

Stakeholder Engagement Tools for Studies

Study participants and other stakeholders are often the intended end users of research results. In stakeholder-engaged research, they can provide integral feedback to help shape the formation, dissemination, and utilization of research results and increase enrollment and retention in clinical trials. It is important that the stakeholder engagement process be implemented equitably and with open space for both technical team members and stakeholders to share thoughts and feedback. This can be challenging, and communication barriers will vary based on the audiences relevant to each study question.

This toolkit serves as a guide for study teams to execute stakeholder engagement in their project. The sample tools model some of the activities and principles that facilitate meaningful participation and decision-making of stakeholders in large, multisite studies. The tools included below were developed using lessons learned and stakeholder feedback from the

[PCORnet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth](#).

There are three resources in this toolkit:

- A sample Memorandum of Understanding between stakeholders and lead study investigators
- A checklist guide for stakeholder engagement activities
- A sample of a survey used to assess quality and improve stakeholder activities

See the [PCORnet Engagement Glossary](#) for definitions of engagement terms used throughout this toolkit.

Template: Memorandum of Understanding for Stakeholder Partnerships

Memorandums of Understanding can be used as agreements between study teams and stakeholders to describe the scope of work that will be completed. Both formal and informal forms of these agreements have been used to set expectations for stakeholder participation and ensure that roles and responsibilities are clear for all involved. While the below template outlines several sections typically included in a Memorandum of Understanding, the study team should include any legal language that may be required by their host institution and consult their contracts department prior to executing agreements.

Memorandum of Understanding [Name of the Project/Study] [Time Period for Agreement]

This Memorandum of Understanding (MOU) between the [Insert Name of Principal Investigator/host institution] and [Insert Name of Stakeholder] is agreed as of this ___ day of Month_, ___ Year___.

Background

Describe the background for the question being investigated in this project. Include any relevant information on the study team and/or institutions involved and how the project was developed.

Project Overview

Give a detailed description of the project, its aims, and how stakeholders will be involved, written at a basic literacy level so the information is clear, concise, and easily understood by a variety of stakeholders.

Roles and Responsibilities

In a bulleted or numbered list, categorize and describe the duties and expectations for each person signing this agreement (i.e. the Principal Investigator and the Stakeholder). Roles and responsibilities could vary depending on the type of stakeholder (i.e. clinician, patient, caregiver, community member, etc.).

Principal Investigator

In support of the stakeholders involved in this project, the Principal Investigator (on behalf of the study team) agrees to do the following:

[Insert specific roles and responsibilities. Examples included below.]

- *Provide updates on the study during regular meetings and calls*
- *Identify and ensure opportunities for stakeholder involvement and decision making*
- *Incorporate stakeholder feedback in study protocols, documents, and dissemination plans*

Stakeholder:

As a stakeholder participating in this project, [insert name] agrees to do the following:

[Insert specific roles and responsibilities. Examples included below.]

- *Serve on the Stakeholder Advisory Group*
- *Attend regular meetings and calls (include frequency)*

- *Assist in selecting the study question*
- *Provide feedback on study protocols, documents, and dissemination plans*

Stakeholder Deliverables

List any deliverables that are expected for the stakeholder and give a short description of each.

Communication Plan

Describe how the study team (represented by the Principal Investigator) and the stakeholder will be expected to communicate. Include information about regular meetings or calls if necessary. Describe planned communication methods: e.g. email, in-person meetings, conference calls, etc.

Timeline of Activities

Describe the project period and include an anticipated number of hours per week/month required to fulfill the roles and responsibilities outlined. A table is a helpful way to illustrate the expected timeline of the deliverables and activities over the duration of the project.

| Activity | Date |
|----------------------|--|
| Ex. Signed MOU due | 7/30/2018 |
| Ex. Kick-off Meeting | 8/20/2018 |
| Ex. Monthly Calls | The first Monday of each month beginning 10/2018 |
| Ex. Final Report | 8/31/2019 |

Funding

Describe monetary and any other compensation that will be provided in this role. If any expenses will be reimbursed, describe along with the process for requesting reimbursement.

Signature of Stakeholder: _____

Date: _____

Signature of Principal Investigator: _____

Date: _____

Engaging Stakeholders in a Research Project: A Planning Checklist

This checklist is designed to help investigators and study teams meaningfully involve stakeholders throughout all phases of the research process, including:

- Identification of research priorities
- Research planning
- Research design and identification of meaningful outcomes that matter
- Execution of research
- Data analysis
- Dissemination of research results

Lessons learned and examples of engagement activities from the [PCORnet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth](#) informed the development of this tool. For further tactics and examples, reference the [PCORnet Engagement Assessment Tool](#) and [other engagement resources and case studies](#) on the [PCORnet Commons](#).

