

# FORCE

Facing Hereditary Cancer EMPOWERED

**ENGAGING PATIENT AND COMMUNITY STAKEHOLDERS  
IN DESIGNING AND CONDUCTING RESEARCH:**

**TIPS FOR INVESTIGATORS**



# ENGAGING PATIENT AND COMMUNITY STAKEHOLDERS IN DESIGNING AND CONDUCTING RESEARCH: TIPS FOR INVESTIGATORS

This tip sheet was developed as a guide for investigators on how to work with patient stakeholders; including advocacy groups, community-based organizations, community leaders, patient research advocates, patients and caregivers to strengthen and accelerate research. The guide was developed by Facing Our Risk of Cancer Empowered (FORCE) and researchers at the University of South Florida.

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## QUICK TIPS FOR ENGAGING PATIENT STAKEHOLDERS IN RESEARCH

- Reach out to national or community-based nonprofit organizations, colleagues, or the office of community outreach at your institution for direction and input on identifying stakeholders.
- Reach out early and often in the research cycle to advocacy groups and community-based organizations for assistance.
- Provide patient stakeholders with sufficient information and advance notice (e.g., weeks, not days) so that they can make an informed decision about their participation and make meaningful contributions to your research project.
- Share this document with your study coordinator or the person who will be coordinating communications with your patient stakeholders.
- Provide plain language information and communications for all research efforts that involve patients.
- Provide a clear timeline and list of roles and expectations of patient stakeholders.
- Include compensation for patient stakeholders' time and expertise and reimbursement for their transportation/travel. The level of compensation may vary based on the type of stakeholder you are engaging. Make sure that stakeholders understand the steps they need to take to obtain compensation. If possible, provide administrative support to help them obtain a vendor number, prepare an invoice or complete any other administrative requirements.
- Inform patient stakeholders of project updates and outcomes (e.g., funding decisions, changes in scope or timeline, research outcomes). Consider them as part of your research team.
- Acknowledge and thank the contributions of all patient stakeholders (including participants) in publications and presentations.

## WHO ARE PATIENT STAKEHOLDERS?

These stakeholders have a vested interest in getting funding for, supporting and participating in research that improves overall health and wellbeing, medical care and outcomes for the patient community now and in the future.

Patient and community stakeholders include:

- patients
- caregivers
- advocates
- advocacy groups
- community-based organizations

They can share their individual and collective experiences, connect researchers with additional members of the patient community and provide researchers with invaluable understanding of the burden of disease, the burden of treatment and social determinants of health.

As active participants on a study team, their contributions may improve the speed, efficiency, representativeness and effectiveness of your research as well as the dissemination of successful results and uptake in improvements in care.

## WHY SHOULD YOU ENGAGE PATIENT STAKEHOLDERS IN YOUR RESEARCH?

Patients and the public are end-users of successful clinical research and experts in the personal experience of living with a disease or condition. As such, they have a lot to contribute to the research process. Traditionally, patients have been viewed purely as subjects of research, a very important role. However, they have more to offer the research enterprise beyond enrolling in a study. Listening to patients, caregivers and advocates share their experience of navigating a disease or condition can help you improve your research design and protocol, improve your research funding applications, and identify barriers and facilitators to research enrollment, retention and use of research results in clinical care.

These stakeholders can help researchers build studies that:

- are more responsive to patient needs.
- answer research questions that are relevant and important to patients.
- are easy to find and enroll in.
- encourage participant retention.
- assist patient decision-making.
- are implemented to improve the lives, health and well-being of patients and their families.

## WHAT TYPES OF STAKEHOLDERS DO YOU NEED?

Depending on your study needs, you may engage one or more of the following stakeholders.

- **COMMUNITY MEMBERS**

Stakeholders who are members of the community you are studying may include:

- Patients
- Relatives or family members
- Caregivers
- People who share a set of circumstances, challenges or conditions

These individuals typically do not have formal scientific training, although many may have researched the topic, condition or challenge of interest. They are subject matter experts based on their lived experiences.

- **TRAINED ADVOCATES**

These individuals often represent stakeholders from one of the categories of listed above. They may have received research advocacy training through a nonprofit organization, clinical research program or funding agency (e.g., the Department of Defense Congressionally Directed Medical Research Program) to learn more about the research enterprise, their disease or condition and how patients can engage in research. Or, they may have gained expertise from contributing to multiple research opportunities. They may also have relevant professional experience that can improve the study's success.

