# *How Public Contributors can manage overlapping roles in health research*

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## Contents

## 1. Introduction and scope

People with lived experience of a health condition or disability are often called 'experts by experience'[1] and sometimes find that they have multiple roles that overlap. This paper seeks to name and then discuss some of these overlapping roles as they might be experienced by a single person. A few of the many possibilities include:

- Serving as a research participant (this used to be termed a research subject) on two studies at the same time
- Serving as a research participant and a member of the Lived Experience Advisory Panel (LEAP) for the same study.
- Serving as a LEAP member while being paid by a relevant campaigning group
- Experiencing the health condition under investigation in a research study and working as a researcher on the same study.

Some people occupy more than two roles and so the complexities increase exponentially, as with the person who brings lived experience to their clinical role whilst also working as a researcher. To keep the discussion as clear as possible, each section below will refer to a simple pair of overlapping roles. For brevity, issues are named only once in this paper, even where they apply to several situations, so readers should consider the whole document when thinking through their circumstances.

This paper considers the circumstances where a single person occupies multiple roles and may be subject to a conflict of interest; it does not consider how roles held by different people may overlap and cause conflict between those persons. A conflict of interest occurs where one duty cannot be fulfilled without compromising the other[2], where trust is broken and one role distorts the person's judgement in fulfilling the other, even if the person is not consciously aware of it.

In this paper, primary interests are concerned with general patient benefit and the integrity of research, while secondary interests include financial gain and advancement for the person, friends or a particular subgroup of society. Conflicts of interest vary according to four factors:

- the **reach** of the person's power and influence and so the range of decisions that may be affected
- the **likelihood** that the conflict of interest will change the decision that is being taken
- the **proximity** of the secondary interest to the primary interest – as a conflict may be more difficult to detect and manage if the secondary interest is closely related to the primary interest
- the scale of **harm** that may occur.

Some advisors recommend that anyone with a potential conflict of interest should simply be excluded as any overlap is inherently coercive or corrupt, but they rarely seem able to specify the specific reach, likelihood, proximity or harm – or even the nature of the interest. This amounts to a preventative approach in which opportunity is denied rather than working to manage risk or repair damage after it has occurred. An alternative approach is to acknowledge that recognition of a potential conflict of interest does not suggest that the person has behaved in an unethical manner. However, as evidence to the Undercover Policing Inquiry has shown, overlapping roles can give rise to abuse and cause intense distress[3].

The matter is further complicated when the conflict of interest is merely perceived rather than real. For example, in a survey of 265 Institutional Review Board chairpersons in the USA[4] (equivalent to the UKs Research Ethics Committee chairs), 27% of chairpersons reported that their IRB considers

patients serving in non-traditional roles to be research subjects even if they were not formally enrolled as subjects in the same study. This erroneous perception will restrict the role of Public Contributors to health research and dampen efforts to coproduce it.

The harms that may arise from a conflict of interest include:

- Loss of objectivity. Studies of Public Contributors have not yet been found that would shed light on this point, but the issue can be illustrated through its application to researchers, where one study found an asymmetric effect, in that a financial relationship with a drug manufacturer did not result in academics inflating positive research findings but did make them less likely to report negative results[5].
- Reordering of priorities
- Degradation of the quality of scientific endeavour
- Secrecy rather than openness and transparency across the whole team
- Exploitation of others
- Misallocation of time, effort, and publicity
- Loss of public trust.

The discussion set out in this Guide assumes that most citizens live with multiple, overlapping roles every day of their lives, constantly juggling the conflict of interest between their identity as employee and homemaker, neighbour and parent, and so on. In the workplace, in leisure activities, and in research[6], it is normal for people to hold multiple roles and pursue a variety of interests. As discussions of work/life balance illustrate, it can be helpful to explore how competing roles interact, try to pin down the nature of the threats involved and adopt practices that mitigate the risks. This *How To* guide therefore attempts to identify the value of involving Public Contributors in research who occupy multiple roles within the research community, appraises the potential risks, proposes ways to mitigate them, and embraces rather than excludes people with multiple roles, identities and relationships. In passing, we note here that:

- overlapping roles can provide positive opportunities as well as threats to the research process[7].
- It would be unfair to demand full clarity and resolution of all difficult issues in respect of the roles of Public Contributors when parallel arrangements for academic colleagues remain murky[8].
- Conflicts of interest arising from overlapping or clashing roles are not always conspicuous; indeed, one group of authors[9] introduced their paper with a declaration that asserted with admirable humility, “there are no known conflicts of interest.”

In general, the following paragraphs address overlapping roles which all occur within or close by the research world. Others may wish to explore the potential for conflicts to occur across more life domains. For example, when recruiting a ‘Patient and Public Voice’ representative, NHS Improvement ask for a declaration of all employment, commercial sponsorship and volunteering as they expect that these activities may cause a conflict of interest to arise[10], but say no more about the mechanism of the presumed conflict or potential mitigations.

Where power is exercised and there is potential for misuse of it, ethical analysis, capture of case studies of abuse and practice development all feed into training, formal guidance documents and sanctions for the most egregious offences. All these systems are in place to regulate conflicts of interest for academic researchers. What has been striking about some reactions to earlier drafts of this paper has been the absence of interest. In its place has been something that resembles

patronising indulgence from staff, with respondents nonchalantly indicating that 'our Public Contributors are not a problem' and 'we have never experienced any of these difficulties'. This is perhaps akin to the denial of conflict of interest that is practiced by some academic researchers when faced with ethical dilemmas[11].

The Health Research Authority helpfully observes that Public Contributors can act as an independent challenge to a team of academics[12], pressing them to be principled and rigorous in their reasoning and so to declare conflicts of interest or face a challenge to do so. While such observations are no doubt true, just as they would be if an academic attended a meeting of Public Contributors and listened to their debate, the argument overlooks the potential for conflicts of interest to afflict Public Contributors.

The comparative lack of attention to conflicts of interest as experienced by Public Contributors[13] leaves one wondering if they exercise such a small amount of actual power that there is no need to even consider these matters or build a system in parallel to that constructed for the scrutiny and regulation of academics, for whom bribes, rewards and risks can be substantial. Such judgements are rooted in organisational and professional interests and callously dismiss the potential for gains and losses to individual Public Contributors.

## 2. Managing conflicts of interest

In organisational governance, it has long been recognised that Trustees or Board members may find themselves in a situation where they have a conflict of interest. The usual way to address these matters consists of a combination of the following components:

- A clear ethical position, set out in writing, that specifies what these influences may be and that promotes a culture of freedom from undue influence upon decision-making. This is usually set out in a policy that meets legal obligations in respect of bribery and corruption as well as organisational rules regarding gifts and hospitality. Unfortunately, researchers are not always sufficiently aware of these issues for their own practice[14] and can be guilty of self-deception[15], so cannot be relied upon to carry the ethical burden for Public Contributors as well as themselves.
- An obligation laid on all participants to be diligent in recognising and acknowledging any conflict of interest that may arise from time to time[16].
- A recruitment policy that balances the need to engage the right people with the need to exclude persons who are unfit to serve due to a profound conflict of interest[17]. Some organisations ask applicants to make a written declaration of interests as part of the selection process and exclude individuals who meet specific criteria[18].
- An opportunity to declare any conflict of interest that is relevant to a particular discussion. This is necessary, but it may not be sufficient on its own to manage powerful competing interests[19]. The declaration may remind others of a longstanding continuing interest or a recently expired interest[20], announce a new interest, or consist of something that was not previously declared as it was not generally relevant but intersects with this particular discussion. Disclosure may be for a number of different purposes:
    - To transfer responsibility for deciding how to respond to a more senior individual or group and then follow their direction in relation to the issue under consideration

    - To seek advice from others and then make one's own decision about what to do
    - To notify others and continue with one's original plan, unless the senior individual or group categorically prohibits it.
    - To notify others and continue with one's original plan, but now with shared responsibility should anything go wrong
- A register which records any conflicts of interest that are declared from time to time.
- A well-known and understood repertoire of different ways to respond once a conflict of interest has been identified, including:
    - remaining involved, once other participants are aware of the potential conflict, and welcoming challenge should it be needed
    - involvement of independent observers or third-party reviewers who are free to report on what they have witnessed[21]
    - permission to withdraw from a particular discussion[22] or project with specific duties being reassigned
    - the option of resigning entirely, should the conflict of interest overwhelm the person's capacity to add value and be seen as independent
    - the duty to report any evidence of fraud or misconduct to the funder and appropriate regulatory bodies[23].