Research Question Generation and Prioritization

- ✓ Involve stakeholders (i.e. patients, caregivers, clinicians, and communities) in research question identification and prioritization prior to securing funding (i.e. using online platforms, including registries, community forums, or social media to crowdsource ideas; in-person meetings, conferences, etc.).
- ✓ Develop a research question that matters to patients, families, and communities.
 - For examples of tools, resources, and processes that PCORnet networks have used to involve stakeholders in research question generation and prioritization, see this [guide](#).
- ✓ Identify specific individuals who are interested in working with you on a proposal to identify funding opportunities and move identified research questions forward.

Developing Your Study Proposal

- ✓ Consider the inclusion of a stakeholder Co-Principal Investigator or Co-Investigator as part of the lead investigator team for the proposed study.
- ✓ Plan for engagement activities to occur from the beginning of the study and create opportunities for stakeholders to contribute to the development of research and engagement plans.
- ✓ Avoid tokenism by finding opportunities for stakeholder involvement and contributions to add value to the project.
 - Have a process to ensure that you have the time and ability to meaningfully incorporate stakeholders' input.
- ✓ Develop specific aims for which stakeholders can either lead or significantly contribute.
- ✓ Establish core principles to guide your project's engagement efforts throughout the entire research process.
 - The [PCORnet Engagement Assessment Tool](#) provides recommendations for key principles for partnership.
- ✓ Allocate sufficient budget and staff full-time equivalence (FTE) hours towards engagement activities, as well as monitoring and improving these activities over time.

Launching the Study

- ✓ Inform stakeholders involved in the proposal phase that the project was awarded and assess how you can actively involve them across the phases of the study.

- ✓ Identify and provide all involved stakeholders with a memorandum of understanding or contract to outline the roles and responsibilities, timeline, and compensation expectations at the outset of the project.
- ✓ Compensate stakeholders fairly according to their contributions to the project.
- ✓ Give all stakeholders an opportunity to be involved in identifying needs and priorities for the project, including topics to cover at a study kick-off meeting.
- ✓ Host a kick-off meeting with all project stakeholders to define roles and responsibilities, align on project goals and objectives, and confirm timeline and deliverables.
- ✓ Have investigator teams develop and provide resources, guidance, and training to ensure that stakeholders can meaningfully engage in study activities as outlined by their respective roles and expectations.
- ✓ Formally train all investigators on stakeholder engagement.
- ✓ When finalizing project timeline and deliverable schedules, build in sufficient time for stakeholders to review and provide input on all study materials throughout the project.

Study Implementation and Analysis

- ✓ Convene stakeholders frequently (e.g. monthly) to ensure members receive ongoing study updates, review and provide feedback on study documents and plans, and identify opportunities for future engagement activities.
- ✓ Have a mechanism in place to capture stakeholder feedback, including a plan for how to implement changes accordingly.
- ✓ Develop materials that include lay language to ensure all stakeholders have the ability to understand the project aims, goals, and other details.
 - Reference this [Plain Language Principles](#) guide to help develop these materials.
- ✓ Select individual members of each stakeholder group (i.e. patients/participants, caregivers, clinicians, etc.) to serve in a more involved capacity, such as an advisory committee or workgroup.
- ✓ Create metrics or measures for engagement that allow you to track progress towards engagement goals and objectives.
- ✓ Continue to monitor staff time and budget to ensure you have accounted for engagement activities throughout the entire project duration.
- ✓ Work with stakeholders to find activities and roles that best leverage their strengths and expertise (i.e. participants may have greater involvement in participant requirement or research questions development; clinicians may have greater involvement in study cohort development).
- ✓ Identify opportunities for stakeholders to inform analysis activities.

Dissemination

- ✓ Integrate stakeholders into publication and dissemination planning activities.
- ✓ Include stakeholders as authors on publications. It may be helpful to hold conference calls to review manuscripts with stakeholders before they have the opportunity to provide feedback on study manuscripts.
- ✓ Work with stakeholders to identify non-traditional channels for disseminating research findings (outside of publication).

Monitoring Stakeholder Engagement in a Study: A Sample Survey

The [PCORnet Obesity Observational Study: Short- and Long-term Effects of Antibiotics on Childhood Growth](#) was one of the first demonstration projects in PCORnet, the National Patient-Centered Clinical Research Network. As part of this project, stakeholder engagement was built into multiple layers of the project; most notably through the formation of the Executive Antibiotics Stakeholder Advisory Group (EASAG). The EASAG was a governance committee comprised of parents, health systems leaders, pediatricians, pharmacists, and organization leaders. EASAG members became integral working parts of the team, connecting frequently with the investigators; providing feedback on study plans including protocols, analysis approaches, and dissemination planning; and reflecting on the value of the project and their role.

