Patient and/or other stakeholder engagement involves having patients and/or stakeholders as partners in research instead of as research subjects only. For example, patients and/or other stakeholders can be involved in activities such as:

- Deciding what to study;
- Designing the study;
- Choosing study outcomes;
- Tracking study progress; or
- Sharing study findings

These questions will ask:
- Who was engaged in your project (stakeholder communities represented),
- When they were involved (which parts of the research process),
- How they were engaged (what approaches you used and the level of engagement),
- How much influence they had, and
- What they did

1. Engagement may not occur during all reporting periods or may not occur as planned. Did you engage with patients and/or other stakeholders in any way during the current reporting period?
   ☐ Yes
   ☐ No

1a) [Answer if Q1 = No] Why not?
   ☐ Engagement was not planned to occur during the reporting period
   ☐ Plans for engagement have changed
   ☐ Other: (Please describe)

2. [Answer if Q1 = Yes] Describe progress on your engagement plan during the current reporting period. Refer to Methodology Standard PC-1 and describe how this standard is being met. *(If Q1 = “no”, skip to Q10, challenges)*
3. WHO? Which communities were engaged with this PCORI project during the reporting period? Check all that apply.

☐ Patient/consumer
☐ Caregiver/family member of patient
☐ Advocacy Organization (e.g., patient/consumer or caregiver advocacy organization)
☐ Clinician
☐ Clinic/ Hospital/ Health System Representative
☐ Community Based Organization (CBO)
☐ Purchaser (small or large employers)
☐ Payer (public or private insurance)
☐ Life Sciences Industry
☐ Policy Maker (government official)
☐ Training Institution (non-research health professions educator)
☐ Subject matter expert – Please describe:
☐ Other – Please describe:

4. HOW?

a) How did you engage with patients and/or other stakeholders in this research project during the reporting period? Check all that apply.

☐ As Research team member(s): Consultants, advisors, experts listed as research staff or team members.
☐ Via Advisory group(s): Individuals participating in an advisory panel, community advisory board, focus group, community forum, town hall meeting, or other type of group forum to give input on what to study or how to design the project.
☐ Via Opinion poll(s) or interview(s): Individuals complete a set of questions to give input on the research process.
☐ Other: Please describe: ______________________________

b) [Answer if Q4a = Research Team Member] Are any of the patient and/or stakeholder partners serving as Co-Investigators? Co-Investigators typically devote a specified percentage of time to the project and share responsibility for the project with Principal Investigator(s).

☐ Yes
☐ No
5. WHEN?
In which phases of the project were patients and/or stakeholders engaged **during the reporting period**? Check all that apply.

- Study topic/question development
- Design: interventions/tools/comparators
- Choice of outcomes and measures
- Study design: other
- Participant recruitment/retention
- Data collection
- Data analysis or results interpretation
- Dissemination
- Another phase - Please describe: __________________________

6. [For each part of the project selected in Q5] Which choice(s) reflects the ways in which patients and/or other stakeholders were engaged **during the reporting period**? Check all that apply.

Definitions:
- **Information**: Researcher(s) describe decisions to patients and/or other stakeholder partners after decisions are made.
- **Consultation**: Patients and/or other stakeholders provide input to researchers that may inform decision-making.
- **Collaboration**: Patients and/or other stakeholders work directly with the researcher, in active partnership, to ensure that their perspectives are incorporated in decision-making.
- **Patient/Stakeholder Direction**: Also known as “user control,” patients and/or other stakeholder(s) have control over the research process and the final decision-making.

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7. HOW MUCH?

[For each part of the project selected in Q5, plus two additional fields for all respondents: The way the research team and partners work together; Research projects other than this specific PCORI funded project] Rate how much influence patients and/or other stakeholders had during the reporting period. By influence, we mean affecting or contributing to decisions or processes related to the project.

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8. WHAT? [For each part of the project selected in Q5] For the current reporting period, describe what patients and/or other stakeholders actually did and any impact this had on the project (e.g., how engagement activities informed decisions or led to project modifications). Include specific examples.

9. Describe challenges with patient and/or other stakeholder engagement during the reporting period. How have you overcome these challenges? What is your continued plan for addressing these challenges?

(THE FOLLOWING QUESTIONS ARE FOR THE FINAL REPORT ONLY)

Now please report on your experience engaging with patients and stakeholders across your entire PCORI project:

- What were the most notable impacts, both positive and negative, of engaging with patients and/or other stakeholders on the study operations (e.g., logistics, budget, efficiency, etc.)? Please provide specific examples.

- What were the most notable impacts, both positive and negative, of engaging with patients and/or other stakeholders on the study quality (e.g., scientific rigor, recruitment and retention, credibility of findings, etc.)? Please provide specific examples.

- What were the most notable impacts, both positive and negative, of engaging with patients and/or other stakeholders on the usefulness of study findings to patients and healthcare decision makers and the potential for uptake of findings? Please provide specific examples of each.

- Please describe any impacts of engagement on:
  - the investigators,
  - the study participants, or
  - your institution.

- What experiences from this project or other factors affect the likelihood that you will engage with patients and/or other stakeholders on future research projects?

- Across your entire project, what strategies worked well for engaging with patients and other stakeholders? Why?

- What strategies, if any, didn’t work as well as intended for engaging with patients and other stakeholders? Why?

- Please feel free to share any other information about patient and other stakeholder engagement in your project.