a dynamic document

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Supporting Through the Process

- Remember the PP is NEW to this process!
- Have pre-meetings to prepare if necessary.
- Pair a new PP with an experienced PP who can mentor.
- Provide ongoing education.
- Be responsive to emails & calls.
- Send printed materials in advance of the meeting.
- Encourage communication/questions/observations.
- Draw the PP into research team discussions.
- Genuine praise & appreciation are wonderful & powerful motivators.
- Gently offer help if it’s not going well.
- Hold periodic check-ins:
  - What is going well & what can be improved?
  - Is your time being appropriately used?
  - Any suggestions going forward?
Summary - General Tips

- Involve the PP from the beginning.
- Be sure their involvement is meaningful & not window dressing or “box ticking”.
- Set clear expectations for the PP.
- Prepare the other team members for working with a PP since this may be new for them.
- Remember - PPs don’t have “institutional history” about research like the rest of the team.
- Be gentle/tactful when commenting on their ideas & suggestions.
- If appropriate, ask the PP to present information at a meeting, and offer time to help them prepare in advance.
- During in person meetings, observe the PP’s body language. Be aware of any non-verbal communication.
My Cool & Meaningful Experience

By being involved from the beginning, I felt an integral part of the proposal development and the actual research itself from survey development to editing articles submitted for publication.

I’d done peer reviews for DoD, NCI & Avon Foundation for 20 years but now saw research from the other side. I have a new appreciation as I review proposals!

It was terrific & important to feel accepted from the beginning by the research team.

I learned a lot about Patient Reported Outcomes & interpreting statistics.

I collaborated with two others to write a paper. It was SO cool to be part of my first published paper!!

Research group also has a published paper & another submitted.
Questions and Comments
Patient, Family, Member Engagement in Research

Thank You!

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ChrisNorton@msn.com