How to avoid doing bad research

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Contents

1. What this paper is about

This paper is one of a suite of papers[1] exploring research ethics and the role of Public Contributors, with this paper offering an overview of what can go wrong when doing research with people. All research has risks, whether it is studying how children learn or finding out which drugs help people to recover from a disease. This guide considers different kinds of harm and how to minimise or eliminate these hazards.

We acknowledge that other types of research can go wrong too. There are ethical implications of research into the strength of metals if poor research results in a bridge collapsing, while investigating climate change may help to secure a future for humanity, and some people think it is wrong to experiment on animals. This guide will focus on research that studies people rather than pursuing these broader types of research.

People described as Public Contributors appear from time to time in this paper. This group includes people who have lived through the experience that is being studied, and so might be considered to be 'experts by experience' in contrast to people who have undergone academic training and study of the experience in question, who might be dubbed 'experts by training'. Some Public Contributors are family carers of the people with lived experience, while others will be members of the general public who have no more than a general interest in the subject under scrutiny and remain outsiders to both the academic community and those who share relevant lived experience.

[1] The companion papers to this guide comprise Bates P & Ward C (2020) *How to navigate research ethics – definitions, history, systems and sanctions*; Bates P & Ward C (2020) *How to gain informed consent*; Bates P (2020) *How to make the case for Public Contributors as Citizen Ethicists* and Bates P (2020) *How to engage Public Contributors as Citizen Ethicists*.

The UK National Institute of Health Research offers the following definition of public involvement which describes the activities of these Public Contributors and distinguishes it from participation, where people are the subjects of study, and engagement, where people are the recipients of the findings of research:

> *Public involvement in research is research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.*[1]

This introduction would not be complete without acknowledging that we believe that most research endeavours are conducted in an ethical manner, but this paper will focus on lapses in order to highlight the need for vigilance. Both paid researchers and Public Contributors need to know that things can go wrong if they are to fulfil their obligation to promote research activities that are legal, competent and ethical.

2. What might go wrong in research?

London (2012)[2] argues that, without ethical controls, the prevailing culture in academic research is rigged so that researchers who gamble with small breaches of ethical practice can win substantial personal rewards while losses are diffused and fall on the wider community. For example, cutting corners on gaining informed consent will accelerate the recruitment of research participants, while doing it properly will slow the process down and increase the number of candidates who decline the invitation to participate. Here, and in a thousand other places, researchers operate in a world where virtue is known only to the heart, while sloppy practice can, in the short term at least, accelerate output, promotion and status. Furthermore, the common good can also be harmed by well-meaning researchers acting independently without considering the broader consequences of their actions[3]. At the other end of the spectrum the system is weighted quite differently and punishes rather than overlooks researchers who commit serious misdemeanours.

For these reasons and many more, it is vital that the research community considers the ethics of what it does so that these primitive forces are curtailed. Everyone knows that scrutiny is needed, but that does not stop researchers and their counterparts in other fields grumbling about it.

This section presents a brief summary of six things[4] that might go wrong in research and then each one is explored in more depth in the following sections, teasing out the ways in which ethical practice provides a measure of protection.

People could be placed under duress
People could be tricked, coerced or bribed to enter the research as participants, continue in it, or leave it.

People could be harmed
Experimental drugs could injure or kill people during the research or afterwards, either because of their direct action or because they trigger other adverse reactions in everyone or in a particular group of participants. The participant's dignity could be undermined or

participation could be unnecessarily burdensome. Public Contributors could be engaged in tokenistic ways, exploited or patronised.

Confidential data could be revealed
Participants could have their private information revealed to others. Their anonymity could be lost, identity stolen or their dignity might be compromised through data breaches. Anonymised data that are inadequately protected may be re-identified if sample sizes are too small or by using big data to correlate and triangulate.

Results could be hidden or unwarranted
Data could be distorted, spoilt or fabricated and analysis flawed by miscalculations[5]. Conclusions could be unwarranted, based on personal opinion or stolen from others rather than distilled from the evidence[6]. Subgroups within society could be under-represented, leading to findings that should not be generalised for all. Some of the findings could be set aside to create a false image in reports and publications, or the whole research study abandoned and its findings suppressed to serve political or financial interests.

