Cancer Research UK comments on HRA paper
“The HRA interest in good research conduct: Transparent research”
June 2013

1. Every year around 300,000 people are diagnosed with cancer in the UK. Every year more than 150,000 people die from cancer. Cancer Research UK is the world’s leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, Cancer Research UK’s vision is to bring forward the day when all cancers are cured. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2011/12 we spent £332 million on research. The charity’s pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.

2. Clinical studies are a vital in advancing our knowledge of cancer. We currently fund over 240 clinical studies in the UK; we are one of the largest funders of clinical research in Europe. In 2011/12 over 37,000 patients were recruited to clinical studies supported by CR-UK.

3. Cancer Research UK welcomes the lead that the Health Research Authority (HRA) has taken with the community in forming this position on transparency in research. We participated in the stakeholder event in April and were encouraged to see the practical steps being considered to achieve transparency, which are reflected in this paper.

4. Cancer Research UK is committed to transparency in all forms of research. While all funders in the research community have a responsibility to make health research findings public, we believe that as a fundraising charity we have a duty to ensure that our research is published and contributes to the collective body of evidence on the causes, effects and treatments for cancer.

5. We believe that the HRA can provide important reassurances to the public on the issue of transparency and welcome the organisation’s involvement in this area. We are also supportive of the HRA’s statement that measures to achieve transparency are important but need to be considered alongside the organisation’s role in streamlining the regulation and governance of research. Improving the research environment in the UK continues to be a major focus for clinical research funders and is critical to ensuring that more research takes place and more patients can benefit from the outputs of research.

We have the following comments on the HRA’s proposals.

Application to a Research Ethics Committees

6. We are pleased that the proposals recognise the need to improve transparency without extending the timelines that National Research Ethics Service has managed to achieve with REC approvals. The paper highlights the key concerns from academic funders that requirements for registration before REC approval would increase the number of provisional opinions issued by RECs, and that registration may not be possible or desirable for all forms of clinical research.

7. If RECs were to set provisional opinions on the basis that a trial is registered in a specific timeframe following the committee meeting, we would look to provide further information on what a reasonable timeframe could be.
8. We look forward to the results of the ethics officer pilot and believe it should help to improve the quality and timelines of REC approvals. Transparency issues and compliance could where possible fall to the officer.

**Monitoring compliance with approval conditions**

9. We look forward to working with the HRA to find manageable ways to ensure that compliance with transparency measures is guaranteed and that RECs are made aware of breaches or possible issues. Proposals to introduce a system whereby the HRA issues high level sponsor or funder reassurance to RECs would be welcomed.

10. In the past 10 years Cancer Research UK has helped finance 298 trials of marketed treatments which have now completed. Of these, 183 have reported results to date and the remaining 115 trials have yet to be fully analysed. One of the reasons for this is that a trial cannot generally report until a pre-defined time point has been reached or a specified number of events have occurred. The HRA should take into account, when deciding on when evidence should be submitted to an ethics committee, the time it takes to analyse data by academic trials units into a form that would be useful for REC members.

**Study titles and the IRAS identifier**

11. Cancer Research UK was initially concerned about proposals to create a single study title as we believed that it would be difficult to ensure that a rigid structure for a title would truly reflect the range of studies that take place. We welcome that the HRA are now considering the use of standard short title for IRAS to help identify trials and putting greater emphasis on the use of the IRAS number for tracking trials.

**Informing research participants of the outcome of research studies they have participated in**

12. We welcome the HRA’s work to support informing patients of research findings, it is an important tool of promoting research and inspiring confidence from the public. We believe that the HRA should ensure that patients have access to study findings but should not be too prescriptive in the way that they are delivered.

13. For example, Cancer Research UK runs the CancerHelp UK website which provides information for the public about cancer trials and studies that recruit people in the UK. It receives around 400,000 views a month. The summaries are written in plain English by our team of specialist nurses and all the information is reviewed and approved by the team or organisation running the trial before it is added to CancerHelp UK.

14. We aim to list all cancer trials and studies recruiting in the UK - not only those supported by Cancer Research UK. We currently have more than 1,500 studies listed on the site, including more than 500 trials that are open to recruitment, over 500 studies that are closed to recruitment but ongoing, and more than 400 trials with results.

15. CancerHelp UK provides a useful model of how an organisation can effectively communicate the results of its trials to patients and the public.

16. We welcome further engagement on the particular issue of reporting an individual patient’s results back to them as this is potentially a complicated process which could require extensive
administration to fulfil and has numerous ethical considerations in studies into diseases such as cancer.

**The UK and the UK position globally**

17. We welcome the HRA’s recognition that measures taken by the HRA cannot perceived to be overly bureaucratic and therefore damage the UK as a location to conduct clinical research. We believe a proportionate approach that is well communicated to the research community would help alleviate possible issues.

18. The issue of transparency should be addressed on a global scale in the major pharmaceutical markets. We believe that the UK is well placed to lead international discussions on this issue.

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