In some settings, the roles assigned to Public Contributors are structured in a manner which bakes in some of these features. For example, NICE technology appraisal committees[24] include both clinical and lay members, who are directed by the same rulebook, attend every meeting and vote on decisions. In addition, the committee welcomes relevant clinical and lay guests to enrich an individual discussion about a particular technology before excluding them all from the voting process. On first glance, it may appear that Public Contributors who are guests are relatively powerless in comparison to clinical standing committee members, but in reality, of course, there is a parity between clinical and lay persons in each role. Systems to protect the decision making from conflicts of interest can be layered in proportion to the differences in power held by standing committee members and guests.

Arrangements should be proportionate to the threat; fair to all; transparent and open to scrutiny; and accountable, so that implementation arrangements can be challenged. If the matter is confidential, it should be possible for the person to negotiate and agree the way forward with the chairperson or another trusted individual without their private circumstances being disclosed to everyone. In the light of this, the Health Research Authority distinguishes minor issues where risks should be mitigated, calling them 'competing interests' that are different from a full-blown 'conflict of interest' which should prohibit continuation[25].

Perhaps more significantly, the fundamental approach taken to such matters is also influenced by the approach to boundaries taken by the individual organisation or team[26]. In some settings, boundaries are believed to be rigid and require vehement enforcement, like the strict standardisation of a chemical experiment, which is transferred directly to ethics discussions and in/out decisions are taken which include 'safe' examples in the dataset and exclude all others. In other environments, ambiguity is embraced, terms like 'boundary breach' and 'boundary violation' are reserved for those that result in obvious harm and everyone is expected to be thoughtful rather

than adhere to a binary worldview[27]. A flexible 'Boundary Attitude' assumes that roles overlap all the time and almost all of the time this adds richness[28], while boundary spanners[29] enhance productivity in complex environments.

It would appear that the discussion about conflicts of interest in public involvement in research has not yet adopted this approach and largely confines itself to discussions of unsuitability, rather than positive recognition and mitigating action. More needs to be done.

## 3. Conclusion

Care is needed to navigate the ethics of these arrangements, but it can be done by clearly identifying potential benefits and harm and ensuring that these risk factors are clearly evaluated and reported.

## 4. What is the status of this paper?

Most of the documents we read are finished pieces of work, carefully crafted and edited in private before being shared with anyone else. This is a different kind of paper – it was shared online here from the first day, when the initial handful of ideas were incomplete, poorly phrased and tactless. I hope that the work will be edited many times, and on each occasion a revised version will replace the earlier material online. This process has hardly yet begun and so this paper may still be lacking crucial concepts, evidence, structure and grammar[30]. As readers continue to provide feedback[31], further insights will be used to update it, so please contact peter.bates96@gmail.com with your contributions[32].

It is one of a suite of documents that try to open up debate about how to empower disabled people and share decision-making in health and social care services – in research, implementation and evaluation.

This way of writing is risky, as it opens opportunities to those who may misunderstand, mistake the stopping points on the journey for the destination, and misuse or distort the material. This way of writing requires courage, as an early version can damage the reputation of the author or any of its contributors. At least, it can harm those who insist on showing only their 'best side' to the camera, who want others to believe that their insights appear fully formed, complete and beautiful in their simplicity. It can harm those who are gagged by their employer or the workplace culture, lest they say something in a discussion that is not the agreed party line. It can harm those who want to profit from their writing, either financially or by having their material accepted by academic journals.

In contrast, this way of writing can engage people who are not invited to a meeting or asked for their view until the power holders have agreed on the 'right message'. It can draw in unexpected perspectives, stimulate debate and crowdsource wisdom. It can provide free, leading edge resources.

## Appendix: A list and discussion of overlapping roles

The appendix simply lists potential overlapping roles and discusses each one in turn.

## A. Research participant on concurrent studies

Getting involved in a second research study whilst already participating in the first study is usually going to confound the results and so is generally avoided. However, one study[33] in 2007 found 10% of research participants in their sample admitted to dual enrolment, which undermines the view that *all* participants are motivated entirely by altruism.

## B. Research participant on consecutive studies

Some participants in drug trials are prohibited from joining a second research project until a washout period has elapsed, so that the intervention from the earlier study does not impact the baseline measurements taken for the later study, or the combination of pharmacological interventions cause harm. As some people are willing to take part in more than one study[34], the UK Health Research Authority maintains a register[35] of research participants called TOPS which is administered to prevent participants from engaging in two or more concurrent studies and ensure that the washout requirement is met.

We might discern a principle at work here. TOPS is not applicable to all research studies but is confined to a small group where the risk of harm is highest. TOPS is used solely in Phase 1 research, which means:

- drug trials rather than all research
- the first time that the new drug is tested on humans, so the risk of harm is greatest
- the drug is tested on healthy people who will gain no therapeutic benefit if it works
- drug trials where payments to research participants are highest[36].

Beyond this specific situation, there is no national register, so the Health Research Authority has considered that the risks which attend participation in research do not need such stringent controls. Instead, rules appear in the guidance from Ethics Committees, are set out in exclusion criteria for individual studies and considered by the patient's clinician and through a stringent process of informed consent. It seems fair to conclude, therefore, that risk associated with participation in research must vary by context and so must be individually defined, evaluated and mitigated. Even in the case of drug trials, there appears to be no standard duration for a washout period[37], as it varies according to the way in which the drug is metabolised and how long it remains in the body.

The idea of a washout period may also be helpful in thinking about psychological engagement with a research study. Both researchers and Experts by Experience may need a similar 'washout' period to appropriately leave behind the old study before fully engaging with a new one, or they may bring assumptions and expectations into the new work that should have been left behind. Bearing these things in mind, if there are no scientific reasons to prevent people from participation in more than one research study, then the decision should be taken by the patient themselves[38].

## C. Research participant and service user

Despite a clear Participant Information Sheet and an excellent consent process, there are occasions when the researcher is mistaken for a service provider. This may occur if the participant is asked about some difficult experiences that are ongoing, and so they ask the researcher for advice. Secondly, research participants may mistakenly think that the purpose of their participation is to benefit them therapeutically and so decisions will be made with this end in mind, rather than primarily to produce generalisable knowledge and proceeding via a protocol[39]. Other respondents may actually be very unclear about the different roles of the various people who visit and ask them

questions, and the researcher is seen as simply another such individual, irrespective of the explanations they are given. Public researchers who are eager to help others need to be prepared for this possibility and, in collaboration with their academic co-interviewer, work out how they will respond. In one example, Faulkner[40] recommends that interviewers prepare a list of helping agencies that they can give the participant afterwards, should they need it. Such advice is helpful, but, as Morain and Largent observe, the issue may extend to reframing the whole relationship between all the people and institutions involved[41]. Others[42] have recommended that anyone who is currently receiving clinical care from any member of the research team should be excluded from the study – in other words, overlap of roles is acceptable for the academic but not for the patient!

## D. Expert by experience and Lived Experience Advisory Panel (LEAP) member

Forming a new Lived Experience Advisory Panel of people with lived experience of the relevant health condition and then consulting with them about decisions throughout the project (design, funding application process, recruitment of staff and research participants, data collection, analysis and dissemination of findings) is only one way to organise the partnership with patients and the public, but it will be used in this paper to represent all the varying forms of research coproduction.

At first glance, it sounds obvious that a LEAP should be made up of Experts by Experience and to do anything else would be to subvert its essential contribution. However, this Guide is reflecting on potential conflicts of interest, so we must consider this as an overlapping role and look for any potential conflicts or concerns.