The research team could be blamed
The research team could be blamed if they started their work without the necessary knowledge, competence or experience. Unethical conduct, or even an allegation of it, could close down the research career of an employed member of the research team, destroy their reputation and result in unwanted attention from the media or the courts. Researchers who are also practicing as education, health or social care professionals could find that the problems in their research activity affect this part of their lives too, especially if they are subjected to disciplinary action by their professional body. Public Contributors who blow the whistle on unethical conduct by their research colleagues may find that their help is no longer wanted in this or other studies. Everyone involved could pay a high emotional price for their involvement with a study that goes wrong, especially if people have been harmed.

Resources could be wasted
Research could waste money by pointlessly re-investigating a question where the answer is already known[7]. Participants could endure unnecessary intrusion, discomfort and inconvenience. Public money could be spent on research that is futile or not in the public interest[8], leaving less money for more worthwhile projects. The research could interrupt busy staff in hospitals or schools, diverting them from more important work. The people who draw on the results of research could design faulty schools and hospitals, commission flawed services and send the next generation of researchers off in the wrong direction. The wider public could lose faith in science.

The following sections investigate these six areas in turn by considering what needs to be set in place to strengthen good practice and protect from harm.

3: Protect choice to prevent coercion

Research participants must enjoy freedom of choice about whether to join, remain or leave a research study. This means that they must be provided with information that accurately and fairly represents the purpose of the research and what will happen to them. They must not be manipulated or bribed. As there are quite a number of distinct issues that apply to the issue of informed consent, this topic is expanded further in a separate paper[9]. It appears that some commentators[10] suggest that this theme and the next one (i.e. informed consent and harm) are the only topics addressed within health research ethics, but in this paper, all six areas are addressed.

4: Promote safety to minimise harm

Risks must be minimised whilst achieving the goals of the research. Research that is excessively risky to participants, and especially to vulnerable people[11] must not be undertaken or must be suspended or stopped once these risks become apparent. If the six goals set out in this paper were to be listed in priority order, then this principle, of 'do no harm' would be given precedence and will be used to close down dangerous research projects, even if all the other factors are secure.

Finding the point at which the risks are too great to justify the research going ahead is a challenging ethical issue, and Public Contributors can help to set the threshold. Similarly, Public Contributors can help in ranking risks and working out which will be considered the most serious adverse consequences, as this may be viewed differently by academics or particular communities[12]. Debates also arise when setting the threshold at which researchers set aside their duty of confidentiality and are obliged to report what they have heard in an interview to clinicians, safeguarding professionals or the Police; again, Public Contributors can help with these delicate ethical decisions.

The freedom to withdraw from a research study must be offered to all research participants, as set out above, but this is also relevant here, as the participant may withdraw from any research which they themselves deem to be too risky.

Prior to the start of research, arrangements are set in place regarding what to do if a participant experiences harm. This may be an unconnected event, such as a medical crisis during the intervention, or it may be an adverse reaction to the intervention itself. Both funding and regulatory bodies may need to be informed, the person may need to be withdrawn from the study and referred to their General Practitioner or elsewhere, and the entire research project may need to pause or stop until the situation has been fully assessed. Such incidents may trigger a proposed revision of operating procedures and an additional review by the Research Ethics Committee[13].

It is not only medical research, however, which has the potential to cause harm. Studies that explore traumatic, shameful or stigmatised experiences have the potential to distress survivors or disrupt relationships. The participant's cultural, educational, and socio-economic background must be treated sensitively[14], respected and protected throughout the research project. This may be as practical as working around festivals in a particular community or engaging with community leaders in advertising the research.

In the event of harm, the research team may need to show that they followed procedures and carried out a thorough risk assessment. If they can demonstrate that their intention was to uphold the dignity and safety of the participant[15], and that no malice or incompetence was shown, then individual researchers should be cleared of liability. If legal redress is sought, the institution that funded the research would be liable for any damages awarded.

