How to navigate research ethics – definitions, history, systems and sanctions

Written by Peter Bates and Catherine Ward
Email for correspondence: peter.bates96@gmail.com

Contents

1.   What this paper is about

Within a suite of papers[1] exploring research ethics and the role of Public Contributors, this guide provides background information. It is divided up into four topics – definitions, history, systems and sanctions. Companion papers describe harm and how to minimise it, informed consent and how to obtain it, and the role of, and support for, Citizen Ethicists.

2.   Definitions

Ethics is a very broad term[1] that may be used to convey any of the following:

- Compliance with the law – avoiding criminal wrong

- Compliance with contractual and procedural requirements – avoiding disciplinary action by competently delivering what is expected

- Acting in accordance with best practice norms held by a professional group, whether or not these are set out in writing, and whether or not the group is formally constituted in any way

- Adhering to moral standards in both professional and private life rather than behaving in a dishonourable or shameful fashion[2]

- Sacrificing personal comfort and gain by taking risks to meet the highest ideals of a society

- Exercising personal integrity by acting in accordance with one's personal convictions

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[1] The companion papers to this guide comprise Bates P & Ward C (2020) *How to avoid doing bad research*; 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*.

- Recognising that others may hold different views about the right way to act, especially when the items listed above clash with one another, and bringing these matters into the open so that they can be debated.

- Careful analysis to work out what to do when it is not at all obvious what is right (e.g. the ethics of human tissue research or migration) but also analysing the 'obvious' to lay bare the ethical structure of cultural norms.

Davis[3] offers a simple set of tests to support ethical reasoning:

1. **Harm test**: does this option do less harm than alternatives?
2. **Publicity test**: would I want my choice of this option published in the newspaper?
3. **Defensibility test**: could I defend choice of option before Congressional committee or committee of peers?
4. **Reversibility test**: would I still think choice of this option good if I were adversely affected by it?
5. **Colleague test**: what do my colleagues say when I describe my problem and suggest this option as my solution?
6. **Professional test**: what might my profession's governing body or ethics committee say about this option?
7. **Organisation test**: what does the company's ethics officer or legal counsel say about this?

Examining relevant literature on this topic is complicated by the range of terms that are in use, with each conveying a slightly different emphasis. Some writers consider science to be about facts, while *politics* is about power to enforce *value* judgements, and they go on to suggest that the politics should be taken out of scientific endeavours as they are *extrinsic*, confounding factors. For others, discussions of *moral* judgements are confined to private, unobserved behaviour or perhaps expand into self-righteous declarations of what constitutes the *right* thing to do. Yet more taxonomists consider morality to be the unexamined *norms* that shape unthinking responses in a particular community while *ethics* is the deliberate examination of these topics leading to a specification of the *right* answer to the question. Finally, *virtue* might refer to the entire lifestyle of the person, including their relationships with other people and the planet, while others use the term to emphasise the inner, unobserved life that shapes the person's conduct in distinction to externally imposed *rules* or social expectations. In this suite of papers, the term 'ethics' is used, as this is the dominant term in health research – after all, people do not refer their proposals to a Research Politics Committee or a Research Norms Committee.

Experts in ethics have listed some of the possible approaches as:

- The 'consequentialist' approach which looks at what happens as a result of the decision. From this perspective, if you do not cause an accident or get arrested then there is nothing wrong with driving faster than the speed limit on a quiet road.

- The duty or 'deontological' approach declares that there are certain universal moral laws, such as 'do not kill' and expects people to obey them irrespective of the consequences.

- The 'proceduralist' approach considers that people who follow laws and procedures are doing the right thing. Adolf Eichmann used the Nuremberg Defence to claim that, as he was following orders from a superior officer, he was not guilty of war crimes.

- The 'virtue' approach considers whether the person had good motives, like Julian Assange who claimed to be acting ethically when he published secret papers.

- The 'relational' approach situates the person in a particular encounter with another person and considers how that relationship is conducted.

The first of these approaches, sometimes termed 'normative' implies that any action can be separated from its context and then judged as right or wrong, by ignoring the multiple layers and complexities of any individual act. To extend the first example given above, speeding to reach the hospital in time to save a life is virtuous, while unobserved racing on a quiet road may create a habit of lawlessness. In contrast, the relational approach is highly contextual, as described in the following table:

Table 1: Relational Ethics[4] vs. Normative Ethics as described by Simon Nuttgens[5]

Relational Ethics	Normative Ethics
Answers the question: How should I be with the other?	Answers the question: What is the right thing to do?
Reflects continuously on the quality of the unfolding relationship	Examines rightness and wrongness of actions after the fact
Is based on interdependency, relational personhood, dialogue, and ongoing questioning	Is based on principles that tend to be prescriptive, broad, and abstract
Embraces contingency, humility, and uncertainty	Seeks universality and certainty
Ethical knowledge is developed in, and through, the relationship	Ethical knowledge is developed through prevailing Western ethical theories
Promotes ongoing sensitivity to ethical tensions throughout the relationship	Focuses on making reasoned and defendable decisions when confronted by an ethical problem or dilemma

People described as **Public Contributors** appear in this paper. This group includes people who have lived through the experience that is being studied, and so are 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'[6]. The group also includes family carers of a person with lived experience, and members of the general public who have no more than a general interest in the subject under scrutiny and remain outside both the academic community and the group who share the lived experience.

