



NHS
Research and Development Forum

The NHS and Human Tissue for Cancer Research

A report of the discussion workshop held on 16th May 2005 by onCore UK in partnership with the NHS Research and Development Forum

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Contents

Contents	2
Notes	3
Executive Summary and Key Conclusions.....	4
Context and Origins of onCore UK.....	7
Introduction to onCore UK.....	7
Human Tissue Banking and the Human Tissue Act 2004	8
The Purpose of the Workshop	10
What are the future benefits of success of onCore UK for patients, donors, researchers, the NHS and the fight against cancer?.....	11
For patients the future benefits are:.....	11
For donors the future benefits are	11
For researchers the future benefits are	12
For NHS Trusts, the future benefits are.....	12
For other stakeholders the benefits are	13
The overall future benefits for the discovery and development of new interventions for the fight against cancer are	13
How will NHS Trusts be optimally involved with onCore UK?	15
Opportunities:.....	15
Challenges:	16
What are the critical ethical and regulatory considerations at this time?	18
Ethical considerations	18
Regulatory Considerations	19
What are the key issues related to patient involvement and confidentiality and access by users to samples and data?	21
Information about patients:.....	21
Access by users:	21
Willingness of participants to recommend that their NHS Trust becomes a working partner of onCore UK.....	23
Acknowledgements.....	24
Attending Participants.....	25

Notes

This document reports on the key themes from the group discussions. The views reported do not represent a consensus view of all the participants or views of any specific and identifiable individual participants. The report is also not intended to present the views of onCore UK or of the NHS Research and Development Forum.

Any conclusions and recommendations made as a result of the workshop are made by onCore UK and are not directly accountable to the participants in the workshop.

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Executive Summary and Key Conclusions

1. onCore UK has been formed as a new part of the National Cancer Research Institute portfolio to serve as the national biospecimen and information resource for research into new interventions against cancer.
2. It is being founded as an independent charitable company funded via collaboration between the Department of Health (England), the Medical Research Council and Cancer Research UK.
3. The major tasks for onCore UK in 2005 are to set up the new charity and complete a consultation and planning process towards commencing operations by the year end.
4. This workshop was held as part of the consultation process. It brought together patients, professionals interested in the work of onCore UK and NHS Trust managers to discuss key aspects of the interaction between the NHS and onCore UK.
5. The objectives of the discussions were: to increase awareness of onCore UK and its mission, including the critical role of NHS Trusts in its success; to discuss the opportunities and challenges related to involvement with and conduct of this type of work; to identify any key consensus or lingering issues resulting from the discussions; and to gauge the willingness of NHS Trusts to become working partners of onCore UK.
6. There was broad agreement that, were onCore UK to be successful, it would deliver a wide variety of benefits for the wider cancer patient population, patients who donate samples and information, cancer researchers, NHS Trusts, the wider stakeholder community and for the search for new interventions against cancer.
 - a. The principle predicted benefits for patients were improved understanding through education, leading to an improved sense of active participation in cancer research and an improved healthcare experience through involvement and by benefiting from the outcome of better research.
 - b. For patients who become donors, the predicted benefits were improved opportunity and choice to participate and feel that they were personally contributing to the fight against cancer. Furthermore, the improved opportunity for donation - and related feedback on progress - would be perceived as a cultural norm within the NHS rather than an unusual and sensitive event.
 - c. Researchers were predicted to benefit through the adoption of a system that improves access to samples and information, speeds up research, improves quality and consistency of

resources, removes the burden of red tape and streamlines issues related to research governance.

