Patient Advisor Toolkit 1:
Orientation for Patient Advisory Committees

Wisconsin Network
for Research Support

Betty Kaiser, PhD, RN

Gay Thomas, MA

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About the Patient Advisor Toolkit 1: Orientation for Patient Advisory Committees (PAT-1)

What is the Patient Advisor Toolkit 1 (PAT-1)?

PAT-1 is a comprehensive set of modifiable resources for conducting an orientation with patient advisors. The toolkit provides a complete, step-by-step guide to preparing patient advisors to work effectively with researchers.

PAT-2 (in development) will be a complementary resource to help researchers plan and facilitate ongoing meetings with patient advisors.

Who are "patient advisors," and how can they help researchers?

"Patient advisors" are patients, family members, caregivers, and other members of the public who advise researchers at one or more stages of a research project.

This toolkit focuses on orientation of adult patient advisors who do not have professional roles as health care providers, administrators, or members of a research team.

Patient advisors provide unique and valuable feedback to researchers from the perspective of people who are not embedded in the world of research. Their input can help researchers conduct patient-centered research that aligns with the real priorities, concerns, and interests of the target population the research seeks to help. Patient advisors can help researchers:

- identify patient-centered outcomes for research
- develop recruitment plans and materials
- refine data collection instruments and processes
- troubleshoot challenges with study implementation
- interpret study findings
- disseminate results

What does PAT-1 contain?

PAT-1 contains an introduction on using the toolkit; 8 essential modules for a patient advisor orientation; 4 optional modules; and 3 appendices with additional resources for planning, tailoring, conducting, and following up after orientation.

Each PAT-1 module includes:

- Overview

        - **Participant Objectives** – what patient advisors learn by completing module activities
        - **Background** – purpose of module activities
    - Training Materials
        - **Outline of Activities and Steps** – list of module activities and facilitation steps, with links to orientation handouts
        - **Advance Prep** – list of tasks for research team, including writing on flip chart and printing copies of handouts
        - **Sample Facilitation Script** – suggested language for facilitators

Who should use PAT-1?

We developed this toolkit for researchers who conduct clinical trials and want input from patient stakeholders to improve the design, implementation, and dissemination of their research. We specifically created PAT-1 as a user-friendly guide for researchers who are not conducting community-based participatory research, but want the benefits of engaging patients as advisors on research projects. Researchers can use the toolkit to develop customized orientation programs for various groups of stakeholders and a wide variety of projects.

Other potential users of the toolkit include organizations who want to develop institutional patient and family advisory councils or community advisory boards.

How should PAT-1 be used?

PAT-1 consists of several modules and appendices.

- The first eight modules are the **essential modules**. These modules are the "core" of this toolkit, and contain the information and tools needed to conduct a 2-hour orientation for patient stakeholders.
- The next four modules are **optional modules**. You can choose to include any of these in your stakeholder trainings, based on the specific needs of your project and stakeholder group.
- The three **appendices** contain additional resources for planning, tailoring, conducting, and following up after orientation.

We encourage users of the toolkit to contact WINRS for help adapting the orientation materials: http://winrs.son.wisc.edu/

How was PAT-1 developed?

PAT-1 is based on an orientation program developed by WINRS from 2010 - 2013 under a National Institute of Nursing Research grant (Principal

Investigator: Barbara Bowers, PhD, RN). As part of the grant, WINRS developed two community advisory boards, the Community Advisors on Research Design and Strategies (CARDS)®. The CARDS® provide feedback to researchers on recruitment flyers and letters, informed consent documents, survey and focus group questions, smartphone aps, websites, and other materials. To prepare the CARDS® for their role as advisors, WINRS developed an interactive orientation focused on concrete skills for providing feedback to researchers.

In 2014, WINRS collaborated with Dr. Elizabeth Cox at the University of Wisconsin - Madison to adapt the CARDS® orientation program for the parent advisors in her study funded by the Patient Centered Outcomes Research Institute (PCORI). The resulting Toolkit on Patient Partner Engagement in Research (TOPPER) contained original and revised materials from the WINRS orientation program, along with new materials to meet the specific orientation needs of Dr. Cox's parent advisors.

Since 2014, WINRS staff have consulted with researchers on orientation programs for 15 distinct patient advisory boards, continuously revising orientation materials to make them easier for researchers to use and more interesting and relevant for patient advisors. PAT-1 incorporates "lessons learned" from these consultations, as well as specific suggestions from the CARDS® for improving orientation materials and activities. **PAT-1 replaces TOPPER as WINRS' current toolkit on orientation for patient advisors.**

About the Wisconsin Network for Research Support (WINRS)

WINRS is a patient and community engagement center based at the University of Wisconsin-Madison School of Nursing. You can learn more about WINRS on this page: http://www.hipxchange.org/winrs and you can download another WINRS toolkit, Hard-to-Reach Patient Stakeholders: An Engagement Guide, on this page: https://www.hipxchange.org/HARPS

About the developers

Betty Kaiser, PhD, RN is Director of Stakeholder Training with the Wisconsin Network for Research Support (WINRS) at the UW-Madison School of Nursing. She provides in-depth consultation on stakeholder engagement to research teams, with a focus on developing tailored orientation programs for project-specific patient advisory boards, as well as train-the-trainer programs that help research teams build skills for delivering stakeholder orientation programs.

Gay Thomas, MA is Director of Stakeholder Engagement with the Wisconsin Network for Research Support (WINRS) at the UW-Madison School of Nursing. Her background encompasses a broad range of professional positions on Capitol Hill, with Planned Parenthood, for several health insurance organizations, and on multiple health sciences research projects. Her work with WINRS focuses on creating tailored stakeholder engagement strategies that empower patients and community members to draw on their own lived experience to give "expert advice" to researchers on how best to connect and communicate with people researchers seek to reach. She is passionate about helping research teams build and sustain effective stakeholder partnerships which benefit all participants and produce meaningful research outcomes.

PAT-1 funding

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Re-using the toolkit

This toolkit exists for the benefit of the research community. These materials are available free of charge and can be used without permission; however, we ask that you register with HIPxChange prior to using the toolkit so that we may provide information on usage to our funders. It is acceptable to link to this website without express permission.

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Introduction

WINRS Approach to Patient Advisor Orientation

Our eight years of experience developing and running Patient Advisory Committees (PACs) has taught us this: providing a thoughtful orientation for patient advisors is key to the success of your project!

A well-designed, interactive orientation sets a firm foundation for successful patient engagement throughout a research project by accomplishing several key objectives. A thoughtful orientation helps to create group norms and prepares patient advisors to share their experiences and advice in a focused, constructive way. It helps to establish a positive, non-hierarchical group culture, excite patient advisors about their role, and demonstrate that their work will make a meaningful contribution to the project. It also provides a chance to clear up any misunderstandings that patient advisors may have about the project and their role.

We have four key goals for a patient advisor orientation:

1. Start developing a sense of community and trust
2. Provide clear information about the project goal and advisor role
3. Give advisors practice applying lived experience to give meaningful feedback
4. Have fun!

We intentionally exclude from our orientations any content or activities that are not directly relevant to the job of being a patient advisor. In our experience, patient advisors do not need extensive knowledge of human subjects requirements or research methods in order to provide helpful feedback on research plans and materials. (If you have a project that would specifically benefit from content on these topics, please see "Optional Module B: Research Process, Terms, & Ethics.")

We also exclude content or skill-building activities for work that patient advisors will do months or years in the future. Content related to future activities is best delivered "just in time," at the point when the information or skills are required.

How to Use the PAT-1 Toolkit

Getting Started

PAT-1 is a flexible, modular toolkit that can be tailored to your project, research team, and patient advisors. The eight "essential" modules comprise a two-hour orientation (excluding several optional activities within the modules). We offer the toolkit as a Microsoft Word document to make it easy for researchers to edit PAT-1 and add new materials.

- ***If you want step-by-step instructions on facilitating orientation activities***, read the outline of orientation activities and the detailed facilitation script in each module. (We have designated "Facilitator 1" as the main facilitator in the Sample Facilitation Scripts, but you can distribute the facilitation responsibilities between two facilitators however you like.) We strongly recommend using the detailed scripts, which help keep discussions on topic and the meeting on time. With practice, using a detailed script feels natural. Some research teams prefer using an outline rather than a detailed script as a facilitation guide. If you decide to use outlines instead of facilitation scripts, practice and fine-tune what you will say several times before the orientation. Without practice, 5-minute activities can easily morph into 15 minutes of unnecessary details or disorganized conversation and decrease time available for other key orientation activities.
- ***If you want to see activities and learning objectives for a two-hour patient advisor orientation***, see the Facilitator Agenda at the end of Module 1.
- ***If you want practice-based tips*** to help you prepare for, conduct, and follow up on patient advisor orientation, see Appendix I. Our tips are a compilation of many "lessons learned" from eight years of designing and delivering orientations and conducting over 250 meetings with patient advisors.
- ***If you want an example of a complete task list for preparing for orientation***, see Appendix II. If you tailor PAT-1 materials to create your own orientation, revise Appendix II as needed to match your prep needs.
- ***If you want examples of how to mix-and-match modules to tailor an orientation***, see Appendix III for a 45-minute agenda and a 4-hour agenda. You can mix-and-match essential and optional modules and add your own materials to create tailored orientations for your projects.
- ***If you want to quickly view handouts for patient advisors and your research team***, click on the hyperlinks in the "Outline of Activities and Steps," "Advance Prep," or "Sample Facilitation Script" section of each module. (Some modules do not use handouts.)

Legend

- The light bulb symbol designates a WINRS tip.
- Underlined, blue text is hyperlinked to module-specific handouts. (This example is not an active link.) Hover over a hyperlink and press CTRL+click to follow the link. After viewing a handout, press ALT+left arrow to go back.
- Gray shading denotes an optional activity.
- <Yellow highlights in brackets> denote places where the research team should insert its own project-specific text to tailor the materials.
- *(Italicized text)* in the "Sample Facilitation Script" for each module provides specific instructions for facilitators.
- A centered single line designates the end of the Overview in each module.
- A centered double line designates the end of a module.

Module 1: Welcome and Introductions

Overview

Objectives for PAC Members

- Get to know PAC and project team members
- Start to feel comfortable speaking in the group

Background

Module 1 includes activities to welcome members of a patient advisory committee (PAC), help them learn about each other and the research team, and set the stage for the rest of the meeting. The activities communicate several key messages to PAC members: we all bring something unique and valuable to this group; our meetings will be interesting and fun; our meetings are well-organized and make good use of everyone's time.

We recommend starting each PAC meeting with an opening question and brief agenda review. The opening question, in which all PAC members and research team members participate, helps people get to know one another and feel comfortable sharing their ideas. The agenda review helps orient participants to the planned activities for the meeting and establishes that the facilitators will respect everyone's time by keeping the meeting on task.

The optional Bingo activity is a fun way to energize participants and establish a friendly atmosphere, and we have used it successfully in groups of lay advisors as well as mixed groups that include lay people, health care providers and administrators, and researchers.

Module 1 is an **Essential Module** that takes 20 minutes to complete or 30 minutes with the optional Bingo activity. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Informal welcome
    - Welcome participants as they enter.
    - Hand out name tags and participant folders.
    - Offer refreshments.
    - Circulate and introduce yourselves to all members.
2. ((Optional activity—Bingo))
    - Hand out Patient Advisory Committee Bingo and read instructions out loud.
    - Play game—all patient advisors and research team staff participate.
    - When someone has “Bingo,” read answers out loud to confirm; award prize.
3. Introduction of research team
    - Give name and role of research team staff who are present.
    - Identify main contact for participants.
4. Opening question
    - Pose opening question.
    - Complete introductions.
5. Logistics
    - Explain plan for snacks or meal.
    - Identify bathroom location.
    - Request that participants turn off cell phones or place on mute. Ask people to exit meeting to deal with urgent calls.
6. Review of meeting agenda
    - Hand out Participant Agenda and read out loud; briefly describe each item.
    - Answer any questions before continuing.