Public Contributors support the research project by advising the research team on all stages of the research, from selecting the research question to publishing the final report. There are three main ways in which they might engage with ethics:

- by understanding the nature and administrative processes of ethical research, so they grasp how each stage of the research process should be undertaken, with a particular consideration of ensuring that research participants are not harmed

- by enjoying the benefits of an ethically designed mechanism for their engagement and contribution, so that they are not harmed themselves through their involvement[7]

- by adopting the role of Citizen Ethicist, by bringing a distinctive contribution to the process by which the whole research enterprise maintains its ethical vigilance.[8]

Knowledge politics explores how differences in power and influence accrue to expert over lay opinion, to scientific over other ways of knowing and to facts over values[9]. When these political processes are ignored, people rendered invisible and silent by them may choose to step away, leaving decision-making to those with only one kind of knowledge about the world. Without the diverse views of Citizen Ethicists, a particular worldview becomes 'obvious' and uncontested, potentially privileging numbers over stories as a way of finding stuff out, learning stuff over helping people as the purpose of the work, and academics over patients as the preferred audience with whom to share the results. Public Involvement facilitators may adopt the role of knowledge broker[10] by encouraging respectful dialogue[11] between groups who hold different ways of knowing and reasoning as well as different skills, knowledge and awareness.

The matters addressed through research ethics relate to notions of the public interest, or what some people like to call the common good[12]. These are simple terms that belie the complexity that underpins them, as all ethicists, political thinkers and indeed ordinary citizens are well aware. Choosing to fund research into rare rather than common diseases, measuring biochemical changes rather than social capital, and reporting findings in the Lancet rather than on Twitter[13] are decisions that have an ethical as well as a political dimension, that all serve distinctive interpretations of what constitutes the public interest. Citizen Ethicists can contribute.

Ethical labour[14] is a term coined here to mean the effort required to come to a decision about the right way to think, speak or act in a particular situation. Haidt collates evidence[15] to show that in many circumstances, humans have a rapid, gut-level judgement about right and wrong, and rationalisation appears as an afterthought, providing a convenient justification to gloss the original instinctual reaction. Sauer[16] adds a third system that enables humans to select moral issues and conduct a thought experiment without disrupting ordinary processing. Ignatieff explains that, for him, virtue is a 'life skill, a practice acquired through experience, rather than an exercise of moral judgement or an act of deliberative thought'[17]. These explanations belie the amount of ethical labour ordinary people expend in teasing out the rights and wrongs of the situations they encounter[18]. This effort may be needed when using one or more of the following approaches to discovering the right thing to do:

- **Obligation.** Investigation of external, relevant, legal, contractual or social requirements followed by application of these requirements to the particular situation – an example of the 'duty' approach mentioned above. Considerable

ethical labour may be needed when the law is hard to find, difficult to interpret or where more than one law is relevant and directives appear to contradict. Sometimes the ethical labour is expended in taking the dilemma to the court of public opinion and taking a lead from what others direct as the right way forward.

- **Moral principles.** Analysis of the particular dilemma to gather relevant data and uncover its fundamental issues. One then searches one's personal moral principles in order to find relevant universal laws that can be ranked and then consistently applied to situations of this type. This exercise in moral reasoning reveals the right response to the individual situation whilst also adding a new case study to memory that confirms the importance of these rules of life. From time to time, an entirely new situation emerges and, after considerable ethical labour, a new rule is created.

- **Comparison of stories.** For individuals who have little interest in conscious learning or making universal rules, stories may capture and distil a sense of right and wrong. Where things are ambiguous and there are several possible outcomes, each is accessible as a story, myth or piece of gossip. These may be accounts of just desserts or second chances and redemption, of martyrdom or the triumph of love over power. Ethical labour is required to curate these stories, to compare the current dilemma with the storybank, to select and apply the relevant story or stories and so to decide what is the right thing to do.

- **Introspection.** This refers to the internal processing that may yield a sense of what seems right. People sleep on it or meditate, ask God or the tea leaves, or visualise alternative outcomes and then attend to their emotions. The process of musing over or cogitating on the issue is not primarily a process of moral reasoning or the application of universal moral laws, but, despite this, it is effortful. In holding the issue in mind, searching the heart and working around numerous vantage points from which to view the issue, the person eventually settles on a conviction about the right way forward. This involves a great deal more ethical labour than the unthinking virtuous acts that are directed by society's norms or that are a natural part of the character and make-up of that individual.

Considered moral judgement. Whichever approach or combination of approaches is employed, the goal has been termed a 'considered moral judgement. The individual has completed their ethical labour and come to a settled view about the best way forward. The impact on each potential stakeholder has been considered and ranked, each possible benefit or harm has been weighed and compared, mitigations have been set in place, and the person is reconciled and at peace with the decision they have made. Where others are involved, the person has strategies for dealing with disagreement and is content to hold their position without regret. This individual judgement adds to the person's 'reflective equilibrium' and is coherent with their personal understanding of themselves and of the principles by which they wish to live. For example, we might imagine that Nelson Mandela achieved this position when he supported armed struggle and again when he refused Botha's offer of release from prison after 20 years' incarceration.

Restless Vigilance. Nor is the ethical labour over once the decision has been reached about the right way forward. While egregious examples of abuse are comparatively easy to judge, most everyday ethical moments are mundane and ambiguous, loaded with multiple potential outcomes, both practical and moral. Opening a foodbank may reduce malnutrition amongst the poorest sectors of society (good), whilst simultaneously delaying the introduction of decent welfare benefit payments (bad); strengthen community cohesion (good), whilst also increasing passivity and dependency (bad); reduce food waste (good), whilst giving retailers a means of virtue signalling rather than addressing supply chain issues (bad); increase educational attainment (good) whilst doing nothing about income inequality and mass unemployment (bad). All these potential consequences may arise concurrently and so can be considered in the preparation for a decision point, and afterwards the horizon must be scanned for unexpected events and unintended consequences. Once a decision is made, restless vigilance is needed to monitor for unpredictable harms and adjust if the balance shifts from benefit to harm.

