How to gain informed consent

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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. Within this suite, the introductory paper *How to avoid doing bad research* sets out six areas where research involving people can be defended against going wrong. These are:

- Protect choice to prevent coercion
- Promote safety to minimise harm
- Guard data to uphold privacy
- Do good science to advance real knowledge
- Behave well to earn respect
- Use resources wisely to maximise benefit

The first of these six areas is concerned with the notion of 'informed consent'. This paper considers what informed consent means in relation to specific types of research and specific participant groups.

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.

A clear distinction arises here between citizens who enrol as research participants, so that their data are collected and analysed by a researcher, and Public Contributors, who join the research team to advise on the process by which the research is carried out. In summary, the formal 'informed consent' process is an essential part of the process that protects

[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 navigate research ethics – definitions, history, systems and sanctions*; 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*.

research participants and does not apply to Public Contributors[1]. There are three caveats to this:

- These two roles sometimes overlap, as when a Public Contributor is subsequently offered the opportunity to become a participant, or vice versa.
- While the formal processes covered by the informed consent procedure do not apply to Public Contributors, they nevertheless should enjoy similar ethical practices – such as knowing what they are getting involved with, freedom to withdraw, freedom from coercion, confidentiality and so on.
- When the activities of Public Contributors lead them into direct contact with research participants (which would happen if they were, for example, collecting data from them[2]), then additional safeguards may be needed to keep everyone safe[3].

Researchers may normally only engage participants who have given their Informed consent[4]. This is commonly taken as written and signed consent and includes the following:

- An explanation of the purpose of the research and the intended benefit to science
- A clear explanation of eligibility, so that the person can decide for themselves if their circumstances suit the requirements of the study
- An explanation of what will happen to them as a participant
- The risks of participation and any mitigations designed to reduce harm
- A check that they understand the language and imagery used to describe the research
- Their choice in whether to participate and their freedom to leave the study at any time
- The availability of support for the participant if there are concerns or worries affecting them before, during, and after the research
- What will happen to their personal information[5] and to the overall results of the study.

Gillies et al (2021) worked with international stakeholders to generate a core list of outcomes for an effective process by which informed consent is achieved. This is paraphrased in Table 1 below.

Table 1. A paraphrase of the ELICIT core outcomes[6] on informed decision-making regarding participation in a research study

Domain 1: Experience of decision making
• I am comfortable and feel happy and relaxed with my decision
• I found the consent process helpful in making my decision
• I made an authentic, genuine decision
• I understood all the written and verbal information about the trial

• I felt empowered to become stronger and more confident, took control my own life and exercised my rights
• I found the 'informed consent questions' relevant and important
Domain 2: How people make decisions
• My decision was driven by a selfless concern for the well-being of others
• I grasp the uncertainty which is driving the trial – that nobody knows which of the treatments being studied is most effective
• I can recall facts, information and skills
• I understand how this works, even if I don't know how it relates to other things
Domain 3: What decisions people make and/or the quality of those decisions.
• I understand that the treatment I receive as part of the research is designed to advance scientific knowledge rather than to benefit me personally
• I complete the study rather than drop out

While it is only a small part of the overall informed consent process, much attention has been given to the quality of the Participant Information Sheet, which is usually augmented with a personal explanation to help the participant understand and decide if they wish to be involved. Guidance may also be provided to the researcher to help them structure the process of gaining informed consent. Both the Participant Information Sheet and the Protocol for the consent process need to be approved by the Research Ethics Committee before they are used to ensure they uphold the rights of the participant.

Information Sheets and Protocols which are co-designed by Public Contributors and reviewed by the lay members of the Research Ethics Committee are more likely to be effective[7], not least because plain English has been used instead of jargon[8] and things are expressed in accessible language for people who have not received scientific training. But that is not to say that they are more ethical, for Public Contributors may help with removing jargon without considering the ethics of the proposed activity itself, as if they were drafting an Easy Read guide to committing crime.

In some communities, formal documents are intimidating, and the requirement for a signature is reminiscent of authority figures such as the Police. Meaningful informed consent will respect these contexts[9].

It is helpful if the participant has an opportunity to ask questions and receive honest and helpful answers as well as sufficient time to absorb what they have been told. It is prudent to allow a 'cooling off' period between giving the information and inviting the person to give formal consent so that the participant has space to digest the information they are given. In addition to gaining informed consent, the researcher will collect other information from the participant at this stage, such as checking the person's eligibility.

Evidence suggests that, despite all these efforts to ensure that people understand the research and their role in it, a substantial proportion of participants fail to grasp what they have signed up to. A crucial factor here is what is known as therapeutic misconception,

which means that the person thinks that the research is being delivered in a way that will prioritise their personal clinical care, rather than to derive generalisable knowledge. Appelbaum's team[10] found 60% of his research participants held a therapeutic misconception, while a quarter of Joffe's[11] participants did not realise that the treatment was not proven to be the best for their cancer. These studies are dated, but should lead researchers to question whether their efforts to obtain informed consent have been effective.