> Having one contact person helps prevent communication problems throughout project.

> Start self-introductions with member of research team, who can model brief response to opening question.

Advance Prep

✓ Replace <highlighted generic text> in facilitation script with tailored text.

✓ Write on flip chart, p. 1:

- Line 1: Patient Advisory Committee (or project-specific name)
- Line 2: Project name (in plain language)

✓ Print copies of Participant Agenda for stapled member packet, Facilitator Agenda for research team, and ((optional Bingo))

✓ ((If using optional Bingo activity, obtain mug, water bottle, fun refrigerator magnet, or other small prize for winner.))

Sample Facilitation Script

Module 1
Welcome and Introductions

Estimated Length
20 min. (30 min. if using optional activity)

Supplies + Documents
- Easel and prepped flip chart, markers
- Pens, name tags
- Member folders
- ((Optional handout: Bingo))
- ((Small prize for Bingo winner))
- Participant Agenda in stapled member packet
- Facilitator Agenda and printed Outlines or Facilitation Scripts for research team

1. Informal welcome

- Research team welcomes people individually as they enter.
- Give each person a name tag.
- Invite people to help themselves to refreshments.
- Circulate and introduce yourselves to as many people as possible.

*(**Facilitator 2** distribute folders with stapled packet)*

2. ((Optional activity—Bingo))

- After people have helped themselves to refreshments, <facilitator name> hand out Bingo sheets and pens. Read instructions; encourage people to mingle and talk with others.
- Everyone plays game as they settle in, including research team.
- First person who says “bingo” hands completed form to <research staff>. <Staff person> reads answers aloud to confirm answers are correct. Award small prize.

3. Introduction of research team

Facilitator 1 (Fac. 1): Let's get started. We're so glad that you're all here. Welcome to the first meeting of our Patient Advisory Committee!

*(**Fac. 2** point to flip chart with PAC acronym spelled out.)*

Fac. 1: I'm <name>. I'll be your main contact for this project and will coordinate our meetings. I'm here with <other project staff>. We're excited to welcome you to the PAC, explain this project, and help us all prepare for our work in this group. We hope the next two hours will be fun and interesting for you.

4. Opening question

Fac. 1: Let's go around the table and introduce ourselves. If it's all right, we'd like to use our first names. Please tell us your name and one reason that you decided to join this Patient Advisory Committee. Our project team members will share one reason we are excited about working with this group. Can you please get us started, <name of research team member>?

*(**Member of research team** gives 30 – 60 sec. self-introduction to model brief response).*
*(**PAC members** complete introductions.)*

5. Logistics

Fac. 1: Great! So, let's go over a few quick housekeeping details. Please help yourself to snacks. You'll find restrooms <location>. If you have a cell phone with you, this is a good time to turn off the ringer and put it away, if you can. If you need to take a call during the meeting, please step out of the room and then join us when you're finished.

6. Review of agenda

Fac. 1: On page 1 of your stapled Packet, you have a copy of our agenda for today. Let's take a quick look at it. We'll start by discussing our project goal and all the people involved in this project. Then we'll talk about working together and how you can give helpful feedback to our team. Next we'll ask for your feedback to help us improve some of our project documents. We'll wrap up by explaining the process for our regular meetings and asking you to fill out a couple of forms. Before you leave, we'll give you <$xx> to thank you for your time.

You'll notice that we've included times for each item on the agenda. This is just to help us keep on track and make sure we finish on time! So, please excuse us if we have to cut discussion a little short to move on to the next agenda item. We're very interested in all of your ideas; we just want to respect and make good use of our time together. Any questions before we move on?

Patient Advisory Committee Bingo

The goal of this game is to match the description in each box below with one of the people in this group.

- Talk with as many people as you can.
- Find a person who matches the statement in a box. Write that person's name in the box.
    - Don't use your own name.
    - Don't use any name more than twice.
    - There is more than one answer for some of the boxes.
- When you have one name in every box, say "bingo" and raise your hand. First person to complete the entire sheet correctly will win a cool prize!

Has owned a Chevy car	Has had a pet other than a dog or cat	Plays the piano	Has at least two children
Was born in April, May, or June	Has the same favorite sport as you (to watch or play)	Has taken any kind of dance class	Is the youngest child in their family
Can whistle a song	Has more than three siblings	Likes to cook	Knows how to swim
Has worked in a restaurant	Was born outside of <this state>	Has sung in a choir	Has the same favorite color as you

<Institutional or Project Logo(s)>

<Project Name—in plain language>

Meeting of the Patient Advisory Council (PAC)

<Date>
<Time>
<Location>
<Address>

Agenda

1. Welcome and introductions (20 min.)

2. Project goal; role of PAC and other stakeholders (5 min.)

3. Working together (10 min.)

4. Helpful feedback (10 min.)

5. PAC feedback on <research materials> (40 min.)

6. PAC meeting process (10 min.)

7. Membership agreement (20 min.)

8. Meeting evaluation (5 min.)

Facilitator Agenda (for research team only)

2-hour Orientation for Patient Advisory Committee

Module	Content	Time	Objectives for Patient Stakeholders
1	Welcome, introductions, opening question	:20	○ Get to know PAC and project team members ○ Start to feel comfortable speaking in the group
2	Project goal; role of project stakeholders	:05	○ Understand project goal ○ Recognize PAC's role in relation to other project stakeholders ○ Understand how research team will use input from PAC
3	Working together	:10	○ Create group norms to support candid discussions ○ Establish agreement to protect privacy of all PAC members
4	Helpful feedback	:10	○ Distinguish key elements of helpful PAC feedback on research materials: specific, relevant, respectful
5	Feedback on research materials	:40	○ Experience typical PAC work ○ Practice giving helpful feedback to research team
6	PAC meeting process	:10	○ Describe PAC role comfortably and accurately ○ Recognize steps for attending PAC meetings and typical structure of meetings
7	Membership Agreement	:20	○ Understand mutual responsibilities of project team and PAC members ○ Choose whether to participate in PAC
8	Meeting evaluation	:05	○ Reflect on usefulness, quality of meeting

Module 2: Project Goal and Stakeholder Roles

Overview

Objectives for PAC Members

- Understand project goal
- Recognize PAC's role in relation to other project stakeholders
- Understand how research team will use input from PAC

Background

Module 2 is a brief module with activities to describe the project goal, the major stakeholders in the project, and the role of the PAC relative to other stakeholders.

The activities provide a straightforward explanation of what you hope will be better as a result of your project and how the research team will use PAC input. In addition, the activities in Module 2 help clear up any misperceptions that patient advisors may have about the project. Common misperceptions include believing that the primary role of the PAC is to serve as a support group for members or believing that the research team will use every recommendation that the PAC makes.

In our experience, detailed explanations of project design, specific aims, methods, and analysis can be counter-productive at PAC orientations. Extensive background on the project, while essential for the research team, does not prepare patients for their real work as advisors—sharing their lived experiences and advice in a focused way with researchers. In addition, long periods (anything more than 5 minutes) of passive listening can disengage participants and palpably reduce their interest and enthusiasm.

Module 2 is an **Essential Module** that takes 5 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Project goal
   - Give short overview of project goal in plain language (What do you hope will be better or different as a result of this project?)
   - Answer any questions from PAC members about goal and major project activities.

> Limit Q&A to 3 min. If members have many questions, offer to stay after to answer.

2. Big picture of stakeholder engagement
   - Present diagram that displays key stakeholders in project, including PAC.
   - Distinguish the type of input various stakeholders will provide to the research team; describe how the research team will synthesize input and apply it to the project processes and materials.

> Consider using low-tech approach of flip charts to present project goal and stakeholders. If you choose to use PowerPoint or other presentation software:
> - Limit number of slides for this module to 2 - 3.
> - Use plain language and simple graphics (no complicated flowcharts).
> - Confirm availability of computer, projector, and projection screen or wall in meeting room. Your team may need to provide these.
> - Test equipment on-site before orientation meeting.

Advance Prep

- ✓ Replace <highlighted generic text> in Facilitation Script with tailored text.
- ✓ Write/draw on flip chart, p. 2:
  - Project goal
  - Study Stakeholders diagram (tailored to your project)

Sample Facilitation Script

Module 2
Project Goal and Stakeholder Roles

Estimated Length
5 min.

Supplies + Documents
- Easel, markers, flip chart prepped with Study Stakeholders diagram

1. Project goal

Facilitator 1 (Fac. 1): <Brief 2-min overview of the project goal, what the team hopes will be better as a result of this project.> Does anyone have any general questions before we move on?

*(**Fac. 1** answer questions. Limit Q&A to 2-3 min.)*

2. Big picture of stakeholder engagement

Fac. 1: Now let's talk about how the PAC fits in with the other stakeholders on this project.

*(**Fac. 2** show flip chart w/ tailored stakeholder diagram.)*

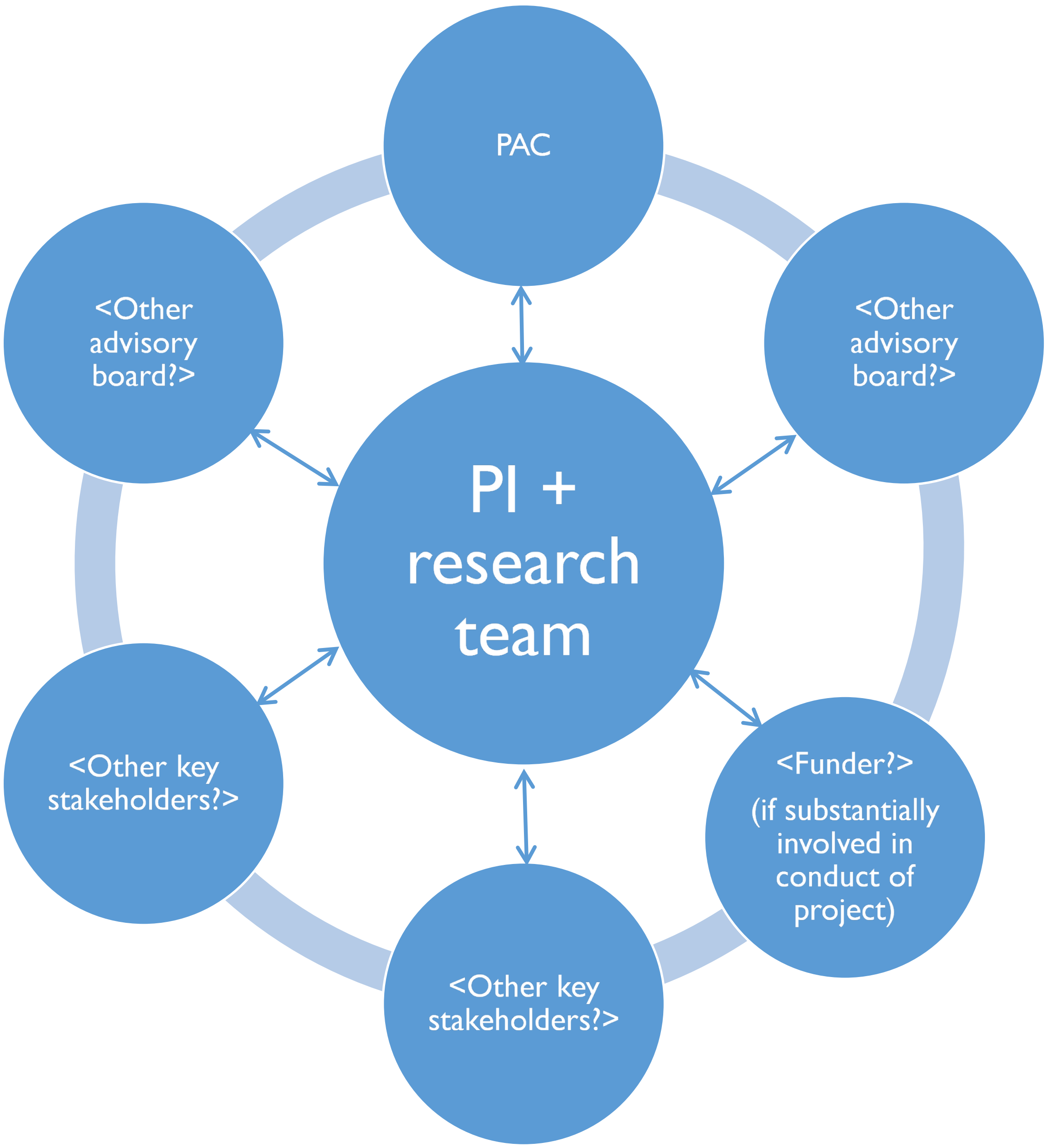
Fac. 1: This shows the key groups and people involved in this project. We call these groups "stakeholders" because they all have a stake in how this project turns out! <Briefly describe the roles and responsibilities of each group.> Here's an important thing to remember. These stakeholders are people who advise the research team; they are not research participants, like people who actually sign up to BE PART OF a study. So, all of you are PATIENT stakeholders for this project, but you are not research participants. Does anyone have any questions about that?

