



## **Submission of Evidence from onCore UK to The Academy of Medical Sciences' Review of the Regulation and Governance of Medical Research**

1<sup>st</sup> June 2010

### **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](http://www.oncoreuk.org)

### **2. Evidence of the Complexity of Research Regulation**

In February 2009 onCore UK, with the assistance of several other organisations, conducted a survey of researchers in the UK that provides direct evidence that there are problems with the current provision of guidance relating to the regulation and governance of biomedical research. As a result, some healthcare workers and potential researchers are put off participating in or assisting with research.

The results of the survey led to clear recommendations on how appropriate guidance on regulatory and governance matters can be obtained. Recommendations, however, are only effective if accompanied by appropriate actions to address existing problems. We were, therefore, particularly pleased to be able to include an announcement by the Medical Research Council (MRC) in response to the evidence and arguments contained in the report.

(See

<http://www.oncoreuk.org/documents/EffectofRegulationandGovernanceSurveyReport-onCoreUK2009-09-07o.pdf> for a copy of the report, including the full survey results, recommendations and the MRC's announcement)

onCore UK conducted this cross sectional survey specifically to: gauge the diversity, utility and availability of guidance that purports to assist researchers navigate the regulatory and governance environment; and gather direct evidence from pathologists and other cancer researchers such that an assessment of the overall opinion of the regulatory and governance environment could be made and the opinions of pathologists could be compared to other professional groups.

A total of 242 individuals participated in the survey. Of these **73% described themselves as active in research using human tissue or biological samples**, 61% of respondents were involved with pathology and approximately equal numbers of respondents described themselves as being active in NHS service as being academics.

The subgroups investigated included: those working in pathology laboratories (consultant pathologists, trainee pathologists, clinical scientists in pathology and biomedical scientists); those who are currently active in *human tissue or biological sample research*; those whose professional setting was a combined NHS and academic setting in comparison to those working wholly in the NHS or those working wholly in an academic role.

### **Awareness of appropriate regulators of researchers**

Presumably because most of the respondents conduct some form of human subject based research, whether using human tissues / biological samples or not, most (93%) considered NHS Research Ethics Committees as regulators of their research.

Eighty three percent considered the governance role of NHS Research and Development approvals as being appropriate to their work.

Eighty six percent considered the Human Tissue Authority as applicable to their work.

Notably, **79% of those described as not active in human tissue based research still considered the Human Tissue Authority applicable to their work.**

**Only 46% considered the Health and Safety Executive as appropriate for their work** and this view was consistent across all subgroups examined.

**Only 23% thought that the National Information Governance Board**, and 12% the Office of the Information Commissioner, applicable to their work and 10% admitted that they were not entirely clear which regulators were important to their work.

### **Strictness of environment**

Seventy eight percent assessed the environment as either strict or very strict, with only 19% considering it about right.

**More than half of the respondents (60%) find doing research difficult because of access to appropriate guidance.** Thirteen percent don't do research as a consequence of this difficulty.

### **Accessibility and provision of guidance**

In terms of accessibility of guidance on regulation and governance of research, 76% of all respondents thought that it is "accessible but requires some work to find" it or is frankly "difficult to find".

Those who are active in tissue based research reported that appropriate guidance either took some work to find or was difficult to find (81%) compared to those who are not active in human tissue based research (63%). Those with combined NHS and academic roles found accessibility more work or difficult to find (95%) in comparison to the other groups or the overall group of all respondents.

Seventy percent of respondents reported that the provision of guidance by different sources can be confusing and unhelpful (47%) or time wasting as they assess the guidance from more than one source (23%). This was increased to 89% of respondents with combined NHS and academic roles.

**Most respondents reported using a number of sources for guidance on research regulation and governance** with the average number of currently used sources being 3 (range 0-8), with all respondents and **all subgroups of respondents consistently wishing to use fewer sources** (average 1.6, range 0-7).

The most popular *current* sources of guidance are directly from the applicable regulators (20% of responses), from local NHS Research and Development Offices (22% of responses) and from trusted contacts and colleagues (24% of responses).

**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.**

The nature of the guidance preferred was clear with 75% of respondents stating that they would like to see guidance that included, but distinguished between, best practice and minimum standards for regulatory compliance.

Most respondents to this survey currently seek guidance from multiple distinct sources and would prefer to reduce this necessity. It is also perceived as being provided by enough or too many bodies.

### **Recommendations from the survey**

Three recommendations extend from the observations made in this survey:

**Recommendation 1** – Guidance should be consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource. This will require relevant regulators to be willing and free to cooperate on the production of such a resource. The MRC Regulatory Support Centre has developed Tool Kits to consolidate available guidance and regulations. It is recognised that such Tool Kits have increased authority and confidence when developed with the endorsement or support of relevant regulators.