Ongoing assent is just as important as the initial declaration of consent. Researchers must be aware of the participant's continuing willingness to remain involved and provide a way to withdraw should this be what the participant wishes. Some topics explored during the interview gives rise to distress, and this can affect the person's willingness to participate, so they may withdraw part way through the interview or ask that they data is withdrawn from the study. Advice is available on responding to distress in a research interview[12].

2. Research involving children

The international Declaration of Helsinki clearly states that research may involve children. The Gillick competence[13] and Fraser guidelines allow children between the ages of 5 and 18 to give their consent to medical intervention as long as they have 'sufficient comprehension and understanding' about what is going to happen to them, although this is rarely invoked for the younger children within this age bracket[14].

Anyone under 18 must be protected by additional safeguarding measures, such as the consent of their parent or guardian. However, it is noted that in the UK, the age of majority is set at different points for different issues, creating a ambiguous space that is confusing for both the young person and others[15]. Offering or denying payments for participation may influence consent[16].

Current legislation considers what to do if there is a difference of view between a young person and their parent or guardian in relation to accepting or refusing medical treatment but is silent in relation to research participation. Young people aged 16-18 who have mental capacity and:

- are considered able to act independently from their parents and accept treatment; but they may not refuse it.
- want to take part in research but do not want their parents told; should have their right to privacy upheld.
- do not want to be involved in research should not be required to take part, even if their parents have given consent for them to do so.

No research should be carried out on children where the goals could be met by conducting the research on adults. Research with children and young people may also require some of the accommodations set out in the next section.

3. Research involving people who may lack capacity

The Mental Capacity Act 2005 assumes that people can make their own mind up about whether to take part in research unless a formal assessment has determined that they lack:

- capacity to receive information about the research
- capacity to weigh up the merits of different options, such as whether to participate or not
- capacity to choose their own preferred option
- capacity to communicate their decision.

Carrying out these tasks depends on both cognitive and communication skills, which vary from one individual to another and cannot be inferred from a medical diagnosis or use of care services. Sections 30-34 of the Act cover participation in research and are partly designed to protect people from the risks of participation if it can be avoided, so, wherever possible, researchers should achieve the outcome by confining the study to people with capacity[17]. People with learning disabilities or dementia may give consent to take part in research but may need reasonable adjustments or independent advocacy to enable them to participate. Similarly, whilst some groups in society are under-represented in research[18], studies have been successfully carried out with people who have learning disabilities[19], people living in care homes, homeless people, offenders and others. Those who do lack capacity may be involved through the consent given by the person who is designated to act on their behalf[20], such as the Decision Maker or someone holding a power of attorney for health and welfare.

Consent forms with photographs, diagrams or cartoons may be used to communicate the purpose of the research and why it is important. A carer, friend or relative may be able to communicate with the person, perhaps using simple language, flowcharts, diagrams, or pictorial information to illustrate what is proposed by the researcher. People will find it easier to express their views and needs better in their preferred language[21], particularly those whose mother tongue is not English. Duress must not be used and any refusal to take part must be accepted, without the person needing to provide an explanation for their withdrawal or refusal[22]. People with deteriorating or fluctuating capacity may provide an advance directive, indicating their wish to participate or withdraw from the research.

The Medicines and Human Use (Clinical trials) Regulations 2004 provides special arrangements for people who are unconscious or otherwise entirely unable to give consent. People who are unable to indicate their own clear preference may be supported through the techniques of Non-Instructed Advocacy[23]. In general, when obtaining consent in the ordinary way is difficult or the process is unusual, Public Contributors can help in the decision about what is ethically acceptable[24].

After providing accessible information and before asking for consent, steps should be taken to assess the person's understanding of the research, and particularly of the risks to participants. Teach-back, quizzes or other tests will provide opportunities for the person to demonstrate that they have thoroughly understood before they are invited to declare their consent[25].

Once admitted to the participant cohort, people should not be excluded in practice because they are unable to engage with the data collection methods chosen by the

researcher. For example, people with dexterity challenges may struggle to use smartphone apps to self-report their experience of an intervention should be provided with an alternative means to do so; people with speech difficulties may be observed rather than interviewed or may use an interpreter or other communication support during the interview.

4. Research Involving Deception

Some research, particularly in the field of psychology, involves deceiving participants, which can be considered a form of harm. However, studies into unconscious bias or the placebo effect[26] would not have worked if participants were told all of the information about the study from the outset. In order for a research proposal to be approved, ethics committees will want to know if the aims of the research can be achieved without the use of deception. If they cannot, then the research may still be allowed to proceed but only if the risk of physical or psychological harm to the participants is considered to be extremely low.