As well as minimising harm to research participants, research should avoid causing harm to Public Contributors or drawing them into involvement in a project that causes harm to others. The process by which Public Contributors are engaged in supporting research should be shaped by an understanding of what constitutes best practice in the field. This is illustrated in a paper by Mitchell and colleagues[16], who elegantly describe their practice in involving young people using palliative care services in research. Pandya-Wood et al[17] and Ludwig et al[18] adopt similar positions. All these papers describe their vision of best practice as 'ethical' practice, which, of course, it is. However, none of them focus on the role of public contributors as Citizen Ethicists[19], but instead view them as consumers of the ethical practices of those who organise the public involvement activities.

Serving as a Public Contributor can be distressing, especially when it involves witnessing or recounting upsetting events, and this highlights some important ideas about harm. The teenager who describes their experience of living with a life-limiting illness to the researcher may judge it to be worth the tears, even if it troubles her parents. Faulkner reminds her readers that while attempts to protect people from harm can be patronising, some people experience distress but want to continue, and distress is not the same as harm[20]. This issue is further discussed elsewhere[21], and Burke and Newman set this in a broader context that challenges assumptions about the identity of Public Contributors:

> *'Fundamental to the ethical involvement of service users is not only an understanding of their individual and collective experiences of marginality, disadvantage and oppression, but also their narratives of resistance, struggle and challenge.'* [22]

Indeed, the general advice 'do no harm' is complicated when one looks at these matters for individuals, and for communities too, as actions to promote equality will inevitably harm the elite status of the powerful[23]. Power is an ethical matter that will be of interest to Public Contributors, whether it appears in the guise of elites in society or when all the research subjects are drawn from one section of society[24] and the findings are then assumed to apply to everyone.

5: Guard data to uphold privacy

Research must minimise intrusion and so data which is not relevant to the research being carried out should not be collected. Anything that is acquired needs to be handled in line with Data Protection law[25] and guidance on handling sensitive data[26]. Data must be:

- Collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes

- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures required by the GDPR in order to safeguard the rights and freedoms of individuals
- processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage

As was mentioned above, participants must be given the right to withdraw their data from the research. This obliges the researcher to be able to identify each participant's data so that they can remove it from analysis if necessary. To do this without gathering more data than necessary, researchers may need to issue each participant with a unique participant number, or some other identifier, so that an individual's data can be found. The right to withdraw begins at the start of contact with the research study and ends at an agreed deadline before analysis and dissemination is begun, so that a late withdrawal does not nullify these stages. Some participants in long-term projects may wish to discontinue before the project is complete but are willing to leave the data that have already been collected in the study, rather than asking for it to be withdrawn.

Personal information, including contact details, which has been collected for one study may not be used to market another unless specific consent has been given. Confidentiality needs to be assured, especially when using direct quotations in published material, as they might contain hidden identifiers that people who know the person well will recognise.

Some researchers have adopted the practice of returning data to the individual or community from whom it was collected at the end of the study, rather than destroying it[27]. Others have obtained permission for it to be deposited in a databank in anonymised format where it may be interrogated by researchers in the future[28].

6: Do good science to advance real knowledge

It is important to be explicit about the selection and use of research methods, as poor methods erode the quality of scientific work[29] and each one contains inbuilt assumptions about the nature, location and ownership of knowledge, as well as the appropriate relationship between researchers and citizens[30]. Public Contributors can be involved in all stages of research production, whether the methods are positivist, participatory or something else. That being said, participatory research probably offers the most explicit

and intertwined examples of the issues that may affect the involvement of Public Contributors in every approach[31].

Public Contributors may not have received training in research methods, and as a result, may be unable to effectively challenge incompetent study design[32], but it cannot be assumed that others involved in reviewing and commenting on the research proposal will fare better[33]. A conflict of interest[34] can result in evidence being ignored or some findings being promoted over others. The interests of pharmaceutical companies may distort medical research as may the interests of lobby groups, especially where money is involved[35]. Since many stakeholders in research have multiple interests that could conceivably create conflicts, explicit and proportionate approaches should be adopted to manage them, reserving disqualification for the most potent risks.