Experts by experience will be anything but neutral about the outcome of the research, generally taking a passionate and committed view on the importance of finding ways to improve patient care for the individuals affected by the condition under examination. In one example, the LEAP considered that a treatment would be worth it, even if, irrespective of cost, just one patient benefited, setting them at odds with the funder who may decide to close down the study if the cost outweighed benefits. Indeed, it is this passion for patient benefit that is perhaps the unique value which the LEAP can add to a study, but there may be other specific decision points during the course of the study where this passion could come into conflict with academic or funder priorities.

At the other end of this spectrum is the Expert by Experience who is passionately opposed to the purpose of the research. This may occur when the treatment under scrutiny is contested, such as the use of restraint or ECT in mental health care. Some research teams will insist that LEAP members must consider the research to be legitimate and worthwhile, as anyone who thought otherwise would undermine or sabotage the project.

## E. Service user and LEAP member

An Expert by Experience may or may not be actively receiving health or social care services at present, but for those who are service users, their experience of it will influence their contribution to the LEAP, so the panel may need to include both enthusiasts and critics. For example, LEAP members will be involved in a research project that may generate findings which are critical of the service under examination, and this may generate some difficulties for the person who is receiving a service from the professional or organisation that has been publicly challenged. The service may treat the LEAP member differently before or after results are published, and the LEAP member may anticipate this, whether it in fact happens or not.

In an ideal world, health and social care services will welcome scrutiny[43] and respond positively to it, thus relating cooperatively with the LEAP member and indeed the whole research team.

Whether the Public Contributor actively challenges the way that services are provided or offers encouragement and praise, their presence will deliver an 'identity shock' to social and healthcare professionals, especially where these staff have not had prior experience of coproduction[44]. In particular, the professionals' idealised role of caregiver will be challenged by the new role of colleague, leading to a variety of responses, ranging from a search for ways to remove the threat to their identity to excessive gestures of appreciation towards the Public Contributor. These effects will not only affect the professionals, but be reflected in the Public Contributor, who will also be obliged to navigate the shifting nature of their relationship.

This is not to say that everyone will necessarily adopt the new relationships required for coproduction. Indeed, Rose describes the potential for an advisory panel to slide into behaviour that is reminiscent of being the patient under examination in a ward round[45].

## F. Research participant and LEAP member

Some experts by experience wish to sign up to the study as research participants, so this creates a specific subset of the previous section. In 2018, Vale and colleagues[46] recommended that research participants should be routinely included in a LEAP and went on to explore why this should be so, and the potential safeguards that may be needed. This recommendation was set out in direct contradiction to the advice[47] available at the time from NIHR INVOLVE and PCORI[48], which, save for participants in action research studies, worried that involvement of trial participants would generate an unspecified conflict of interest. The same point has been made elsewhere[49]. There is indeed a specific issue with blinded studies where participation in the LEAP would unblind them, and so they could not join the LEAP until follow up was complete.

Hoddinott and team[50] recommend that research participants can be invited to contribute as LEAP members in a future study and comment that the overlap will be synergistic. A formal solution is to add an option to grant permission to be contacted about future participation or coproduction opportunities to all consent forms, and then build the results into a Consent to Approach Register[51].

In the early design stages of a research project, no-one has yet participated in the research, so limiting membership of the LEAP to participants is impractical. At the other end of that spectrum lies the possibility that it might be hard to find potential LEAP members who have not participated in the research project, perhaps because it is a rare condition or an action research methodology is being used.

A research participant will add value by bringing their knowledge of the condition being treated and the precise details and experience of participation to the LEAP. Their personal experience of receiving the treatment will enrich LEAP discussions and help to suggest improvements to protocols and patient care throughout the study, thus sharpening the focus of the research and enhancing adherence and retention, so that fewer participants drop out. They will be powerful communicators of the research findings, able to blend their personal experience of the condition and the relevance of the treatment as well as their knowledge of the overall project acquired through participation in the LEAP.

In an alternative scenario, an established LEAP member may subsequently enrol as a research participant on the same study and would then bring their commitment to the study gained through

the LEAP into their role as participant. However, they will be much more knowledgeable than other participants, potentially distorting their responses. They may also be 'unblinded', using their knowledge of the research method to work out whether they have received the intervention or 'treatment as usual', and data may be contaminated by their belief about which intervention they received.

If the research intervention is attractive and seems to be of value to the LEAP members, there is a possibility that they may seek preferential access to it because of their contribution to the overall study. For example, it took some time for one LEAP member who was unemployed to fully understand that he was not eligible for the employment support that was being evaluated through that particular study.

Rules of confidentiality are likely to vary between roles, with duties towards the trial participant being stricter than the rules that apply to LEAP members, although, in Europe and the United Kingdom, the General Data Protection Regulation covers all. For example, while ethics committees insist that study participants are anonymised in academic reports, LEAP members may wish to be acknowledged as co-authors of published outputs from the work.

Both trial and LEAP participation may attract financial or other rewards and people eligible to receive something from both systems will need to understand the separate basis for each financial transaction. Similarly, publicity, marketing activities and selection processes must be entirely clear, so that people who participate in both understand the basis on which they attend each event. There is potential for some people to be confused at this point, and to offer or expect the rewards associated with the LEAP activities to apply to trial participation, and vice versa.

Whilst the LEAP will want to conduct its business in an ethical manner, it is not subject to the local regulation of the Research Ethics Committee, in contrast to the study's engagement with research participants which is more closely regulated. Nevertheless, local ethics committees will have an overall view on how Patient and Public Involvement is woven into the fabric of the whole research project, as will the funding body.

## G. Research participant and research interviewer/data handler

One expert panel[52] describes patients who take on the task of interviewing research participants or handle confidential data as study personnel and recommends that they should not, in normal circumstances, also be participants in the research itself. This is because of the risk of unblinding and other kinds of bias, as well as the possibility that the interests of the research participant were in conflict with the aims of the research. However, this panel acknowledged that there might be exceptions to this general principle, as in circumstances where the goals of the research cannot be achieved unless participants occupy these roles. The panel also provides for the person to take up a role as a interviewer, data handler or indeed LEAP membership once their responsibilities as research participant are complete[53].

The methodology known as autoethnography studies community life through the overlapping of two roles. First, the researcher engages in participant observation by joining in with community activities and events and studying the behaviour and attitudes of other citizens from this standpoint. Second, they reflect on their own engagement and draw this into the pool of evidence to be interpreted.

## H. Research participant and academic author

There are an increasing number of opportunities for non-academics to contribute to the authorship of academic papers[54]. There is a potential conflict of interest between the academic publisher's insistence that they accept only new, previously unseen data, and some traditions of emancipatory research that encourage findings to be shared with all participants as they emerge[55]. In this situation, findings may be considered to have already entered the public domain and therefore be of no interest to the academic publisher. In contrast, where the public co-author is a member of the LEAP and findings are shared with them, results will be confined to a closely defined and limited group and so will not be considered to have entered the public domain, especially if a condition of LEAP membership is to maintain confidentiality.

## I. Co-Applicant and LEAP member

Increasing numbers of research funding calls are asking for one of the research funding co-applicants to be a Public Contributor, so this person will usually join the study prior to the appointment of the LEAP and attend both LEAP meetings and meetings of the management group for the study. This means that there may be some repetition or, rarely, a need for confidentiality to be held within one of these groups so the Public Contributor will need to adapt their role for each different meeting they attend. Participation payments are simplified if they are awarded on the same basis in both groups. There may be circumstances when the Co-Applicant acts as convenor or takes a leadership role in the LEAP, but this is not a requirement and their role should be entirely transparent to all.

## J. Researching the LEAP process

The Health Research NIHR and HRA have been clear that PPI folk who are advisers to the academic research team are not research participants and therefore do not need the extensive protective arrangements afforded to participants, viz consent forms, ethics committee approval and so on. In this sense, a LEAP is in a similar position to an International Advisory Group – they are owed an ordinary duty of care, but do not need to be treated as if they were research participants.

Asking LEAP members to help interpret findings or participate in Collaborative Data Analysis is part of the knowledge production process. Inviting coproduction partners on the research team to reflect on their learning, and even systematically do so via a learning log or a series of feedback sessions, perhaps using a focus group format, is just what Research Assistants or an International Advisory Group may be asked to do. It is part of reflective practice by the study team. Capturing comments from participants in these processes and publishing them in an account of the collaboration does not make it research, while a detailed thematic analysis of recorded and transcribed interviews may do so, if it is the use of specific methods that convert a conversation, survey or audit into a piece of research.

