

## 2020 Tufts CTSI Pilot Studies Program Stakeholder Engagement Plan Toolkit

Clinical and translational research is most relevant and impactful when it addresses issues important to patients, communities, caregivers, clinicians, researchers, and other individuals invested in the translation of research discoveries into impact on health. Stakeholders also provide perspectives, knowledge, skills, and awareness of unmet needs that can stimulate productive questions and highlight crucial evidence gaps, thereby helping us to improve all aspects of research: from problem identification and specification, protocol design and recruitment, through interpretation and dissemination.

Stakeholder engagement plans became a required section of the Pilot Studies Program application beginning in 2019. Our survey of 2019 applicants indicated that a vast majority of our research community (72.1%) considered stakeholder and community engagement to be extremely, highly, or moderately relevant to their study proposals; however, most (62.5%) had little or no prior experience conducting research with stakeholders and/or community members. Nearly half (43.4%) found developing an engagement plan moderately or very difficult. In response to these survey results, we developed this toolkit that provides practical advice on stakeholder engagement plan development and describes its review process and criteria in detail.

### **GENERAL GUIDANCE**

- ✓ Be specific. Propose a stakeholder engagement plan that is focused and supports the overall objectives of your particular research project.
- ✓ Be realistic. Take into account your research team's strengths and weaknesses. Consider what you can accomplish individually and as a team.
- ✓ Do not delay. Timely engagement is an imperative. Make sure you have enough time to get feedback and comments from those who have a stake in your proposed research project.
- ✓ Explain the *who*, *what*, *when*, *where*, *why*, and *how* of your stakeholder engagement strategy in a clear and concise manner. Include enough background information and detail to enable reviewers to accurately assess your proposed plan. You may include tables and figures to help reviewers visualize your proposed engagement structure and timeline.
- ✓ Integrate elements of your stakeholder engagement strategy throughout your application. The stand-alone stakeholder engagement section is meant to give you an opportunity to present the specific details of your plan, but the remaining sections of the application are there to support it.
- ✓ Whenever possible, provide letters of support to demonstrate a real connection with the identified stakeholders. They can be uploaded in the Additional Supporting Documents section.
- ✓ Do not leave the stakeholder engagement plan section blank, even if you think stakeholder engagement is not relevant to your specific project (or that you have covered it elsewhere). Incomplete applications will not be considered for funding.
- ✓ Tufts CTSI is here to help. Reach out to us for assistance by requesting a consultation at <https://informatics.tuftsctsi.org/pims/> or contacting us at [pilots@tuftsctsi.org](mailto:pilots@tuftsctsi.org).

## **ENGAGEMENT TIPS**

As you write your plan, it is important to think through how the engagement will actually work. Below are some suggestions:

- ✓ Before you start developing your stakeholder engagement plan, identify your stakeholders. This includes a range of individuals and groups who may be affected by your research project and/or who may have an impact on your research project. Assess the investment of each stakeholder group is by considering their level of interest, influence, and power.
- ✓ If using the [7Ps framework to identify stakeholders](#) (patients and public, providers, purchasers, payers, policymakers, product makers, and principal investigators), provide a compelling rationale for involving those stakeholders who are most relevant to your proposed project. There is no expectation that all seven groups of potential stakeholders would be involved.
- ✓ Consider all stages of your research project, from design to dissemination, that might be relevant to engage stakeholders. Engagement may start in the project identification and development phase and continue through the study design, implementation, and result dissemination phases.
- ✓ Think and plan ahead. Intentionally apply a stakeholder engagement lens to ensure your proposed research project achieves its intended results and that you and your team reach your intended audiences.
- ✓ Avoid linear thinking. The flow along the translational continuum is often bidirectional. Discoveries made by early translational phase investigators can inform the work of late translational phase investigators and vice versa. For example, observations made in clinical practice may circle back to inform pre-clinical research.
- ✓ Consider budgeting support to effectively involve the identified stakeholder groups in your proposed research project. While their institutions may not be considered as funded sites for a multi-site proposal, you have the option of subcontracting services provided by and/or signing a professional service agreement with them.
- ✓ Stakeholder engagement is a two-way street and works best when there is a balance between give and take. It requires a strong commitment to collaborative work and direct and meaningful interaction with those involved.
- ✓ Tailor your engagement and communication strategies to meet the specific needs of your unique partnerships with each stakeholder group. Ensure that you interact with your stakeholders in a culturally-appropriate and inclusive manner using language they understand.
- ✓ Building trust, respect, mutual understanding, and shared vision takes time and effort. Do not get discouraged if you are not able to win everyone over. Also, remember to follow up with any of your stakeholder collaborators even if your project does not get funded.
- ✓ Be flexible. Do not treat your initial plan as if it is cast in stone. Be ready to revise it as your project evolves.