Many research designs study phenomena by looking for differences between groups. Some research finds differences big enough to be reasonably sure they are not due to chance. Some does not. Reporting a null finding, where no significant differences were found in the research can still be useful information. An example of this is research into same sex parenting, where researchers have designed studies to seek differences in wellbeing, social skills and academic achievement between children raised by heterosexual and homosexual couples. The null finding – that there is no evidence of differences - is useful information in the debate surrounding gay rights[36].

7: Behave well to earn respect

In Westernised societies, experts have sometimes formed professions to regulate the conduct of their members. Unethical practice could trigger sanctions for the research team, and this is best avoided by ensuring that everyone involved in the research is aware of and compliant with the requirements of ethical conduct. Whilst some regulators have attempted to define ethical research by creating a catalogue of offences to avoid, Mayan & Daum have encouraged a positive stance by describing the virtuous researcher[37] and the same approach may be taken in respect of Public Contributors. We might imagine that the ethicist is applying moral reasoning to generate ideas about the right way to conduct the research, while the virtuous person is translating those ideas into conduct. The consequence of this approach is that everyone involved in producing the research, both academic and Public Contributor, is expected to conduct themselves in an ethical manner, which may be set out in a Code of Conduct which applies equally to all, whether employed or not[38].

Some research projects insist that participants are not involved in any other research at the same time and for a specific time afterwards, since participation in one study might affect the evidence collected for the other. This is explained to potential participants when they enrol in the study, but, despite this, some people lie[39]. Researchers also misbehave[40] while organisations can inflict moral distress and injury[41] on staff, Public Contributors and research participants, so there is a need for vigilance for all.

This would be much easier if there was a universal, shared understanding of right and wrong. The more severe offences, such as fabricating data, are easy to judge, but Groot and colleagues[42] tell an important story about report writing. For one peer researcher, telling the truth meant writing a damning report, while for other team members, a more

sympathetic report would be more likely to win support and achieve change. Citizen Ethicists will have views on such matters.

8. Use resources wisely to maximise benefit

For some Public Contributors and others, research that merely adds to the store of knowledge without improving services is unethical[43], so a proper balance is needed between finding things out and implementing change. This balance also underlies some disagreements over what constitutes the benefits of research, since some see this as confined to additions to the store of knowledge as published in the academic press, while others consider impact as the true benefit, which arises when people's lives get better[44]. There is evidence that patients and researchers do not often agree what should be considered to be the most important outcome of a healthcare intervention[45].

Studies that fail to recruit enough participants will be unable to generate results that are meaningful and so they may be stopped and the savings used for other projects. The number of participants required to produce meaningful results will vary significantly with the research subject and design. Some qualitative research designs produce detailed case studies of small number of participants. These studies should not claim to describe a universal experience but can be useful to prompt thought, discussion and further research. In other cases, quantitative research designs use statistical analysis of large numbers of participants to understand phenomena throughout a wider population. In each case the number of participants and amount of data collected should be sufficient to support the claims being made in any published research.

Historically, lots of research has focused on the experiences of people from ethnic majorities in Europe and North America[46]. Some of this research has employed poor practices where people with power and privilege have presumed their own experiences to be universal. New research designs should work to ensure that the group of participants taking part in the research are broadly representative of the populations about which the research hopes to make claims.

Proper stewardship of financial, human and environmental resources will result in savings and worthwhile purchases. Public Contributors sometimes reject offers of payment, preferring instead to retain their ability to challenge from a position of financial independence from the research project, but others feel devalued if they are expected to serve for nothing.

Good stewardship also demands lean administrative systems that avoid wasting staff time and squandering funds. Streamlining burdensome approval processes for research would release resources for use in other projects[47].

9: Conclusion

Having established a framework of six goals, each with its concomitant hazard, the question of their relationship to one another must be addressed. For some, promoting safety is the pre-eminent goal and the other five targets comprise no more than mechanisms to deliver this, subordinate goals that must be pressed into the service of the

one dominant purpose. In this suite of papers, the six goals are idealised as mutually interdependent and considerably overlapping, but conceptually distinct and with no general hierarchy between them. This is not one river with several tributaries, but six rivers that together water the land, frequently overflow their banks and can both destroy life and nourish growth. So, for example, an over-zealous concern for avoiding harm will infantilise research participants, while promoting choice, advancing knowledge and maximising benefit all point to a better partnership between research participants and researchers[48].