Having said this, many everyday decisions are effortless reflexes, simply because it is impossible to review everything all the time, and so intuition[19], habits and cultural norms take over, reducing the ethical labour required to get through the day to a manageable level. Whether ethical labour is expended or not, there is still an ethical aspect to the outcome.

3. A short history of research ethics

Research ethics regulate the conduct of health research and try to prevent researchers causing harm by hurting research participants or making unjustified claims. They are used as a framework to train and monitor scientists who conduct research, both in the public sector and in for-profit organisations such as drug companies.

The first significant attempt to write down detailed ethical standards[20] for researchers arose from the trials that took place in Nuremberg in 1946-47 of doctors who had carried out experiments on Nazi concentration camp inmates. These experiments were judged to be unacceptably brutal and injurious to the prisoners, amounting to torture[21]. The judgements handed down at this court contained what has become known as the Nuremberg Code of medical ethics which aimed to protect the rights, dignity and safety of participants in medical research. Subsequent international declarations, such as The Declaration of Geneva in 1948 and the Helsinki Declarations of 1964-2013[22] have refined this code of ethics.

The Helsinki Declarations extended the Nuremberg Code to include research persons who were judged to be vulnerable. They also looked at the period of time before the research formally starts; anticipated the role of the modern Research Ethics Committee by appointing a research investigator to review potential research projects; considered the nature of informed consent; and designed arrangements to preserve the accuracy of research results.

Despite these regulations, unethical and dangerous research continued[23]. For example, from 1932 to 1972 at Tuskegee, Alabama[24], African American prisoners were denied access to diagnosis and treatment for syphilis so that researchers could track the natural progress of the disease. In 1939, Wendel Johnson told ten orphans picked at random that they were

destined to become stammerers, leaving several with lifelong speech impediments[25]. In 1951, a group of children were removed from their parents in Greenland and taken to Denmark[26]. In the 1960s, researchers deliberately infected children with learning difficulties with hepatitis in return for a reduction in fees at Willowbrook School[27] on Staten Island. In New Zealand, the 'Unfortunate Experiment' withheld treatment from women with carcinoma between 1966 and 1982[28]. In the United Kingdom, the harmful drug Thalidomide was prescribed to pregnant women. The debate about research ethics was heightened by Milgram's experiments on obedience in the early 1960s[29], Zimbardo's Prison Experiment of 1971[30], both of which subjected participants to distressing experiences, and Laud Humphreys' questionable data collection methods when studying men who have sex with men[31]. Critics such as Beecher[32] and Pappworth[33] highlighted the ways in which unethical research continued to violate participants' rights, amplifying the call for regulation.

The response to these abuses was twofold – firstly, the creation of Research Ethics Committees empowered to grant or deny approval to research proposals, and secondly, the introduction of lay members to these bodies. These two developments point to the fact that the decisions made by researchers must be open to scrutiny by others, as experts, who have vested interests in their own plans, cannot be relied upon to do the right thing. This holds true for expert researchers, who clearly thought the experiments listed above were acceptable, and for expert ethicists, who can also find their intellectual reasoning and 'rational' conclusions to be out of step with the judgement of ordinary people[34]. Whether it be the theologian Karl Eschweiler who supported the Third Reich in Germany[35] or Peter Singer, Professor of Bioethics, who considers infanticide acceptable in some circumstances[36], ethics is too important to be left entirely in the hands of the experts.

The new academic discipline of medical ethics has risen and expanded its remit[37] in response to these concerns, paying particular attention to those persons who are unable to control what happens to them, and also those persons who have little understanding that they are being harmed. This eventually gave rise to the Office of Research Integrity in the USA which in turn formed a campaign encouraging the responsible conduct of research[38]. Internationally, more than 1,000 laws, regulations and guidelines have been created to protect research on human subjects[39].

In the UK, research ethics committees were established within the NHS between 1966 and 1972[40], while social care research had to wait until 2005 before acquiring its own Committee. Other organisations self regulate by establishing their own internal research ethics process[41]. Governments underpinned these arrangements with legislative action to protect research participants through the Human Tissue Acts of 2004 and 2008, the Medicines for Human Use Regulations 2004 and 2012, the Mental Capacity Act 2005 and the Data Protection Act 2018.

The following table gives some indication of the degree of challenge provided by Research Ethics Committees and shows little difference between all opinions and those that included the word 'mental' in their title, as a crude attempt to check if mental health is treated differently.

Table #2: Opinions given by Research Ethics Committees

Studies with a REC opinion listed on the HRA database at 25/04/2021[42]	All	'mental'
Percentage of studies given a 'favourable opinion'[43]	32.0	29.8
Percentage given 'further information favourable opinion'	64.3	63.8
Percentage given 'further information unfavourable opinion'	0.1	0.1
Percentage of studies given an unfavourable opinion	2.8	4.7
Total number of studies	45,230	3,162

These figures suggest that fewer than one in twenty applications to a Research Ethics Committee receives either an outright unfavourable opinion, or an unfavourable opinion following a request for more information. This indicates that the main activity of the REC is to shape rather than approve. The consistency in the way that these options are used across different health conditions also begs the question of whether there have been changes over time.