- **ADVOCACY GROUPS AND COMMUNITY-BASED ORGANIZATIONS**

Many organizations have both interest and expertise in assisting investigators with research design, grant applications, participant recruitment and results dissemination. Some offer training programs to help people who do not have a scientific background participate in the research process. These organization can often match you to qualified research advocates or constituents who represent the desired participant community to review patient-facing materials or participate on research study teams. Some organization have specific programs or tools that assist with research study enrollment and dissemination of research study findings.

The table below summarizes the roles patient community stakeholders may play at each phase of the research cycle.

<b>PROJECT NEEDS</b>	<b>PATIENTS/ CAREGIVERS/PUBLIC</b>	<b>TRAINED ADVOCATE</b>	<b>ADVOCACY GROUP OR COMMUNITY BASED ORGANIZATIONS</b>
<b>Identify research gaps</b>	Provide personal and individual perspective.	Provide insight into individual and community perspective.	Provide a range of community perspectives or access to multiple patients to provide insights or feedback.
<b>Review study design, materials and communications</b>	<ul style="list-style-type: none"> <li>• Provide individual perspective on understandability and acceptability of communications.</li> <li>• Provide input to ensure cultural competence.</li> </ul>	<ul style="list-style-type: none"> <li>• May be trained to spot gaps in understanding, access to, or protections and barriers to participation.</li> <li>• May be trained to develop recruitment strategies and materials to engage diverse patient groups.</li> </ul>	<ul style="list-style-type: none"> <li>• Provide a range of community perspectives or access to multiple patients to provide insights or feedback.</li> <li>• Spot gaps in understanding, access or protections and barriers to participation.</li> <li>• Provide guidance for cultural competence.</li> </ul>
<b>Assist with study recruitment and enrolling</b>	<ul style="list-style-type: none"> <li>• Provide testimonials and personal experiences with clinical research.</li> <li>• Provide outreach to a community, community-based organizations and trusted community leaders.</li> </ul>	<ul style="list-style-type: none"> <li>• Provide testimonials and personal experiences with clinical research.</li> <li>• Provide outreach to community, community-based organizations and trusted community leaders.</li> </ul>	<ul style="list-style-type: none"> <li>• May have means for multi-channel, broad outreach, study promotion and patient matching.</li> <li>• May have access to specific groups or populations.</li> <li>• Are considered trusted leaders within the patient community.</li> </ul>
<b>Disseminate study results</b>	<ul style="list-style-type: none"> <li>• Share study results with peers, community-based organizations and social networks.</li> <li>• Inform their care providers about the study and results.</li> </ul>	<ul style="list-style-type: none"> <li>• May have means for the dissemination of results through ties to organizations and the community.</li> </ul>	<ul style="list-style-type: none"> <li>• May have broad dissemination channels that reach patient, clinical care and policymaker stakeholders.</li> <li>• Provide guidance for cultural competence.</li> </ul>

## WHERE DO YOU FIND PATIENT STAKEHOLDERS?

Whether you are seeking a patient community member with no research experience, a seasoned advocate or professional engagement assistance, you should be able to find a patient stakeholder to meet your needs.

Here are some places to start:

- If your focus is hereditary cancer research, FORCE has a research advocate training program and can match you to community members affected by hereditary cancer who are eager to participate in the research process.
- Reach out to research-oriented national or community-based nonprofit organizations.
- Your institution's office of community outreach or engagement may be able to provide direction and input on identifying interested and engaged community stakeholders.
- Your colleagues may have recommendations for advocates who have assisted them with similar projects.
- Contact professional societies in the area of your research. They may have advocacy contacts or advocacy branch that can recommend patient stakeholders.
- Contact the Patient Advocate Committees that are associated with the National Cancer Institute's National Clinical Trials Network (NCTN) groups, listed in the resource section below.

Engage patient stakeholders as early as possible in your process to give them enough time to provide meaningful input.

## HOW CAN ADVOCACY ORGANIZATIONS HELP IN THE RESEARCH PROCESS?

Some advocacy groups (including FORCE) offer other services and resources for researchers including:

- Identification of research gaps.
- Providing input on research design.
- Providing strategies and opportunities to broaden the diversity of participants.
- Helping you create a patient stakeholder advisory board.
- Clinical research promotion and matching of eligible patients to studies.
- Study material review.
- Dissemination of research findings.

Some organizations may have fixed costs or fees associated with these efforts. Depending on your funding and phase of research, these fees may be negotiable. Consider advocacy group compensation, including staff time and effort in your budget where possible and be prepared to have an open conversation with the organization about costs associated with these efforts.