Where a study design involves deceiving research participants researchers must debrief participants after they have taken part in whatever activity the research involves. Debrief information should be provided in writing and, where possible, should be supported by a verbal explanation. Debrief information should include an explanation of how research participants were deceived, and why it was necessary. Debrief information should also repeat the information that research participants received before beginning their participation in the study about informed consent and their right to withdraw from the study, as well as information on how to withdraw their data should they wish to do so.

Whilst it is always important to ensure that research participants understand their right to withdraw it is arguably most important in research involving deception where participants may change their minds once they have all the information. Researchers should allow time between debriefing and final analysis so that participants may withdraw their data if they wish to. Some may decide as soon as they have been given debrief information while others need to leave the premises where the research was carried out and think over how they feel.

5. Blinding

Like in deception, blinded research involves withholding information at the start of the research. In drug trials research participants may not be told whether they are being given a placebo or the experimental medication. This way researchers can be reasonably sure that differences between the control and experimental groups are due to the drug being trialled and not the psychological effect of whether participants believe that the pills will work.

In a blinded study, research participants are told at the outset what information will be withheld and why. The final debrief therefore simply notifies participants that they were in either the study group or the control group, while in a deception study, researchers reveal at the end that participants have been deceived.

In some studies members of the research team are also blinded. In drug trials a researcher who asks participants about any changes in their symptoms might not be told whether the participants are in the study group or the control group. This prevents them from accidently dropping hints about whether they expect the pills to have made a difference to the participant's condition. Where both research participants and members of the research team are blinded studies are described as double blinded.

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[27]. As readers continue to provide feedback[28], further insights will be used to update it, so please contact peter.bates@ndti.org.uk 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] A definitive statement on this was made by the UK National Research Ethics Service – see NHS National Institute of Health Research (2015) *Patient and public involvement in health and social care research: A handbook for researchers.* Downloaded from https://www.rds-yh.nihr.ac.uk/wp-content/uploads/2015/01/RDS_PPI-Handbook_2014-v8-FINAL-11.pdf on 25 October 2020. Also see INVOLVE, Health Research Authority (2016) op cit. Similar arrangements exist in Canada, where arrangements for engaging research participants must be approved by the ethics review board, but 'patient partners' do not. See the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), available at https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html.

[2] Bates P (2019) *How to involve the public as co-interviewers in research*. Downloaded from https://peterbates.org.uk/wp-content/uploads/2019/12/How-to-involve-people-as-research-co-interviewers.pdf on 1 Nov 2020.

[3] For a discussion of the interaction between lived experience and employment, see Bates P (2016) *How to take your lived experience to work*. Downloaded from https://peterbates.org.uk/wp-content/uploads/2017/04/how_to_take_your_lived_experience_to_work.pdf on 25 October 2020.

[4] http://www.jme.bmj.com/content/28/5/318.full

[5] GDPR gives the data subject the right to inspect personal information that is held by them, the right to correct errors and to ask for data to be deleted. How are these rights managed in the research field?

[6] The ELICIT authors present these as sliding scales in the form of 'the extent to which' outcomes are met and use more complicated statements which have been simplified and rephrased before being presented here. Scholars should review the original text as some nuances may have been lost in the paraphrase above. See Gillies K, Williamson PR, Entwistle VA, Gardner H, Treweek S & Campbell MK (2021) An international core outcome set for evaluating interventions to improve informed consent to clinical trials: the ELICIT Study, *Journal of Clinical Epidemiology*, doi: https://doi.org/10.1016/j.jclinepi.2021.02.020

[7] Hanley B (2004) *Involving the Public in NHS, Public Health, and Social care* Southampton: NIHR INVOLVE. Also Boaz A (2002) *Department of Health consultation on research ethics in Social Care: a summary of the consultation event with social care users, and their Representatives Published* by INVOLVE.

[8] Regulation 4.8.6 (ICH harmonised guideline integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) ICH Consensus Guideline GCL) asserts that, 'The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject.' Despite this, consent forms are incomprehensible to 25-50% of the general public – see Tam NT, Huy NT, Thoa LT, Long NP, Trang NT, Hirayama K & Karbwang J (2015) Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. *Bulletin of the World Health Organization*. 93:186-98H. https://doi.org/10.2471/BLT.14.141390. Despite this, anecdotal evidence suggests that some ethics committees insist that detailed scientific information and complex legal declarations appear on the consent form, despite their presence making the overall document impenetrable to many participants. The readability of academic papers is falling over time – see Plavén-Sigray P, Matheson GJ, Schiffler BC, Thompson WH. The readability of scientific texts is decreasing over time. *Elife*. 2017 Sep 5;6:e27725.