The following table shows that the use of these options by the Research Ethics Committee has been remarkably stable over the past five years, despite an overall reduction in the number of decisions that are reached, a tiny shift away from a straight 'unfavourable opinion' to asking for more information, and the appearance of coronavirus.

In general, a third of applications go forward without need for much additional information, while in two thirds of the proposals submitted, more substantial additional information is requested. This may, of course, be a habitual response by the Committee, sharing out the applications into predetermined piles, or it may be driven by the skill level of different applicants, with only a third showing high levels of competence. It suggests that efforts to upskill applicants may have had no effect, or perhaps that the threshold has been shifting in perfect alignment with their developing skills.

Table #3: Changes over time in the opinions given by Research Ethics Committees

Studies with a REC opinion listed on the HRA database at 25/04/2021	2008-2015	2016	2017	2018	2019	2020
% of studies given a 'favourable opinion'	31.7	33.0	33.3	32.5	33.1	31.4
% 'further information favourable opinion'	66.4	63.0	62.6	63.6	63.1	65.2
% 'further information unfavourable opinion'	0.1	0.1	0.1	0.2	0.2	0.3
% 'unfavourable opinion'	1.9	3.9	3.9	3.7	3.6	3.2
Total number of studies	21449	5628	5266	5065	4761	2621

A further change occurred when the Department of Health established Consumers in NHS Research in 1996, which was renamed INVOLVE[44] around 2005 and gradually broadened its remit and its influence both at home and abroad[45]. These events took place in a broader emancipation movement amongst patients[46], but despite regulation and vigilance, people receiving public services continue to suffer harm[47], indicating that further work is needed to keep people safe both in research and across social care and health. Most recently, actions related to research ethics have been set into a broader framework that has been built to raise standards of research integrity[48], covering everything from supervision of PhD students to data handling.

4. Systems for regulating research to ensure ethical conduct

The following bodies and mechanisms have a role in maintaining ethical practices in research:

- Research Ethics Committees run by the NHS[49], Universities and Social Care. They comprise professional and lay people and must approve research proposals and key documents[50] before the research begins and also approve substantial amendments before they are implemented. Since 2002, NHS Research Ethics Committees have invited members of the research team to attend in person and answer questions and Public Co-applicants[51] sometimes attend as part of the research team. Members of the public may also attend REC meetings as an observer by prior arrangement[52].

- Funding bodies and employers, such as the National Institute for Health Research, UK Research & Innovation[53] and universities who train[54] and approve[55] researchers and exercise budgetary control.

- Regulatory bodies, such as the Health Research Authority, issue directions and protocols which guide the research process and grant permission for research to proceed[56]. From January 2022, the HRA will register all clinical trials and monitor to ensure that their results are published within twelve months of completion[57].

- Professional bodies, such as the General Medical Council and Social Work England, require their members to act ethically, including adherence with good research ethics. In addition to these formal bodies, informal groups and networks provide networking opportunities for reflexive development of practice[58].

- Policies and practices. The law[59] protects whistle-blowers – employees who act in the public interest to draw attention to someone who is acting dishonestly or endangering another person's health and safety. Procedures also guide specific decision points, such as the processes for marketing a study to potential participants and gaining informed consent, procedures for responding to adverse reactions during the study and systems for suspending or stopping a study before completion.

- Gatekeepers, who control the access given to researchers to enter their premises and interact with the people in their care. For example, hospitals have mechanisms for checking that researchers are bona-fide and their proposed activities are legitimate before they will be allowed to meet potential participants or see their files[60].

- Independent scrutiny, which provides a constructive challenge to the research team. The Steering Committee for the research project may include external experts who report to the funding body, as will the Data Management and Ethics Committee, where there is one.

- Feasibility and pilot studies enable new ideas and approaches to be tested in a small way before more substantial work is done. This helps to minimise the risks involved.

- Training in research ethics is included in qualifying courses for professional researchers, and the national course *Good Clinical Practice*[61] provides an introduction to people new to research[62].

Research which is publicly funded and involves universities, the NHS or social care[63] is subjected to scrutiny throughout its journey from idea through implementation to dissemination and adoption. Comments are sought from peer academics, who know the specific topic area under examination; methods specialists, who are skilled the process of research; people with lived experience, who can advise on the acceptability of the proposed intervention, bring a citizen's perspective and an external challenge from outside the research establishment; and sponsors, who understand how the findings of the research will be of practical value. In many cases, this scrutiny leads to recommendations for improving the proposal which in turn will enhance the benefits for the general public.

In addition to delivering benefit to participants and other citizens, ethical scrutiny protects researchers, participating organisations and funders. Avoiding the scrutiny process or ignoring its advice can result in adverse publicity and shame[64], especially when dubious practices cause harm, and when fraudulent or specious claims are made about research findings.

Public scrutiny requires public access to information, and this is not always available. For example, the NIHR website[65] places the protocols of funded research studies in the public domain. However, a sample of 120 studies revealed that fewer than one in five were available, as shown in the following table. The number of studies that had uploaded their protocols gradually increased over time, but a year after starting, no more than around a third were available for scrutiny. Furthermore, these protocols have all the detailed financial information excised from the documents before they are placed in the public domain, preventing any consideration of value for money questions by the public.