(***Fac. 1*** *answer questions.)*

Fac. 1: Now let’s talk a little about the roles of these stakeholders. <Briefly describe the roles and responsibilities of each group; describe how research team will consider and combine input from stakeholders.> Does anyone have any questions about this “big picture” of who is involved in this project?

(***Fac. 1*** *answer questions.)*

Study Stakeholders



Module 3: Working Together

Overview

Objectives for PAC Members

- Create group norms to support candid discussions
- Establish agreement to protect privacy of all PAC members

Background

Module 3 includes activities to help the PAC generate group norms, recognize how to protect each member's privacy, and self-monitor participation during PAC meetings. The activities demonstrate that the research team cares about creating a supportive, respectful environment in which everyone can feel comfortable and contribute.

In orientation meeting evaluations, patient advisors consistently rate the major activity in this module—the discussion on group norms—very highly. Members generate <u>their own</u> group norms by responding to a discussion question, rather than simply accepting a list of ground rules generated by the research team. We recommend against using a predetermined list of rules, which can convey several negative messages: you expect PAC members to act inappropriately, and you are not confident that members know how to make group conversations satisfying and friendly for everyone.

The optional, intentionally humorous examples on protecting the confidentiality of PAC members use realistic scenarios to remind PAC members that personal information shared in the context of a PAC meeting should not be shared outside the meeting.

Module 3 is an **Essential Module** takes 5 minutes to complete or 10 minutes with the optional activity using privacy and confidentiality examples. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the [Wisconsin Network for Research Support]() for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Discussion on group norms
    - Explain that you want PAC members to feel comfortable sharing their ideas and opinions at meetings.
    - Invite members to answer "what helps you feel comfortable speaking up in a group?"; write responses on flip chart.
    - Add ideas from research team to list as needed.

> Wrap up this activity by reviewing the list generated by the PAC and highlighting particularly important items, such as "people don't interrupt me" or "there aren't any side conversations."

2. PAC members and privacy
    - Acknowledge that members may hear personal information at meetings.
    - Ask that members respect the privacy and confidentiality of PAC members and people they may see at PAC meeting sites.
    - ((Optional activity—Review and discuss examples of how to protect privacy and confidentiality of PAC members and others.))
3. "Step up, step back"
    - Encourage members to self-monitor their participation during meetings by "stepping up" if they have not said much and "stepping back" if they have said a lot.

Advance Prep

- ✓ Write on flip chart, p. 3:
    - In your experience, what helps you feel comfortable speaking up in a group?
- ✓ ((Optional—print copies of examples of how to protect privacy and confidentiality for stapled member packet))

Sample Facilitation Script

Module 3
Working Together

Estimated Length
5 min. (10 min. if using optional activity)

Supplies + Documents
- Easel and prepped flip chart, markers
- ((Optional: Examples of how to protect privacy and confidentiality in member packet))

3. Discussion on group norms

Facilitator 1 (Fac. 1): Now let's talk a little about working together at PAC meetings. Obviously, this is a group of people with different backgrounds and different life experiences. We all want to feel comfortable sharing our ideas and experiences with each other. So, let's talk about how we can make this group a place where everyone feels comfortable speaking freely with each other. We've all been in groups where there is a mix of opinions – this happens at work, at church, and with our families. Let's each think about our experience in groups like that and answer this question.

*(**Fac. 2** show question on flip chart.)*

Fac. 1: In your experience, what helps you feel comfortable speaking up in a group? For example, it helps me feel comfortable when other people make good eye contact with me when I'm talking. That makes me feel like they're really listening to me. What are some other examples?

(Provide additional examples as needed)
- People don't cut me off.
- There aren't side conversations—people aren't talking while I'm talking.

- People have good body language—they nod at me and smile while I'm talking. They're not turned away from me with their arms crossed.
- I feel comfortable when I know that what I say in the room stays in the room.
- People don't judge or criticize my ideas.
- People use language that I can understand. They're not using technical terms.

*(**Fac. 1** lead discussion, summarize key points; **Fac. 2** write participants' comments on flip chart)*

Fac. 1: Let's take one more look at our list. Have we left out anything that you think is important for helping everyone feel comfortable sharing their ideas?

*(**Fac. 2** add any additional ideas to list.)*

4. PAC members and privacy

Fac. 1: When we talk about what makes us feel comfortable speaking up in a group, people often say "people will respect my privacy" or "my comments won't be discussed outside this group." These are really important ideas for PAC members. During meetings of this group, all of you may share personal examples or stories.

Fac. 1: We want this to be a safe space where everyone feels comfortable talking freely, knowing that we will all respect the privacy and confidentiality of people in this group. We also want to respect the privacy of people we may accidently see or hear about while attending PAC meetings. It's important so that everyone here feels respected and comfortable. Are there any questions or concerns about privacy and confidentiality before we move on?

5. ((Optional activity: Privacy and Confidentiality Examples))

Fac. 1: We have some examples to help you think about confidentiality in your role as a PAC member. You'll find this sheet in your stapled packet.

*(**Fac. 2** show Examples of how to protect privacy and confidentiality.)*

Fac.1: Each example asks a question about the best way to protect confidentiality, and we'll talk about the best response as a member of the PAC. Let's read the first example.

*(**Fac. 1** read example #1 out loud and review response options one-by-one.)*

Fac. 1: What about answer A? Is that the best answer? (Continue with B – C and example #2.)

Fac. 1: We know that some of the answers are funny and a little ridiculous—but we hope they're a good reminder of how important it is to maintain privacy and confidentiality.

6. "Step up, step back"

Fac. 1: I'd like to share something that I've seen work really well in groups. It's the expression "Step Up/Step Back." It's pretty simple. During the meeting, we all stay aware of our own participation. If you notice that you haven't spoken much, then maybe it's time to "Step Up" and try to participate more actively. And if you notice that you have been sharing a lot, then maybe it is time to "Step Back" and open up space for other people to talk. Does that make sense? Do you have any questions or thoughts about using "Step Up/Step Back" in this group?

Privacy and Confidentiality Examples for PAC Members

#1

You run into Ann, another PAC member, at a coffee shop. Ann tells you that after the last PAC meeting, she saw a man she knows in the waiting area outside the clinic where the PAC was meeting. Ann tells you his name and how she knows him.

What is the <u>best</u> thing to say to Ann?

A. "Are you sure it's OK with him that you talk about him?"
B. "Let's go somewhere else. I feel funny talking about this in a public place."
C. "Let's not talk about him, please. I don't want to violate his privacy."

#2

During a PAC meeting, Mary shares some personal medical information that you think is very interesting.

What is the <u>best</u> thing to do with that information?

A. Keep this information to yourself.
B. Post the information on Facebook and see how other people respond.
C. Go home and talk about Mary's medical situation with a family member.

Module 4: Helpful Feedback

Overview

Objective for PAC Members

- Distinguish key elements of helpful PAC feedback on research materials: specific, relevant, respectful

Background

Module 4 demonstrates to PAC members the type of work that they will do at regular meetings. The module starts with a brief introduction that summarizes typical PAC work, followed by a skit that portrays specific, relevant, and respectful PAC feedback on research materials. A debriefing on the skit gives PAC members a chance to share their ideas about what makes feedback on research materials helpful and, conversely, what contributes to feedback that is not helpful.

This module demystifies the job of "patient advisor." The skit provides a concrete example of the type of materials that the PAC will review and models useful feedback before participants give their own feedback on research materials in Module 5. The helpful feedback portrayed in the skit is straightforward, uncomplicated, and stated in plain language; it conveys "you can do this" to members.

Module 4 is an **Essential Module** that takes 10 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Set-up for skit on helpful feedback
    - Briefly describe typical PAC work—giving feedback on research materials and processes.
    - Introduce skit; ask PAC members to watch for differences in how skit actors provide feedback on sample research materials.
2. Skit on helpful feedback
    - Read aloud Sample Letter for skit.
    - Perform Skit for Demonstration of Feedback with two members of research team.
3. Debrief on PAC reactions to skit
    - Ask PAC members to compare and contrast feedback provided by actors in skit; write comments on flip chart.
    - Reinforce key differences between helpful/not helpful feedback; emphasize that feedback on research materials is most helpful when it is specific, relevant, and respectful.

Rehearse the skit several times before Orientation to ensure that both actors can read their lines comfortably and clearly demonstrate helpful or unhelpful feedback. It is not necessary to memorize the skit.

Advance Prep

- ✓ Replace <highlighted generic text> in Facilitation Script with tailored text.
- ✓ Rehearse skit
- ✓ Print copies
    - Sample Letter for skit for stapled member packet
    - Skit for Demonstration of Feedback for research team

Sample Facilitation Script

Module 4
Helpful Feedback

Estimated Length
10 minutes

Supplies + Documents
- Easel and prepped flip chart, markers
- Pens, name tags
- Sample Letter in member packet
- Skit for Demonstration of Feedback

1. Set-up for skit on helpful feedback

Facilitator 2 (Fac. 2): Your role as a PAC member is to give feedback to the research team at meetings like this. We will bring all sorts of documents to this group and ask for your advice on how to make the materials more engaging, easier to read, and easier to understand. We have a little skit about what helpful feedback sounds like in a group like this. <Facilitator 1> and I are going to play the role of PAC members giving feedback on a recruitment letter. Please find this sample letter in your stapled packet.

*(**Fac. 1** show letter.)*

Fac. 2: We want this letter to be as friendly, clear, and easy to understand as possible! As you watch the skit, think about the differences in how <Facilitator 1> and I give feedback. After the skit, we'll talk about how useful you think our feedback was and how it made you feel.

2. Skit on helpful feedback

Fac. 2: Would someone like to read the letter aloud for us?

*(**PAC member** read Sample Letter aloud.)*

Fac. 2: Thank you. Now <Facilitator 1> and I will play the role of PAC members and give some comments on the letter.

(***Fac. 1 and Fac. 2*** *read skit.*)

3. Debrief on reactions to skit

Fac. 2: OK. Let's start with <Facilitator 1's> feedback. What stood out to you about the feedback that she gave? Were her comments specific? Relevant? Respectful?

(**Fac. 2** facilitate discussion; **Fac. 1** record comments on flip chart. After discussing Fac. 1's feedback, ask about Fac. 2's feedback.)

Fac. 2: The main point of this skit, besides having a little fun, is to show that feedback is most helpful when it's specific, relevant, and respectful. <Fac. 1> had a lot of comments about things that could be better, but gave her feedback in a very respectful way. She pointed out things that were confusing and made specific suggestions for how to improve the wording. That was all really helpful! But my feedback wasn't very helpful to the research team. I talked about things that weren't relevant to this letter, like my mom being a nurse. And I was pretty critical, but I didn't give any specific suggestions to help improve the letter. And I wasn't very respectful about <Fac. 1's> ideas.