Taking this multidimensional approach to research ethics rather than attempting to reduce the discussion to risk and harm also aligns a little with Haidt's analysis of the emotions that drive moral psychology. He too offers a six-factor model, using the metaphor of a tongue with six taste receptors, and he too does not claim that his factors are mutually exclusive or collectively exhaustive. Further work may lead to the discovery of additional items, while individual circumstances may blend factors or set them at odds with one another. In this way, the factors are more probabilistic than categorical – they describe drivers that might be in play in any particular scenario - but building fences to separate them would be difficult and unhelpful.

It is not the intention of this suite of papers to map the six goals of research ethics on to Haidt's six 'moral taste' receptors. Instead, two simple conclusions may be drawn as a conclusion to this paper, and these conclusions will appear in subsequent documents.

- First, ethical work in research is broader than minimising harm. The broader view includes promoting cooperation in diverse communities, valuing contribution by marginalised people, and upholding the sanctity of the ecosystem. These broader goals are not merely subsets of the 'harm' agenda but appear in their own right. Citizen Ethicists can contribute to these debates alongside technically knowledgeable academic researchers.
- Second, while a single factor model tends to lead to convergent thinking, assuming that there is a single right answer, a multiple factor model acknowledges that there are many different 'right' answers, since the factors interact in multiple, creative ways. Most of the time, ethical issues are complex and ambiguous, so that different people come to different views about the best way forward. Whilst a funding body, research team or ethics committee will need to converge on a decision about what to do, prior to this, they need to obtain a range of viewpoints and listen to a diverse range of opinions. Citizen Ethicists can contribute to these debates.

9: 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[49]. As readers continue to provide feedback[50], further insights will be used to update it, so please contact the authors with your contributions.

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.

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[1] NIHR Involve (2012) *Briefing notes for researchers: public involvement in NHS, public health and social care research*. Southampton: Involve. Available at https://www.invo.org.uk/wp-content/uploads/2014/11/9938_INVOLVE_Briefing_Notes_WEB.pdf.

[2] London AJ (2012) A non-paternalistic model of research ethics and oversight: Assessing the benefits of prospective review. *The Journal of Law, Medicine & Ethics.* 40(4):930-44.

[3] There are many fictional accounts of the naïve scientist working for the common good who has their invention misappropriated by the despot. Climate change scientists would make a similar point about a whole range of scientific fields that have resulted in global warming and overconsumption of the worlds natural resources.

[4] The six-item taxonomy presented here is an alternative to the four-item analysis of Beauchamp and Childress (autonomy, non-maleficence, beneficence and justice) which is less explicit about duties to science, funders and the environment. Beauchamp T & Childress J (2019) *Principles of biomedical ethics*. 8th edition ed. Oxford, UK: Oxford University Press. It also contrasts with the seven criteria set out by the WHO (i) research must be designed in accordance with valid scientific methods; (ii) risks are minimised to the extent that they are reasonable in relation to the possible benefits; (iii) participants represent those most likely to gain from resulting knowledge; (iv) conflicts of interest have been evaluated; (v) participant privacy and data confidentiality have been carefully considered; (vi) respect for persons is demonstrated via an informed consent process; (vii) the greater community is actively involved in the design and conduct of the research. See Bouesseau M-C, Coleman C, Kass N, et al. (2011) *Standards and operational guidance for ethics review of health-related research with human participants*. World Health Organisation. http://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf;jsessionid=5E488F141667C3CEA6FED5BE49301ED4?sequence=1.

[5] Steen analysed 743 papers that had been retracted and found evidence to suggest that the incidence of research fraud has been increasing. See Steen RG (2011) Retractions in the scientific literature: is the incidence of research fraud increasing? *Journal of Medical Ethics* **37:**249-253.