Table #4: Few protocols are placed in the public domain

Month and year	Number of studies started	Of the first ten that started this month, how many protocols available by 13 May 2021?	Month and year	Number of studies started	Of the first ten that started this month, how many protocols available by 13 May 2021?
May 2020	26	2	Nov 2020	39	3
June 2020	17	3	Dec 2020	31	1

July 2020	24	3	Jan 2021	95	0
Aug 2020	41	4	Feb 2021	53	1
Sept 2020	58	3	Mar 2021	47	1
Oct 2020	61	2	April 2021	56	0

Researchers who are invited into other settings to carry out their work may witness abuse perpetrated by education, health or social care staff, which they have a duty to report, just as they should any unethical conduct carried out by their own research colleagues. They may notify the alleged perpetrator that they intend to report them for their actions. Depending on the circumstances, this may include reporting to the Police, the local Children or Adult Safeguarding Board, the Care Quality Commission, professional bodies, the Principal Investigator, the research funder and the relevant people in the organisation who are hosting the research activity.

5. Taking action and sanctions

Ethical practice requires at least two things – an awareness that something has gone wrong or might go wrong on the one hand, and an action on the other. Whether the action means that the person takes the step of distancing themselves from the unethical conduct of others, prompting discussion about it or reporting misdemeanours to the authorities, to be aware without action is a kind of unethical conduct in itself.

Training in bioethics may help Public Contributors and others to understand some aspects of what constitutes ethical research, and training in deliberation skills[66] may help individuals and groups resolve competing issues and interests to find a way forward, but this training is unlikely to cover the whole topic or change behaviour[67]. Public Contributors are generally subject to power inequalities in comparison to salaried members of the research team, and these power differentials are exacerbated when Public Contributors are drawn from marginalised and seldom heard groups[68].

Available sanctions include the following:

- Participants, the public and colleagues can withhold or withdraw their support and cooperation.

- The Research Ethics Committee can deny permission to start or continue

- The funder can pause or stop the research by withholding funds

- Employers can sack employees or deny opportunities for promotion

- A professional body can use its fitness to practice process to withdraw protected title[69]

- Publishers can refuse manuscripts submitted for publication, or retract those previously published

- The court can prosecute a civil or criminal case[70]

- The media can vilify.

6. 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[71]. As readers continue to provide feedback[72], 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] Koehn presents a profession as (i) licensed by the state, (ii) is regulated and disciplined by a membership body, (iii) has specialist and skills, and (iv) enjoys autonomy. See Koehn D (1994) *The Ground of Professional Ethics*. Routledge. Also the critique of experts in Nussbaum M (1997) *Poetic Justice.*

[2] These ideas are alluded to in Nolan's 'Seven principles of public life and the 2019 Kark report on the 'fit and proper person' test in the NHS. See Nolan at https://www.gov.uk/government/publications/the-7-principles-of-public-life/the-7-principles-of-public-life--2. For the Kark report, see https://www.gov.uk/government/publications/kark-review-of-the-fit-and-proper-persons-test.

[3] Davis, M. (1999) *Ethics and the University.* London: Routledge.

[4] Gabriel, L., & Casemore, R. (2009). *Relational ethics in practice: Narratives from counselling and psychotherapy.* New York, NY: Routledge. Also Pincoffs, E. (1971). Quandary ethics. *Mind*, 80(320), 552-571.
[5] Used with permission via personal correspondence, February 2021.

[6] The term 'expert' is contested. I use it to refer to the insight and understanding that the person holds about themselves, while others take it to mean that the person has authorisation to speak on behalf of others or to silence the voices of those who do not qualify as experts. Some take it to refer to the ability to articulate and

write about relevant personal lived experience. Yet more link it with the sociological critique of professionals, which argues that mechanisms (such as accredited training and restricted title, infrastructure organisation to lobby for and defend group interests, define acceptable conduct and discipline those who commit misdemeanours) all work to confer and maintain inappropriate power over others. Yet more have contrasted studies of expertise with studies of the professions.

[7] This second point is partly addressed by the whole suite of *How To* guides found at https://peterbates.org.uk/home/linking-academics-and-communities/how-to-guides/. The need to design systems of involvement and engagement that treat individuals and communities well is set out in NIHR (2021) *Ethical dimensions of community engagement and involvement in global health research.* Downloaded from https://www.nihr.ac.uk/documents/ethical-dimensions-of-community-engagement-and-involvement-in-global-health-research/28258?pr=. Ensuring that Public Contributors are not harmed is one of the reasons for building a safe system for their recruitment and participation, but the basis for doing so has been debated. Rather than blurring the distinction between Public Contributors and research participants as a means to grant similar protection to them, Murphy and Weijer argue that the rationale is that as citizens caught in the tension between the state's obligations to conduct health research and to protect all its citizens, they are owed a duty of care – that they are akin to other research bystanders. See Murphy N & Weijer C (2022) Research bystanders, justice, and the state: Reframing the debate on third-party protections in health research. *Bioethics*, 1– 9. https://doi.org/10.1111/bioe.13070.

[8] Further reading on this topic may include Eric Schwitzgebel (10 Nov 2020) *A theory of Jerks* as this includes material on how professional ethicists go wrong. For an example from outside health research, we might consider the mismatch between Helen MacNamara's role (Director General for Propriety and Ethics at the UK Government Cabinet Office) and her attendance at a raucous, illegal party on 18/06/2020 during covid lockdown for which she was subsequently fined -Former government ethics chief 'fined' over Cabinet Office lockdown karaoke party (civilserviceworld.com).

[9] Pandey P, Sharma A (2021) Knowledge politics, vulnerability and recognition-based justice: Public participation in renewable energy transitions in India. *Energy Research & Social Science*.;71:101824.

[10] Martinuzzi A & Sedlacko M (2017) *Knowledge brokerage for sustainable development: Innovative tools for increasing research impact and evidence-based policy-making*. Routledge.