## WHAT ROLES CAN PATIENT STAKEHOLDERS HAVE IN THE RESEARCH PROCESS?

Regardless of where you are in the research study cycle, there are likely opportunities for advocates to assist you with your research. Below are some examples of ways that advocates may help:

- **RESEARCH PLANNING AND DESIGN**
  - Help design studies that are responsive to patients' questions and needs.
  - Define important outcomes, including patient-reported outcomes.
  - Help identify and address barriers to patient participation.
  - Review study proposals.
  - Identify possible funding sources.
  - Review and provide feedback to improve study materials, such as consent forms, study communications and IRB submissions.
  - Provide letters of support for funding.
- **CONDUCTING RESEARCH**
  - Promote study awareness and enrollment.
  - Play an advisory role throughout the course of the research.
- **EVALUATION OF RESULTS**
  - Review the data and assist in determining conclusions by highlighting what has most relevance for patients.
  - Help prepare plain language summary of findings.
  - Suggest next steps and areas of future research.
- **DISSEMINATION AND IMPLEMENTATION**
  - Share results with the patient community, healthcare professionals, policymakers and the public.
  - Help incorporate new findings in practice guidelines and policies to improve care and outcomes.

# HOW DO YOU ENGAGE PATIENT STAKEHOLDERS AS PARTNERS IN RESEARCH?

## PREPARING FOR STAKEHOLDER ENGAGEMENT

Meaningful engagement of patients in research takes time and planning. Provide patient advocates with sufficient orientation information about your project in advance so that they can make an informed decision about their participation. Before you reach out, you may want to assemble the following information:

- Plain language summary of your project, including:
  - study objectives.
  - the relevance or importance for patients.
  - the stage of project planning or implementation.
- The specific activities or areas of input where you plan to engage advocates.
- The type of expertise/personal experience you are looking for.
- A list of specific questions or topics where you would like patient stakeholder input.
- A project team management chart, including the name and contact information for the person who will be organizing communications with the advocate.
- A realistic estimate of the time commitment.
  - Note that if your project requires stakeholders to complete paperwork, such as a subcontract, biosketch, registration as a consultant, description of their role or invoices, these can be time-consuming and may require additional resources that your stakeholders don't have. Consider assigning supportive staff on your team to assist with these tasks.
- Any compensation you are planning to offer for efforts.
  - If your project includes engaging patients as part of your study team, we encourage you to include compensation for their time. Compensation of engaged patient partners should reflect the level of expertise, commitment, responsibility, the type of work involved and the degree of participation.
  - If your project includes engaging representative participants as reviewers, we encourage you to offer them a stipend/gift card/compensation for their assistance. Additionally, make sure to reimburse them for any related expenses, including travel, parking, etc.
- If your institution's IRB requires patient stakeholders to undergo Human Subjects in Research training, you may need to provide stakeholders with access to training. Ask your IRB if your institution can provide training through the Collaborative Institutional Training Initiative (CITI). Alternatively, the Center for Clinical and Translational Science (CCTS) has a free training program for community partners in research (registration is required, but it's free). See the resource section below for links.

It is important to be as detailed and organized as possible. Patient stakeholders have expressed frustration when they have been asked to participate in meetings that include advanced scientific information but received no prior preparation. Clearly explain your expectations for their participation in a meeting ahead of time, and communicate where their input is needed most. If there will be scientific presentations, provide definitions, pre-reading or other resources so that they can follow the discussion and provide meaningful input. Ask for their comments during meetings. Let them know that you appreciate their contributions.



## PROVIDE A WELCOME AND ENGAGING ENVIRONMENT

Academic members of your research team may have a common background, training, vocabulary and understanding that may not be shared by patient stakeholders, whose diagnosis, condition, circumstances or lack of scientific training may leave them feeling stigmatized or vulnerable, especially at the beginning of a project. You can help them feel welcome and encourage their active participation in the following ways.

### AT THE BEGINNING OF A PROJECT OR MEETING:

- Arrange an introductory call between the patient stakeholders and one or two core study team members. This is an opportunity to align expectations. Let the stakeholders know that you and your team value their input and encourage them to speak up during meetings. This is especially helpful for projects that include large group meetings.
- Introduce advocates to the study team and acknowledge their lived experience and other expertise.
- Designate a member of your project team as a consistent point of contact for patient stakeholders. If you are still in the planning stage of your study, consider who that contact might be and budget accordingly.
- Explain your project, timeline and expectations in plain language with clear examples.