[6] Fanelli's meta-analysis of 32 surveys found 2% of scientists admitted to have fabricated, falsified or modified data or results at least once and up to 33% admitted other questionable research practices. See Fanelli D (2009) How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data. *PLoS ONE* 4(5): e5738. https://doi.org/10.1371/journal.pone.0005738

[7] There can be merit in deliberately revisiting previous work to confirm, extend or refute the previous findings. However, it has been estimated that half of research is never published, half of the publications are so badly described that they are no help, and half again suffer from faulty design, wasting around 85% of research. See Paul Glasziou and Iain Chalmers: Is 85% of health research really "wasted"? - The BMJ.

[8] The principle that research should be for the common good is sometimes called beneficence. "Evidence of patient involvement can help to demonstrate the public interest of an activity", according to the Question Specific Guidance on completing IRAS forms for submission to NHS RECs, question A14-2. See https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx#596. In one review of 44 studies, only 28% of the primary outcomes of the research identified by the trialists matched that chosen by Public Contributors - see Treweek S, Miyakoda V, Burke D et al (2022) Getting it wrong most of the time? Comparing trialists' choice of primary outcome with what patients and health professionals want. *Trials* 23, 537 (2022). https://doi.org/10.1186/s13063-022-06348-z.

[9] Bates P & Ward C (2020) *How to gain informed consent*.

[10] See, for example, Grotz J, Ledgard M & Poland F (2020) *Patient and Public Involvement in Health and Social Care Research.* Palgrave Macmillan, Cham. Page 7. https://doi.org/10.1007/978-3-030-55289-3_4.

[11] Ethics Committees sometimes refuse permission to interview participants about traumatic events, assuming that talking will re-ignite the trauma, despite the fact that traumatised people benefit from having the chance to talk. See Sieber JE (2008) Protecting the vulnerable: Who are they? *J Empir Res Hum Res Ethics*. Mar 1; 3 (1): 1–2.

[12] INVOLVE (2012) *Public involvement in research: impact on ethical aspects of research.*

[13] For a discussion of the systems and mechanisms through which research is governed, see P & Ward C (2020) *How to navigate research ethics – definitions, history, systems and sanctions*.

[14] Sensitivity of information: http://ccnmtl.columbia.edu/projects/cire/pac/foundation

[15] Alleged research misconduct http://www.bristol.ac.uk/secretary/dataprotection/research/consent/html

[16] Mitchell SJ, Slowther A, Coad J*, et al* (2019) Ethics and patient and public involvement with children and young people *Archives of Disease in Childhood - Education and Practice* **104:**195-200.

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

[18] Ludwig C, Graham ID, Lavoie J *et al.* (2021) Ethical considerations for engaging frail and seriously ill patients as partners in research: sub-analysis of a systematic review. *Res Involv Engagem* **7,** 8. https://doi.org/10.1186/s40900-021-00254-5.

[19] See Bates P (2020) *How to make the case for Public Contributors as Citizen Ethicists* and Bates P (2020) *How to engage Public Contributors as Citizen Ethicists*.

[20] 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 8.

[21] See Bates P (2017) *How to choose between an actor and an expert by experience*. Downloaded from https://peterbates.org.uk/wp-content/uploads/2017/10/How-to-choose-between-an-actor-and-an-expert-by-experience.pdf on 26 October 2020.

[22] Burke B & Newman A (2020) 'The ethics of service user involvement', chapter 5 in Mclaughlin, H. Beresford, P., Cameron, C. Casey, H. and Duffy, J. (2020) *The Routledge Handbook of Service User Involvement in Human Services Research and Education,* London: Routledge

[23] Many traditional research methods have been criticised as 'extractive' since they collect data from participants but do not benefit those same people in any way.

[24] It has been suggested that WEIRD people and communities are over-represented in research studies – Western, Educated, Industrialized, Rich, and Democratic. See Henrich J, Heine SJ & Norenzayan A (2010) The weirdest people in the world? *Behavioral and Brain Sciences,* 33, pp 61-83. doi:10.1017/S0140525X0999152X.

Some Public Contributors may want to question the reasons put forward for exclusion criteria that shut out some potential participants and ask whether greater effort should be expended to include them.

[25] The European Union General Data Protection Regulation 2015, as adopted by the UK in the Data Protection Act 2018 and redrafted in post-Brexit terms by the Data Protection Act 2020. Guidance on what this means for health researchers is available from the Health Research Authority at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/. Additional resources are available from the Medical Research Council at https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/gdpr-resources/.