Everyone here has great experience to bring to this group, and it will be most helpful when you use it to give feedback that is specific, relevant and respectful. Does anyone have any other comments or questions?

Sample Letter for Skit Demonstrating PAC Feedback

Dear <Name of Patient>,

Two researchers at Big University, Doctors Lisa Jackson and Pat Gomez, are studying the effectiveness of a lifestyle intervention to improve physical function in older adults. We are recruiting individuals age 65 or older who are not currently active. Research participants will attend group exercise classes twice a week for three months and will undergo a walking test at the start of the study, after three months, and six months after the classes end.

Thank you very much for your consideration of this very important research endeavor. Please call us at xxx-xxx-xxxx for more information.

Sincerely,
Lisa Jackson RN, PhD and Pat Gomez, MD

Skit for Demonstration of PAC Feedback

Fac. 1: Well, here is my first thought -- if I opened this at home, I might throw it out before reading it. Without a logo, I'd probably think it's just think it's a scam.
Fac. 2: Hmmmm. I don't know.
Fac. 1: I do like that the letter is pretty short! If a letter is too long, I'm not likely to read it!
Fac. 2: Well, some letters are long, some are short.
Fac. 1: You want this letter to be easy to understand, right? So, "lifestyle intervention"… I really don't know what that means. And the word "intervention" sounds a bit scary to me, like you're going to do something bad to me.
Fac. 2: That's just dumb! If you doesn't understand what "intervention" means, maybe you shouldn't be in this study!
Fac. 1: Well, I'm just thinking that if you want to make sure that a lot of people are interested in this study, maybe "lifestyle intervention" isn't the best phrase to use. Could you just give a short description of the exercise classes?
Fac. 2: Well, my mom was a nurse, so I'm used to hearing a lot of medical words. She worked in the Emergency Room, so she really saw a lot of wild things. I could tell you some really crazy stories!
Fac. 1: Maybe what I'm trying to say is that medical jargon can be scary and confusing for a lot of people! My mom isn't in the medical field, and I honestly think saying "lifestyle intervention" wouldn't mean much to her.
Fac. 2: Well, I don't think you should dumb down research.
Fac. 1: Okay, well, can I ask about something else? The letter says that the group classes are twice a week for three months. But I feel like most people would want a few more details. Like, where do the classes take place? I might be interested in this project, but the location has to be convenient.
Fac. 2: I don't think you need more information in this letter! I think people are either interested in joining a study like this or they're not.

Module 5: Feedback on Research Materials

Overview

Objectives for PAC Members

- Experience typical PAC work
- Practice giving helpful feedback to research team

Background

Module 5 is the core of orientation for patient advisors—work with real research materials. A brief set-up with background information about the materials helps advisors "put themselves in the shoes" of the target audience who will actually see the materials. The review and discussion of the materials is carefully structured to support the participation of all patient advisors and produce feedback that will be useful to the research team.

In our experience, providing feedback on research materials is always a favorite orientation activity of patient advisors. The activity concretely illustrates the work of being a patient advisor, and advisors have the opportunity to practice skills discussed earlier in the orientation: working effectively with group members and researchers and giving specific, relevant, respectful feedback on research materials.

We recommend the following practices when preparing research materials for the PAC to review:

- Only bring materials that the research team can actually revise. Do not ask the PAC for feedback on materials that you know cannot be changed, such as mandatory language in consent forms or validated survey questions. Patient advisors want meaningful work.
- Bring a manageable amount of research material that you can discuss in the time allotted (40 min.) for the review activity. At the most, you can expect to review and discuss 3 – 4 pages of material.
- Talk through a step-by-step plan for reviewing the materials with your research team. Develop specific questions for the PAC and practice asking them out loud to make sure that they are clear and straightforward.

Module 5 is an **Essential Module that** takes 40 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Background for review of research materials
    - Hand out copies of research materials. Encourage PAC members to write notes on materials during discussion. Tell members that you will collect materials after discussion.
    - Briefly describe purpose of materials and target audience. Describe setting or context where materials will be viewed.
2. Review and discussion of research materials
    - Read materials aloud, one small section at a time.
    - Facilitate discussion on each section; (see Discussion Questions in facilitation script.)
    - At end of discussion, collect handouts with members' notes.
3. (Repeat steps 1 and 2 for additional research materials)

> If some advisors do not comment on materials, encourage them: "Let's hear some more ideas. Even if you have the same opinion as other people, we really want to hear it in your own words. Does anyone have other ideas or comments?"

Advance Prep

- ✓ Replace <highlighted generic text> in Facilitation Script with tailored text.
- ✓ Print copies of research materials that you want to discuss with group; keep loose in member folder. Examples of materials include recruitment flyers, letters, or scripts; informational or educational handouts; and survey or focus group questions.
- ✓ Prepare questions to use during discussion. For materials such as lay abstracts, recruitment flyers, information sheets, study brochures, and consent forms, you can start with the Discussion Questions in Sample Facilitation Script.

NOTE: WINRS (http://winrs.son.wisc.edu/) can provide useful advice on additional discussion questions, creative group activities, and other strategies to assure that the research team gets optimal feedback and that patient advisors feel engaged with the review of research materials. WINRS can also advise on specific strategies to review website pages.

Sample Facilitation Script

Module 5
Feedback on Research Materials

Estimated Length
40 min.

Supplies + Documents
- Copies of research materials
- Pens
- Flip chart, markers

1. Background for review of research materials

Facilitator 1 (Fac. 1): Now we're going to look at <research materials> from our project.

(***Fac. 2*** *hand out materials.)*

Fac. 1: We know that you will have great ideas for how to improve this <name/type of material>, so please feel free to write notes directly on the documents as we're talking. After we are done with this activity, <Fac. 2> will come around to pick up the papers. We are doing this to make sure we get all of your feedback and because these materials are still being developed, so they are not ready to be shared outside this room.

Fac. 1: <Describe context for group members. What is the purpose of this document? Who is the target? Where and when will target audience see it? Will people receive document from research team member or clinician? Through email or postal mail? Will people read the document alone, or will someone from the study review it with them?>

2. Review and discussion of research materials

Fac. 1: We're going to read the <document> out loud, a few sentences at a time. After each section, we'll stop and talk about it. Before we start reading this, let's scan it to get some first impressions.

- What stands out to you when you look at this?
- Anything you particularly like or don't like?

(***Fac. 1*** *facilitate discussion and take notes on handouts;* ***Fac. 2*** *take notes on flip chart.*)

(After discussing first impressions, ***Fac. 1 or 2*** *read document aloud, one paragraph or short section at a time. Pause after each section and ask "Discussion Questions" below and additional questions from research team. Repeat process for each section of document.)*

Discussion Questions

(For lay abstracts, recruitment flyers, information sheets, study brochures, consent forms)

- Do the headings make sense to you?
- Is anything confusing?
- Anything offensive, off-putting, scary?
- Is there enough information about each topic? Too much information?
- Is anything missing? Any more information you think people will want to know?
- Is the information well-organized?
- What do you think about the graphics?

If you want PAC input on possible research topics, write a short list of ideas on a flip chart and discuss with PAC. Ask:

- Does this topic seem important to you?
- Please say more—what makes this important/not important to you?
- What is missing from our list? What other important topics should we add?
- Which of these topics is most important to you? Please pick your top two choices.

3. Review and discussion of additional research materials (*Repeat steps 1, 2*)

Fac. 1: This has been a great discussion! Your comments are really helpful, and we'll use them to revise our materials. Does this give you a feel for the work you'll be doing at future meetings? Any more comments or questions before we move on?

Module 6: PAC Meeting Process

Overview

Objectives for PAC Members

- Describe PAC role comfortably and accurately
- Recognize steps for attending PAC meetings and typical structure of meetings

Background

Module 6 includes a brief summary and discussion of the PAC role and a review of the process that the research team will use for scheduling and conducting meetings. The discussion on the PAC role reinforces what patient advisors members have learned at the orientation about their role and provides another opportunity to address any misunderstandings about the work of PAC members. The review of the process for future PAC meetings sets clear expectations for arriving on time for PAC meetings and participating fully.

Module 6 is an **Essential Module** that takes 10 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Role of the PAC
    - Summarize role of PAC; refer to feedback members gave during review of research materials in Module 5 as example of PAC work.
    - Ask members "how would you describe the PAC to a family member or friend?" Write their comments on flip chart; address any misunderstandings about the role of the PAC.
    - Remind members that acronym P-A-C explains what the PAC does
2. Review of process for regular PAC meetings
    - Refer members to PAC Meeting Process in stapled packet.
    - Read handout aloud.
    - Answer any questions about meeting process.

Gently reframe any misunderstandings about PAC role. For example, if a member describes the PAC as a support group, say: "PAC meetings can feel very supportive! We all like to talk with people who can relate to our personal experience. But at PAC meetings, we're asking you to share your experiences and ideas for a very specific purpose—to help make sure our research project plans and materials are as good as they can be. This PAC is an advisory group."

Advance Prep

- ✓ Replace <highlighted generic text> in Facilitation Script with project-specific text.
- ✓ Print PAC Meeting Process for stapled member packet

Sample Facilitation Script

Module 6
PAC Meeting Process

Estimated Length
10 min.

Supplies + Documents
- Flip chart, markers
- PAC Meeting Process, in member packet

1. Role of the PAC

Facilitator 1 (Fac. 1): We want to talk a bit about the role of the PAC. As you just experienced, the PAC is so important because you can all give advice based on your experiences as people who come from different backgrounds and have different points of view. Researchers often get advice from people at the university, but they don't often get advice from people who are not involved with medical research.

When you leave today, we want you to feel comfortable explaining what the PAC is and what you do. So, based on what you've seen so far, how would you describe the PAC to a friend or family member?

(Members respond; ***Fac. 2*** *write responses on flip chart.)*

Fac. 1: One way to think about the PAC role is just to remember P-A-C. The PAC is a group of **p**atients who **a**dvise researchers on how to make their research plans and materials better. We meet as a **c**ommittee <how often>.

That's it! That's really all you need to describe this group and the work you do. Is that useful? Does anyone have a question about how you would describe this group?

2. PAC meeting process

Fac. 1: Let's talk about the details of a PAC meeting. Please find this handout on the last page of your packet.

*(**Fac. 2** show [PAC Meeting Process])*

Fac. 1: Please follow along while I read the steps. Then, we'll go back and see if there are any questions.

*(**Fac. 1** read PAC Meeting Process aloud.)*

Fac. 1: Does anyone have questions about this process?
(Answer questions.)

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PAC Meeting Process

- Read meeting announcement before meeting.
- Arrive at <<meeting location>> on time. *
- Participate in “opening question” to help PAC and research team get to know each other.
- Listen, participate in meeting discussions, and give feedback to research team.
- Stay for the entire meeting. Meetings will last <<xx>> hours.

*** Being late disrupts the meeting for everyone.**

Module 7: Membership Agreement and Check-In

Overview

Objectives for PAC Members

- Understand mutual responsibilities of project team and PAC members
- Choose whether to participate in PAC

Background

Module 7 includes a review of a short Membership Agreement for PAC members, an optional activity with questions about the Membership Agreement, a brief explanation of the research team's process for "checking in" with members about their participation, and a request for members to confirm whether they want to join the PAC. The Membership Agreement addresses respective responsibilities of the research team and PAC members that help to ensure an effective working relationship.

At this point in the orientation, patient advisors have learned about the project, created their own group norms, observed and practiced giving helpful feedback on research materials, and reviewed the process for attending PAC meetings. As a result, they understand what being a PAC member involves and can make an informed decision about joining the PAC.

