Health Research Authority Policy Framework - Feedback from the NHS Forum Service User and Carer Working Group (SUCWG)

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Summary document:

The summary for "patients, service users and the public" is far too succinct to give a good picture of the complexity of the issues at stake.

Main document:

Overall issues:

- The survey totally misses out questions about PPI.
- There is some confusing language: while the framework is a high level policy document, therefore describing governing principles, it also talks about refers to guidance and implementation when operational details appear in the middle tier (exploratory) document.

On the topic of PPI:

- PPI is mentioned throughout the document: this is positive.
- However, it would have been useful for it to have its own section thus making visible and reinforcing the importance of PPI in research at high level. It would also match what the HRA is already doing, i.e. involving patients and members of the public. This is about communicating the PPI status as part of the health and social care landscape and policy.
    - This would, for instance, have helped clarify issues certain issues such as transparency of responsibility, e.g. should there be a statement of responsibilities? It would also appear that neither the funder, the sponsor nor the principal investigator has specific responsibility to ensure good practice with regard to PPI.
- References to PPI need to be tightened up and made more specific. It would also have made clearer and reinforced the idea that PPI members must, rather than should, be members of the research team (should they wish to).
- Some research funding is, and should be, dependent upon satisfactory [stress good practice] PPI. This is currently not the case; as long as the research is deemed sound, the decision to fund it will override the issue of the quality of PPI.

Main issues

Section1

There have been discussions amongst service users who are members of INVOLVE, that the distinction between engagement, participation and involvement are again becoming blurred and

there seems little commitment to service users and patients being able to be co-applicants in research, let alone that research could be led by service users and patients.

Section 2

There should be a commitment to PPI members being involved in the dissemination of research, research findings being put into straightforward, accessible, language and delivered to patient/service user groups.

Section 3

- The scope of the Framework should match the HRA's own remit and not be restricted to the current public health remit. This will have implications for the HRA in terms of resources
- **3.3** What and who are these local controls? What is their remit and what are the mechanisms for monitoring.
  Also, last comment regarding context – there should be something about patients/service users influencing research questions/topics.
- **3.6** This is so vague, it looks like a get out clause.

Section 4

4.1

- Add resources for PPI members from NIHR and INVOLVE

4.2

- Involving "Appropriately" is rather vague.
- Meets their needs... and concerns!
- Accesses patients and information: Which information?

Section 6

- If this document is "guidance" (6.2) why is it called "policy framework" (6.3)? What is then its actual power? The Law (care Act 2012/14) is the law and this policy is framed as guidance, setting the legal requirements, good practice to promote, facilitate research as well as protect participants. One of the issues is with compliance.

Section 8

8.2

Need to clarify: does this also apply to PPI as co-researchers? We think it does but needs spelling out.

8.3

"scientifically": Could be read as a bias towards clinical research.

8.4

Who decides if PPI is appropriate or not? This should perhaps be spelt out?

Dissemination should also be mentioned here.

PPI involvement in research is always appropriate. It may not always be possible and when this is the case, the lack of involvement should be justified with strong arguments. For instance, we hear of lab researchers who think that PPI is not something that someone in their position can or should do. However, what they are researching may have an impact on treatments at some point down the line. They are therefore never that far remote from patients and real people. In which case, they should really think about involving PPI members. This issue also links to the Responsible Research and Innovation framework. This is about reflexivity and the ethics of doing research while emphasizing openness, transparency and dialogue, not just with funders and organisations, but also with society … and PPI is part of this framework.

8.8

This statement either contradicts or at the very least undermines 8.1?

While safety of the research process is paramount, the notion of risk needs to be spelt out much more clearly. In fact, is this the right question? Should we talk about risk or about 'informed consent' in order to make an informed decision? What needs to happen to reach that 'informed' stage? The quality and format of this information is paramount. There is no such thing as less risk equals less information; some seemingly innocuous questionnaires may trigger adverse effects (e.g. upset). This is a paternalist view.

Information should also include detail and tiered opt-out options of what is intended for the data further down the line once the study is over. Does this happen systematically? All options must be spelt out from the beginning and not left to the participant to ask or guess.

Information must be written in layman's terms and be truthful so that potential participants do not feel misled.

Potential participants should also be allowed to take risks. This reiterates the point that consent must be (properly informed).

8.10

- Replace "normally" with "must", whether this concerns public or commercial research (especially that which uses public resources).
- It should probably happen once approval has been obtained
- This is a moral duty
- It would improve transparency
- Reliability of the published findings: must include negative outcomes

- Researchers may be worried about sharing information (Intellectual property issues... sensitivity issues for commercial research...)

