Patient Engagement Workbook

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HCSRN Patient Engagement in Research Scientific Interest Group [PER SIG]

10/2/14

Using this workbook

WHO?

- Research staff preparing to engage patients (or other stakeholders) as members of their research teams

WHEN?

- As soon as a decision is made to engage patients in the research process, whether or not a specific study or research question has been identified

HOW?

- This workbook walks research staff through the steps of, and considerations and suggestions for, the engagement process.
- Print the workbook one slide per page for a printed manual
- Use the spaces provided for notes or other documentation of decisions made about your engagement process.

STUDY Information:

- Title: ___________________________________

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- Principal Investigator:

____

- Study begin/end dates:

__________________ - ____________________

- Engagement Plan completed by:

____

- Date: _______________

I. Why Engage Patient Partners on This Study?

Justify the need for engaging patients on the research team:	**Notes:**
Is engagement required for the study proposal?	
How will the patient perspective enhance the study?	
How much will it cost to engage patients on the study? (see following slides)	
Do the benefits of engagement outweigh the costs?	

***OUTCOME**: Reasons for engagement are clearly articulated*

TIP: Estimating Costs of Engagement (1/2)

Consider cost of time to:	Notes:
Identify and recruit patient partner(s)	
Train patient partner(s) and research team	
Consult with IRB/Compliance	
Consult with HR, IT, Sponsored Projects, or Member Relations	
Other	

Tip: Estimating Costs of Engagement (2/2)

Consider costs of:	Notes:
Compensating patient partner(s)	
Reimbursing partner(s)’ expenses (transport, mileage, etc)	
Travel for patient partner(s) to conference(s) to present study findings	
Other	

II. Define the role(s) of patient partner(s) on the team:

Roles	#	Stage(s) of Research	Define the roles and list the responsibilities
Advisory panel member			
Steering committee member			
Co-investigator			
Focus group member			
Consultant			
Research staff: who will have primary responsibility for communicating with patient partner(s)?			

***Outcome**: Clear role statement(s) for patient partners*

III. Engagement Logistics

For each patient partner to be engaged, answer the following:	
How often will s/he be needed and for how long?	
When will s/he be needed?	
Where will s/he need to go?	
How many weeks/months/years will s/he be needed?	
How much will s/he be compensated?	
In person or virtual participation?	
What kind of contract(s) will be needed?	

***OUTCOME**: Logistics are thought through; preparations begun*

TIP [1/2]: Compensation Considerations

Compensation depends on role(s) the patient partner(s) plays	
List any limitations or compensation restrictions below	**List planned means of sharing data with partner below**
• Organizational restrictions?	• Organizational email?
• Budget limitations?	• Personal email?
• Equity with other team members?	• Document sharing site?
• Other?	• Other?

TIP (2/2): Engagement Considerations

Context?	Contracting?
• Adopt compensation rates used in other studies – adequate?	• Any relevant organizational requirements?
• Use the government consultant rate? (recommended by PCORI)	• Volunteer basis (not recommended)?
• Will you reimburse participant travel? (recommended by PCORI)	• Consulting/service agreement?
	• Confidentiality issues?

IV. Identification & Recruitment of Patient Partners

Define any inclusion or exclusion criteria for recruiting patients to the team according to the specific needs of the study:	
Particular disease burden	
Particular demographic	
No exclusions apply	

***OUTCOME**: Clear description of patient population you want to target*

V. Recruitment: assess options and "fit" with study

Options:		**Options:**	
Existing patient panels or patient support groups		Social media	
Referrals from clinicians/providers		Internal patient registry	
Health system broadcast communications to members		Online "matching" registry	
Flyers in clinics		Flyers at disease specific fundraisers/community events	
Referrals from/network with community organizations		Local media advertising	

***OUTCOME**: Recruitment strategy(ies) that best fits study needs*

VI. IRB/Compliance

Review recruitment and engagement plans with IRB:	**Notes:**
Does your IRB require oversight or review of patient engagement?	
What documentation is required by your IRB for patient partners on your research team?	
Are you accessing PHI in your identification or recruitment processes?	
What are the potential risks – and benefits - to the patient(s) in joining the research team?	