### THROUGHOUT THE PROJECT:

- Provide timely updates on changes in the study that may affect their scope of work, involvement, timeline or the project as a whole.
- Request patient stakeholders to attend those meetings where they will be able to follow and feel productive. If you invite them to all meetings, emphasize which ones are most relevant to their role in the study.
- Schedule meetings that accommodate their availability and accessibility.
- Incorporate pause points during meetings for people to ask questions or provide feedback. If you want advocate feedback on specific items, let them know ahead of time if possible, so they are not caught off guard during a meeting. Encourage them to speak out, and make sure to ask for their opinions or feedback.
- If assigned reading is long and/or technical, provide plain language versions and direct stakeholders' attention to the specific sections where you would like their input.

### AT THE END OF A PROJECT:

- Inform patient stakeholders of the project outcome.
- Acknowledge them in publications/presentations.
- Offer them a stipend/gift-card/compensation for their assistance.

## PROMOTING PATIENT ENROLLMENT IN CLINICAL RESEARCH STUDIES

- Engage patient stakeholders to help you identify and address barriers to participation. Include community-based organizations that serve populations who experience health disparities.
- Have a plan and reasonable budget for enrolling participants who are representative of the population that is affected by the disease or condition you are studying. Devote resources to outreach and bi-directional engagement with people from groups that are underrepresented or disenfranchised.
- Avoid excluding specific populations without justification. Examples include:
  - men with breast cancer.
  - people with brain metastasis.
  - pregnant women.
  - people with limited fluency in English.
  - people with comorbidities. Certain co-morbidity exclusions may decrease your chances of achieving representative enrollment.
- Choose a plain language study title that conveys at a glance what the study is about.
- Consider a study design that allows crossover or expanded access to new treatments for patients with advanced disease and limited options if they are initially assigned to receive standard care or placebo.
- Try to budget for and notify participants about reimbursement for travel or other out-of-pocket costs. Recognize that participation in research can present many burdens, including costs that insurance may not cover, travel to and from appointments, parking, income lost from missed work, child-care and more.
- Offer multiple enrollment sites including in rural areas; consider reducing appointment burden through telemedicine or combined visits.
- Draft communications and recruitment materials in language that:
  - people can understand the first time they read it.
  - keeps grammar simple and avoids run-on sentences.
  - avoids jargon.
  - spells out abbreviations.
  - avoids words or expressions that objectify or stigmatize people.
  - conveys clearly the goals and main eligibility in the study title and overview (if possible).
- Include advocates and other patient stakeholders in the materials development and review process, but do not expect them to be the writers, designers or content providers. Hire professionals to do this.
- Test your messaging and recruitment materials among members of the study population before seeking IRB approval. Offer them a stipend/gift card/compensation for their assistance.
- Adapt study consent and patient-facing communications into culturally competent materials in key languages when recruiting participants who might not be fluent in English. Test materials with native speakers who represent the participant community.
- Consider setting up a website to provide details about the study and to encourage participation from a broad and diverse community.
- Consider setting up Twitter and Facebook accounts, but make sure there is someone who will keep them updated, interesting and moderated. Make sure to get IRB approval of shorter versions of your recruitment language for social media—longer messages are not conducive to social media.

## EXAMPLES OF PATIENT-FRIENDLY LANGUAGE FOR STUDY DESCRIPTIONS

INSTEAD OF THIS TERM	CONSIDER USING THIS TERM
Adverse event	Side effect or harmful effect
Cohort	Group or sub-group
Comorbidity	Other illnesses or diseases people may have
Familial cancer	Heredity cancer or cancer that runs in the family
Germline mutation	Inherited mutation
Identify	Look for
Intervention	Treatment/Tool/Test
Mutation carrier	Person with an inherited mutation
Pathogenic variation	Mutation
Patients who failed treatment	Patients whose cancer got worse or returned during or after treatment
Progression free survival	The amount of time before a patient's cancer grows or gets worse
Somatic mutation	Tumor mutation or acquired mutation
Subjects	Participants
Treatment arm	Group receiving treatment
Trial	Study

## ADDRESSING QUESTIONS AND CONCERNS RELATED TO PATIENT STAKEHOLDER ENGAGEMENT

Below we address some questions and misperceptions about patients' ability to contribute to the research process.