**Recommendation 2** – A consolidated guidance resource should be made freely available to researchers from a restricted number of well publicised points of access, principally via a single web portal, the use of which can be supported by the network of NHS Research and Development Offices. Direct and specific guidance should continue to be provided by the applicable regulators, many of whom have statutory requirements to provide guidance. Some provision should also be made for academics via a body such as a university research governance advisory service. These sources of the consolidated guidance resource can then be relied upon by researchers without the need to check alternative sources.

**Recommendation 3** – A consolidated guidance resource should clearly provide and distinguish minimum requirements for regulatory compliance and best practice standards and expectations where applicable.

(NB We sent a letter to the Better Regulation Commission's Better Regulation Task Force to suggest consolidated guidance however we received no response.)

Within the MRC Regulatory Support Centre's (RSC) statement they provided a commitment to update and relaunch their Data and Tissues Toolkit. They also stated that they would "*Explore opportunities to work with NHS R&D Forum and others to promote the [Data and Tissues] Tool Kit as an expert source of advice for staff in NHS R&D Offices throughout the UK who have a key role in advising many researchers on relevant requirements.*

NHS R&D offices were also highlighted as a potential barrier to research during a workshop held at the NCRI Cancer Conference in October 2009. The audience was asked to vote on the 'barriers' and NHS R&D were seen as the biggest obstruction to working with human tissue in research.

### **3. Examples of Recent Initiatives to Aid Researchers Navigate the Regulatory Framework**

A number of recent initiatives have been implemented which we feel are a good step forward in providing greater clarity and guidance for researchers to help reduce the perceived complexity of research involving human subjects. In many cases they have involved collaborations between several regulators, which we feel should be the standard approach. These include:

- a. IRAS (Integrated Research Application System): Streamlining the research application process: <https://www.myresearchproject.org.uk/>

- b. NIHR central sign off procedure (for portfolio studies) – this initiative is also aimed at streamlining the processes and reducing obstructions at R&D level.
- c. onCore UK/NRES Training Workshops on Ethical Principles of Consent  
This series of one-day workshops was developed by ourselves and NRES in direct response to the action areas identified in the report published by the NCRI's Pathology and Research Task Force (view executive summary of report at [http://www.ncri.org.uk/includes/publications/reports/PathologyReport\\_Summary.pdf](http://www.ncri.org.uk/includes/publications/reports/PathologyReport_Summary.pdf)). The target audience is a combination of Research Ethics Committee members and researchers/research support staff – co-education of this mixed audience was felt to be key to greater collaboration and understanding between all parties involved in research. Five workshops will be delivered across the UK during 2010 and include speakers from the HTA and NIGB (England) and MRC RSC and Information Services Division in Scotland. The first workshop took place in London in March with 75 delegates participating (full capacity) and over 30 on a waiting list. The second workshop was held in Scotland in late May and an even greater interest level was shown - with the event being over-subscribed 100%. By the end of the workshop series over 350 people involved in conducting or supporting medical research and the workshop content and discussions will be written up and made publicly available. The interest in these workshops demonstrates the great need in this area and for events such as this to be provided on a continual basis.
- d. MRC RSC e-learning module on research and human tissue legislation  
This online training module was designed for researchers working with human tissue but will also be of interest to a wider audience. It provides an overview of the legislation in the UK (with specific sections on Scotland), practical tips on compliance, what constitutes best practice and where to find help. It takes around 45 minutes to complete and includes a short assessment at the end. (See <http://www.rsclern.mrc.ac.uk/>)

In addition we are aware of two other activities in progress. The first is the revision of the MRC RSC's Data and Tissue Toolkit and the second is a collaborative group including NIGB, HTA and NRES that is reworking the guidance on use of data in research.

### **3. Shaping the Future**

The changing focuses of research and accompanying methodology and available technology mean that the regulatory framework and the relevant guidance need to be continually reviewed and promoted.

Within cancer research clinical trials (and many other disease areas) over 90% of trials now take samples from trial participants on a regular basis. This opens up a much greater audience of researchers that were not previously aware of the regulations and requirements for working with human samples.

Our strong recommendation is that the governance and regulatory bodies continue to work closely together and collaborate on joint initiatives and that they actively promote these collaborations. There is a danger that with cuts to these organisations' funding and reductions in licence fees the provision of training will be decreased – a situation which will only serve to hamper research and potentially deter more people from conducting research.