[26] See DARE_UK-Paving_the_way_coordinated_national_infrastructure_sensitive_data_research-Aug2022.pdf (dareuk.org.uk) Published 31 August 2022 by ADR UK, HDR UK and UKRI.

[27] Banks S & Brydon-Miller M (2019) *Ethics in Participatory Research for Health and Social Well-Being: Cases and Commentaries* Abingdon: Routledge. Page 164.

[28] The advent of 'big data' processing has increased risks that previously anonymised data may be re-identified. See Rocher L, Hendrickx JM, De Montjoye YA (2019) Estimating the success of re-identifications in incomplete datasets using generative models. *Nature communications.* Jul 23;10(1):1-9.

[29] Van Calster B, Wynants L, Riley RD, van Smeden M & Collins GS (2021) Methodology over metrics: Current scientific standards are a disservice to patients and *society Journal of Clinical Epidemiology* 30 May. Doi: https://doi.org/10.1016/j.jclinepi.2021.05.018.

[30] For example, Newman and McNamara argue that qualitative research methods are coherent with the ethics of social work, since they attend to narrative, address intersectionalities and empower service users. See Newman A & McNamara Y (2015) Teaching qualitative research and participatory practices in neoliberal times *Qualitative Social Work* 0(00) 1–16. DOI: 10.1177/1473325015624500

[31] Banks S & Brydon-Miller M (2019) op cit.

[32] Pirosca's team checked the study design of 1659 randomised trials that took place in 84 countries and found only 8% carried a low risk of bias. See Pirosca, S., Shiely, F., Clarke, M. *et al* (2022) Tolerating bad health research: the continuing scandal. *Trials* **23,** 458. https://doi.org/10.1186/s13063-022-06415-5. Pirosca et al recommend that funding is provided on the condition that research teams include a statistician and a methodologist. However, Shaun Treweek (who is co-author dealing with correspondence), acknowledges that there is not yet evidence to indicate whether the poor studies lack these professionals while the well-designed studies include them, or the problem is due to the incompetence of these team members. An MSc student is interrogating the data on UK trials to answer this question (personal correspondence, June 2022).

[33] In a study of Institutional Review Boards in the USA, Mhaskar's team found that a third of members who were qualified medical doctors failed a test designed to elicit their knowledge of the appropriate way to conduct a randomised controlled trial. Mhaskar R, Pathak EB, Wieten S, Guterbock TM, Kumar A, Djulbegovic B (2015) Those responsible for approving research studies have poor knowledge of research study design: a knowledge assessment of institutional review board members. *Acta Informatica Medica* Aug;23 (4):196.

[34] For a discussion of conflicts of interest that may apply to Public Contributors, see Bates P (2020) *How to manage overlapping roles in research.* Downloaded from https://peterbates.org.uk/wp-content/uploads/2019/11/How-to-manage-overlapping-roles.pdf 24 October 2020.

[35] For a discussion for Public Contributors of the potential impact of commercial interests on health research, see Bates P (2020) *How to decide whether to support public involvement in commercial projects*. Downloaded on 24 October 2020 from https://peterbates.org.uk/wp-content/uploads/2020/01/How-to-decide-whether-to-support-public-involvement-in-commercial-projects.pdf. The following paper underlines the need for an ethical approach in partnership work between people with mental health issues, industry and academia - Lignou S, Singh I. Pharmaceutical industry, academia and people with experience of mental illness as partners in research: a need for ethical guidance. *Wellcome Open Research.* 2020 Aug 20;5(196):196.

[36] Knight KW, Stephenson SE, West S, Delatycki MB, Jones CA, Little MH, Patton GC, Sawyer SM, Skinner SR, Telfer MM, Wake M, North KN, Oberklaid F (2017) The kids are OK: it is discrimination not same-sex parents that harms children. *The Medical Journal of Australia* 207 (9) : 374 – 375.