8.11

- Participants must be given the choice of receiving information about the findings.
- There may be a box to tick on the Patient Information Sheet, on the Consent Form or participants may be contacted at the end of the study. There are practical and ethical issues to consider:
    - Long term studies: participants may have moved and forwarding details are unknown
    - Participants may have changed their mind and no longer wish to know or be contacted
    - The onus could (?) be put on the participant to find out about the research findings by consulting a register. However information about and access to these registers (which are numerous) is not user friendly.

8.12

Issue of capacity: the way this is formulated is problematic. It does not take into accounts the human rights legislation, in particular the Equality Act 2010 or the UN CRPD (which the UK has ratified and according to which everyone has capacity) nor does it state more explicitly that all provisions should be put in place to support people with disabilities to take part in research either as a participant or as a subject of research (the Mental Capacity Act is weaker in this respect than international human rights standards). Again this is about informed consent.

8.13

Again there is a lack of clarity regarding what is meant by physical and mental integrity.

8.16

- How does this happen in practice? It is very difficult to ascertain what the mechanisms might be. One could imagine staged funding processes but not all research is either financed (e.g. Student research) or financed outside of the NHS (e.g. commercial research).
- Publication costs must be included in the funding application, and ring fenced.
- Greater PPI in RECs.

Section 9

9.1

How does this apply to PPI members, whether they are involved in a consultative or more in-depth way? Should their role and involvement be formalised and if so, how, and what guidance is there or should be used?

9.2

d. Need to clarify/confirm this also applies to PPI members

e. Follow good practice guidelines and review by PPI members

9.3

a. Disagree partly. There is no reason why students should not be allowed to be chief investigators from Masters level up, if robust management is in place. The policy framework should on the contrary encourage students to undertake this role in order to understand the complexities of the ethics of conducting research. There are many examples of good work being done by students, specifically on pure research degrees. By allowing students to take on this responsibility early on, it also prepares them for any research they may do at PhD level.

One of our group members received NHS funding under the now defunct 'small grant scheme' which allowed her to conduct a piece of unique and grounded research which was developed as an MPhil in parallel (published).

The main issues are:

- Not discouraging students from taking on research responsibilities.
- Defining what is an appropriate scope for research by students who come in contact with patients, children and vulnerable adults; the fact is that many students do research on their peers, for convenience usually. However these participants may (for instance) be people with mental health issues. Are their circumstances or level of vulnerability always that different from those of NHS participants?
- This is as much an ethics as a management issue that need defining:
    - Who has responsibility for what? Need to clarify the university supervisor's role, of the university department in which the research is being conducted.
    - Would establishing a steering group help?
    - Student projects would benefit from (where appropriate): if not harmonisation between NHS and University ethics committees, at the very least from an alignment of ethical standards, closer ties and exchanges: is the whole support structure around the student and their project robust enough? Some students will find themselves caught between different systems (NHS and academia) potentially creating weaknesses in the process.

b. How can this happen fully and satisfactorily if students are not encouraged to take more responsibility early on?

Mention of business studies: It depends at which level. Some business studies have common research training modules with students from other disciplines, such as psychology. It is clear that students reflect the values of their learning context, and will implement them in their future professional settings. To counter this effect which in some settings can be less than satisfactory, it would be really useful to involve PPI members in higher education institutions (experiences of

being involved in research, principles of involving PPI members, ethics of involving participants etc.)

9.4

Not following protocols not only compromises any informed consent given. It may also have implication for their physical or mental integrity as mentioned in 8.13 (in other words cause harm)

9.6

Should there be contracts for PPI members of a research team? If so, what should it establish and how? Should such a contract be formal or informal?

PPI members should be offered the possibility of being trained as relevant

9.7

a. "including systematic reviews": this feels unworkable.

c. When should consent not be documented and available? This is odd.

9.8

While proportionality may be viewed as a pragmatic approach, this view is rather paternalistic and potentially places the onus of finding all the information that they may wish to have about the research on the potential participant themselves.

At the very minimum, links to a name, documentation etc. should be included in any patient information sheets so that potential participants can make a truly informed decision.

9.9

It should be spelt out more specifically that funders are also responsible for ensuring that the budget includes realistic costs of the proposed PPI.

9.10

g. There is no mention of sponsors' responsibility for PPI. This also links back to the issue of roles and responsibilities for PPI members and the potential need for some form of contract for PPI members

9.19

a./b./c./d. What are the mechanisms in place for PPI members who are employed as research team members, e.g. involved in data collection/analysis?

9.20

Who takes responsibility for this for PPI members involved as research members?

9.21

How will whistle blowers be protected?

GLOSSARY

Missing: ‘public’: we now talk about “patients and public involvement", or PPI. While the term ‘patients’ is easy to grasp, what ‘public’ means is not always that clear to people. So, by ‘public’, we mean carers, and anyone with an interest in research, in a research topic or area.

LEGISLATION

Missing: The NHS Constitution which stresses the right of patients to be heard.