**QUESTION:** Can patient stakeholders contribute meaningful input into the design of research studies?

**OUR EXPERIENCE:** Many investigators have shared that engaging FORCE advocates enhanced their study design.

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*The FORCE advocates provided invaluable feedback on my research study and survey materials. They brought up issues that I hadn't considered, helped me clarify my research goals, and led me to refine the questions that I asked participants. Having patients involved in the research process changed my study for the better.* – Claire Conley, PhD, Assistant Professor, Georgetown University

**CONCERN:** Patients do not have enough training to understand the science or the research process.

**OUR EXPERIENCE:** Most clinical research can be described in plain language that is understandable to patients. Many organizations (including FORCE) have programs that train people with no scientific background to engage as advocates in research. Advocates can help researchers more clearly explain the science in straightforward terms, which will be needed for consent forms, lay abstracts and patient-facing communications. Patient stakeholders can review these materials to see if they are understandable and engaging.

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*Advocate input led us to modify our goals somewhat to increase the potential relevance/application of the work.* – Karlene Cimprich, PhD, Professor of Chemical and Systems Biology, Stanford University School of Medicine

**CONCERN:** Most patients are not interested in the science behind research.

**OUR EXPERIENCE:** Many patients and researchers report their bi-directional research interactions as interesting and engaging. Many researchers find that patient stakeholders bring fresh ideas to the team, bring up important points that need to be addressed and demonstrate how meaningful successful research can be on a personal level.

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*Patient participation creates a motivating synergy for all stakeholders and can accelerate research advances and relieve the frustration patients feel when we are just bystanders in a process, which is critically important to us.* – FORCE research advocate

*The ability to interact with scientific researchers and to discuss advocacy for patients and hear the latest scientific advancements was incredibly fulfilling.* – FORCE research advocate

## FORCE HAS TOOLS FOR RESEARCHERS

FORCE has tools to help you successfully engage patient stakeholders in your clinical research efforts.

- **TRAINED ADVOCATES:** Through our FORCE Research Advocate Training Program (FRAT), we train consumers to participate as partners and research advocates in every phase of research and will match them to your project needs. Whether you need a patient embedded in your research team, people to review or pilot your materials, or feedback on consent forms, our trained advocates are here to help.
- **RECRUITMENT ASSISTANCE:** FORCE can provide multi-touch recruitment assistance for your clinical research studies that are enrolling people with an inherited mutation or a hereditary cancer diagnosis. We provide recruitment assistance for screening, prevention, treatment, quality -of-life studies, research registries and surveys.
- **COMMUNITY INPUT ON RESEARCH DESIGN OR APPROACH:** FORCE has a broad reach into the hereditary cancer community, serving constituents who are at elevated risk for all types of cancer across the cancer continuum. We partner with large and small organizations to reach a diverse cross-section of the hereditary cancer community. FORCE can gather community input on your study design or key components of your research project.
- **RESEARCH RESULT DISSEMINATION AND IMPLEMENTATION:** FORCE has communication channels that allow us to share research results with key stakeholders, including patients, clinicians and caregivers. Examples include:
  - Summarizing research through our eXamining the Relevance of Articles for You (XRAY) program translates research findings into plain language and helps patients understand the clinical relevance of the research and apply it to making health care decisions.
  - Creating a video animation that explains the results for easy dissemination.
  - Writing and disseminating a blog based on your results.

## ADDITIONAL RESOURCES:

- [FORCE Research Collaboration Request Form](#)
- [FORCE Research Search and Enroll Tool](#)
- The Collaborative Institutional Training Initiative (CITI Program)
  - [Community-Engaged and Community-Based Participatory Research Training](#)
  - [Human Subjects Research](#)
- [Center for Clinical and Translational Science Training Center](#)
  - [Community Involvement in Research Training](#)
- [Enabling, Reinforcing and Rewarding Patient Advocate Engagement \(training by TeamScience@SWOG\)](#)
- [How Advocates Support the Clinical Trial Lifecycle](#)
- National Clinical Trials Network (NCTN) Groups Patient Advocate Committees
  - [Alliance for Clinical Trials in Oncology](#)
  - [ECOG-ACRIN Cancer Research Group](#)
  - [NRG Oncology](#)
  - [SWOG Cancer Research Network](#)
- [National Health Council Patient Engagement Activities Framework](#)
- [PCORI Compensation Framework](#)
- [FDA Patient-Friendly Language for Clinical Trials](#)
- [FDA Guidance: Enhancing Diversity in Clinical Trials](#)

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