[11] Dialogue can only happen when power differentials are minimised. A stronger approach is taken by Standpoint Theory, which argues that marginalised people see more and so their perspective should be privileged over the views of the dominant class.

[12] This concept has a long history, having been discussed by Aristotle, Thomas Aquinas and Jean-Jacques Rousseau amongst many others.

[13] The whole business of pushing research beyond the academy so that it is relevant to, guided by and useful for the public is captured in the title 'public scholarship'. See Leavy P. *Popularizing Scholarly Research: Research Methods and Practices*. Oxford University Press; 2021 Aug 17.

[14] This term is used here to refer to the hard work of working out what is the right thing to do. Other writers use the term 'ethical labour' to refer to terms and conditions of employment that treat employees with dignity.

[15] This is different from the activity of Haidt's 'elephant rider' in at least two ways. First, the elephant rider appears after the decision has been made to provide a justification for it; a task that demands more political labour than ethical labour. Second, in many situations, ethical labour does not merely confirm one's initial gut response but may challenge it. To use an extreme example, seeing someone amputate another's limb will evoke an initial response of disgust and horror. Collecting additional information reveals that the person committing the amputation is a doctor, which reverses the judgement and creates images of life-saving surgery. Then finding out that the doctor is Josef Mengele and the setting is Auschwitz turns the tables once more. For more about the image of the elephant rider, see Haidt J (2012) *The righteous mind: Why good people are divided by politics and religion.*

[16] Sauer H (2018) *Moral thinking, fast and slow.* Routledge.

[17] Ignatieff M (2017) *The ordinary virtues: Moral order in a divided world* Cambridge Mass: Harvard University Press, page 27.

[18] The notion of ethical labour does not seem to appear in academic work on ethics. It is not listed on the Ethics Unwrapped online resource (and the founder of this site, Cara Biasucci, recognises the idea but has not found an academic treatment of it, and a similar response was given by Professor Christopher Woodard (personal communications, February 2021). Professor Shaun Nichols hasn't offered an academic term either and suggests that this kind of moral evaluation is natural and even pleasurable, so some people would not count it as burdensome labour (personal correspondence, March 2021).

[19] See work on intuition by Marta Sinclair.

[20] In the 19th century, Thomas Sydenham distilled the Hippocratic Oath, dating from the 5th century BCE into "First do no harm". Nuremberg began the process of adding detail to this aphorism.

[21] A series of experiments were carried out in Unit 731 in Japan between 1937 and 1945 that may be considered even more brutal than those perpetrated under the Nazi regime. However, American authorities granted the perpetrators immunity and details were suppressed after the war, so these events did not make the contribution to the international formulation of research ethics that they should have done. See Unit 731 - Wikipedia.

[22] The Helsinki Declaration of 1964 has been revised seven times, and each revision has generated its own ethical debates and conflicts, showing that there is not a simple unanimous view on everything it covers. See https://en.wikipedia.org/wiki/Declaration_of_Helsinki#:~:text=%20%20%20v%20t%20e%20Research,Nuremberg%20C%20...%20%201%20more%20rows%20 accessed 5 November 2020.

[23] In the USA in 1972, over 90% of new drugs were being first tested on prisoners. 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.

[24] Reverby SM (ed) (2012) *Tuskegee's truths: rethinking the Tuskegee syphilis study*. UNC Press Books. Plans are in place for an apology from one of the stakeholder organisations, fifty years after this abuse was exposed and halted – see New York fund to publicly apologize for its role in Tuskegee syphilis study | New York | The Guardian.

[25] Silverman FH (1988) The "monster" study *Journal of fluency disorders* Vol 13, issue 3.

[26] Helene Thiesen and 21 other children from Greenland's indigenous Inuit community were taken to Denmark in 1951 as part of a social experiment. The aim was to learn the Danish language and culture as a part of an effort to create new Greenlanders who could be models for a modernised Greenland. The experiment was orchestrated by the Danish government, Save the Children Denmark, and the Danish Red Cross. The original plan was to place orphans from Greenland with Danish families for a year and then send them back to an orphanage in Nuuk where they could bridge the gap between the Danish and the Inuit culture. In reality, these children were selected by headteachers and priests who had been asked to find suitable children around the age of six and seven and most of chosen children still had their parents. On arrival in Denmark, they were placed in foster homes and sent back to Greenland in 1956 where they were placed in an orphanage and not allowed to reunite with their families. In 2020 Danish prime minister Mette Frederiksen apologised.

[27] Krugman S (1986) The Willowbrook hepatitis studies revisited: ethical aspects. *Reviews of infectious diseases*. Jan 1;8(1):157-62.

[28] Coney, S (1988) *The Unfortunate Experiment*. Auckland: Penguin.

[29] Stanley Milgram's Obedience study; http://www.youtube.com/watch?v=W147ybOdgpE

[30] The Stamford Prison Experiment by Philip Zimbardo – see http://www.prisonexp.org

[31] Babbie E (2004) Laud Humphreys and research ethics *International journal of sociology and social policy.* 24(3–5): 12–19.

[32] Beecher HK (1966) Ethics and Clinical Research *New England Journal of Medicine*. **274** (24): 1354–1360. June 16. Doi:10.1056/nejm196606162742405.

[33] Pappworth MH (1967) *Human Guinea Pigs: Experimentation on Man*. Routledge and Kegan Paul. ISBN 978-0-8070-2191-0.