***OUTCOME**: Clear guidelines to meet any IRB oversight requirements, or to receive formalized exemption*

VII. Other Departments

Review the implications of your recruitment and engagement plans with:	
Sponsored Projects office	
Human Resources	
IT	
Governance or Member Relations	

***OUTCOME**: Organizational approvals and cooperation in preparing for patient partners*

VIII. Prepare to Screen Promising Candidates

Select screening method(s):	
Personal interviews (phone or in-person)	
Survey or questionnaire administered remotely	
Previous participation on a study	
Prepare screening questions:	

Note: Characteristics of the ideal candidate(s) will depend on specifics of your study. Over-recruit to accommodate attrition during screening.

OUTCOME*: Prepared to select best candidate(s) for positions*

IX. Screening Practices (1/2)

Guidelines to Avoid Bias:	**Comments:**
Patient(s) shows ease expressing self, including when opposing views are aired	
No apparent desire for a platform to communicate dissatisfaction	
Previous experience in a similar capacity (e.g., in a school, faith community, etc.)	
Isn't already "savvy" about negotiating the health system (depends on role(s) – not necessarily a disadvantage)	
Is the study topic controversial? If so, determine whether patient holds extreme views for or against the topic. If so, how will that affect her/his participation?	

Screening Practices (2/2)

Communicate Logistics:	
Role on study	
Expectations for participation	
Study timeline	
Time requirements	
Compensation	
Training	
Ground rules	
Answer patient(s)’ questions; give her/him time to consider participation.	

***OUTCOME**: confirmed patient partner(s) who understand all aspects and expectations of participation.*

X. Research Team Training

Train current research team members in preparation for working with patient team members	
Review goals of engagement and role requirements for patient(s)	
Clarify expectations for patient(s) engagement	
Review any institutional restrictions (e.g., on information sharing)	
Emphasize the rules of engagement; the patient(s)' expertise is her/his experience as a patient	

***OUTCOME**: research team is prepared to work respectfully and effectively with patient partners.*

XI. Formalize

Complete on-boarding formalities with patient partner(s):	
Collect information for initiating the compensation mechanism	
Execute any contractual mechanism(s), including confidentiality agreements	
Provide organizational employee information as needed, including email address and password(s)	
Establish data sharing protocols	

***OUTCOME**: patient partner(s) is assured that her/his participation is formalized, and integration into research team is initiated.*

XII. Train Patient Partner(s)

Conduct as needed for your particular study:	
IRB/HIPAA/Human Subject training	
Health plan or organizational information; required health system training(s)	
Develop ground rules for participation, including grounds for termination	
Specifics of study; context, background, design, etc.	
Specific role(s) on the study and responsibilities for both research staff and patient partner(s)	
Timeline and logistics of participation: when, where, how long, how often	
Value of patient(s)' perspective, importance of speaking up, especially in disagreement or when unclear on an aspect of the study	
Training materials: glossary, acronym list, study abstract (if available), other	
Organizational policies (dress code, etc.)	

OUTCOME*: Patient partner(s) can be fully engaged in the study, feel useful and valued, and share her/his expertise willingly*

TIP: Retention of Patient Partner(s)

Honesty, Transparency, and Respect
Communication = the key to retention
Establish and maintain close relationships with the patient partner(s)
Send regular updates on project progress unless patient partner(s) attends frequent, regular meetings with the rest of the research team
Ask patient partner(s) what you can do for them to enhance the benefits to them of participation.
Maintain good partner relationships throughout lifetime of study, from pre=proposal through closeout and beyond.
Hold team buildings to enhance communication and relationships among all team members (FOOD helps!)

XIII. Monitoring and Evaluation

Schedule a regular opportunity for patient partner(s) to provide feedback on their experiences.	
Should be a "safe" space for truthful feedback	
Establish clear ground rules for facilitated group discussions	
Online or written evaluation	
Provide feedback to patient partner(s) on her/his participation	
Respond to patient partner concerns or issues	
End the patient partner's participation if necessary	
At the final evaluation, ask patient(s)' preferences for being contacted again in the future for information updates or possible participation in other studies	

OUTCOME*: Patient partner(s) feels heard and respected as valued study team member(s)*

XIV. Closure: End of Study

Sun-setting procedures:	
Share study results if patient partner(s) hasn’t been involved in later stages of study	
Make a formal expression of gratitude for patient partner(s)’ contributions	
Hold a team gathering to celebrate and say good-bye	
Provide a certificate of participation for patient partner(s)	

***OUTCOME**: Opportunity for all team members to reflect on value of study and relationships developed*

This is a working document. If you have comments or suggestions for improvement,

PLEASE SEND THEM TO:

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