On some occasions the research process itself comes the subject of research scrutiny. Anyone who is conducting a 'Study within a Trial' and using explicit research methods to formally examine the process will have submitted their plans to an Ethics Committee and the LEAP members will be recruited as participants, provided with information sheets and an opportunity to give formal consent and so on.

So, it is not always clear whether focus groups with LEAP members are being viewed as a SWAT or whether they are more like the evidence-based reflective practice that we should all engage in. This is where the grey zone lies, and a decision needs to be reached about how it is played – or some clarity needs fetching from the original proposal and applying to this. Some academic research

teams have an unwelcome tendency to treat LEAP partners as especially vulnerable and therefore needing all these protections which are not applied to the other partners in the process. So if data are being gathered to inform reflective practice, then LEAP members are coproducing it and do not need any more protection than academic colleagues. On the other hand, if you are treating everyone who has coproduced as research participants, then the other partners, such as academic researchers, need to be offered information sheets and consent forms and be allowed to withdraw from the process at will.

Some research teams may decide that, despite the principle that LEAP members are not deemed to be research participants, the ethical principles designed for participants form a quality benchmark and so should be applied to all. This is fine if they are then applied uniformly to other members of the research team rather than confined to use with LEAP members. There are also benefits to taking a consistent approach across studies so that the learning from earlier studies informs subsequent work and the Public Contributor community, as well as ethics, academic and clinical communities, grow in understanding of the issues in play.

## K. Trial Management Group

The Trial or Study Management Group (TMG/SMG) is responsible for the set-up, routine running and analysis of the research and is usually made up of the research team. They meet regularly, typically monthly, and review the ongoing progress and conduct of the trial. The TMG may have a public member who is a member of the research team and has research management responsibilities. They may also have been a public co-applicant on the research funding application.

## L. Trial Steering Committee member

The UK's National Institute of Health Research appoints members to the Trial Steering Committee for research projects that it has funded[56]. The function of a Trial Steering Committee is to act as an independent check progress, conduct and scientific credibility of the study. Membership must include "at least one individual who is able to contribute a patient and/or wider public perspective" and two Public Contributors are recommended[57]. The purpose of this group is to provide an independent view on the progress of the research and, if necessary, to recommend its early closure if it becomes clear that there is little value in continuing. In order to achieve independence, the Public Contributor who is part of the Trial Steering Committee should not be involved in any other role in this particular research study, such as designing the research, applying for funding, managing the study or membership of other committees or groups that are part of the study. Members are required to sign a 'conflict of interests' declaration.

## M. Data Management and Ethics Committee (DMEC) member

A DMEC may be established by the research sponsor when the research is collecting data from an experimental intervention, but it is not needed for observational studies. Its role is to monitor the progress, safety and efficacy of the study and to recommend to the sponsor whether to continue, modify, or stop a trial. While it is not an NIHR requirement[58] for the DMEC to include a Public Contributor, this sometimes happens. DMEC members may be invited to view the data gathered during the research and can do so 'unblinded', therefore potentially seeing confidential and identifiable information about research participants. For this reason, Public Contributors who become DMEC members will be particularly concerned with the safety of study participants and

must not be involved in any other role in this particular research study, so they should not be members of the LEAP. Members are required to sign a 'conflict of interests' declaration. Questions to help in making suitable recommendations have been considered[59].

## N. Research Ethics Committee lay member

All research proposals in the UK must be reviewed by a Research Ethics Committee (REC) which includes lay members as directed by Schedule 2 of The Medicines for Human Use (Clinical Trials) Regulations 2004[60]. The Health Research Authority interprets these Regulations by adopting a category of 'lay+' member to mean the people who meet additional criteria[61]. Some of the business of the Research Ethics Committee cannot be transacted unless a lay+ member is present. We note that the detailed definitions used at each of these paragraphs vary from one another[62].

The guidance about membership of a Research Ethics Committee is silent on the question about whether lay or lay+ members can or should have lived experience. Indeed, it might be regarded as significant that the lay and lay+ members are defined entirely negatively, by the things that they lack (role in healthcare provider organisations, professional qualification etc.) rather than their positive contributions. Elsewhere in the guidance[63] we find a brief mention of the 'sound judgement and relevant experience' brought by all members of the Committee.

We might assume that these regulations are shaped by the need to ensure that outsiders are given a voice on the Committee so that they can challenge the collusion between academia and clinical interests that otherwise may permit unethical research to arise[64]. From this perspective, lay members must not carry professional privilege or they will inevitably join in with the collusion, as illustrated by studies on intersectionality. If this binary analysis is upheld, healthcare professionals who have lived experience (as patients or carers) should also be excluded from membership of the Committee, since they will inevitably weaken the lay voice, resulting in insipid debate and poor outcomes.

We believe that professionals with lived experience are not routinely excluded. Moreover, the eligibility requirements for membership of the Research Ethics Committee do not identify the nature of any competence that eligible lay persons hold or explain what conflict of interest may arise. By failing to value and recruit people with lived experience, the Research Ethics Committee is weakened. By failing to define the overlapping roles, the rules obscure and prevent clear thinking and mitigation. By simply locking people out of membership[65], the Committee escapes any obligation to understand and manage complexity. Within the meetings, the inconsistency of the rules trains the spotlight of attention on which lay members are eligible to vote on each decision, reinforcing their deficits and increasing demarcations both within and between lay members of the Committee – a divisive and discouraging process.

These unfortunate arrangements occasionally escape the confines of Research Ethics Committees and appear elsewhere. For example, a recent recruitment advert for Public Contributors to join committees run by the National Institute of Health Research temporarily adopted this approach when recruiting Public Contributors to its advisory panels. When the exclusion of persons who have or have ever had a professional role in health or social care or research was challenged, NIHR promptly dropped the exclusion and encouraged previously excluded people to apply[66].

## O. Campaigner and LEAP member

Steffens et al (2019)[67] report on the impact of anti-vaccine campaigners on the work of agencies promoting vaccination and propose actions to mitigate the harm done by misinformation. In this account, campaigners deliberately sought to influence others, using manipulative and aggressive strategies to cause harm. While in this example the campaigners are separate persons in conflict with research teams, it illustrates the potential for campaigners to bring entirely divergent views into the LEAP, or for LEAP members to be under pressure from these views as presented by other members of the lived experience constituency[68]. These things are more likely to occur when the research is focused on contentious theories, behaviours or interventions and when deliberate manipulation is attempted[69]. In less vivid tones, both members of a patient organisation and researchers may be subtly influenced by their affiliation to a pharmaceutical or other for-profit company through receiving funding for an educational or research purpose. Campaigning organisations sometimes adopt a specific approach which then silences those who hold a different view and evokes a myth that lived experience of the condition is homogeneous rather than diverse[70].

Largent et al (2018)[71] suggest that any LEAP member who is affiliated with a patient organisation should consider a potential conflict of interest by asking two questions: (i) do they have any conflicts of interest as an individual?; and (ii) does the patient organisation with whom they are affiliated have any conflicts of interest?

Many participatory researchers, as well as a number of positivist researchers, are engaged in a campaign to empower their community of interest. Indeed, this is regarded as a vital component of participatory action research[72], so there should be no difficulty in principle for Public Contributors to occupy both roles – member of the research team and community activist.

LEAP members are sometimes invited to support efforts to recruit participants and so harness their connections with their particular community to market the research. Later, there may be consequences of becoming the acceptable face of the research team in the community. This may occur if anyone suffers adverse consequences of participation. It may also occur if the research promised considerable impact, but its findings and recommendations are ignored by the wider system, then it is the LEAP member who may be criticised for promising much and delivering little.

A more modest version of the same tensions can occur when the Public Contributor is appointed to the LEAP as a representative of others, rather than as a delegate. The delegate brings their own embodied experiences to the meeting and speaks about their own views and perceptions, while the representative is tasked with relaying the experiences and opinions of others and must check back with them on a regular basis to find out what they want communicated at the meeting and how their message was received. LEAP members should be clear about their role and ensure that others are clear too, so that they are fully aware of their authority for contributing, have time to consult where appropriate, and do not have their credibility undermined by accusations that they are unrepresentative of a broader constituency. In the case of Research Ethics Committee membership, guidance is clear that members are present in their own right and not as representatives of other organisations[73] – but the guidance permits members to have these other affiliations, thereby inferring both individual members and the Committee as a whole are required to manage the overlapping roles and responsibilities.