## **STAKEHOLDER ENGAGEMENT PLAN REVIEW**

Each stakeholder engagement strategy will be reviewed by at least two members of the Tufts CTSI Stakeholder Expert Panel (comprised of community members with diverse professional and cultural backgrounds who will primarily review stakeholder engagement strategies of proposals along the T2-T4 translational continuum) or the Tufts CTSI Stakeholder and Community Engagement Task Force (comprised of Tufts CTSI staff and faculty with expertise in early-stage translational research who will review stakeholder engagement strategies of proposals along the T.5-T1 continuum). Both reviewer groups will evaluate each applicant's ability to identify relevant stakeholders, engage these stakeholders in the research project, and articulate relevance of project outcomes to the identified stakeholder groups and the public based on criteria below.

*Stakeholders* – ability to name key stakeholder groups and determine the role they play or may play in the project.

1. Are key stakeholder groups directly and indirectly affected by the proposed project or that affect the proposed project clearly defined and described?
2. Does the plan provide a compelling rationale for engaging a subset of the identified stakeholders in the research project? If so, are these individuals or groups defined using an explicit criterion (e.g., specific

condition, focus of study, common field of interest, cultural or ethnic background, prior experience, geographic location)? Is the reasoning for their engagement clearly explained?

3. If applicable, does the plan describe how the identified stakeholder groups have been involved in the conceptualization of the project and development of research procedures (e.g., defining or refining research question(s), designing research protocol(s), and identifying research participants)?
4. Is the existing or proposed involvement of the identified stakeholder groups described adequately to assess the role(s) these groups currently play or will play in the project?
5. Does the plan demonstrate the depth of stakeholder engagement and strength of collaborative partnerships? Does it offer evidence that the identified stakeholder groups will play a meaningful role in the project and/or that they will be involved as partners who have a say in the project?
6. If a letter of support is provided, does it reflect an authentic connection with the project's principal investigator and/or research team? Does it offer an insight into how those involved have collaborated in the past or will collaborate in the future?

*Approach* – rigor of the proposed stakeholder engagement plan to meet proposed objectives and goals.

1. Does the plan support the overall objectives of the proposed research project?
2. Does the plan describe how the knowledge, experience, and expertise of the identified stakeholders will be practically applied in the implementation of the proposed research project (e.g., recruitment of participants, data collection and/or analysis, interpretation of findings, verification of conclusions)? Does the proposed engagement strategy foster solid, bidirectional relationships that promote collaboration and an atmosphere of mutual trust and understanding?
3. Is the proposed communication strategy adequate and tailored to meet the specific needs of each partnership with the identified stakeholder groups?
4. As proposed, is the plan realistic? Does it have a high likelihood of being successfully implemented during the award's one-year timeframe? If circumstances were to change, is the plan sufficiently flexible to allow for modifications?

*Relevance* – ability to demonstrate explicit relevance of the project and its outcomes to the identified stakeholder groups and the public.

1. Does the plan provide a clear statement of the project's specific relevance to the identified stakeholder groups? Is the statement supported by compelling and logical reasoning?
2. Does the project address a pressing and/or overlooked health issue impacting the well-being of specific populations (or the public)?
3. Does the plan describe the value and impact of the proposed research project to the identified stakeholder groups and/or specific populations?
4. Does the plan explain how the identified stakeholder groups and/or specific populations will benefit from research outcomes? If so, does the plan specify what the applicant will do to ensure appropriate follow-up?
5. If the aims of the project are achieved, how likely is it that the project's outcomes and results will be applied (e.g., applied in the form of new interventions, treatments, or devices; implemented into clinical practice; used to advance translational science or to inform health policy)?