As the project was underway, the engagement leadership team worked with the stakeholders to develop a survey to collect EASAG members' feedback on their involvement in the project. Goals of the survey included:

- Determining stakeholder satisfaction
- Informing the study's engagement process and opportunities for improvement
- Documenting lessons learned to benefit future studies

Note: This survey was not intended to be a formal evaluation or measurement of engagement in the study. It was a quality improvement effort designed to understand stakeholders' satisfaction with their involvement and to identify successes and challenges that could inform changes to engagement processes for the remainder of the study. The questions were developed in collaboration with the stakeholders and were specific to their role and experiences in this study. Other PCORnet engagement resources, including the [PCORnet Engagement Assessment Tool](#), were also referenced in the development of this survey.

Investigators interested in adapting this survey for their own research projects should consider the context of stakeholder engagement in their study and work with their stakeholders to hone these questions to be relevant to their study. Future efforts should also leverage existing [engagement tools and resources](#) available on the PCORnet Commons.

Stakeholder Feedback on ABX Study

This survey is designed to help us understand your experience as a stakeholder in the PCORnet Antibiotics Study (ABX). The survey is meant to provide feedback on your participation and will be used to improve stakeholder involvement for the remainder of the project. We may present aggregate findings from the survey to the various groups including the executive stakeholders, the principal investigators and project managers, and others involved in PCORnet. This information will also be summarized for the overall PCORnet evaluation team to use for their reports to PCORI and may be presented in summary form in future manuscripts describing the PCORnet Antibiotics Study and its stakeholder engagement strategy.

* 1. What stakeholder role do you play in the ABX study? (you can choose more than one)

- Investigator/Researcher
- Community Organizational Leader
- Advocacy Group Leader
- Parent/Caregiver
- Healthcare Provider
- Healthcare System/Organization Leader
- I am not sure
- Other (please specify)

* 2. In which of the following study groups have you participated?

- Executive Antibiotics Stakeholder Advisory Group (EASAG)
- Secondary Aim Focus Group Site
- Dissemination Workgroup
- Publications Workgroup
- Maternal-Child Linkage Workgroup
- PCORnet Antibiotics Scientific Core

The following questions will ask you how much you agree with statements about the activities (in-person or phone meetings, and any other work that you did as part of these groups) of being a stakeholder in this study. If you are not sure how you feel about the statement, please use the response "Neither agree nor disagree."

* 3. Individuals whose lives are most impacted by children's antibiotics use or pediatric obesity are well-represented.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 4. The study values the differences of contributing stakeholders.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 5. I have decision-making authority and believe I contribute meaningfully to relevant outcomes and objectives for the study.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 6. I feel the study team has a clear understanding of stakeholders' expertise, strengths, and roles.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 7. I feel that I have been compensated appropriately for my time and expertise as a stakeholder.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 8. ABX study stakeholders engage in open communication and demonstrate a willingness to listen to others.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 9. My fellow stakeholder participants respect what I have to say, even when they do not agree with me.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 10. I have enough information about the general topic area of antibiotics and pediatric obesity to participate effectively.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 11. Study information and materials are always shared and presented in ways that I can understand.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 12. Participating in these activities has helped me better understand research on antibiotics and obesity in early childhood.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 13. I have learned a lot from participating in these activities.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 14. I feel I could explain the ABX study to others.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Additional comments

* 15. We would like to know if 1. you expected to participate in each study activity when you first became a stakeholder, and 2. if you later had the opportunity to participate. Please also rate your satisfaction with your participation. If you were not satisfied, we ask that you provide further feedback using question 19.

| | Did you expect to participate? | Were you able to participate? | How would you rate your satisfaction with participation? |
|--|--------------------------------|-------------------------------|--|
| Planning the research aims | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Planning stakeholder engagement | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Planning data analysis/interpretations | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Interpreting results | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Planning the Secondary Aim | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Planning for dissemination | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Participating in conferences and presentations to research audiences | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Participating in publication development | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| Participating in engagement of partners and other groups | <input type="text"/> | <input type="text"/> | <input type="text"/> |

* 16. How much time per month on average do you spend on work related to the study? (min OR hours)

* 17. Do you consider this amount of time:

- Not enough. I could do more
- Just right
- Too much
- Not sure

* 18. Overall how satisfied have you been so far with our role as a stakeholder in the study?

- Extremely Satisfied
- Satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Dissatisfied
- Extremely dissatisfied
- Not sure

Additional comments:

19. What could be changed to improve your stakeholder experience?