For the research team, the Membership Agreement serves as a helpful framework for addressing any future concerns about a member's participation. The practice of "checking in" with members every few months provides an opportunity to affirm what is working well, respectfully address any concerns, and mutually agree on whether the member will continue in the group.

Module 7 is an **Essential Module** that takes 20 minutes to complete or 25 minutes with the optional activity. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Review of Membership Agreement
    - Ask members to find two-page Membership Agreement in folder.
    - Read Agreement aloud, section-by-section.
    - Ask members to agree to not share members' personal information outside of group or on social media.
    - Answer any PAC questions about Membership Agreement.
2. ((Optional activity—"What does PAC membership involve?"))
    - Ask members to find "What does PAC membership involve" in packet.
    - Read handout instructions aloud, then read questions one-by-one.
    - After each question, ask group for best answer; confirm answer.
3. Description of Member Check-Ins
    - Explain that member of research team will contact members every few months to check-in about how things are going with the PAC. (Use Check-In Form during calls with members, but do not distribute at orientation.)
4. Confirmation of membership and contact information
    - Thank members for attending orientation. Say that you hope they decide to join PAC, but it's OK to not join.
    - Ask members to complete 2nd page of Membership Agreement to confirm their membership and, if joining, their contact information. Collect completed pages.

The Membership Agreement is a brief summary of the respective responsibilities of the research team and PAC members. If you revise the Agreement, maintain the document's brevity, plain and respectful language, and balance of responsibilities between PAC members and the research team. We do not recommend using detailed contracts or by-laws with patient advisors.

Advance Prep

- ✓ Replace <highlighted generic text> in facilitation script with tailored text.
- ✓ Print
    - Stapled, two-page Membership Agreement, loose in member folder
    - ((Optional—"What does PAC membership involve?" for stapled member packet))

Sample Facilitation Script

Module 7
Membership Agreement and Check-in

Estimated Length
20 min. (25 min. if using optional activity)

Supplies + Documents
- Flip chart, markers
- Membership Agreement, loose in member folder
- ((Optional handout—What does PAC membership involve?))

3. Review of Membership Agreement

Facilitator 1 (Fac. 1): Now let's take a look at our mutual responsibilities as we work together. Please find this Membership Agreement in your folder.

*(**Fac. 2** show Agreement.)*

Fac. 1: Let's go through this together. I'll start by reading the introduction and the first section.

*(**Fac. 1** read intro and first section.)*

Fac. 1: Do you have any questions about our responsibilities to you?

*(**Fac. 1** answer member questions.)*

Fac. 1: OK, let's go through next section.

*(**Fac. 1** read section.)*

Fac. 1: Do you have any questions about your responsibilities?

(Fac. 1 answer member questions.)

Fac. 1: We included this point about confidentiality because we expect that you'll want to talk to other people about our meetings. That's perfectly fine. But sometimes PAC members will share personal information at meetings. Out of respect for everyone's privacy, we ask that you not share anyone's personal information outside of this group or on social media like Facebook. Does anyone have any questions about anything in the Agreement?

4. ((Optional activity—What does PAC membership involve?)

Fac. 1: Now let's look at a few questions about your PAC membership. Please find this sheet in your stapled packet.

*(**Fac. 2** show What does my PAC membership involve?)*

Fac. 1: Let's go through these questions together. Would someone like to read the first question?

*(**Volunteer** read first question; **Fac. 1** repeat if any corrections needed.)*

Fac. 1: What is the best answer to that question? Is it true or false? *(**Members** respond.)*

Fac. 1: That's true. It's very important to RSVP for every meeting, whether you plan to come or not.

(Continue one-by-one with questions on handout, asking for different volunteers to read each question. Ask members which answer is best, and confirm correct answer. Question 1 is true, Questions 2 and 3 are false, and only the first response is correct for Question 4.)

5. Member check-ins

Fac. 1: We also want to stay in touch about how this group is going for you. We will <call, email> you every few months to check in. We also encourage you to get in touch with us if you have any concerns or questions. The staff contact information is right here on the Member Agreement Form.

(Research team can use Member Check-In form for check-in calls. Do not distribute form at orientation; send form to members 1 – 2 weeks before check-in calls.)

6. Confirmation of membership and contact information

Fac. 1: We know that joining a group like this is a commitment, and we appreciate you taking the time for this first meeting. Now that you know more about the PAC, we hope that you'll decide to join the group, but if you decide not to join, that's okay too. Whatever you decide, please keep page 1 of the agreement for your own information.

Fac. 1: Let's look at the second page now. Please check one of the boxes at the top of this page. If you definitely want to join the PAC, please write down your contact information on that page. If you don't want to join the PAC, don't fill out the contact information page – we only need this for members. We'll give you a minute and then come around to collect all the second pages. Remember to keep the first page for yourself.

*(**PAC members** sign forms; **Fac. 2** collect.)*

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Membership Agreement

Patient Advisory Committee (PAC)

<<Project Name>> (in plain language)

Thank you for your interest in being a member of the PAC! Here is a summary of our responsibilities to you and your responsibilities as a member of this group.

I understand that the project team will:

- Send me meeting announcements one week before the PAC meeting date
- Give me a chance to share my opinions and ideas at meetings
- Pay me <$XX> for each meeting I attend (must RSVP, be on time, stay for the entire meeting)
- Check in with me about how meetings are going for me

I understand my responsibilities related to PAC meetings. I will:

- Let <staff name> know as soon as possible if my contact information changes
- Let <staff name> know by <date, time> if I can come or not
- Arrive on time for meetings and stay for the whole meeting
- Provide feedback that is specific, relevant, and respectful
- Not discuss members' personal information or comments outside of the group or on social media
- Talk with <staff name> if I have concerns about the PAC or my participation

Project Team Contact Information

<name>

<telephone number>

<email>

Please check one of these boxes:

☐ I do <u>not</u> want to be a PAC member.

OR

☐ I <u>do</u> want to be a PAC member, and I understand my responsibilities. Here is my contact information (see below).

Contact Information

(Only complete if you plan to join the PAC)

Name ____

Date _______________

Preferred telephone ____

Do you use email?

☐ **Yes** (We will <u>email</u> meeting announcements to you.)

Email: ____

☐ **No** (We will <u>mail</u> meeting announcements to you or make other arrangements.)

Address: ____

Cell phone: ____

What does my PAC membership involve?

For all of the questions below, pick just one answer.

1. I need to RSVP for every PAC meeting, whether I plan to come or not.

______ True

______ False

2. If I miss half of a PAC meeting, I will receive half of the regular payment.

______ True

______ False

3. I should use social media to share information about PAC members.

______ True

______ False

4. My responsibilities as a PAC member include:

______ Contact the PAC coordinator if my phone, address or e-mail changes

______ Recruit people for the project

______ Get other PAC members to agree with my opinions

Check-In Form for Members of Patient Advisory Committee (PAC)

The Check-In is a chance for PAC members to talk individually with the project staff about how things are going and decide whether to continue membership in the group.

Did project staff:

- ☐ Send easy-to-read meeting announcements?
- ☐ Facilitate meetings in an organized way?
- ☐ Give you a chance to share your opinions and ideas at meetings?
- ☐ Treat you respectfully at meetings?
- ☐ Protect your personal information?
- ☐ Work with you to address any problems or conflicts?

Did you:

- ☐ Let <PAC Coordinator> know as soon as possible if your contact information changed?
- ☐ Let <PAC Coordinator> know by the RSVP deadline if you could come or not?
- ☐ Arrive on time for meetings and stay for the entire <length of meeting>?
- ☐ Provide feedback that was specific and relevant?
- ☐ Protect the confidentiality of other members?
- ☐ Show respect to everyone at the meeting?

Signature of member ____

Signature of project staff ____

Date ________________________________

Module 8: Orientation Evaluation

Overview

Objective for PAC Members

- Reflect on usefulness, quality of meeting

Background

Module 8 wraps up the orientation with a reminder about the next PAC meeting, brief pen-and-paper evaluation by PAC members, and payment of member stipends. The evaluation underscores how the research team values PAC member input and provides the team with useful feedback on orientation content, meeting facilitation, and ideas for improving future PAC meetings. The meeting closes with one or more members of the research team personally thanking each member.

The five-minute evaluation period at the end of the meeting is the ideal time to capture members' opinions about the orientation, while the experience is still fresh for them. In-person evaluation is more convenient than mailed or emailed evaluations for most patient advisors and yields better response rates.

Module 8 is an **Essential Module** that takes 5 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Reminder of next meeting date or plan for setting date for next meeting
   - Give date, time, location of next meeting OR
   - Explain plan for scheduling next meeting
2. Evaluation of Orientation
   - Ask members to complete Orientation Evaluation form in their folders; ask members to not put their names on forms.
   - Collect completed evaluations
3. Payment and thank-you
   - One member of research team circulate (or stand at door) to thank members and pay them
   - Other members of research team circulate to personally thank each member for attending

Advance Prep

- ✓ Edit Orientation Evaluation form to match key meeting activities
- ✓ Print Orientation Evaluation to hand out to members
- ✓ Obtain stipends for members and place in individual envelopes

> Pay members a stipend that appropriately compensates them for their contributions to a project. We recommend a minimum of $25/hour for patient advisors, and many researchers pay more. We also recommend cash stipends, as PAC members without checking accounts may need to pay fees to cash checks.

Sample Facilitation Script

Module 8
Orientation Evaluation

Estimated Length
5 min.

Supplies + Documents
- Orientation Evaluation, to hand out to PAC members

1. Next PAC meeting

Facilitator 1 (Fac. 1): We'd like to wrap up with a reminder about details for our next PAC meeting. *<Give date, time, location OR brief review of how you will set date for next PAC meeting>.*

2. Evaluation of Orientation

Fac. 1: We'd also love your feedback on how this orientation meeting went from your perspective. We're handing out an evaluation form.

*(**Fac. 2** hand out Orientation Evaluation form.)*

Fac. 1: Don't put your name on this form—just fill it out and leave it face down on the table. We really appreciate your feedback, so please share any comments about what went well or how we can do things better!

*(**Members** complete evaluations; **research team** collects.)*

3. Payment and thank-you

Fac. 1: Thank you so much for your terrific energy and participation today! We're really looking forward to working together, and I will be in touch with you before our next meeting.

*(**Members of research team** circulate to pay stipends to members and personally thank members before they leave.)*

Evaluation: Meeting #1 (Orientation), Patient Advisory Committee

<Project Name>

Please answer each question below by making a check mark in the appropriate box.

How did you like the following activities?

	Liked very much	Liked	Did not like	Did not like at all
Talking about what helps you feel comfortable sharing your opinions in a group				
Watching and discussing demonstration skit about helpful feedback				
Giving feedback on <research materials reviewed by PAC>				
Reviewing the Meeting Process handout				
Reviewing the Membership Agreement				

How well did the meeting facilitators do today?

	Always	Usually	A few times	Never
Did they present material clearly?				
Did they give you enough time to make comments and ask questions?				
Did they do a good job answering questions?				

What changes would you suggest to improve this first meeting of our PAC?

____

____

____

Thank you!

Optional Module A: How the PAC is making a difference

Overview

Objective for PAC Members

- View concrete examples of how research team has used patient advisor feedback

Background

Optional module A can be used by research teams who have had previous patient advisor input in their research. This short module includes just one activity, a review of a handout with examples of patient advisor feedback and its impact. W*e recommend the "How the PAC is making a difference" activity as a consistent agenda item at all ongoing PAC meetings.*

We refer to this module as "closing the loop" because it demonstrates the iterative process that the research team will use with the PAC. The basic steps of the iterative process are obtaining PAC feedback on project materials and processes; using PAC feedback to revise or develop project materials and processes; and returning to the PAC with a brief, plain language-summary of how the research team used PAC input. The "How the PAC is making a difference" handout is an efficient, effective way to affirm the value of patient advisors.

This optional module takes 5 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. How the PAC makes a difference
    - Ask members to find handout How the PAC is making a difference in their stapled packet.
    - Ask members to read the handout to themselves, or read out loud. Ask for any comments or questions.

