



Submission from onCore UK to the Academy of Medical Sciences' call for evidence on the function and scope of a proposed 'single research regulator'.

31st August 2010

Follow-up submission to the initial call for evidence Review of the Regulation and Governance of Medical Research

1. About onCore UK

onCore UK is a national cancer biobanking organisation. We are a charity formed and funded by the Department of Health (England), the Medical Research Council and Cancer Research UK. Our mission is *to serve as an action team that informs, coordinates and develops cancer biobanking to enable research towards the discovery and development of new interventions against cancer.*

www.oncoreuk.org

In our initial submission of evidence

(<http://www.oncoreuk.org/documents/onCore%20UK%20submission%20to%20AMS%20review%202010-06-01.pdf>) we focussed mainly on the results of a survey we carried out in early 2009 that provided direct evidence of the problems with the provision of guidance relating to the regulation and governance of biomedical research. The report from this survey also contained key recommendations on how guidance could be improved. We are not reiterating our evidence in this submission but will refer to it where relevant in our answers to the questions raised in this second call for evidence.

2. Advantages/Challenges of a 'Single Research Regulator'

Based on the results of our survey and the recommendations developed from this, we feel that there would be significant potential advantages in the 'single research regulator' in that the guidance would be collected in one place and there should be enhanced communication and collaboration between the current regulators when housed together.

From our survey: Eighty three percent of respondents said that they would be more likely to be (more) research active if there was an easily accessible source of consolidated guidance endorsed by all regulators.

Ethics and governance are two topics that are closely associated with regard to research with human tissue and therefore the closer association of NRES and the research regulatory activities of the HTA should provide benefits for all stakeholders. The other key element of conducting research with human tissue that is less well understood by researchers is the regulatory framework for the use of personal data - *the survey found that only 23% of those active in research using human tissue or biological samples thought that the National Information Governance Board (NIGB) was applicable to their work.* We therefore feel that incorporation of this body into the 'single research regulator' would be beneficial. If this is not possible then greater 'overt' collaboration between this body and the new regulator would be important.

3. Role and remit of 'single research regulator'

a. Approvals/permissions

Our perspective is that 'as many as possible' of the approval steps should be within the remit of the 'single research regulator' and for those where this is not possible there should be clear guidance and directions on where to go to obtain the approval/permission(s). As mentioned in our previous submission the IRAS (Integrated Research Application System) has been a good step forward in streamlining the research application process and this should be built on going forward.

b. Key functions beyond permissions

In line with the recommendations from our survey that guidance should be consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource – one of the key functions of the 'single research regulator' should be **education and training** of all those involved in the design, support and management of research projects. This should be broad-based, ongoing training that is aimed at the practical application of the guidance and should include all elements of the regulations – eg including data.

The regulator should also have a **proactive** rather than reactive **role** and be exploring ways to continually improve the research regulation environment – not just on a novel ethical issues front.

Public engagement should be a strong element of the work in order to engage with those people who get involved in medical research and without whom medical research would not be possible without the generosity of their participation in clinical trials or donation of tissue/samples.

It is also important that some level of **inspection/audit** of research sites should be carried out and this complements the public engagement element to reassure the public that there is strong governance of research in the UK.

c. UK-wide remit

We feel that ideally this regulator should have a UK-wide remit, however the different legal frameworks for use of tissue for research may make this difficult.

4. Additional measures to improve the regulation and governance framework for medical research.

Greater communication with stakeholders involved in research, including the public, is needed along with ongoing education of those involved in conducting, approving or managing medical research.

Even with the set up of a 'single research regulator' and potential cost-reductions there is a danger that the provision of training will be decreased – a situation which will only serve to hamper research and potentially deter more people from conducting research.