Davis[74] suggests that LEAP members can be awarded a 'credibility excess' where academic colleagues treat them as a spokesperson for the whole disability community and the person then

suppresses unique elements of their testimony in favour of what they believe to be a typical experience.

Allies are not immune from these tensions too. For example, when a champion of coproduction is writing up the process by which Public Contributors are engaged, there is a danger that they will inflate the role and contribution of the LEAP and correspondingly underplay the role of academics[75]. This will be a well-meant attempt to boost the self-esteem of Public Contributors by congratulating them for their work, but risks sacrificing truth for the sake of the campaign to emancipate research.

## P. LEAP member on concurrent studies

Early career researchers may find themselves fully occupied by the work associated with a single study, while their more experienced counterparts commonly contribute to multiple research projects simultaneously. Some LEAP members may quickly become involved in several studies at the same time, either where the LEAP is a generic panel covering a group of research projects, or where Experts by Experience join more than one LEAP. In this event, the fit between their life experience and the subject of the research begins to vary, as they are likely to have a more tenuous connection with one study rather than another.

Involvement in two or more studies can accelerate the LEAP member's learning about research methods and enrich their contribution as they bring insights from other studies. However, the LEAP member quickly loses their naivety as they acquire an understanding of jargon and becomes skilled in navigating relationships with academics and clinicians. This means that their contribution as an outsider to the research community, bringing fresh perspectives and challenging the status quo, will be a diminishing asset, while their ability to target key issues because they are familiar with research processes, will grow over time[76].

## Q. Peer Researcher

When people with lived experience also have full academic training and are employed as academic researchers, there can be a creative synergy of these roles, but, less positively, Carr also describes straddling two identities in which she was othered by both the academic and the mental health survivor community[77]. Ross et al (2023)[78] cite a peer researcher who found that her status as an expert by experience was taken seriously when talking about her life experience, but her academic expertise was dismissed when discussing research methodology or other academic aspects of the work, as if the other members of the team enacted a 'primary identity' mindset in which the person with lived experience must therefore be a non-academic. These processes can be internalised too, especially when different kinds of lived experience are somehow ranked and one's own is considered 'not enough'[79]. The overlapping roles of 'expert by experience' and 'researcher' can trigger a broader re-evaluation of identity[80]. Dr Nisreen Alwan[81] makes the simple but important point that no researcher is objective but is rather influenced by their life, whether or not they have relevant lived experience of the condition being studied.

Some individuals occupy three roles – expert by experience, clinician and researcher. Each of these roles, and their respective communities, will take a different view of a respondent's integrity. Some clinical teams are routinely suspicious of the account given by their client, while researchers are at pains to exercise neutrality, and the community of experts by experience may be enraged at the idea that some people may exaggerate or otherwise distort their account. The person who inhabits these competing roles may be especially sensitive to the differences in perspective and may be able to

trigger reflection and development for all.

## R. Peer Researcher and friend

The peer researcher has lived experience and is employed as a researcher. They may have been employed as a researcher first and then experienced the health condition; they may have lived with the health condition for a long time and subsequently obtained employment as a researcher; they may have responded to an advert that specifically sought to appoint people with this sort of 'dual identity'. Guidance is available on taking your lived experience to work[82].

Alison Faulkner has helpfully pointed out[83] that organisations that employ people with lived experience may start to mistakenly think that the task of coproduction is now accomplished and stop listening to or even providing funding support to independent 'user led' groups. This approach, of course, pays scant attention to the conflicts of interest that could silence the peer researcher or tame their challenges. Even where there are amicable relationships between the employee and the organisation, it can be argued that the employee already has a voice and an opportunity to declare their view, so consultation and engagement processes should reach beyond staff in order to hear the views of other citizens. The National Institute of Health Research suggests that naming an employed researcher or clinician as providing their experience of a health condition or service to a research team may be perceived as a failure to engage with or involve the wider public[84].

Participatory research methods often engage members of the community being researched as peer researchers, while anthropologists commonly adopt 'immersive' approaches in which they attempt to blend into the ordinary life of the community under scrutiny. Wilkinson described the way in which the role of researcher and friend can overlap:

> "*I positioned myself as 'researcher as friend'…. Some examples of how I built this friendship include: I accepted the young people's 'friend requests' on Facebook; I passed on my mobile number; I invited volunteers to call me by my nickname; and I enjoyed activities with the young people outside of the [radio] station including cinema excursions, shopping sprees and celebratory meals*."[85]

Wilkinson is an academic researcher, and so we might imagine that the issues are amplified for peer researchers, especially as the friendship roles between the peer and their friend may be much more significant and long-lasting than their short-term formal relationship they have as peer researcher and researched.

The issue is further complicated in ethnographic settings where there is sometimes a blurring of roles between peer researchers and researched. Macfarlane and Roche[86] describe situations where members of the target community are engaged as peer researchers and then begin to provide useful insights into the research topic from their own lived experience. This often happens, Macfarlane and Roche explain, in informal moments such as during a car journey, and the researchers then must decide whether this is 'off the record', revealed as part of the collegiate relationship or even friendship between them, or used as data in the research. If person loses control of their revelations they are likely to feel tricked.

But it would be naïve to imagine that these informal moments are unique to peer researchers; they may occur more often, but they can appear in the course of many types of qualitative research, particularly when the target community is small and tight-knit, and where the researcher has been involved for a long time. Indeed, Mayan & Baum[87] actively encourage researchers to build

relationships that look like friendships with their respondents. So attempts to regulate or eliminate such moments (such as ensuring that researchers do not collect data from people they already know) cannot always be applied and a deeper rationale must be found. In the meantime, any rules that are applied must be even-handed and treat peer researchers respectfully in relation to their long-term connections and fairly in comparison to their academic colleagues.

In another twist of this kaleidoscope, Di Lorito and his co-researchers[88] wanted to level their relationship and so took some of their meetings away from the institution's offices and met in the co-researcher's homes. One might ask why they did not also meet in the academic researcher's home, and whether it was effective in shifting the relationship towards a personal, reciprocal friendship or merely felt like a care worker entering the person's home in a traditional, one-way transaction.

## S. Peer researcher as a LEAP member

Emma Sutton[89] lists the following barriers that might prevent her as a physiotherapist and researcher with lived experience joining a Lived Experience Advisory Group for a research project:

- "I may not be able to contribute my views while simultaneously enabling others to speak because my professional authority could predominate. Perhaps others would worry about this too and I may not have permission to join a PPI team at all. When discussing a subject which is clearly emotive for me as a patient, I might not be able to avoid asserting the power that my professional knowledge as a clinician and researcher brings." This could lead to other members being accidentally disenfranchised.
- "What if exposing my own experience as a patient could affect my academic career?" This is particularly relevant for conditions that are stigmatised or associated with fluctuations in performance such as some mental health issues, chronic pain or fatigue. Assumptions and stereotypes held by managers and occupational health departments may result in disclosure being a career-limiting move.

If the advice needed from the Lived Experience Advisory Group is mostly concerned with improving communications with patients who do not understand clinical interventions, research methods or jargon, then a peer researcher will not be much use, as they know too much about such matters. On the other hand, if the goal is to generate ideas for service improvement, then understanding the mechanisms of evidence-based improvement science would be an asset to the LEAP.

A further consideration is one of power. Paul Radin[90] has argued that the overall research team is heavily populated by powerful people, and therefore the small number of places on the LEAP should not be wasted by filling them with professionals who already have a voice. Rather, these places should be occupied by patients who do not otherwise have a way to be heard.

If peer researchers are experts by training who happen to have some relevant lived experience, co-researchers are experts by experience who get involved in coproducing the research, perhaps by conducting qualitative interviews. In one recent example[91], two experts by experience sat on the Trial Management Group and one of them was a study co-applicant. This gave them influence in decisions regarding the amount of expenditure to be devoted to Patient and Public Involvement, which they subsequently benefited from when claiming payment for their co-research activities. This is a clear conflict of interest which is simply acknowledged and reported, thereby permitting the innovative work to proceed.