## **RESOURCES AND SERVICES**

### *Resources*

- ✓ Agency for Healthcare Research and Quality (AHRQ)'s resources on [Engaging Stakeholders in the Effective Health Care Program](#)
- ✓ Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). [Principles of Community Engagement](#). NIH Publication, 11-7782.
- ✓ Concannon, T. et al. (2012). [A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research](#). Journal of General Internal Medicine, 27(8):985-991. PMCID: PMC3403141
- ✓ Concannon, T. et al. (2019). Practical Guidance for Involving Stakeholders in Research. Journal of General Internal Medicine, 34(3):458-463. PMCID: PMC6420667

- ✓ Conversation with Drs. Jonathan Garlick, DDS, PhD and Thomas Concannon, PhD about [how T1/basic researchers can use stakeholder engagement to strengthen their research team and impact population health](#)
- ✓ [I LEARN Online Training](#) materials on stakeholder and community engagement
  - [Stakeholder and Community Engagement: Why It's Important](#) by Laurel K. Leslie, MD, MPH
  - [Stakeholder and Community Engagement: Lessons Learned](#) by Laurel K. Leslie, MD, MPH and Carolyn Rubin EdD, MA
  - [Methods of Stakeholder Engagement](#) by Carolyn Rubin, EdD, MA and Laurel K. Leslie, MD, MPH
  - [Community Engagement to Improve Asian Health](#) by Carolyn Rubin EdD, MA and Mei-Hua Fu, MS, Med
  - [Stakeholder Engagement in Patient-Centered Comparative Effectiveness Research](#) by Thomas Concannon, PhD
  - [Preparing for Patient-Centered and Stakeholder-Engaged Research](#) by Thomas Concannon, PhD
  - [Civic Life and Health Research](#) by Thomas Concannon, PhD and Peter Levine, PhD
  - [Engaging Stakeholders in Community-Based Participatory Research Partnerships](#) by Thomas Concannon, PhD and Carolyn Rubin, EdD, MA
- ✓ Patient-centered Outcomes Research Institute (PCORI)'s [the Value of Engagement](#) online resources and [Sample Engagement Plans](#)
- ✓ The Alliance for Research in Chicagoland Communities (ARCC) [resource directory for community partners, healthcare providers, and academic partners](#)
- ✓ Tufts CTSI's [Community Engagement Tools and Resources](#)
- ✓ Tufts CTSI's [Community Member's Guide to Submitting a Community-Engaged Research Federal Grant Applications](#)

#### Services

- ✓ Request an in-person or virtual consultation free of charge with the Tufts CTSI Stakeholder and Community Engagement Program Team by submitting a service request consultation at <https://informatics.tuftsctsi.org/pims/>.
- ✓ Reach out for assistance by contacting the Pilot Studies Team at [pilots@tuftsctsi.org](mailto:pilots@tuftsctsi.org).
- ✓ Attend a virtual drop-in session offered by the Pilot Studies Program Team on Tuesdays and Fridays from 4:00 to 6:00PM July 30 through September 27. To attend, go to [WebEx](#) and enter meeting number 852 300 353 and password "CTSI".

## **CASE STUDIES**

Stakeholder engagement plans should reflect the needs of their particular studies and thus can be structured in various ways. What follows is a small sample of engagement plans along with "key observations" on the strategies and activities they contain. The case studies are meant to illustrate *some* potential approaches applicants might consider. They may not fit every research team's unique circumstances and are not meant to serve as "models" that have to be followed.

#### *Case Studies Included:*

1. Development of an Animal-assisted Intervention to Promote Physical Activity and Nutrition in Youth with Autism
2. Development of Novel Behavioral Intervention for Sustainable Weight Loss in Obese Hispanic Adults
3. In-home Prostate Cancer Monitoring Using a Smartphone-based Application

*Disclaimer:* Case studies #1 and #2 have been generously provided by research teams funded by the Tufts CTSI Pilot Studies Program. They represent real-life cases but the names and other sensitive information have been changed or omitted to protect the privacy of the identified stakeholders. Case study #3 is a fictitious composite drawn from a variety of sources. Any resemblance to actual plans, projects, or events is unintentional and purely coincidental.