Advance Prep

✓ Revise How the PAC is making a difference with project-specific examples.
✓ Print "How the PAC is making a difference" for stapled member packet.

To revise the handout:

- Remove SAMPLE text box. Click on text box to see borders, click on box, and delete.
- Remove acknowledgment to Dr. Yao Liu below table.
- Replace sample text with project-specific text.
- When writing project-specific examples, choose previous meeting topics that are easy to explain, with clear examples of PAC feedback and impact on project. Keep text in each cell of table brief. Handout is not intended to be a complete summary of all PAC feedback. Select only 2-3 vivid examples to share with PAC.

Sample Facilitation Script

Optional Module A

How the PAC is making a difference

Estimated Length

5 min.

Supplies + Documents

- How the PAC is making a difference, in stapled packet

1. How the PAC is making a difference

Facilitator 1 (Fac. 1): We want to show you a few examples of how patient advisors have already helped our research. Please find this handout, How the PAC is making a difference, in your stapled packet.

*(**Fac. 2** show handout.)*

Fac. 1: At every meeting, we'll take a few minutes to look at a handout like this that lists some of your suggestions from the previous PAC meeting and shows how our research team is using your input. Please take a minute to read this. (Or "Let's take a minute to read this together.")

*(Members read handout, or **Fac. 1** can read out loud.)*

Does anyone have any comments on this examples?

*(**Fac. 1** respond to comments.)*

How the PAC is making a difference!

Topic	PAC Feedback	Impact
Why might someone choose to get an in-person eye exam rather than an eye photo test?	Results from vote on top reasons why people choose in-person exam: ○ Have not heard about eye photo test ○ Have other vision issues that they want checked ○ Suspicious of new technology/lack of information	Research Team response: ○ Created a sample script for providers and staff to explain eye photo tests ○ Shared suggestions with all clinic providers and staff at February meeting
What makes people decide to get diabetic eye checks?	Key reason PAC members mentioned: ○ Encouraged by family members ○ Newly diagnosed with diabetes ○ Have trouble with vision in general	Wrote two research articles to share PAC perspectives and feedback with researchers and doctors around the world.

SAMPLE

Used with permission of Dr. Yao Liu, University of Wisconsin-Madison Department of Ophthalmology & Visual Sciences

Optional Module B: Research Process, Terms, & Ethics

Overview

Objectives for PAC Members

- Recognize differences between personal research and medical research with human subjects
- Practice working with terms that researchers may use at PAC meetings
- Examine milestones in the development of research ethics
- Compare unique roles of PAC and IRB

Background

Optional module B can be used by research teams who want to provide PAC members with basic information on the research process, common terms related to human subjects research, and protections for human subjects. In our experience, this is not essential content for preparing patient advisors to share their ideas and perspectives with researchers. However, this module may be helpful in certain contexts:

- Your PAC includes members who come from a population with a history of unethical treatment by researchers.
- You are conducting a study with substantial risks for participants and want PAC members to understand how human subjects are protected.
- Your funder specifically requires that you provide training to patient advisors on the research process and the protection of human subjects.

The activities in this module use a wide variety of methods to address content on research in a fun, interesting way. Several activities help PAC members understand the requirements and constraints that researchers have to manage, providing the PAC with context for decisions that researchers may make about using PAC suggestions. If you revise the activities, we recommend that you keep each activity brief and use plain language in all materials and during facilitation. If you want to add content, have a thoughtful discussion with your research team to identify WHY the additional content is essential for your patient advisors and HOW you expect advisors to apply the content in their work at PAC meetings.

This optional module takes 45 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. What is research?
    - Ask members "what comes to mind when you hear the word 'research'?" Provide sample answers to stimulate ideas. Record comments on flip chart.

> This question often elicits a wide variety of answers, some focusing on people's own personal research into various topics and others focusing on medical research. The question generates an interesting discussion that leads into a comparison of medical and personal research.

2. Steps in research process
    - Discuss major steps in research process and identify major differences between medical research and personal research.
3. Terms about research subjects
    - Ask PAC members find terms about human subjects in packets and work together in pairs to complete activity. Review answers as a group.

> Explain to PAC members that they will not need to memorize terms and definitions. The activity is intended to familiarize members with a few key terms and acronyms.

4. Ethics Timeline
    - Create a research ethics timeline using Research Ethics Timeline handouts.
    - After completing activity, show members Summary of Research Ethics Milestones in their stapled packets.
    - Emphasize that researchers have to follow many federal and institutional guidelines that have been created to protect research subjects.
5. IRB-PAC comparison
    - Ask members to find handout on roles of the PAC and IRB in their packets. Ask member of research team or two PAC members to handout out loud.
    - Ask members for any questions about respective roles of PAC and IRB.

Advance Prep

✓ Print
- Steps in research process, Terms about human subjects, Summary of Research Ethics Milestones, and roles of the PAC and IRB for stapled member packet
- One set of Research Ethics Timeline handouts, for research team to hand out to members

Sample Facilitation Script

Optional Module B
Research Ethics, Terms, & Processes

Estimated Length
45 min.

Supplies + Documents
- Flip chart, markers
- Steps in Research Process, for stapled packet
- Terms about Human Subjects, for stapled packet
- 1 Set of Research Ethics Timeline handouts
- Summary of Research Ethics Milestones, for stapled packet
- Roles of the PAC & IRB, for stapled packet

1. What is research?

Facilitator 1 (Fac. 1): Now let's talk about research. As a PAC member, you're going to give feedback on a variety research materials. So, what is research? What comes to mind when you hear the word "research"? Let's start a list of ideas. Who would like to get us started?

*(**Fac. 2** write participant comments on flip chart. Use sample answers to stimulate ideas, as needed.)*

Sample answers for "What comes to mind when you hear 'research'?"
- Microscopes
- Curing diseases
- Testing drugs
- Trying to improve health

2. Steps in research process

Fac. 1: Thanks for all those great ideas! It is interesting to see the variety of ideas that come to mind when people think about research!

(If PAC members have said things like "Tuskegee" or "treating people like guinea pigs", say the following:
"Some of the words suggested are clearly not positive. And that is totally understandable, as some very bad things have been done in the name of

medical research. We are going to talk about that in a few minutes – and talk about what has been done to respond to these abuses.")

Fac 1: One thing that we think about is how the research that all of us do in our private lives – such as research about health symptoms we may have or research to find a good restaurant – is different from the kind of medical research that is done at a health center or university. To understand this a bit better, let's take a look at steps in the research process. In your stapled packet, find this sheet that says "Steps in Research Process."

*(**Fac. 2** show handout)*

Fac. 1: In the left column, there's a list of five steps in the Research Process. Let's focus on that to start. Would someone like to read the list?

*(**Member** read list in left column aloud.)*

Fac. 1: Now, anyone can use this process to research something. But when medical researchers follow these steps, they have to meet specific requirements. Medical research has a lot of structure and rules compared to personal research; personal research has a lot of freedom. Let's take a closer look at the requirements for medical research compared with personal research. Can we have two volunteers to read out loud the descriptions in the "medical research" and "personal research" columns?

(Identify volunteers)

Fac. 1: OK, the first step is "decide on specific interest or topic to research." What's involved for medical research?

*(**1st volunteer** read answer for medical research.)*

Fac. 1: What's involved for personal research?

*(**2nd volunteer** read answer for medical research.)*

*(**Fac. 1** continue reading each step in left column of handout. Volunteers continue reading descriptions aloud.)*

Fac. 1: So, does anything here surprise you? Are there any questions about differences between medical research and personal research?

*(**Fac. 1** respond to PAC comments.)*

3. Terms about research subjects

Fac. 1: Now let's work with more words and ideas that you may hear in PAC meetings. We want you to feel comfortable if you hear them during meetings. Don't worry—you won't need to memorize any words or definitions. In your stapled packet, you have this sheet that says "Terms about Human Subjects."

*(**Fac. 2** show sheet.)*

Fac. 1: In medical research, the people who participate in research studies are often called "human subjects," so you see these words at the top of the handout. You may hear that phrase "human subjects" at our meetings. For this activity, you're going to work in pairs, so please pair up with someone sitting near you.

(Pair participants.)

Fac. 1: The handout has several terms related to research with human subjects. Some of these terms may not be familiar, but that's totally okay! We think that you can figure out what they mean when you discuss the terms and definitions together. We'll take three or four minutes to work in pairs, and then we'll go over the answers as a group. We will come around as you talk with your partner to see if you have any questions. Please follow along while I read the instructions.

*(**Fac. 1** read aloud instructions and highlight example of pairing term with correct definition. PAC members work together on remaining terms. **Fac. 1 and Fac. 2** circulate and answer questions.)*

Fac. 1: OK. Let's go over the answers. (Review answers one-by-one.) Any questions about these terms?

4. Creating a research ethics timeline

Fac. 1: We're going to build a timeline of major events related to research ethics over the past 70 years. The timeline will present some well-known examples of unethical research, when people were terribly mistreated in the name of "research." But the timeline will also explain what has been done over the last 40 years to make sure that researchers protect the rights of people who participate in research.

Fac. 1: We're each getting a sheet that describe a major milestone related to research ethics—each of us is getting a different milestone with a different date at the stop.

(Fac. 2 *hand out eight individual Research Ethics Timeline handouts. Depending on group size, may need to assign two members to one milestone, or give two milestones to some members.)*

In the "Milestone" handouts, we have substituted plain language for research ethics terms that are unfamiliar and difficult to pronounce, such as "beneficence" and "autonomy."

Fac. 1: First, let's each read our milestone to ourselves. If you're not sure about any word or phrase, just let one of us know.

*(**PAC members** read handouts to selves. **Facilitators** quickly circulate to answer questions, help with pronunciation as needed.)*

Fac. 1: Now, let's get in a line based on the order of the dates listed on our handouts, from oldest to most recent. Let's have the person with the oldest date stand here (*point to spot*), and the line will go in this direction (*point*), and we'll end with the most recent date over here (*point to spot*). Go ahead and get together to see what dates are on your handouts, and them put yourselves in order from oldest to most recent.
*(**PAC members** share dates and put themselves in ordered line.)*

Fac.1: Now let's read our milestones in order.

(Member with "Nazi Experimentation" reads aloud first, followed by other members in sequence.)

Fac. 1: Thank you! We can all sit down now. Does anyone have any questions or comments about this timeline and the milestones we just heard about?

*(**Fac. 1** answer questions)*

Fac. 1: You have a Summary of Research Ethics Milestones in your stapled packet with all of the examples you just read.

*(**Fac. 2** show summary.)*

Fac. 1: The main point of this activity, besides getting us moving around and talking a bit, was to show that there have been examples where medical researchers have behaved in ways that are totally unethical and cruel. But we also want to show that researchers and policy-makers have responded to these terrible situations. There are many more rules and regulations now to make sure that research meets standards for ethical, appropriate treatment of people who participate in research. Are there any questions before we move on?

5. IRB-PAC Comparison

Fac. 1: We've heard a little about Institutional Review Boards, also called by the initials, IRB. As you saw on the handout with terms and definitions, an IRB is "a group of experts in research, ethics, and law who approve research at academic institutions or health care organizations." Earlier in this meeting, we talked about the PAC and what you do. So, let's directly compare what the PAC does and what an IRB at a university does. You have this handout on roles of the PAC and IRB in your stapled packet.

*(**Fac. 2** show handout.)*

Fac. 1: Can we please have a volunteer to read the top section on "what does the PAC do?"

*(**Volunteer** read top section.)*

Fac. 1: Can someone please read the bottom section on "what does the IRB do?"

*(**Volunteer** read top section.)*

Fac. 1: So, these two groups do very different things, but both are very important. Let's do a quick review of what these groups do; refer to your handout if you want. (*Correct answers underlined below*)

Fac. 1: Whose job is it to tell a researcher that a recruitment flyer is not interesting or appealing? Is that the IRB's job or a job for the PAC?