- d. NHS Trusts were predicted to benefit from the reassurance and security of working to nationally applied standards, using newly acquired infrastructure and without diverting resources from core patient care activities.
 - e. Future economic benefits were predicted for those who fund cancer care and cancer research as a result of economies of scale, harmonised systems, partnership with high technology industries and from a more collegial, more effective research effort. The exemplary system will have been transferred and adopted by initiatives in other diseases with replication of the economic benefits to those communities.
 - f. New interventions against cancer were predicted be more successfully developed as a consequence of more efficient, more concerted and more relevant research that actively involves patients and in which the UK will lead the world.
7. NHS Trusts who partner onCore UK will have opportunities to commence a new addition to their service portfolio, using easily applicable packages developed by a credible national initiative, whilst managing risk and restoring confidence in staff and the public. NHS Trusts require onCore UK to provide centrally generated standard practical workflows and documentation packages to encourage participation by Trusts. An effective communications strategy is required to deliver this.
8. Willing participation by key staff, particularly medical staff, and effective local leadership represent major challenges to effective Trust participation. Overcoming personnel capacity and capability deficiencies, streamlining administrative burden and reducing competitive tensions are areas where onCore UK could assist NHS Trusts.
9. Harmonisation of nationally applicable approaches to wide-ranging informed donor consent processes and ethics committee approval processes are key factors for success. Similarly, attempting to reach consensus on the need to respect the mandate of the donor's consent, particularly in relation to scope of use and access by users are priorities that onCore UK should consider addressing.
10. The timeliness of the formation of onCore UK and of the establishment of the Human Tissue Authority may offer onCore UK a chance to work closely with the HTA and allow onCore UK to foster wide dissemination and adoption of best practices and regulatory compliance by its NHS partners and research community clients. onCore UK should consider contributing to this work by acting as a central source of coordinated information, advice and practical guidance for its stakeholder

communities. This could extend to the creation of benchmark professional standards and “how to do it” packages for use by its partners. An effective communications strategy is required to deliver this.

11. Information technology that is powerful, scalable, allows interoperability with NHS systems and that preserves confidentiality is key for success. Applicable and affordable systems, as well as the trained staff to create and run such systems are in short supply. Donors and carers might be useful motivated personnel for information curation and real-time updating.
12. Access to samples and information are critical to the operation of a useful resource. The policies and rules for access should be simple, transparent and easily applicable. Stakeholders, other than donors, should be given minimal emphasis in deriving access policies because of inevitable conflicts of interest.
13. The privilege of access to the resource should confer responsibilities on all users to further foster the culture of sharing of donor samples and information as well as research data derived from the study of the resources.
14. onCore UK should widely publicise the availability of resources to prevent restriction of access through secrecy.

Context and Origins of onCore UK

The National Cancer Research Institute (NCRI) is the partnership strategic body that coordinates the activities of the key funders of cancer research in the UK. It consists of a collection of governmental, charitable and industry partners. In 2001, the National Cancer Research Institute recognised the need to provide a means of coordinating the collection of biosamples and information from cancer patients on a national scale for use in research to discover and develop new approaches to the prevention, diagnosis and treatment of cancer. The National Translational Cancer Research Network (NTRAC) developed a strategic justification, on behalf of the National Cancer Research Institute, for the creation of a “national cancer tissue resource”. In 2003, collaborative joint funding for this initiative was announced by the Department of Health (England), the Medical Research Council and Cancer Research UK. onCore UK is the new organisation formed in 2005 to serve as the national cancer biospecimen and information resource and it is in the process of being established as a charitable company limited by guarantee. onCore UK complements the other existing biobanks and specimen resources throughout the UK.

Introduction to onCore UK

All who are touched in some way by cancer, are involved in cancer care or conduct cancer research strive for the day when cancers can be effectively prevented or, where they do occur, can be accurately diagnosed with ease and effectively treated. onCore UK shares this vision. However, despite some notable advances in the fight against some cancers, others continue to present a significant challenge and others are increasing in frequency.

Amongst the many potential approaches to enhance the success of cancer research, the increased study of human biosamples from cancer patients is widely considered an important contributor to more effective translation of new research ideas into innovations in cancer care. This is not a new idea as samples from patients have been the subject of many research projects in the past. What is new, however, is a determination to create a culture where samples are widely collected and recorded to standard protocols, where information about the donors is routinely recorded in support of the samples, where sharing of samples within the entire country is realistic and where these activities are done on a scale that enables the most powerful science to be conducted. This has not been the case in the past when human tissue based research more often floundered and disappointed than it delivered progress. Faced with this fact, researchers often based their work on other apparently more reliable, more easily accessible and often cheaper models of biology that, whilst contributing valuably to a balanced research portfolio, may not always have been the most effective models to deliver benefits to patients.

onCore UK has been formed to overcome this anomaly - to produce a means by which human biosamples are more readily available for cancer research, supported by robust quality systems and better information sets. In addition, to fulfil its mission, onCore UK must help alleviate the obstacles that prevent the

creation of a culture where large numbers of samples are shared by researchers in pursuit of the common vision. The founding funders have chosen to establish onCore UK as a stand alone charitable company to ensure that it serves as a visible, transparent and accountable honest broker for samples donated by patients to reach the research community. onCore UK will not conduct cancer research itself and will have no vested interest as a client of its own service. Instead, it will exist to facilitate the process for others.

