Forthcoming practical framework for ethics committees and researchers on post-trial access to the trial intervention and healthcare

Neema Sofaer, Penney Lewis, Hugh Davies

When research concludes, post-trial access (PTA) to the trial intervention or standard healthcare can be crucial for participants who are ill such as those in resource-poor countries with inadequate healthcare, British participants testing ‘last-chance drugs’ unavailable on the National Health Service (NHS) and underinsured US participants. Yet, many researchers are unclear about their obligations regarding the post-trial period, and many research ethics committees (RECs) do not know what to require of researchers. Consequences include participants who reasonably expect but lack PTA to the trial intervention, unplanned financial liabilities for NHS Trusts forced to fund this, negative press and potential to undermine public trust.

One reason for the lack of clarity is controversy over whether and when participants should have access, after the study, to the study intervention. At one extreme is the view that continued access should be guaranteed for those participants who reasonably require them. Consequences of this view include participants who reasonably expect but lack PTA to the trial intervention, unplanned financial liabilities for NHS Trusts forced to fund this, negative press and potential to undermine public trust.4–3

Another reason for lack of clarity may be the absence of practical guidance. Certainly, there are many international and national legislation and guidance documents on PTA to trial drugs, healthcare and information, but these are inconsistent, ambiguous or silent about many crucial details.7 8 Many reports with content on PTA that is relevant to research conducted in the UK are unlikely to be read by British RECs due to international focus and length.9 10 British regulations,11 which are weaker than international guidelines, merely require each application to a REC to include ‘details of the plan for treatment or care of subjects once their participation in the trial has ended’ or ‘an explanation of why that information is not being provided’; they prepare RECs neither to pre-empt issues about PTA to the study intervention nor to ensure adequate disclosures to participants of what PTA they will or will not have to the study intervention.

The discussion on PTA has focused mostly on research conducted outside resource-rich countries with universal healthcare. However, these issues arise worldwide, including in the UK,1 2 12 whenever participants want continued access to a study intervention that is unaffordable or otherwise unavailable. They are most pressing when participants are seriously ill and the study intervention has a better clinical profile than the standard treatment or is the only (remaining) option.

The UK Health Research Authority’s forthcoming document Care after research: A framework for NHS RECs13 (see online supplementary appendix 1) seeks to address RECs’ and researchers’ need for practical guidance in the face of various incompatible, yet often individually reasonable views. It prompts RECs to address specific questions about researchers’ plans for the post-trial period; ensure there are plans for transitioning sick participants to healthcare; examine any plans to ensure PTA to the study intervention; and verify that documents for participants explain what will (or will not) happen post-trial, and identify any uncertainty. It allows RECs to decide when PTA to the trial intervention may be feasible or appropriate but, to inform their deliberations, summarises important legal, ethical and practical issues, and key legislation and guidance.

Care after research results from a collaboration between two King’s College London academics and the Research Ethics Advisor of the Health Research Authority. With funding also from the Wellcome Trust and Brocher Foundation, these authors developed it iteratively via a 3-year international consultation that engaged major pharmaceutical companies, patient advocacy groups, the British Medical Association, Nuffield Council on Bioethics, National Research Ethics Advisors’ Panel, European Forum on GCP Uganda National Council for Science and Technology, World Health Organisation, the Editor of the Indian Journal of Medical Ethics, a member and international panellist of the US Presidential Commission for the Study of Bioethical Issues, REC members and Chairs, members of the NIH’s Clinical Center Department of Bioethics, two heads of the NIH’s Fogarty International Center programmes in Bioethics, as well as prominent research ethicists.

Care after research applies to the 79 British RECs14 and so, indirectly, to the researchers who apply to them for permission to conduct research. Four consultation sessions that piggy-backed on large-scale training events for UK RECs should drive domestic adoption. It is too early to assess its impact on RECs,
RCTs, intended to raise awareness of financial liabilities. The international consultation, intended to raise awareness of the consultation’s product, revealed support for the document’s practical approach and belief in its adaptability outside the UK. It will be important not only to foster and monitor domestic impact, but also to encourage international adaptations.

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