Nuffield Council on Bioethics

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Dear Teresa

I am writing in response to the HRA consultation on transparency and openness in health and social care research.

Whilst we are not in a position to offer an opinion on your specific survey questions, I would like to take this opportunity to draw out a couple of key points from our work, which are complementary to the overall aim of increasing transparency in the research system.

Several of our recent in-depth inquiries have examined the ethical considerations relating to different aspects or areas of clinical research, such as the use of biological and heath data in research, the involvement of children in clinical research and the responsible development and use of novel neurotechnologies. A common theme that emerges from our work is that clear and publicly accessible communications about clinical trials - starting from the initial recruitment stage through to reporting of results and feeding back to participants - is extremely important both for contributing to the ongoing knowledge base and for building a respectful relationship between researchers and the people taking part in research. We are pleased that the HRA has recognised the important role it has to play in setting standards to encourage and facilitate this as a matter of course for clinical trials in the UK, and we broadly welcome the proposals for a range of measures to increase transparency across various stages and contributors to the research system.

More specifically, regarding the sharing of results of research studies with the people who took part, we would like to raise a couple of key points from our work:

- In our report on children and clinical research, we set out a number of points to consider for researchers working with children, including: "*Does the information provided for children, young people and parents explain how and when they can find out about the outcomes of the research? Will those outcomes also be explained in accessible language*?" Although this is most relevant for clinical trials involving children, we strongly believe that the provision of publicly available and accessible information should apply across all types of clinical trials, and we would like to see the HRA encouraging this wherever possible.

NUFFIELD COUNCIL ON BIOETHICS

- In our report on the collection and use of biological and healthcare data we state that feeding back to participants in research projects should be a minimum requirement of any research project. We further suggest that this feedback should be part of broader efforts to ensure patient participation *throughout the course* of a clinical trial or other research project. We recommend that steps are taken during the recruitment phase of a project or trial to discover what participants expectations are about their involvement (for example what this will entail for them and their families, how their data/the results will be used), and ensure that these expectations are engaged with on an ongoing basis throughout the trial and respected as far as possible. Involving people as far as possible in the design and governance of a trial or other data initiative allows their interests and values to be expressed, transformed and reconciled. It can also help to secure their commitment to the outcome and build trust.

If you would like to meet us to discuss the above / further work on your strategy for transparency, we would be very happy to do so.

Yours sincerely,

Hugh Whittall
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