[37] "Being friendly and possessing strong social skills; being honest and authentic; demonstrating care, empathy, compassion, concern, and commitment; and being a clear and open communicator." Mayan MJ, Daum CH. Worth the risk? Muddled relationships in community-based participatory research. *Qualitative health research*. 2016 Jan;26(1):69-76.

[38] In some settings, employees have a disciplinary procedure and Public Contributors have a Code of Conduct. The expectations for self-regulation and challenge, the threshold between forgiveness and action, transparency of the process and confidentiality afforded to offenders should be fair and equitable, while the mechanisms for maintaining standards and applying sanctions will be tailored to the person's employment status. Discussing a Code of Conduct with Public Contributors whilst making no reference to the disciplinary procedures that bind staff would likely send a message that Public Contributors are untrustworthy.

[39] 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. Ten percent of participants in their sample admitted to dual enrolment. In the UK, a few studies are protected by a participant register called TOPS - see https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/. This is used for Phase 1 studies only, 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.

[40] For example, Phillips et al found that more than half of CVs submitted by academics applying for a job included at least one publication that was unverifiable or inaccurate in a self-promoting way. See Phillips T, Saunders RK, Cossman J, Heitman E. Assessing Trustworthiness in Research: A Pilot Study on CV Verification. *Journal of Empirical Research on Human Research Ethics*. 2019;14(4):353-364. DOI:10.1177/1556264619857843.

[41] British Medical Association (2021) *Moral distress and moral injury: recognising and tackling it for UK doctors.* Downloaded from https://www.bma.org.uk/media/4209/bma-moral-distress-injury-survey-report-june-2021.pdf. Also Sunderland N, Catalano T, Kendall E, McAuliffe D & Chenoweth L (2011) Exploring the Concept of Moral Distress with Community-Based Researchers: An Australian Study, *Journal of Social Service Research*, 37:1, 73-85, DOI: 10.1080/01488376.2011.524526.

[42] Groot B, Haveman A, Abma T (2020) Relational, ethically sound co-production in mental health care research: epistemic injustice and the need for an ethics of care. *Critical Public Health*. May 28:1-1.

[43] See Faulkner A (2004) op cit. page 4.

[44] This can result in research proposals being rejected, especially if scientific knowledge is also perceived narrowly, so that a proposal that employed qualitative rather than quantitative methods, small sample sizes and contextual approaches may be seen as generating only small amounts of generalisable findings, and thus to be of little benefit, even if participants reported life-transforming gains. See Bradley M (2007) Silenced for their own protection: How the IRB marginalizes those it feigns to protect. *ACME: An International Journal for Critical Geographies*. 6(3):339-49. At the other end of the research journey, Groot and colleagues describe the process of writing recommendations for crisis psychiatric care. The academic is under pressure because of the demands on productivity and the implications for her career, but this is dwarfed by the pressure on the expert by experience who may have to endure the reforms (or their absence) in the emergency room of the hospital. See Groot, Haveman & Abma (2020) op cit.

[45] Treweek, S., Miyakoda, V., Burke, D. *et al* (2022) Getting it wrong most of the time? Comparing trialists' choice of primary outcome with what patients and health professionals want. *Trials* **23**, 537. https://doi.org/10.1186/s13063-022-06348-z.

[46] Ashuntantang G, Luyckx V, Naicker S & Venkatapuram S (2021) Reform of research funding processes could pave the way for progress in global health *The Lancet Global Health* Open Access. 1 August, 2021. Vol 9, issue 8, E1053-E1054. DOI: https://doi.org/10.1016/S2214-109X(21)00207-2.

[47] Petrova, M., Barclay, S. Research approvals iceberg: how a 'low-key' study in England needed 89 professionals to approve it and how we can do better. *BMC Med Ethics* **20,** 7 (2019). https://doi.org/10.1186/s12910-018-0339-5.

[48] Beebeejaun and colleagues challenge the stance of Ethics Committees that focus on vulnerability. See Beebeejaun Y, Durose C, Rees J, Richardson J, Richardson L. (2015) Public harm or public value? Towards coproduction in research with communities. *Environment and Planning C: Government and Policy.* Jun;33(3):552-65.

[49] 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.

[50] All errors and weaknesses that remain in this document are the responsibility of the authors.