Forming a completely new charitable company and commencing its service in as short a time-scale as possible are big challenges for onCore UK staff throughout 2005. To make the best decisions on how to deliver these challenges, onCore UK is in a brief consultation period with its many and diverse stakeholder communities. As much of the journey a sample takes from a donating patient to a researcher takes place within the NHS, and it is perceived that many of the obstacles on that journey occur in the healthcare setting, onCore UK is consulting with representatives of healthcare workers and with NHS managers. By understanding what is required to facilitate the passage of samples from donors to researchers, onCore UK can focus its efforts on helping to provide the necessary resources, education or other assistance required. Mindful of its organisational values of safety, quality, service and ethics, onCore UK believes that by working in partnership with the NHS, it can help to fuel future advances in oncology.

Human Tissue Banking and the Human Tissue Act 2004

The discovery by the UK public of the apparent widespread retention of organs and other body samples from patients after death and without the knowledge of relatives led to high profile public enquiries in Bristol, at Alder Hey Hospital in Liverpool and elsewhere. These, in turn, led the government to examine the scope and scale of these practices throughout the UK and to the establishment of the Retained Organs Commission as recommended by the Chief Medical Officer in 2001. A further recommendation included a comprehensive review of the laws governing human tissues and other body samples. The laws in effect at that time were multiple, disjointed and did not provide a coherent or comprehensive framework for the regulation of human biosample related activities in the UK. The existing laws included the Human Tissue Act 1961, the Anatomy Act 1984, the Human Organ Transplant Act 1989 and elements of the common law. As a result, a single comprehensive new piece of legislation was proposed and has now been passed as the Human Tissue Act 2004.

The key elements of the new Act are donor consent, regulation by a newly established competent authority, criminal sanctions for certain breaches of the law and a set of accessible and authoritative codes of practice to guide those active in the field.

The Human Tissue Authority was established on 1st April 2005 and has the legal rights to issue licenses, conduct inspections and issue codes of practice

and Directions. It is anticipated that consultation on the initial set of codes of practice will take place during the course of 2005 and that licensing will then take effect from 1st April 2006. The Human Tissue Authority will also be a source of advice and provide legitimate and authoritative guidance to allow the Act to work effectively for all stakeholders.

Human tissue banking for research use, as intended by onCore UK, will ordinarily require the consent of donors for the storage of human biosamples. Exceptions to the need for consent do exist, but consent should be seen as the gold standard wherever possible. It is important to recognise that activities that are clearly legal under the Act are still required to also be approved by a research ethics committee and that the two standards of laws and ethics are not necessarily exactly overlapping. Premises of organisations holding biosamples for or on behalf of onCore UK are likely to require a license from the Human Tissue Authority and may be subject to inspection.

The Human Tissue Act is intended to provide a modern and comprehensive framework to protect patients and their relatives, foster medical research and maintain public confidence - onCore UK expects to work comfortably within this legal framework. A draft Human Tissue (Scotland) Bill has also recently been published for consultation and is intended to govern human tissue related activities in Scotland.

The Purpose of the Workshop

This workshop was held to bring together patients, professionals interested in the work of onCore UK and NHS Trust managers who may become involved with onCore UK on behalf of their Trust to discuss key aspects of the interaction between the NHS and onCore UK.

There were four main objectives of the discussions:

1. to increase awareness of onCore UK and its mission - including the critical role of NHS Trusts in its success
2. to discuss the opportunities and challenges related to involvement with and conduct of this type of work
3. to identify any key consensus or lingering issues resulting from the discussions
4. to gauge the willingness of participants to consider recommending to their own NHS Trust that it becomes formally involved as a partner of onCore UK should the opportunity arise.

These objectives were tackled by a series of 4 specific discussion topics that all participants in the workshop considered within facilitated small groups during the course of the day. The remainder of this report describes the key outcomes of the discussions on each topic.

The outcomes of discussions and any conclusions reached will be used to inform onCore UK, its funders, the NCRI partners and other relevant parties for their strategy and planning processes. Specifically, onCore UK may make recommendations in its business plans based on information gathered in this workshop.

What are the future benefits of success of onCore UK for patients, donors, researchers, the NHS and the fight against cancer?

In this discussion participants were asked to project themselves forward to a time when onCore UK had been successful and to look back on what benefits had been achieved as a result. In essence, this session aimed to project a vision of what should be achieved rather than focus on the barriers likely to be experienced along the way.

