## Patient and Public Involvement Planning Tool

			Planning for PPI & assessing its impact								
Торіс	Questions To Consider	Has this question been addressed?			Which PPI options are needed to answer this question						
		Yes		No Public		How will you Consultation with		Consultation /		How will you	
		When? (Pre-Award / Post- Award / Pre and Post Award)	Provide details including dates and type of PPI involvement and impact	If no provide reason	contributor/s on Trial Management Group	assess the impact of public involvement?		assess the impact of public involvement?	survey with larger group of public contributors	assess the impact of public involvement?	Other, specify
	Is this research question a priority for patients?										
Relevance	Has this topic / research question been prioritised by an existing project that had patient involvement e.g. James Lind Alliance Priority Setting Partnership: http://www.lindalliance.org/top-tens.asp?										
Outcomes	Does a core outcome set exist for this condition? (Consider whether the core outcome set was developed with patients / carers and how many).(e.g. http://www.comet-initiative.org/)										
	Do you know (from the expertise of a patient perspective) whether the outcomes intended for use in the study are relevant for patients (those outcomes that you intend to use in addition to the core outcome set, if one white new lawsterme it is desay (12)										
	exists, or all outcomes if it doesn't)? If you are developing patient questionnaires specifically for this trial do you know (from the expertise of a patient perspective) whether the questionnaires are relevant, appropriate and understandable? (E.g.										
	PROMIS - http://www.nihpromis.org/?AspxAutoDetect CookieSupport=1#2)										
	Do you know (from the expertise of a patient perspective) what ethical issues there may be with the trial? If there are potentially complex ethical issues										
Ethics	with the trial, has qualitative research already been conducted with patients with regards your approach to consent e.g. Deferred consent.										
	If there are potentially complex ethical issues with the trial, do you need to gain additional patient perspectives about the aforementioned complex ethical issues in your trial?										
	Has previous research been conducted with patients about specific methodological aspects of your trial?										
	Do you need to gain further patient perspectives on methodological issues relevant to your trial?										
	Do you know from the expertise of a patient perspective:										
	What potential patient preference     issues there may be with your trial?     What concerns patients might have with										
	the risks identified in this trial?										1

Topic	Questions To Consider	н	Which PPI options are needed to answer this question								
		۲ -When? (Pre-Award / Post	es Provide details including	No	Public contributor/s on	How will you assess the impact	Consultation with small group of	How will you assess the impact	Consultation / survey with	How will you assess the	
		Award / Pre-Award / Post- Award / Pre and Post Award)	dates and type of PPI involvement and impact	If no provide reason	Trial Management Group	of public involvement?	public contributors	of public involvement?	larger group of public contributors	impact of public involvement?	Other, specify
	<ul> <li>What concerns patients might have with the likely burden of your trial on a patient / family?</li> </ul>										
Logistics	<ul> <li>What practical issues patients might be concerned about with regards your trial (e.g. frequency / timing/ location of visits / interventions / examinations)?</li> </ul>										
	<ul> <li>What concerns patients may have with the planned investigations / interventions in the trial and the risks associated with these?</li> </ul>										
	<ul> <li>Whether there are specific issues that may be of concern for particular patient groups in your trial e.g. patients with additional learning needs / patients with specific beliefs / patients from co-morbidities / patients without transport etc.</li> </ul>										
	<ul> <li>How best to raise awareness about your trial to the appropriate patient group?</li> </ul>										
	<ul> <li>How best to maintain patient interest in this trial over time?</li> </ul>										
	• How to address recruitment challenges from a patient perspective during the trial?										
	Do you know (from the expertise of a patient perspective):										
	<ul> <li>How readable and understandable your plain language summary is?</li> </ul>										
	• How readable and understandable your patient information and consent forms are?										
	<ul> <li>How best to address any required changes to patient information sheets / consent forms during the trial to ensure that the changes are readable and understandable to patients?</li> </ul>										
	• What information patients might like to receive through your website / newsletters?										
	<ul> <li>How navigable / useful and understandable your patient information is on your website (at the outset and during your trial)?</li> </ul>										
	• How readable and understandable your newsletters are (if these are to be used in your trial)?										
	<ul> <li>How patients will want to be provided access to the study results at the end of the trial?</li> </ul>										

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	<ul> <li>How readable and understandable your</li> </ul>											
	end of study participant information sheets											
	are?											
	<ul> <li>The best ways of disseminating your</li> </ul>											
	study results to the wider patient community											
	at the end of your trial?											
	<ul> <li>How readable and / or understandable</li> </ul>											
	your information about the study results is											
	for the wider public (either as written											
Information and	information or as a presentation to patient											
dissemination	groups)?											
	Is your interpretation of the trial results / sub											
	study results, the same as patients /											
Trial results	members of the public might have?											

	Documenting PPI activities and impact									
	Which PPI options have been used to answer this question									
How will you assess the impact of public involvement?	on Trial Management	Impact of public involvement activity	Consultation with small group of public contributors	Impact of public involvement activity	Consultation / survey with larger group of public contributors	Impact of public involvement activity	Other, specify	Impact of public involvement activity		

	Which PPI options have been used to answer this question									
How will you assess the impact of public involvement?	Public contributor/s on Trial Management Group	Impact of public involvement activity	Consultation with small group of public contributors	Impact of public	Consultation / survey with larger group of public contributors	Impact of public involvement activity	Other, specify	Impact of public involvement activity		

	Which PPI options have been used to answer this question										
impact of public involvement?	Public contributor/s on Trial Management Group	Impact of public involvement activity		Impact of public involvement activity	larger group of	Impact of public involvement activity	Other, specify	Impact of public involvement activity			