## T. Peer Clinician

This rather ambiguous term is often used to refer to a person who is has personal lived experience of the condition being investigated and is also a clinical professional working in this field, such as a cancer survivor who is also working as an oncologist. Professor Trisha Greenhalgh and Dr Liz O'Riordan have reported on the difference it has made to their work to live through breast cancer themselves, rather than just undertake research and treat patients. Similarly, Emma Sutton has reported[92] on the difference it has made to live through healthcare interventions as a patient as well as work as a physiotherapist and researcher.

While lived experience has the potential to make the clinician more empathic, this is not inevitable, as some may assume that every patient has had the same experience as themselves. If the peer clinician discloses their experience, then this may help the patient to feel understood, or it may damage the confidence that the patient has that the clinician will be available next time they are needed. That 'availability' includes both physical presence, where the clinician is at work rather than relapsing and taking time off for health reasons; and mindfulness, as the patient needs the clinician to be emotionally and psychologically present with them rather than revisiting their own experience. For that matter, if the clinician's disclosure in the LEAP meeting or elsewhere became known to their patients, the tables could be turned and the patient may use the clinical interview to offer help and comfort to the worker. These hazards are exacerbated where either party expect the clinician to normally be a faceless technician rather than someone with whom they share a common humanity.

Some clinicians have a second job as a researcher, and so attempt to compartmentalise their working week, by spending some time in their research role and the rest in their clinical. This may work well on paper, but there must be occasions when the roles blur, and the person experiences overlapping roles. It has been commented that ethics review boards do not look favourably on proposals that have both investigatory and therapeutic goals, so in one case at least, the therapeutic element remained covert[93]. This is of some concern, partly as it is unclear (to this author at least), what concerns or assumptions underpin such a judgement, and secondly, hiding ethical matters from the ethics committee will subvert their purpose.

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[1] Others use or contest the use of a variety of other terms, including 'service user', 'patient', 'Public Contributor' and many more – see https://peterbates.org.uk/wp-content/uploads/2017/04/11n_-_clients_or_what.pdf

[2] Some commentators have suggested that a conflict of interest occurs when a public duty clashes with a private interest, but this public/private distinction does not really help. The broader definition of two interests used in the main text is more helpful.

[3] See Covert policing in the United Kingdom - Wikipedia. Alternatively, there can be a clash between the role of neighbour, friend and researcher, as illustrated by one researcher who was welcomed by the community, but, once her publication was available, she was redefined as a person who had betrayed the trust of the participants and was expelled from the community. see Scheper-Hughes N (2000) Ire in Ireland. *Ethnography* 1(1):117-140. doi:10.1177/14661380022230660. However, the story of Scheper-Hughes is open to various interpretations. Perhaps the problem she faced was not created by her overlapping roles but by her unwarranted and offensive report that she wrote.

[4] Weissman JS, Campbell EG, Cohen IG, Lynch HF, Largent EA, Gupta A, Rozenblum R, Abraham M, Spikes K, Fagan M, Carnie M. IRB oversight of patient-centered outcomes research: a national survey of IRB Chairpersons. *Journal of Empirical Research on Human Research Ethics.* 2018 Oct;13(4):421-31.

[5] Friedberg, M., B. Saffran, et al. (1999) Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology *JAMA* 282(15): 1453-1457.

[6] See Wilkinson, Catherine. (2016). "Babe, I like your lipstick": Rethinking Researcher Personality and Appearance. *Children's Geographies.* 14. (1). pp. 115-123.

[7] Martin et al report an occasion when sensitive personal information was stolen from a research team. Whilst others would have separated out the awkward task of informing the participants that their privacy had been breached and assigned it to the principal investigator, the research team (in collaboration with the ethics review board) asked the peer researchers on the study to carry out this delicate task, thus creating the potential for role overlap and conflict of interest in the peer. The result was that a range of adverse consequences were avoided. See Alana Martin et al: Case 6.1 'Handling a privacy breach and participant notification: Challenges for a community-based research project with people who use drugs in Ottowa, Canada **in** Banks S & Brydon-Miller M (2019) *Ethics in Participatory Research for Health and Social Well-Being: Cases and Commentaries* Abingdon: Routledge.

[8] For example, Valkenburg's team found that responsibilities for ensuring that research was conducted with integrity were distributed between the higher education institution and the individual researcher in a chaotic and inconsistent manner. Valkenburg G, Dix G, Tijdink J. et al. (2020) Making researchers responsible: attributions of responsibility and ambiguous notions of culture in research codes of conduct. *BMC Med Ethics* 21, 56. https://doi.org/10.1186/s12910-020-00496-0.

[9] Hillman K, Pedlar D & Bibb J (2021) My Space, Your Space, Our Space: Exploring the Potential of Collaborative Group Facilitation Between Therapists and Peer Workers in Mental Health Settings. *Community Mental Health Journal* https://doi.org/10.1007/s10597-021-00859-w.

[10] See NHS Improvement (2017) *NHS England Patient and Public Voice Partners Policy* Section 13, page 26. Available at https://www.england.nhs.uk/wp-content/uploads/2017/08/patient-and-public-voice-partners-policy-july-2017.pdf

[11] In the investigation carried out by Mecca et al, five participants denied the existence of a conflict of interest when presented with standardised scenarios that contained such a conflict. See Mecca JT, Gibson C, Giorgini V, Medeiros KE, Mumford MD & Connelly S (2015) Researcher Perspectives on Conflicts of Interest: A Qualitative Analysis of Views from Academia *Sci Eng Ethics.* August; 21(4): 843–855. doi:10.1007/s11948-014-9580-6.

[12] National Research Ethics Advisors' Panel (2012) *Conflicts of interest/competing interests.* Health Research Authority 13 February. Page 3. Downloaded from https://www.hra.nhs.uk/documents/272/nreap04-guidance-national-research-ethics-advisors-panel-13-february-2012.pdf 3 August 2020.

[13] Few published papers seem to discuss conflicts of interest experienced by Public Contributors to health research. An exception is the comment that "Engaged patients, who are being held up as important contributors to research, should be held to the same standards." Largent EA, Fernandez Lynch H, & McCoy MS (2018) Patient-Engaged Research: Choosing the 'Right' Patients to Avoid Pitfalls *Hastings Center Report* 48, no. 5 (2018): 26-34. DOI:10.1002/hast.898.

[14] Zeynep G. Aytug, Hannah R. Rothstein, Mary C. Kern & Zhu Zhu (2019) Is There Social Consensus Regarding Researcher Conflicts of Interest?, *Ethics & Behavior*, 29:2, 101-140, DOI:10.1080/10508422.2017.1402683.

[15] Boyd EA, Cho MK, et al. (2003). "Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators." *Acad Med* 78(8): 769-774.

[16] Rose L (2013) Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness *Journal of Law, Medicine & Ethics* 41, no. 3, 680-87.

[17] NHS Improvement has prepared a role description for the Patient and Public Voice members of its National Patient Safety Alert Committee. This role description requires PPV candidates to declare any conflict of interest, but the document itself does not provide any guidance on what a conflict of interest might consist of and what would be done should it arise. See https://www.thurrockccg.nhs.uk/your-health/information-leaflets/information-leaflets-2018/4469-patient-and-public-voice-representative-role-description/file.

[18] Largent et al (2018) op cit, recommend that patient organisations that receive more than a particular percentage (they suggest 10%) of their funding from industry should be excluded. Moreover, they advise that the number of Public Contributors with industry affiliations should be capped. We might ask if the same rule is applied to the academics on the team. For a longer discussion about the relationship between Public Contributors and commercial interests, see Bates P (2020) *How to decide whether to support public*

*involvement in commercial projects*. Available at https://peterbates.org.uk/wp-content/uploads/2020/01/How-to-decide-whether-to-support-public-involvement-in-commercial-projects.pdf.