## CASE STUDY 1

### Development of an Animal-assisted Intervention to Promote Physical Activity and Nutrition in Youth with Autism

*This example was generously provided by Drs. Deborah Linder, DVM, Cummings School of Veterinary Medicine at Tufts University and Christina Mule, PhD, Tufts Medical Center.*

#### **Award grant summary:**

Investigative Team: Our team represents an innovative One Health collaboration that spans veterinary and human health and is uniquely able to achieve the project goals due to our combination of strengths. Dr. Linder is a board-certified veterinary nutritionist at the Tufts University Cummings School of Veterinary Medicine as well as co-director of the Tufts Institute for Human-Animal Interaction who brings knowledge and experience in AAI and pet obesity. Dr. Mulé is a pediatric psychologist at the Center for Children with Special Needs at Tufts Medical Center and assistant professor in the Department of Pediatrics at Tufts University School of Medicine. She has extensive expertise in the diagnosis and treatment of autism, physical activity promotion in autism, as well as stakeholder engagement. [ . . . ] This investigative team is joined by a panel of stakeholders, who will bring their own expertise. These stakeholders have successfully collaborated previously with members of the core investigative team, both in research and clinical work, and we anticipate continued successful partnerships.

#### **Stakeholder engagement plan:**

Stakeholder input will be integral to both aims of this study and our stakeholder panel will be involved throughout the pilot award period, as noted in the Research Procedures. Our stakeholder panel will be comprised of five individuals each with expertise and experience in one or more aspects of the project. This panel will consist of a provider of animal-assisted intervention (Ms. Y.), an applied behavioral analysis therapist (Mr. C.), two parents of children with autism (Ms. P. and Ms. F., who also is a project director of the Organization A.), and an individual with autism. Ms. G., who works at the Organization T., is a licensed instructor with years of experience in evaluating safety and efficacy of human-animal partnerships for AAI. More specifically, she is also involved in AAI work for children with disabilities. Dr. C. is the board-certified behavior analyst that we have recruited for our panel. Dr. C. specializes in treating children with autism and is well-aware of the challenges these individuals face with weight maintenance. Their experience practicing ABA with children with autism means they will provide a hands-on perspective in the development of the curriculum. The two parents that will be involved are Ms. P. and Ms. F., each with different backgrounds and insight into raising a child with autism. Ms. P. and her daughter primarily experienced challenges with language development and behavior regulation while issues with weight maintenance were emerging in the background. Ms. F. has a young adult with autism, is the owner of two pet dogs, works for the Organization A., and has been involved in autism advocacy groups. She has personal experience observing the relationships between pet dogs and her child with autism and professional experience working with other families and insurance agencies. Our final stakeholder is expected to be a young adult with autism who, with a degree in sociology, brings both the autism perspective and an understanding of research. We were unable to obtain a letter of support in time for the proposal submission. If this individual is unable to participate, we will draw upon our collective network to identify another suitable person for the stakeholder panel. In addition to the role they will play as outlined in the Research Procedures, members of the stakeholder panel will be involved in dissemination of study results. They will help prepare conference abstracts and publications, and will receive authorship credit, as appropriate. They will help the study team disseminate results to non-scientific audiences such as parent support groups and advocacy groups. They may present results at local chapters of larger organizations, such as the Organization B.

#### **Key observations:**

- ✓ Stakeholder panel members are clearly identified and their qualifications discussed. Members have complementary skill sets and subject matter expertise through both professional and lived experiences. Contingency plan is included (review criteria 1 and 2 – *stakeholders* and *approach*).



- ✓ Stakeholder panel members are an integral part of the investigative team. Their involvement in all key steps of the work is detailed throughout the proposal (review criteria 2 and 3 – *approach* and *relevance*). Below are excerpts from the Research Procedures section:

