

How to form a risk register for Patient and Public Involvement in research



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Introduction

Specific coproduction tasks in the journey of research production require a 'risk assessment' document to be completed. One example is where Public Contributors are invited to engage in collecting data for the research from NHS patients.

I am grateful to the people¹ who have responded to inquiries and contributed ideas to this group of papers. Please send me your suggestions for further improvements.

General remarks

Deficit thinking is an essential requirement in the task of generating risk documents. We are not interested in things going well, Public Contributors adding value by their presence and their insights. Nor are we interested in the concomitant opportunity cost that is incurred when Public Contributors are excluded

or ignored in the process of research production. This exercise is to simply list what might go wrong and what has been set in place to prevent it or to mitigate its harmful effects.

If the register is kept to one or two sides of paper, then it will help to focus on priorities, while a longer list is difficult to manage.

Risk register

Risk	Mitigation	Likelihood	Impact	Score
Fail to recruit the right Public Contributors	Adapted CV focussed on relevant competencies Advertise and monitor Process in place for removing unsuitable people ²	Low	Missed opportunity	1
The selection and appointment decision is challenged	Fair and defensible process for advertising, selecting and appointing Public Contributors Equality, diversity and inclusion policy is established and maintained to ensure that direct or indirect discrimination is avoided. Complaints and grievance mechanisms in place			
Engagement arrangements infantilise Public Contributors ³	Stereotypes of Public Contributors as fragile and vulnerable are replaced by a recognition of their strengths and resilience. Practices are subject to restless vigilance.			
Engagement arrangements destabilise other elements of the Public Contributor's life	The process by which Public Contributors gain approval for their role is clear, efficient and effective so that people are not subjected to contradictory instructions, undue delays or bewildering expectations.			

Risk	Mitigation	Likelihood	Impact	Score
	<p>Provide accurate information about interaction with welfare benefits and tax systems</p> <p>Role description is achievable, specifies what good looks like and is understood by all</p> <p>Public Contributors are included in the Delegation of Responsibilities statement for the research</p> <p>Clarify relationship between all relevant organisations where the Public Contributor is involved.</p> <p>Public Contributor feedback is included in monitoring systems</p> <p>Training for all on the role of the Public Contributor, unpinned by a Communication Plan⁴. Access to other relevant training.</p> <p>Where applicable, liaise in advance with care coordinator or GP (e.g. advance directive)</p>			
Confidential data is disclosed	<p>Be explicit about assumptions: can we be sure that bigger sanctions, such as the ability to fire an academic researcher from their job, produce a less leaky system than one designed to support personal, voluntary commitment?</p> <p>Mandatory GDPR training</p> <p>SOP maintains information security</p> <p>Confidentiality agreement covers both patient data, intellectual property and publication rights</p>	Low	Litigation	3

Risk	Mitigation	Likelihood	Impact	Score
Public Contributor is harmed by patient	Lone worker policy Indemnity insurance			
Public Contributor is alleged to have harmed a patient by their misconduct	Code of conduct for all includes Public Contributors Informed consent processes are understood and upheld, including the right to withdraw at any time Training for Public Contributors explains clearly when and how to refer to the therapeutic team for additional support Indemnity insurance is acknowledged to include Public Contributors			
Anyone is distressed or harmed by the data collection process	Support systems uphold the wellbeing of Public Contributors – including regular contact with a named member of the team who oversees engagement of Public Contributors. Distress protocol includes Public Contributors ⁵ , including sources of further help Protocol for reporting adverse events and incidents includes Public Contributors			
Accident happens while on NHS premises	Health and safety policy Records kept of name and address, contact details of next of kin of Public Contributor. The Public Contributor knows how to contact other team members, including the sponsor, if the need arises.			
Patients with compromised health conditions are subjected to infection	It is clear when referral to Occupational Health Department is appropriate. Advice obtained from Occupational Health Department is an appropriate and proportionate response.			

Risk	Mitigation	Likelihood	Impact	Score
A crime is committed	Where relevant, DBS identifies previous offences and a risk mitigation plan facilitates management, or, if there is no safe alternative, excludes the offender. Police and judicial system			

¹ Inquiry posted on People and Communities forum of the Future NHS Collaboration Platform, 20/05/2024 – no responses.

² See, for example, <https://peterbates.org.uk/wp-content/uploads/2023/03/How-to-respond-to-vexatious-behaviour.pdf>

³ Dembele, L., Nathan, S., Carter, A., Costello, J., Hodgins, M., Singh, R., Martin, B., & Cullen, P. (2024). Researching With Lived Experience: A Shared Critical Reflection Between Co-Researchers. *International Journal of Qualitative Methods*, 23. <https://doi.org/10.1177/16094069241257945>.

⁴ See, for example, [Guidance for Researchers: Feedback: Patient and Public Involvement \(PPI\): Feedback from Researchers to PPI Contributors – University of Hertfordshire \(Research Profiles\) \(herts.ac.uk\)](https://www.herts.ac.uk/research-profiles/guidance-for-researchers-feedback-patient-and-public-involvement-ppi-feedback-from-researchers-to-ppi-contributors)

⁵ See <https://peterbates.org.uk/wp-content/uploads/2021/06/How-to-respond-to-distress.pdf>