[19] Most researchers in Glaser and Bero's analysis thought that simple disclosure of interests would effectively eliminate bias – see Glaser BE & Bero LA (2005) Attitudes of academic and clinical researchers toward financial ties in research: A systematic review. *Science and Engineering Ethics* 11:553–573. Mecca et al (2015, op cit) dispute this and suggest that trusting in declaration alone to eliminate bias would be naïve.

[20] NICE ask for interests that expired a year ago or less to be declared, as well as current interests. See https://www.nice.org.uk/news/blog/how-nice-manages-the-potential-conflicts-of-interests-of-patient-experts accessed 30/08/2023.

[21] Bruton and Sacco have shown that third party reviewers of a financial conflict of interest are themselves at risk of being lenient to decisions that favour their own personal or institutional interests, so this strategy has limited value as a solution to the problem of overlapping roles and conflicts of interest. See Bruton SV & Sacco DF (2017) What's it to me? Self-interest and evaluations of financial conflicts of interest *Research ethics* Vol. 14(4) 1–17. DOI: 10.1177/1747016117739940.

[22] In the legal profession, stepping back from involvement in a single case where one has a conflict of interest is termed recusal.

[23] General Medical Council (2013) *Good practice in research and Consent to research* Downloaded from https://www.gmc-uk.org/-/media/documents/good-practice-in-research-and-consent-to-research_pdf-58834843.pdf?la=en&hash=9AF84CA914317D54BB27A94CA3ABD1B3654D9F2E on 3 August 2020.

[24] Personal communication, September 2023 from Dr Jacoline Bouvy, National Institute for Health and Care Excellence.

[25] National Research Ethics Advisors' Panel (2012) op cit. Page 3.

[26] NIHR Involve suggest that people who have both lived experience and a job in research or clinical care might need 'support… in setting relevant boundaries between their professional and personal experiences when contributing to the group'. No further explanation is offered. See NIHR Involve (undated) *Different experiences* op cit.

[27] For a discussion about the role of Public Contributors in relation to research ethics, see Bates P (2020) *How to engage Public Contributors as Citizen Ethicists*.

[28] Bates P, Lymbery M & Emerson E (2013) Exploring boundary attitude, *The Journal of Adult Protection*, Vol. 15 Iss: 1 pp. 26 – 36.

[29] Long JC, Cunningham FC & Braithwaite J (2013) Bridges, brokers and boundary spanners in collaborative networks: a systematic review. *BMC health services research.* Dec 1;13(1):158.

[30] As a result, the author assumes no responsibility or liability for any errors or omissions in the content of this paper. The information contained is provided on an "as is" basis with no guarantees of completeness, accuracy, usefulness or timeliness.

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[32] Undated or early versions should be replaced with the most recent, available here.

[33] Kass NE, Myers R, Fuchs EJ, Carson KA, Flexner C. (2007) Balancing justice and autonomy in clinical research with healthy volunteers. *Clinical Pharmacology & Therapeutics*; 82:219–227.

[34] IRAS guidance at https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx#596, question A32.

[35] See https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/. This is used for Phase 1 studies, which test new drugs on healthy volunteers. As there is no therapeutic benefit

to these citizens they are at risk if the drug has unintended consequences, and payments are made to these volunteers for their participation, extra safeguards need to be set in place, as represented by TOPS. Participation in other kinds of health and social care research is regulated through Ethics Committees, recommendations by the patient's doctor, robust patient information and the process of gaining informed consent. There is no fixed washout time, as this depends upon how the drug is metabolised, so TOPS record the date of the last dose and the follow up appointment to ensure that a new trial does not start until these dates are past.

[36] Observers may fear that large payments increase the likelihood of deception, but this is not supported by the available evidence – see Fernandez Lynch H, Joffe S, Thirumurthy H, Xie D, Largent EA (2019) Association Between Financial Incentives and Participant Deception About Study Eligibility. *JAMA Net Open* 2(1):e187355.

[37] The duration of the washout period is not specified for the public at https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/. TOPs does not offer a specific duration - TOPS FAQs v1.8, 20/11/2017. In contrast, IRAS guidance asserts that the Association of the British Pharmaceutical Industry (ABPI) recommends that there should be a gap of 4 months between trials, while the Food and Drug Administration in the USA set it at 28 days (see https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx#596, question A32.

[38] IRAS guidance at https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx#596, question A32.

[39] Appelbaum PS, Anatchkova M, Albert K, Dunn LB, Lidz CW. Therapeutic misconception in research subjects: development and validation of a measure. *Clin Trials* 2012;9(6):748–61.

[40] Faulkner A (2004) *The ethics of survivor research: Guidelines for the ethical conduct of research carried out by mental health service users and survivors*. Policy Press, page 23.

[41] Morain S & Largent E (2022) Think Pragmatically: Investigators' Obligations to Patient-Subjects When Research is Embedded in Care, *The American Journal of Bioethics*, DOI:10.1080/15265161.2022.2063435.

[42] Hoddinott P, Pollock A, O'Cathain A et al (2018) How to incorporate patient and public perspectives into the design and conduct of research [version 1; peer review: 3 approved, 2 approved with reservations]. *F1000Research* 7:752 https://doi.org/10.12688/f1000research.15162.1.

[43] See Bates P (2014) *How To engage the public in scrutiny.* Nottingham: East Midlands Academic Health Science Network. Available at https://peterbates.org.uk/wp-content/uploads/2017/04/how_to_engage_the_public_in_scrutiny.pdf

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[47] See http://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research/.

[48] Weissman JS, Cohen IG, Campbell E, et al. (2020). *Developing Recommendations for Oversight of Patient-Centered Outcomes Research—The PCOROS Study.* Patient-Centered Outcomes Research Institute (PCORI). https://doi.org/10.25302/08.2020.ME.140921701. Recommendation 7, page 48.

[49] Pandya-Wood, R., Barron, D.S. & Elliott, J. A framework for public involvement at the design stage of NHS health and social care research: time to develop ethically conscious standards. *Research Involvement and Engagement* **3,** 6 (2017). https://doi.org/10.1186/s40900-017-0058-y

[50] Hoddinott et al (2018) op cit.

[51] Bates P (2014) *How to form a consent to approach register: the headlines.*

[52] Weissman JS et al (2020) op cit. Recommendation 6, page 48.

[53] Weissman JS, et al (2020) op cit. Recommendation 8, page 48.

[54] See How to involve the public as co-authors.

[55] Wright D, Foster C, Amir Z, Elliott J & Wilson R (2010) Critical appraisal guidelines for assessing the quality and impact of user involvement in research *Health expectations* December, DOI: 10.1111/j.1369-7625.2010.00607.x.

[56] See https://www.nihr.ac.uk/documents/research-governance-guidelines/12154

[57] See Good practice guidelines on the recruitment and involvement of public members on Trial Steering Committees (TSCs) / Study Steering Committees (SSCs) (nihr.ac.uk)

[58] See https://www.nihr.ac.uk/documents/research-governance-guidelines/12154

[59] Readers who want more suggestions about appointing Public Contributors to these roles may note the following. The research team may be asked for suggestions, but the funder makes the appointment. Possible questions to help with selection include: (1) Duration of the study? (2) One person for the TSC and a separate person for the DMEC? (3) Will face to face meetings be needed eventually and if so, where? (4) How much research knowledge/qualification will be required? I would expect prior experience of sitting on a Lived Experience Advisory Panel, perhaps even involvement with 2+ studies to give breadth of vision, but no need for formal academic qualification or career experience in research. (5) Do you want people who are demonstrably intelligent and able to engage in fast-moving technical discussions without the need of substantial interpretation, or are you expecting to make substantial adjustments to your meetings so that the person can understand and participate? (6) What kind of lived experience do you hope to bring into each committee – loneliness, severity of depression and/or anxiety, use of secondary mental health services, carer? (7) Selection process. I'd assume it is by recommendation and invitation, rather than competitive interview. This mirrors what I assume to be the process with other appointments to these committees and addresses the need for the right kind of competent, ethical and critical friend to the funder and to science. (8) Identified link person. This might be the chair of the relevant committee, but that person needs to be clear that they will provide informal support to the PPI member and they will be the go-to person in the event of issues arising. (9) The 'usual' financial arrangements, as practice does vary from study to study and institution to institution.