### **Research procedures:**

Stakeholder input in development of physical activity and nutrition modules: In child obesity prevention programs generally, stakeholder engagement in the development phase has been shown to improve uptake of an intervention, inclusion of underrepresented populations, and engagement by participants; and to support positive outcomes. For Aim 1, we will prepare an initial draft of the facilitator's guide and the two curriculum modules. The first stakeholder meeting will be used to review the facilitator's guide. The draft will be shared with our stakeholders in advance of our meeting so that members will have time to prepare thoughtful feedback utilizing a structured feedback form. During the meeting, stakeholders will be asked to share their initial impressions of the facilitator's guide, feasibility concerns/appropriateness of the intervention for children with autism, personal experiences that relate to working with children with autism and AAI, and we will discuss how these experiences should be incorporated or accounted for in the guide. Following this meeting we will revise the facilitator's guide based on stakeholder input. Our second stakeholder meeting will be used to review Modules 1 (physical activity) and 2 (nutrition). During this meeting, stakeholders will be asked to provide their feedback using another structured feedback form that aims to understand appropriateness of intervention for children with autism in an ABA setting and any feasibility concerns. Following this meeting we will revise the modules based on stakeholder input. Once revisions have been made to both the facilitator's guide and Modules 1 and 2, revised documents will be circulated to the stakeholder panel for a second review. Stakeholders will be asked to complete a feedback form and submit it back to the investigative team so that additional revisions can be made to the curriculum before it is piloted tested in Aim 2 of the study.

Stakeholder input for facilitator guide development: Our third stakeholder meeting will be used to review semi-structured guides for the in-depth interviews with ABA therapist, parents, and children. Draft guides will be shared with the stakeholder panel prior to our meeting. During the meeting, stakeholders will be asked to share their perspectives on how the guide can be strengthened. Following this meeting we will revise the guide based on stakeholder input.

Stakeholder input in interpretation of findings and dissemination: In the fourth and final meeting, the stakeholder panel will be presented with preliminary findings from both the quantitative usability rating scale and the in-depth interviews. Stakeholders will be asked to assist in interpreting the information (how results resonate with their own experiences of the curriculum) and making additional modifications to the curriculum based on the feedback of participants. Finally, they will also be asked to help the team address its plan for dissemination of results to the broader community and generate plans for next steps, including future study designs.

- ✓ Letters of support that demonstrate a real connection with the identified stakeholders are provided (review criterion 1 – *stakeholders*). These letters are not included in the case study materials to protect the privacy of those involved.
- ✓ Stipends for stakeholder panel members are built into project budget (review criterion 2 – *approach*).

### **Budget:**

Stipends for Stakeholder Panel: The stakeholder panel represents a crucial component to the success of this study. This panel, comprised of an AAI specialist, an applied behavior analysis (ABA) therapist, two parents of children with autism spectrum disorder (ASD), and an individual with ASD (TBD), will provide valuable information and feedback in the curriculum development phase. Stakeholder meetings will be held quarterly for the duration of this study. Including communication between formal meetings, stakeholder involvement is budgeted at \_\_\_ hours per person. A total of \$\_\_\_\_\_ (\$\_\_\_ per stakeholder) is requested for the stakeholder panel.

## CASE STUDY 2

### Development of Novel Behavioral Intervention for Sustainable Weight Loss in Obese Hispanic Adults

*This example was generously provided by Drs. Susan Roberts, PhD, and Maria Carlota Dao, PhD, Tufts University Jean Mayer USDA Human Nutrition Research Center on Aging.*

#### **Award grant summary:**

This research initiative addresses the lack of effective lifestyle behavioral interventions to induce clinically impactful weight loss in US Hispanics, and the lack of knowledge about facilitators and restrictors of weight management in older adults of Hispanic background with obesity. Of note, participants and members of the community will be involved throughout the research process, and in the planning of subsequent steps, and two Hispanic junior faculty team members will be strongly involved in the project.

#### **Background and significance:**

Obesity is a major cause of chronic diseases such as type 2 diabetes (T2D), and is becoming more prevalent in groups of various races and ethnicities. In the US, Hispanic adults have a prevalence of obesity of 42% compared to 36% in non-Hispanic whites, and nearly twice the prevalence of T2D. With aging demographics around the world, elderly populations are being severely impacted by obesity, related chronic diseases and their complications. Obesity and chronic disease risk have not been studied in detail in the older US Hispanic population, providing an important impetus for the proposed project. It is particularly noteworthy that, even though overweight Hispanic adults have reported a greater intention to lose weight than other groups, research studies indicate that current approaches are particularly ineffective in this population generally, and no interventions have directly targeted Hispanic older populations.