Fac. 2: Whose job is it to officially approve materials for a research study? The PAC or IRB?

Fac. 1: Whose job is it to decide if a study has more risks than benefits? The PAC or IRB?

Fac. 2: Whose job is it to point out that survey questions are confusing? The PAC or IRB?

Fac. 1: Great work! Are there any questions about the differences between what this PAC does and what the IRB does?

*(**Fac. 1** answer questions.)*

Steps in Research Process:
Differences between personal research and medical research with people

Steps in Research Process	**Medical Research:** ***Lots of structure and rules***	**Personal Research:** ***Lots of freedom***
1. Decide on specific interest or topic to research	Researchers must focus on topics that others in the research world think are important.	You can focus on any topic that interests you.
2. Find people to participate in your project	Researchers must get approval from an Institutional Review Board (IRB) for their plan to recruit participants.	You can talk or work with anyone you want.
3. Decide what kind of data to use; Plan to collect and store data	Researchers must get IRB approval for: • What kind of data they will use • How they will collect the data • How they will store data to protect confidentiality	You can use any kind of data you want. You can collect the data any way you want. You can store the data any way you want.
4. Analyze data	Researchers must use accepted statistical methods for analyzing their data.	You can decide what's most important in the information you gathered.
5. Reach conclusions	Researchers must base conclusions on an explanation of their data that is accepted by other researchers.	You can decide what the data means; you don't need anyone else to accept your conclusions.

Terms about Human Subjects (people who participate in research)

Instructions:

- Turn to a person next to you.
- Read the list of terms and the list of definitions.
- Working together, decide which definition best matches each term.
- Place the correct definition letter (B, C, D or E) in front of the matching term (see example highlighted in blue).
- Each term and definition is used only once.

Term

_____ Institutional Review Board (IRB)

A_____ Principal Investigator (PI)

______ Health Insurance Portability and Accountability Act (HIPAA)

______ National Institutes of Health (NIH)

______ Informed consent

Definition

A. Main person running a research study

B. A group of experts in research, ethics, and law who approve research at academic institutions or health care organizations

C. An organization within the U.S. Department of Health and Human Services that funds biomedical research

D. The law that created rules for sharing patient information and protecting patients' identifiable information

E. The process of learning about a study and deciding whether to participate

Research Ethics Timeline

A short history of the development of protections for people who participate in research

Nazi Experimentation (early 1940s)

Doctors in Nazi concentration camps forced prisoners to take part in dangerous experiments. Examples of unethical experiments were forcing prisoners to be sterilized and be infected with diseases.

Nuremberg “Doctors Trial” (1946-1947)

A U.S. military court in Nuremberg, Germany charged 23 Nazi doctors and officials with war crimes, including unethical medical experiments on concentration camp prisoners. Sixteen Nazis were executed or sent to prison.

Nuremberg Code (1947)

After the Nuremberg Trials, the judges listed important principles of acceptable medical experiments. These principles became known as the Nuremberg Code.

Important principles are:

- Research participation must be voluntary.
- Research participation cannot put people at high risk for disability or death.
- Participants can quit a study at any time.

Willowbrook Study (1963-1966)

Willowbrook was a home for children with mental disabilities in New York City. Researchers deliberately injected children with hepatitis to learn about the disease.

Declaration of Helsinki (1964)

The World Medical Association, meeting in Helsinki, Finland, approved principles for ethical research. Important principles are:

- Research plans should be reviewed by an independent committee, such as an Institutional Review Board (IRB).
- Research participants must give their "informed consent" to be in a study.
- Risks of being in a study should not outweigh benefits.

Tuskegee Syphilis Study (Ended 1972)

Starting in 1932, doctors from the U.S. Public Health Service studied African-American men in Alabama with syphilis. Medications to treat syphilis were available, but doctors wanted to study long-term effects of the disease. Doctors did not give men the medications they needed, and dozens of men died of syphilis or its complications. The study did not end until 1972 when details about it became public.

National Research Act (1974)

The act did two major things to stop unethical research on people:

1. It required the U.S. government to create rules to protect people in research studies.

2. It created a national committee to develop guidelines for ethical research. These guidelines are in the Belmont Report.

Belmont Report (1979)

The report listed three basic principles for the ethical treatment of people who participate in research:

1. **Respect**
2. **"Doing good"**
3. **Justice**

Examples of the three principles are:

Respect: People must have a choice about what happens to them.

"Doing good": The risks of a study cannot outweigh the possible benefits.

Justice: The benefits and risks of research should be fairly shared across society.

Summary of Research Ethics Milestones

A Short History of the Development of Protections
for People Who Participate in Research

1. **Nazi Experimentation (early 1940s)**

   Doctors in Nazi concentration camps forced prisoners to take part in dangerous experiments. Examples of unethical experiments were forcing prisoners to be sterilized and be infected with diseases.

2. **Nuremberg "Doctors Trial" (1946-1947)**

   A U.S. military court in Nuremberg, Germany, charged 23 Nazi doctors and officials with war crimes, including unethical medical experiments on concentration camp prisoners. Sixteen Nazis were executed or sent to prison.

3. **Nuremberg Code (1947)**

   After the Nuremberg Doctors Trial, the judges listed important principles of acceptable medical experiments. These principles became known as the Nuremberg Code. Important principles are:
   - Research participation must be voluntary.
   - Research studies cannot put people at high risk of disability or death.
   - Participants can quit a study at any time.

4. **Willowbrook Study (1963-1966)**

   Willowbrook was a home for children with mental disabilities in New York City. Researchers deliberately injected children with hepatitis to learn about the disease.

5. **Declaration of Helsinki (1964)**

   The World Medical Association, meeting in Helsinki, Finland, approved principles for ethical research. Important principles are:
   - Research plans should be reviewed by an independent committee, such as an Institutional Review Board (IRB).
   - Research participants must give their "informed consent" to be in a study.
   - Risks of being in a study should not outweigh benefits.

6. **Tuskegee Syphilis Study (Ended 1972)**

Starting in 1932, doctors from the U.S. Public Health Service studied African-American men in Alabama with syphilis. Medications to treat syphilis were available, but doctors wanted to study long-term effects of the disease. Doctors did not give men the medications they needed, and dozens of men died of syphilis or its complications. The study did not end until 1972 when details about it became public.

7. National Research Act (1974)

The act did two major things to stop unethical research on people: 1) It required the U.S. government to create rules to protect people in research studies. 2) It created a national committee to develop guidelines for ethical research. These guidelines are in the Belmont Report.

8. Belmont Report (1979)

The report listed three basic principles for the ethical treatment of people who participate in research:

- Respect
- "Doing good"
- Justice

Examples of the three principles include:

- Respect: People must have a choice about what happens to them.
- "Doing good": The risks of a study cannot outweigh the possible benefits.
- Justice: The benefits and risks of research should be fairly shared across society.

Roles of the
Patient Advisory Committee (PAC) and Institutional Review Board (IRB)

What does the PAC do?

The PAC helps researchers understand the patient perspective and gives feedback to researchers on study plans and materials:

- Importance of research topic to patients
- Readability of study materials, use of technical words or jargon
- Appearance of documents and online information
- Effectiveness of recruitment strategies and materials
- Amount and type of compensation for study participants

What does the IRB do?

The IRB protects research participants by applying rules and regulations for ethical research; it officially approves all research study plans and materials. The IRB looks at:

- Scientific value of studies
- Benefits to society
- Balance of risks and benefits
- Appropriate recruitment
- Qualified study team

Optional Module C: “Can You Guess?”

Overview

Objective for PAC Members

- Get to know PAC and project team members

Background

Optional module C includes just one activity, a group “refresher” to help everyone get to know each other better. The module can be used after a break in the middle of a long meeting to refresh everyone, lighten the mood, and smooth the transition from the break back to the orientation. “Can you guess,” similar to the opening question in Module 1, allows people to share something interesting about themselves and helps PAC members feel comfortable speaking up in a group environment.

This optional module takes 20 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Set-up for "Can You Guess?"
    - Read question on flip chart
    - Give example of how you would answer question
    - Tell members to write answers on index cards, fold, and place in bag or basket
2. "Can You Guess" activity
    - Member of research team picks an index card, reads it aloud, and guesses who wrote it. If guess is wrong, group can try to guess. If no one guesses correctly, person who wrote card speaks up.
    - Pass bag to the left and continue reading and guessing.

Advance Prep

✓ Bring index cards
✓ Write on flip chart:
- "What is one thing about you that no one else in this group knows?"

Sample Facilitation Script

Optional Module C
“Can You Guess?”

Estimated Length
20 min.

Supplies + Documents
- Index cards
- Pens
- Basket or bag (for collecting, picking index cards)

1. Set-up for “Can You Guess”

Facilitator 1 (Fac. 1): Welcome back! Let’s get started. Let’s all think about this question.

*(**Fac. 1** point to question on flip chart.)*

Fac. 1: What is one thing about you that no one else in this group knows? Here’s an example—one thing about me that no one else in this group knows is that I <personal example>.

> Provide an example for “Can You Guess” that models possible answers for PAC members and demonstrates that people need not write extraordinary things about themselves. Examples: “I am one of eight children”; “I play the tuba”; “I was born in Canada”; “I sew my own clothes”, etc.

Fac. 1: There are index cards on the table. Please think of your answer to this question, write it on an index card, and then fold your card in half and put it in the basket/bag. Please try to write or print clearly, so that whoever picks your card can read it! Let’s take a minute or so to write our answers.

*(**PAC members and research team** write their answers.)*

2. Can You Guess?

Fac. 1: Okay, let's come back together. Has everyone written down something about themselves and put their index card in this basket/bag? Here's what we're going to do. We'll pass the basket/bag around. When you get the basket/bag, pull out one index card, and read it out loud. You get to guess first – who do you think wrote that card? If you don't get it right, then the rest of us get to guess. If no one guesses correctly, then whoever wrote the card reveals who s/he is. I'll get us started.

*(**Fac. 1** pick card, read aloud, and guess who wrote it. If guess is wrong, then other people guess. If no correct guesses, person who wrote card speaks up. Then pass basket/bag to the left. Repeat process until all cards are read.)*

Fac. 1: Thank you everyone! That was so fun to learn more about everyone.

Optional Module D: PAC Description for Resumés

Overview

Objective for PAC Members

- List PAC experience in resumés, LinkedIn, or job applications

Background

Optional module D can be used by research teams to provide examples of how to present PAC experience in a job resumé, on LinkedIn, or in job applications. The examples can be particularly helpful for highlighting skills related to group work and critical thinking. For many patient advisors, including PAC experience on a resumé or LinkedIn profile can be a tangible benefit of group participation.

This optional module takes 5 minutes to complete. Estimated time for module activities is based on a total group size of 8-12 participants, including PAC and research team members. Contact the Wisconsin Network for Research Support for help adapting toolkit materials.

Training Materials

Outline of Activities and Steps

1. Sample descriptions of PAC experience for resumés
    - Ask members to find handout Listing PAC Experience on Resumes in their stapled packet.
    - Ask members to read the examples in the handout. Ask for any comments or questions.

Advance Prep

✓ Print Listing PAC Experience on a Resumé or LinkedIn Profile, for stapled packets

Sample Facilitation Script

Optional Module D
PAC Description for Resumés

Estimated Length
5 min.

Supplies + Documents
- Listing PAC Experience on a Resumé or LinkedIn Profile, in stapled packet

1. Sample descriptions of PAC experience for resumés

Facilitator 1 (Fac. 1): You might want to include your membership in this group as part of your resumé, LinkedIn profile, or on job applications. We have a few samples to share. Please find this handout in your stapled packet—Listing PAC Experience.

*(**Fac. 2** show handout.)*

Fac. 1: Please take a minute to read these to yourself.