[9] Fitzpatrick EF, Martiniuk AL, D'Antoine H, Oscar J, Carter M, Elliott EJ (2016) Seeking consent for research with indigenous communities: a systematic review. *BMC Medical Ethics*. Dec 1;17(1):65.

[10] Appelbaum PS et al. (2004) Therapeutic Misconception in Clinical Research: Frequency and Risk Factors, *IRB: Ethics & Hum. Res.* 1, 4-5.

[11] Joffe S et al. (2001) Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey, *Lancet* 358: 1772, 1774

[12] Bates P (2021) *How to respond to distress*.

[13] See http://www.bailii.org/uk/cases/UKHL/1985/7.html.

[14] For further insight into this, see Christenson P & James A (3rd edition, 2017) *Research with Children* Abingdon: Routledge.

[15] Young people in England must be 13 years old to have a part-time job, 14 to be fined for not wearing a seat belt, 15 to be sent to prison, 16 to have sex, 17 to hold a driving licence and donate blood, 18 to leave education, vote, marry, rent, buy alcohol and join the armed forces, 20 to lose all entitlement to child benefit, 21 to receive the full National Minimum Wage and 25 to receive the full amount of Universal Credit.

[16] For a discussion of payments for research participation, see Bates P (2021) *How to set payment levels for research participants*.

[17] Boxall K & Ralph S (2010) Research ethics committees and the benefits of involving people with profound and multiple learning disabilities in research *British Journal of Learning Disabilities* 39: 173-180. doi:10.1111/j.1468-3156.2010.00645.x.

[18] Hannigan & Allen found that Research Ethics Committees were cautious in approving research with groups perceived as vulnerable. See Hannigan B & Allen D (2003) A tale of two studies: research governance issues arising from two ethnographic investigations into the organisation of health and social care *International*

Journal of Nursing Studies 40: 685-95. For more recent advice, see National Institute for Health Research (2020) *Improving inclusion of under-served groups in clinical research: Guidance from the NIHR INCLUDE project. UK*: National Institute for Health Research. Available at: www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435 (accessed 20 Oct 2020)

[19] See Nind M & Vinha H (2012) *Doing research inclusively, doing research well? Report of the study: Quality and capacity in inclusive research with people with learning disabilities* Downloaded from https://www.southampton.ac.uk/assets/imported/transforms/content-block/UsefulDownloads_Download/97706C004C4F4E68A8B54DB90EE0977D/full_report_doing_research.pdf on 27 October 2020. Also Frankena TK, Naaldenberg J, Cardol M, Garcia Iriarte E, Buchner T, Brooker K, Embregts P, Joosa E, Crowther F, Fudge Schormans A, Schippers A, Walmsley J, O'Brien P, Linehan C, Northway R, van Schrojenstein Lantman-de Valk H & Leusink G (2019) A consensus statement on how to conduct inclusive health research. *Journal of Intellectual Disability Research,* 63: 1– 11. https://doi.org/10.1111/jir.12486.

[20] The Mental Capacity Act refers to this person as the 'consultee'.

[21] See the Question Specific Guidance on completing IRAS forms for submission to NHS RECs, question A33-1. At https://www.myresearchproject.org.uk/help/hlpcollatedqsg-nhsrec.aspx#596. This particularly refers to equality between the English and Welsh language, but the principle is true for all languages, as shown by the instructions regarding prisoners in the same section of this guidance.

[22] http://www.bristol.ac.uk/secretary/dataprotection/research/consent.html

[23] Greenaway-Clarke JM (2020) *Advocacy and 'Non-Instructed' Advocacy with Disabled Children and Young People with Complex Communication Needs* University of Portsmouth: PhD thesis. Downloaded from https://researchportal.port.ac.uk/portal/files/25037792/Final_Thesis_JM_Greenaway_Clarke_.pdf 9 Dec 2020.

[24] INVOLVE (2012) *Public involvement in research: impact on ethical aspects of research*. Downloaded from http://www.invo.org.uk/wp-content/uploads/2012/06/INVOLVEevidenceresource.pdf on 6 November 2020. "patient involvement can... provide an opportunity to test the acceptability of the use of, and access to, confidential patient information without consent." 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.

[25] Gelinas L, White SA, Bierer BE. Economic vulnerability and payment for research participation. *Clinical Trials*. 2020;17(3):264-272. doi:10.1177/1740774520905596.

[26] The placebo effect is an established effect in which patients report experiencing painkilling effects of a tablet which is in fact only a sugar pill.

[27] As a result, the authors assume 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.

[28] We acknowledge the introductory work carried out by Alison Gallie in 2014. More recently, helpful conversations took place with Jim Elliott and Hugh McLaughlin, although all errors and weaknesses that remain in this document are the responsibility of the authors.