#### **Stakeholder engagement plan:**

The main stakeholders for this research will be Hispanic adults, government agencies that support Hispanic health and nutrition, and Organization A. By publishing the results and presenting them at major national meetings, we will engage with relevant stakeholders for future larger projects based on the work proposed here. In addition, local Hispanic adults will be involved in the design of the intervention, recruitment, and implementation of the project. The research team specified in this proposal will be primarily responsible for the conceptualization of research design and delivery of the intervention, while members of the community and study participants will be actively involved in the cultural adaptation of Intervention H., as well as in summarizing the analysis of qualitative data. To this end, a feedback session with participants will be organized at the end of each testing cycle of the intervention to collect information on strengths and weaknesses of the tested iteration. In the future, when new grants are prepared to test the intervention at a larger scale, feedback from the community will be sought during the study design period. Research findings will be disseminated to the scientific community through peer-reviewed publications, and to the engaged community through presentations, first during a project kickoff meeting and finally in a project wrap-up meeting where results will be summarized (see Description of Next Steps). Dr. Dao and Dr. C. will present findings and prepare paper drafts as part of the study plan. The possibility of involving our participants in the CTSI Stakeholder Expert Panel will also be explored. CTSI will also be consulted to establish connections with other potential stakeholders at Tufts and beyond for whom these findings will be of interest.

#### **Key observations:**

- ✓ Relevance of the project to the study population is demonstrated (review criterion 3 – *relevance*).
- ✓ Roles and responsibilities of key personnel and the identified stakeholder groups are clearly defined (review criterion 1 – *stakeholders*).
- ✓ Stakeholders are included in more than one part of the research process. References to specific stakeholder engagement activities are made. Future action steps are reported (review criterion 1 – *stakeholders*).

- ✓ Study participants' needs are taken into account and they are met where they are (review criteria 1 and 2 – *stakeholders* and *approach*). Below is an excerpt from the Research Methods section:

**Research procedures:**

A community participatory approach will be used to develop a tailored lifestyle program. The process will involve identification of issues that are important to Hispanic older adults in addressing perceived barriers and promoters of healthy weight control, acceptable foods, meeting format and style, communication style and language for such factors as motivation, goals and adherence. [ . . . ] Participants will be recruited with the assistance of local contacts [ . . . ] The study will be advertised locally in community centers, health centers, other local meeting sites, and in social media. We are mindful of the wide diversity of Hispanic cultures, which has never been thoroughly addressed in any previous Hispanic-focused weight management research; given the location of this project we expect to include individuals of South American, Caribbean, and Central American (including Mexican) origin and will routinely capture information on country of birth and number of years living in the US, and administer questionnaires to have data on degree of acculturation. [ . . . ] All participant meetings (focus groups, interventions, outcome assessments) will be conducted locally at community centers and other meeting spaces, including at YMCA, at times convenient to participants. [ . . . ] The focus groups will be conducted in Spanish and English as appropriate by Dr. Dao (a Hispanic team member and native Spanish speaker).

- ✓ Involvement of stakeholders is detailed in different sections of the proposal (review criteria 2 and 3 – *approach* and *relevance*). Below are excerpts from the Research Procedures and Description of Next Steps sections:

**Research procedures:**

Participant feedback will be obtained on perceived barriers to success with a combination of structured and open-ended questions presented to participants during the final program week by a community member who is not part of the intervention delivery team. The program will be revised iteratively to improve adherence with each revision, weight loss and drop out.

**Description of next steps:**

If pilot testing of the adapted intervention does not result in significant weight loss and adherence within the test period, barriers to successful outcomes will be identified through debrief sessions with community members and participants. These barriers will be addressed in future projects, and will also be reported in a peer-reviewed publication, and used to inform subsequent steps in this line of research.



## CASE STUDY 3

### In-home Prostate Cancer Monitoring Using a Smartphone-based Application

*Please note that this case study represents a fictitious stakeholder engagement plan. Any resemblance to actual plans, projects, or events is unintentional and purely coincidental.*

#### **Stakeholder engagement plan:**

Our research plan involves both technical development of robust and reliable algorithms and a user-centered design process aimed at ensuring the tool is appropriately designed for users in both clinical and at-home settings. As described in our approach, our primary goals for involving stakeholders are to improve the acceptability of the app, to identify potential safety concerns or impediments to its usability, and to inform the design and implementation of a successful strategies for recruiting and sustaining the commitment of study participants. Our stakeholders' participation will strengthen the project's relevance and assist in dissemination of its results.