[34] Professionals are not alone in making unethical judgements from time to time – ordinary citizens have similar failings. In addition to matters that are generally regarded as unethical, a whole range of topics

generate diverse views about what is right. For example, in the UK, the death penalty was last used in 1954 and abolished in 1969, but almost half of the population would like to see it reintroduced, with numbers being higher for men, older people, UKIP supporters and people in lower socioeconomic groups. See Yougov survey Report, 2014.

[35] Krieg R (2004) *Catholic Theologians in Nazi Germany*. Bloomsbury Publishing USA.

[36] Peter Singer P (2nd edition, 1993) *Practical Ethics* Cambridge pp. 175-217.

[37] Haggerty and others have suggested that the remit of Research Ethics Committees has expanded too far and regulated areas that should be governed through other mechanisms. See Haggerty KD (2004) Ethics creep: Governing social science research in the name of ethics *Qualitative sociology* 27(4), 391-414.

[38] See Steneck NH (2007) *An introduction to the responsible conduct of research.* Downloaded from https://ori.hhs.gov/sites/default/files/2018-04/rcrintro.pdf on 13 November 2020.

[39] International Compilation of Human Research Protections (2020). Downloaded from 2020 International Compilation of Human Research Standards (hhs.gov) 2 Dec 2020.

[40] Hedgecoe A (2009) "A form of practical machinery": the origins of research ethics committees in the UK, 1967–1972. *Medical history.* Jul; 53(3):331-50. Since then, in a bid to achieve independent, they have become increasingly distanced from the particular organisation that founded them, and they have reduced in number (from around 300 to 64), resulting in more attenuated relationships with individual researchers. See Hedgecoe AM (2012) Trust and regulatory organisations: The role of local knowledge and facework in research ethics review. *Social Studies of Science.* Oct;42(5):662-83.

[41] Many universities have established their own internal Ethics Committee, as have some third sector organisations, such as the National Development Team for Inclusion.

[42] https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/?query=&research_type=&rec_opinion=&date_from=&date_to=

[43] "The favourable opinion data also includes applications which received a favourable opinion with conditions. This is where the REC has requested some fairly minor, specific changes/clarifications attached to the favourable opinion." (personal communication from Alison Barbuti, June 2021). It is unclear how this unpublished subcategory of 'favourable opinion with conditions' relates to the next category of 'further information favourable opinion'.

[44] The infrastructure support provided by NIHR INVOLVE was recommissioned in 2020, leading to the closure of INVOLVE and the launch of the Centre for Engagement and Dissemination.

[45] The UK was a pioneer in seeking Public Contributors to enhance research. By contract, the USA established its Patient Centered Outcomes Research Institute (PCORI) in 2010, and Canada launched its Strategy for Patient-Oriented Research (SPOR) in 2011.

[46] Williamson C (2008) The patient movement as an emancipation movement. *Health Expectations*. Jun;11(2):102–12.

[47] Recent examples of poor practice or tragedy affecting health research and service delivery include the Paterson Inquiry (2020), Cumberledge Report (2020), Shrewsbury & Telford NHS Hospital Trust maternity services (2019), Whorlton Hall (2019), Gosport War Memorial Hospital (2018), BIA 10-2474 (2015), Mid-Staffordshire hospitals (2013), Winterbourne View (2011), TGN1412 (2006) and Shipman (2003). The corrupt and erroneous reporting by Dr Andrew Wakefield of a supposed link between the MMR and subsequent development of autism was implicated in the fall in the number of UK children being immunised, which may have been the cause of the measles outbreaks of 2008/9. The rise of managerialism since the 1980s has assumed that regulation and the reduction of professional discretion will stop bad things happening without stopping good things happening. It may be possible to exonerate health researchers by separating them from clinicians, but we would advocate an approach that closed the implementation gap between research and practice rather than widening it. For more information on BIA 10-2474, see Leuker C, Samartzidis L, Hertwig R, Pleskac TJ (2020) When money talks: Judging risk and coercion in high-paying clinical trials. *PLoS ONE* 15(1): e0227898. https://doi.org/10.1371/journal.pone.0227898.

[48] Mejlgaard N, Bouter LM, Gaskell G, Kavouras P, Allum N, Bendtsen AK, Charitidis CA, Claesen N, Dierickx K, Domaradzka A & Elizondo AR (2020) Research integrity: nine ways to move from talk to walk *Nature* Vol 586, pp 358-360. 15 October.

[49] There are more than 80 NHS Research Ethics Committees across the UK with their composition, training and operating procedures overseen by the National Research Ethics Service – see https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committees-overview/.

[50] This includes Participant Information Sheets in health research.

[51] Bates P (2014) *How to engage people as research co-applicants*. Nottingham: East Midlands Academic Health Science Network.

[52] In order to request a slot to observe, first check the REC meeting dates which are published on the HRA website and contact the Member Support team (member.support@hra.nhs.uk) with which meeting you would prefer to attend. It is helpful to provide two or three options which would suit you as sometimes meetings might already have a number of observers attending.

[53] There are seven Research Councils within UK Research and Innovation (https://www.ukri.org/), including the Medical Research Council and the Economic and Social Research Council.

[54] For healthcare research, the Good Clinical Practice training course provides an essential grounding for researchers. Many employed research staff will also hold a higher degree in research methods or similar qualification.

[55] Healthcare researchers must obtain a 'Research Passport' that grants access to specific sites for a specific research study.