(Allow 1-2 min. for people to read documents)

Fac. 1: Does anyone has any questions on these examples? If you want any feedback from us on your own resumé or LinkedIn description of this group, please let us know.

Listing PAC Experience on a Resumé or LinkedIn Account

Instructions: Replace the text below in <brackets> with your specific information. Copy or cut-and-paste the information into resumés or online resources such as LinkedIn.

For a Resumé

WORK EXPERIENCE

Member, <name of patient or community advisory committee>
<Name of academic institution>

<Start and end date of participation in advisory committee>

- Completed group orientation program for <name of advisory committee>
- Participated in ongoing meetings with research team. Meetings were held (how often).
- Reviewed research plans and materials.
- Made recommendations to improve <recruitment materials, consent forms, interview questions, health education materials, smart phone apps, websites—list whatever type of materials you reviewed>.

For LinkedIn or other website

Member of <Advisory Committee Name>, <start date-end date>: Serves as a <patient or community> advisor for a <number of years> research study to <brief description of goal>. Advises research team on making study plans and materials more appropriate and engaging for the target population.

Appendix I: Key Practices for Effective Orientation

Before the Orientation Meeting

Meeting Space and Logistics

- **Reserve meeting space well in advance** that will be convenient, comfortable, and accessible for patient advisors. Community centers and libraries often have spaces that can be reserved at low cost.
- **Determine if patient advisors will need help with childcare** in order to participate in Patient Advisor Committee (PAC) meetings. If so, develop a plan. Will you arrange for childcare on-site during meetings? Will you pay a stipend that is sufficiently generous that PAC members can cover their own childcare costs?
- **Develop a plan for helping patient advisors with their transportation needs** for PAC meetings. Will you reimburse people for bus or taxi fares or their vehicle mileage? Or will you pay a stipend that is sufficiently generous that PAC members can cover their own transportation expenses?
- **Visit the room where you will hold the orientation meeting**. Ask for tables and chairs to be arranged in a circle or square for the meeting (or be prepared to arrange them yourself). A lecture set-up, with rows of desks or tables facing a lectern or table at the front of the room, is not an appropriate set-up for orientation because it does not encourage group interaction.
- **Pre-test any technologies** that you will use during the orientation.
- **Decide if you will offer snacks or a meal** at the orientation meeting. We recommend offering some kind of refreshments as this conveys caring and helps everyone feel appreciated. The time of day for PAC meetings and the project budget will determine if light snacks (baked goods, cut fruit, or cheese/crackers) or a more complete meal (pizza or sandwiches, fresh fruit, chips) are more appropriate. *If you provide a complete meal, ask members to come 15-30 min. early so that everyone can finish eating before the orientation begins.*
- **Designate members of the research team who will handle all of the details related to food**:
    - Asking PAC members about food allergies
    - Ordering food, beverages, and arranging payment to the vendor
    - Picking up food, beverages, or arranging for delivery
    - Purchasing plates, cups, napkins, etc.
    - Arranging for trash containers in the meeting room
    - Packing up leftovers

Meeting Materials and Team Preparation

- **If you modify any PAT-1 materials, get feedback on your revisions, preferably from several lay people**. This will help to ensure that you maintain the logical flow, clear and uncomplicated language, and tight focus of the original materials. Use plain language that everyone can understand the first time they hear it or read it. We encourage users of the toolkit to contact WINRS for help adapting the orientation materials: http://winrs.son.wisc.edu/ Please see "About the Toolkit" for instructions on how to cite WINRS in your revised materials.
- **Practice!** Whether you use the complete "Facilitation Script" in each module or the "Outline of Activities and Steps," practice speaking the entire orientation aloud with all members of the research team who will participate. This is key to assuring that everyone is familiar with the orientation meeting content, the activities flow smoothly, and each activity stays within the time allotted.
- **To minimize paper shuffling during orientation, create a stapled packet of orientation handouts** for participants and research team members and number the pages. Do not include in stapled packet your sample research materials, the Membership Agreement, and the Orientation Evaluation form, as you will collect these items from PAC members.
- **Plan to have the lead researcher on the project be present for orientation**. Even if that person will not attend future PAC meetings, her/his participation in the orientation meeting will help to answer questions about the project and affirm the importance of patient advisors to the project leadership.
- **Call patient advisors the day of orientation** with a meeting reminder.

During the Orientation Meeting

- **Designate someone from the research team to be a meeting timekeeper** to ensure that orientation activities stay on track.
- **Use two facilitators at all meetings** to manage fast-moving conversations; take accurate notes; pose follow-up questions to advisors' comments; and distribute handouts.
- **Use a flip chart to display key information and record comments** from patient advisors. Seeing ideas recorded on a flip chart serves as a check that the research team has correctly interpreted advisors' comments and demonstrates to advisors that their input matters. (See specific instructions on preparing flip charts in "Advance Prep" for each module.)
- **Use first names with everyone present**, including the lead researcher and members of research team. Using first names for patient advisors and titles for research team members (Dr., Professor, etc.) reinforces hierarchy and implies that the research team deserves more respect than the patient advisors.

- **Have facilitators and other members of the research team monitor each other for the use of technical language** and speak up promptly to ask for clarification.
- **Read orientation materials aloud**, as noted in the “Sample Facilitation Script” for each module. Reading aloud helps keep participants’ attention focused on the same materials at the same time and addresses possible differences in reading abilities.
- **For discussions on research materials, have research team members prepared to offer their own ideas** on materials if PAC members need encouragement to speak up.

After the Orientation Meeting

- **Ask all members of the research team to write down their overall impressions of the orientation** within several days. Follow up with a team meeting within one week to debrief on the orientation, discuss what went well, talk about “lessons learned,” and plan changes for future meetings. Debriefing after meetings is a key strategy for building skills and confidence in working with patient advisors.
- **Within one week of the orientation, send personal notes to PAC members to thank them for participating**. Personal notes from the research team help members feel appreciated and respected, and they strengthen the connection that members feel to your project and your team. We refer to these notes as “affirmations.” Use affirmations to highlight a member’s unique qualities or behaviors that contributed to a positive group experience and helpful feedback. You can also use affirmations to encourage quiet members. Ideally, write hand-written notes on nice stationery or letterhead and send them via postal mail.

  <u>Sample affirmation</u>

  Dear Ben:

  We were so glad that you could come to the first meeting of our Patient Advisory Committee (PAC)!

  We really appreciated your participation and your interesting, helpful comments. You brought a lot of thoughtfulness and sincerity that helped to make the meeting a positive experience for everyone. We know that you have a lot of ideas and opinions to share, and we look forward to hearing more from you at future meetings.

  We will be in touch soon with the date for our next meeting.

  Sincerely,

  Betty and Gay

Appendix II: Sample List of Supplies and Prep

For PAC Orientation using Modules 1 – 8, including optional activities

Supplies

- Easel and flip chart; heavy-duty markers (not dry-erase)
- 2-pocket folders for PAC member documents; pens for participants, facilitators; name tags
- Food, utensils, etc. for participant snacks or light meal

Facilitation script prep

- Replace all <<highlighted generic text>> with project-specific text developed by your team

Printing

- Packet of facilitation materials for research team
    - Outlines or Facilitator Scripts for each module (stapled together in one packet)
    - Skit for Demonstration of Feedback (Module 4)
    - Orientation Evaluation (copies to hand out to members; Module 8)
- Stapled packet of handouts for PAC members and research team
    - Participant agenda (Module 1)
    - Optional Privacy and Confidentiality examples (Module 3)
    - Sample Letter for skit (Module 4)
    - Optional "What does my PAC membership involve?" (Module 7)
- Additional documents for PAC members and research team
    - Optional Bingo activity (Module 1)
    - Research materials (Module 5)
    - Membership Agreement (Module 7)

Participant folder prep: Insert stapled PAC packet and additional documents in member folders; prepare one folder for each PAC member and each member of research team

Flip chart prep (number each sheet in lower right corner)

- Module 1, Sheet 1
    - Line 1: Patient Advisory Committee (PAC)
    - Line 2: Project name, in plain language
- Module 2, Sheet 2
    - Line 1: Project goal, in plain language
    - Below project goal: diagram of major stakeholders in project
- Module 3, Sheet 3
    - "In your experience, what helps you feel comfortable speaking up in a group?"

Appendix III: Alternative Agendas for PAC Orientation

Facilitator Agenda (for research team only)

45-minute Orientation for One-day Meeting

Module	**Content**	**Time**	**Modifications from 2-hour agenda** (do not use any optional activities)
1	Welcome, introductions, opening question	:15	○ For opening question, ask "why are you interested in being part of this meeting on <<topic>>?"
2	Goal of 1-day meeting; role of patient advisors	:05	○ Revise Stakeholder Diagram to portray main types of participants at 1-day meeting
3	Working together	:05	○ Skip "step up, step back"
4	Helpful feedback	:10	○ Revise skit set-up and all materials for skit to make them relevant to patient advisors' work at 1-day meeting
5	Patient advisor practice with <<tasks at 1-day meeting)	:20	○ Use 20 min. instead of 40 min. for getting group feedback ○ Use materials that are relevant to patient advisors' work at 1-day meeting

8	Orientation evaluation	:05	○ Instead of using Orientation Evaluation form, provide index cards and invite advisors to answer one or both questions:
			  ○ What was the most helpful part of this orientation?
			  ○ What was the most interesting part of this orientation?

<<Institutional or Project Logo(s)>>

<<Project Name—in plain language>>

Orientation for <<Name of meeting>>

<<Date>>
<<Time>>
<<Location>>
<<Address>>

Agenda

1. Welcome and introductions (10 min.)
2. Project goal; role of patient advisors and other meeting participants (5 min.)
3. Working together (5 min.)
4. Helpful feedback (10 min.)
5. Patient advisor practice with <<tasks at meeting>> (25 min.)
6. Orientation evaluation (5 min.)

Facilitator Agenda (for research team only)

4-hour Orientation

Module	Content	Time	Modifications from 2-hour agenda
1	Welcome, introductions, opening question	:30	○ Use optional activity "Bingo"
2	Project goal; role of PAC	:10	○ Make this a 10-min. module instead of 5 min. if your project is complex, involves multiple sites, has multiple advisory boards, or if you have guest speakers at the orientation.
Optional A	How the PAC is making a difference	:05	○ Add Optional Module A
3	Working together	:10	○ Use optional activity "Examples of how to protect privacy and confidentiality"
Optional B	Research process, terms, & ethics	:45	○ Add Optional Module B
Optional C	Break; Refresher activity —"Can You Guess?"	:30	○ Insert 10 min. break ○ Add Optional Module C
4	Helpful feedback	:10	○ No changes
5	Feedback on research materials	:60	○ Use 60 min. instead of 40 min. for getting PAC member feedback on research materials
Optional D	PAC descriptions for resumes and LinkedIn	:05	○ Add Optional Module D
6	PAC meeting process	:10	○ No changes
7	Membership Agreement and plan for member check-ins	:20	○ Use optional activity "What does PAC membership involve?"
8	Orientation evaluation	:05	○ No changes

PAC Agenda (for PAC members; delete this label before printing)

4-hour Orientation

<<Institutional or Project Logo(s)>>

<<Project Name—in plain language>>

Orientation for the Patient Advisory Council (PAC)
<<Date>>
<<Time>>
<<Location>>
<<Address>>

Agenda

1. Welcome and introductions (30 min.)
2. Project goal; role of PAC and other stakeholder (10 min.)
3. How the PAC is making a difference (5 min.)
4. Working together (10 min.)
5. Research process, terms, and ethics (45 min.)
6. Break and refresher activity (30 min.)
7. Helpful feedback (10 min.)
8. PAC feedback on <<research materials>> (60 min.)
9. Putting PAC experience on a resume (5 min.)
10. PAC meeting process (10 min.)
11. Membership Agreement and Check-in (20 min.)
12. Orientation evaluation (5 min.)