A consultation with CTSI's SCE program informed our analysis of the stakeholder communities we could reasonably engage in a pilot project. At this stage of our research, our focus is on a primary set of direct users:

*Patients, caregivers, and advocates:* Our project has benefited from ongoing informal consultations we have had with Foundation C., the largest patient support and advocacy foundation for men with prostate cancer. Over the past decade, Foundation C. has increased its focus on conducting research toward new treatments and has a current priority on data and tools to address the "diagnostic odyssey" endured by patients. Foundation representatives we interviewed were excited to learn of our efforts and enthusiastic about the involvement of patients as advisors (see letter of support). We were fortunate to be put in touch with two individuals in the Boston area who volunteer as ambassadors for the foundation, advocating on the need for research. One is a person with the disease (Mr. T.), the other a patient caregiver (Ms. M.). Two additional patient advisors (Mr. H. and Mr. K.) were known to us from previous collaborations.

*Clinicians and practice staff:* We concentrate on specialists at referral centers, who most often make diagnostic decisions in these cases. Those we spoke with pointed to potential challenges to integrating the technology into clinical practice. Importantly, we have included on the panel an oncology nurse and a quality improvement specialist (Ms. S.) who has over 25 years of experience working in this field. She will play an instrumental role in helping identify issues related to workflow and research process improvement.

*Researchers and health technologists:* The late stage at which over 30% diagnoses are confirmed has been a recognized challenge for clinical development programs. The next phase of this project will include drug developers and other representatives of the research community. Specifically, we will work with one expert (a urologist/researcher, Dr. M.) who has been an active participant in national discussions over health IT standards (see letter of support).

#### **Key observations:**

- ✓ A consultation with the Tufts CTSI Stakeholder and Community Engagement Program mentioned (review criterion 2 – *approach*).
- ✓ Stakeholder groups are clearly identified. They include those who can be reasonably engaged in the proposed project (review criterion 1 – *stakeholders*).
- ✓ Rationale for including the identified stakeholder groups is provided and their past involvement is described in adequate detail (review criteria 1-3 – *stakeholders, approach, and relevance*).
- ✓ Elements of stakeholder engagement strategy are integrated into other sections of the proposal (review criteria 2 and 3 – *approach and relevance*). Below is an excerpt from the Research Procedures section:

**Research procedures:**

Advisory group meetings: An initial advisory group meeting will focus on the study plan. We intend to involve the group in reviewing participant information and consent forms. This will be especially important to identifying issues related to participant safety and ensuring study visits and at-home procedures are sensitive to the needs of men with prostate cancer. The advisory group will then meet twice to review iterations of the user interface and report formats. The focus of these reviews will be on improving the acceptability and usability for both patients and clinical staff. Proposed modifications will be discussed as a team. Results and a dissemination plan will be discussed at a final meeting.

- ✓ Letters of support that demonstrate a real connection with the identified stakeholders are provided (review criterion 1 - *stakeholders*).<sup>1</sup>
- ✓ Engagement and communication strategy are tailored to meet the specific needs of the identified stakeholder groups. Stipends for advisors are built into project budget (review criterion 2 - *approach*). Below is an excerpt from the Research Procedures section:

**Research procedures:**

We will encourage in-person attendance at all meetings but recognize that this will be a challenge for some and are prepared to facilitate either telephone or video participation. We focus on meetings of the whole group, feeling that the central objectives for these (usability) would be of equal interest to all. We want to create an atmosphere that actively involves patients and other non-scientists. As mentioned, the patient community advisors each have some level of familiarity with research; however, the PIs will prepare them by discussing core concepts relevant to diagnostic biomarker research in advance. We also recognize that some technical issues would not be suitable for the full group and will pursue discussion of these through individual consultations, which we will summarize for all at the subsequent group meeting. As described in our budget, we will compensate advisors equally for their assistance.

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<sup>1</sup> These letters are not included in the case study materials. For general guidance on Letters of Support, please see "[Hit the Sweet Spot for Letters of Support](#)" article by the NIH/NIAID.