[56] For example, the Integrated Research Application System (IRAS) provides a single mechanism for seeking approvals for research in the fields of health and social care across the UK. IRAS handles approvals on behalf of the following bodies: Administration of Radioactive Substances Advisory Committee, Confidentiality Advisory Group, Gene Therapy Advisory Committee, Health Research Authority, Medicines and Healthcare products Regulatory Agency, Research and Development offices in NHS and social care organisations, NHS Research Ethics Committees, National Offender Management Service and the Social Care Research Ethics Committee. See https://www.myresearchproject.org.uk/ELearning/index.html. Other fields of study will have their own arrangements. IRAS permits anyone to create an account (https://www.myresearchproject.org.uk/Help/HelpPage.aspx), where the suite of forms that together form the IRAS system may be seen. Question Specific Guidance is provided throughout the form and brought together for the casual reader (https://www.myresearchproject.org.uk/help/hlpcollatedqsg-iras.aspx) or the reader who is interested in making a submission specifically to an NHS REC, (https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx).

[57] HRA Make it Public strategy – see https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/implementation-plan/.

[58] For example, some Ethicists connect with one another through the Feminist Approaches to Bioethics network – see https://www.fabnet.org/

[59] Whistleblowing law is located in the Employment Rights Act 1996 (as amended by the Public Interest Disclosure Act 1998). It provides the right for a worker to take a case to an employment tribunal if they have been victimised at work or they have lost their job because they have 'blown the whistle'.

[60] Where researchers wish to gain access to participants in multiple organisations, a 'lead sponsor' may be appointed who will carry out the detailed checks for their own site and then notify subsidiary sites that their approval has been granted. This avoids duplication and delay in the approvals process.

[61] A few attempts have been made to adapt *Good Clinical Practice* and deliver the result to groups of Public Contributors, but in general, little is available. In fact, INVOLVE and the Health Research Authority comment that, 'Where the public are involved in collecting and analysing data or in the recruitment or consenting of participants the training they receive should cover confidentiality and giving and withdrawing consent. However, this is rarely if ever likely to need to include training in ICH GCP (International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use Good Clinical Practice – www.ichgcp.net).' Footnote 5 in INVOLVE, Health Research Authority (2016) *Public involvement in research and research ethics committee review*. Downloaded from

https://www.invo.org.uk/posttypepublication/public-involvement-in-research-and-research-ethics-committee-review/ on 6 November 2020.

[62] For a general discussion about training for Public Contributors, see Bates P (2014) *How to train the public for involvement* downloaded from https://peterbates.org.uk/wp-content/uploads/2017/04/how_to_train_the_public_for_involvement.pdf on 2 November 2020. The Good Clinical Practice course is available online for free to Public Contributors at https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm. The University of Leeds offers a free online course funded by Futurelearn called 'Introduction to Research Ethics: Working with People' – see https://www.futurelearn.com/courses/research-ethics-an-introduction.

[63] We might ask how the boundaries are defined and regulated to ensure that research that should be subjected to REC review is taken through this process, while other activities, such as service evaluation are set aside rather than overburdening the system.

[64] The scientific community generally believe that there should be sanctions imposed on those who violate ethical norms – see Wenger NS, Korenman SG, Berk R, Liu H. (1998) Punishment for unethical behavior in the conduct of research. *Acad Med*. Nov;73(11):1187-94. doi: 10.1097/00001888-199811000-00018. PMID: 9834703. Whether anyone has been fined or imprisoned is less clear.

[65] See https://fundingawards.nihr.ac.uk/search.

[66] Magelssen M, Pedersen R, Førde R (2016) Novel paths to relevance: how clinical ethics committees promote ethical reflection. *HEC forum* Vol. 28, No. 3, pp. 205-216. Springer Netherlands.

[67] Professor Eric Schwitzgebel has searched in vain for differences between the behaviour of ethicists and that of other philosophers, showing that the study of ethics might help people understand what is right but does not make the student behave more ethically. Similarly, early career researchers have been found to be aware of the existence of conflicts of interest in the field of research, but they tend to hold the view that such matters are the responsibility of their supervisor. See Tallapragada, M., Eosco, G.M. & McComas, K.A. Aware, Yet Ignorant: Exploring the Views of Early Career Researchers About Funding and Conflicts of Interests in Science. *Sci Eng Ethics* 23, 147–164 (2017). https://doi.org/10.1007/s11948-016-9764-3. At the same time, departmental heads believe that there are examples of poor research integrity in the world, but their own team are sound and the problems lie with others – see Degn L (2020) Integrating Integrity: The Organizational Translation of Policies on Research Integrity. *Science and Engineering Ethics*. https://doi.org/10.1007/s11948-020-00262-w.

[68] Ní Shé, É., Morton, S., Lambert, V., et al. (2019) Clarifying the mechanisms and resources that enable the reciprocal involvement of seldom heard groups in health and social care research: a collaborative rapid realist review process, *Health Expect*. 10.1111/hex.12865.

[69] Dr Jerome Kerrane was struck off by a tribunal of the General Medical Council for dishonesty in his research activities. The infrastructure that supports professions and manages their restricted title (agreed competencies, awarding body, code of practice, body of knowledge and practice, disciplinary mechanisms and power to exclude, public recognition) gives professionals a crucial identity that distinguishes them from Public Contributors who do not have these mechanisms. When working together it is important to consider how this difference is handled.

[70] Researchers may provide the Research Ethics Committee with details of their indemnity policy in case something happens to the participant (ie death or a worsening of an already existing medical condition) that could give rise to a possible negligence claim.

[71] 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.

[72] We acknowledge the introductory work carried out by Alison Gallie in 2014. The following people have kindly responded to email enquiries, although all errors and weaknesses that remain in this document are the responsibility of the authors - Niels Mejlgaard.