[60] The Medicines for Human Use (Clinical Trials) Regulations 2004 paragraphs 3.4, 3.5. and 6.4.a. – see https://www.legislation.gov.uk/uksi/2004/1031/schedule/2/made.

[61] We might have imagined that the Health Research Authority would have clarified any inconsistencies or omissions in the base legislation by producing a guidance note for operational purposes, but this has not been done. Personal correspondence from Queries Line at the Health Research Authority, 18/02/2021.

[62] Paragraph 3.4. refers to 'the course of his employment or business', suggesting current posts, while 3.5.b. uses the phrase 'are not, nor ever have been', indicating lifetime experience. Paragraph 3.4.a lists 'medical, dental and nursing', while 3.5.b.i. identifies 'health care professionals' raising questions about professions allied to medicine. Paragraph 3.5.b.iii. lists 'chairman, member or director' while 6.4.a.ii adds 'officer or employee' to the list. Each of these paragraphs relate to different functions transacted by the Research Ethics Committee (membership and what counts as a quorate body for the transaction of different kinds of business). Thus, for example, a support worker without professional qualification employed by a NHS Trust would be counted as a lay member rather than a lay+ member, so would not be counted towards the quorum for some of the business transacted by the Research Ethics Committee.

[63] GAfREC 2020, para 4.2.2.

[64] See the group of papers on Citizen Ethicists at https://peterbates.org.uk/home/linking-academics-and-communities/how-to-guides/.

[65] At its heart, this is a discussion about whether a person's job role somehow eclipses or negates their lived experience of disability or exclusion. NIHR Involve has stated its position that this is not the case and people can 'wear several hats' – see NIHR Involve (undated) *Different experiences: A framework for considering who might be involved in research.* Downloaded from https://www.invo.org.uk/wp-content/uploads/2020/03/Different_experiences_FINAL_edit.pdf on 19/2/2021.

[66] The advert initially sought members of the public to join one of the following national and regional committees: NIHR Invention for Innovation (i4i) Programme, NIHR Health Technology Assessment (HTA), NIHR Policy Research Programme (PRP), NIHR Programme Grants for Applied Research (PGfAR), and NIHR Research for Patient Benefit (RfPB) programme. The closing date was 15/03/2021. See https://www.nihr.ac.uk/vacancies/public-committee-member-national-and-regional-committees/23670. When the exclusion of people who work or who have ever worked as a healthcare professional was challenged on Twitter, it was promptly abandoned.

[67] Steffens, M.S., Dunn, A.G., Wiley, K.E. *et al.* How organisations promoting vaccination respond to misinformation on social media: a qualitative investigation. *BMC Public Health* **19,** 1348 (2019) doi:10.1186/s12889-019-7659-3.

[68] Taylor J, Denegri S (2017) Industry links with patient organisations. *BMJ*; 356: j1251

[69] Largent et al refer to deliberate attempts by industry to introduce dishonest persons who misrepresent patient views in order to advance the interests of industry. Creation of a false grassroots organisation for this purpose is sometimes called astroturfing. Largent EA, Fernandez Lynch H, & McCoy MS (2018) op cit.

[70] Largent EA, Fernandez Lynch H, & McCoy MS (2018) op cit.

[71] Largent EA, Fernandez Lynch H, & McCoy MS (2018) op cit.

[72] See Davis E & Vaughan C 'Social action for social change' **chapter 8 in** Banks and Brydon-Miller (2019) op cit. Caroline Lenette calls Participatory Action Researchers 'scholar-activists' and traces their history back to psychologist Kurt Lewin in the 1940s via anthropologist Sol Tax in the 1950s to the pedagogy of Paulo Freire in the 1960s and the sociology of Orlando Fals-Borda in the 1970s. See Lenette C (2022) *Participatory Action Research.* Oxford University Press. DOI:10.1093/oso/9780197512456.003.0001.

[73] GAfREC (2020) para 4.2.2.

[74] Davis, E. (2016) 'Typecasts, tokens, and spokespersons: A case for credibility excess as testimonial injustice', *Hypatia* 31/3: 485-501.

[75] See Miller E, Cook A, Alexander H, Cooper SA Hubbard G, Morrison J, Petch A (2006) Challenges and Strategies in Collaborative Working with Service User Researchers: Reflections from the Academic Researcher *Research Policy and Planning* 24 (3): 197-208.

[76] See Johansson V. From Subjects to Experts - On the Current Transition of Patient Participation In Research. *The American Journal of Bioethics*. 2014;14(6):29-31. Also Lough S. Need to define patient engagement in research. *CMAJ*. 2015;187(12):385-6. Also Ocloo J, Matthews R. From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. *BMJ Quality & Safety*. 2016;25(8):626-32.

[77] Carr S (2019) "I Am Not Your Nutter': A Personal Reflection on Commodification and Comradeship in Service User and Survivor Research Disability and Society." *Disability and Society* 34(7-8): 1140–1153.

[78] Ross LE, Pilling M, Voronka J, Pitt KA, McLean E, King C, Shakya Y, MacKinnon KR, Williams CC, Strike C & Guta A (2023) 'I will play this tokenistic game, I just want something useful for my community': experiences of and resistance to harms of peer research, Critical Public Health, DOI: 10.1080/09581596.2023.2268822

[79] Heney, V., & Poleykett, B. The impossibility of engaged research: Complicity and accountability between researchers, 'publics' and institutions. *Sociology of Health & Illness.* 2021; 00: 1– 16. https://doi.org/10.1111/1467-9566.13418

[80] Gupta V, Golding L, Eames C, Greenhill B, Qi R, Allan S, Bryant A & Fisher P (2022, June 20). Understanding the identity of lived experience researchers and providers: A conceptual framework and systematic narrative review. *PsyArXiv*. https://doi.org/10.31234/osf.io/gjh2c. Veenu GuptaDr Laura GoldingDr Catrin EamesDr Beth GreenhillRobert QiStephanie AllanAlison BryantDr Peter Fisher

[81] See Researching own lived experience: break the taboo! by Dr Nisreen Alwan – Medically speaking… (soton.ac.uk).

[82] See Bates P How to take your lived experience to work.

[83] See https://www.nsun.org.uk/blog/the-inconvenient-complications-of-peer-support

[84] NIHR (2021) *Public Co-Applicants in research: Guidance on roles and responsibilities*, page 6.

[85] Catherine Wilkinson 'Case 3.2: Are you telling me this as a researcher or a friend? Ethical issues for a UK doctoral researcher' **in** Banks S & Brydon-Miller M (2019) op cit. For a specific discussion about the significance of Facebook connections, see Bates P, Smith S & Nisbet R (2015) Should social care staff be Facebook friends with the people they support? *Journal of Adult Protection* 17:2, 88-98.

[86] Macfarlane A & Roche B 'Blurring the boundaries between researcher and researched, academic and activist' chapter 3 **in** Banks S & Brydon-Miller M (2019) op cit.

[87] Mayan MJ, Daum CH. Worth the risk? Muddled relationships in community-based participatory research. Qualitative health research. 2016 Jan;26(1):69-76.

[88] Di Lorito C, Godfrey M, Dunlop M, et al. (2020) Adding to the knowledge on Patient and Public Involvement: Reflections from an experience of co-research with carers of people with dementia. *Health Expectations* 23:690–705. https://doi.org/10.1111/hex.1304.

[89] https://blogs.bmj.com/bmj/2019/10/29/emma-sutton-the-problem-of-too-many-hats-involving-clinician-patients-in-ppi/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+bmj%2Fblogs+%28Latest+BMJ+blogs%29&g=w_bmj-com

[90] Personal communication, 2018.

[91] Di Lorito C, Godfrey M, Dunlop M, et al. (2020) op cit.

[92] https://blogs.bmj.com/bmj/2019/10/29/emma-sutton-the-problem-of-too-many-hats-involving-clinician-patients-in-ppi/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+bmj%2Fblogs+%28Latest+BMJ+blogs%29&g=w_bmj-com

[93] Banks S & Brydon-Miller M (2019) *Ethics in Participatory Research for Health and Social Well-Being: Cases and Commentaries* Abingdon: Routledge. Page 19.