1. For patients the future benefits are:

- a) *They will feel a sense of active involvement and personal contribution to the fight against cancer, rather than feeling like relatively passive subjects of cancer care.* They will have a better understanding of the bigger picture of cancer research and how they fit into that picture. In turn, they will have a feeling of contributing to the saving of the lives of others in the future. Through active involvement, patients will be confident in a system that places their willing contribution and consent at the heart of the process. There will be a sense that cancer research using donated samples and personal information will be a process that is conducted with them and not merely about them or for them.
- b) *The healthcare experience for the cancer patient will be improved as a result of better research with other positive effects on patient confidence and overall psychological wellbeing.* Research using human biosamples will have made progress towards the provision of diagnosis and treatment schedules that are more individualised, with better targeting for therapies, producing better tailored outcomes.
- c) *Patient education will be better* and there will be a greater understanding of the importance of donated tissues and information for cancer research and patients will have a more informed voice enabling them to contribute more in governance of such research. Moreover, onCore UK will improve the availability of information regarding the uses of donated samples - and research outcomes - to patients and their families

2. For donors the future benefits are

- a) It is important to recognise that not all patients are donors of samples or information for use in research. *In the future, with a successful onCore UK in place, patient confidence will have improved to encourage more to make the active change from being simply a patient to be a contributor to the fight through donation.* This will have been achieved because the existence of a national body that has created a harmonised system and processes will be more visible, accessible and trustworthy. Patients who become donors will have a greater understanding of this system and how it works and be assured that it will enable research towards the improvement of care for patient

benefit. Feedback of information about research progress using samples will serve to further inform and encourage donor participation.

- b) The successful implementation of a system for donation will improve *opportunities for altruism and a culture where patients can feel positive about donating.*
- c) Policies and practices will have been adopted to make *the donation of samples a normal part of cancer patient care* and in doing so, all patients will be given the chance to contribute in their own very personal way to the fight against cancer. Donation will no longer be a sensitive exceptional occurrence that requires special consideration - it will be a norm that donors can feel comfortable about.

3. For researchers the future benefits are

- a) *The quality standards of the samples and information supplied to them are assured,* resulting in better controlled experiments, greater comparability between studies using samples to onCore UK' standards and less need for scientists to spend time and effort attempting to control the variables affecting sample quality that occur in the NHS.
- b) *The governance arrangements for patient derived samples and information will be streamlined* through a mechanism provided as part of onCore UK's service.
- c) The increasing and unavoidable *bureaucracy associated with human sample related research will be handled* by onCore UK as a service to the researcher.
- d) *Access will be simpler, easier to obtain and more equitable.* As more samples than ever will be collected, the issues of competitive access and barriers to sharing will have been overcome.
- e) *The quality of the donor information that is linked to the sample will be higher* and more robust allowing investigations that could not be reliably conducted in the past.
- f) *The ready availability and timely delivery of samples and clinical/outcome data will speed up cancer research* leading to an increase in new knowledge, an increased number of publications and more opportunities for innovations in cancer care.

4. For NHS Trusts the future benefits are

- a) *National Standards will be established for the governance and conduct of activities related to human biosample and information acquisition and transfer from the NHS to the research community.* This will make the operation of processes and the management of staff easier where

there are nationally defined standard performance measures for procedures such as sample collection, storage and distribution.

- b) *Infrastructure will have been funded and provided* to participate in this service and to a sufficient level to meet the national standards required by onCore UK.
- c) *Funding mechanisms will be clear to give Trust managers the confidence that sufficient funding to collaborating hospitals will be available* and that participation with onCore UK's will not risk diverting revenue from core patient care.

5. For other stakeholders the benefits are

- a) *onCore UK will have been shown to provide economic benefits for those who fund cancer care and cancer research.* Centralised provision of services, facilities and staff will provide economies of scale and reduce the replication of investment previously required for a decentralised system. This will result in better use of public and charitable monies and also encourage financial contributions from the private sectors who either assist onCore UK through the provision of enabling technologies, or who use its services, such as pharmaceutical/biotech companies who will benefit from improved access to samples and information.
- b) *A culture of sharing and exchange of samples and information will lead to a more coordinated and collegiate research effort,* with reduction in conflicts between groups and the unproductive consequences of competition for access to biosample resources. Competitive advantage within the research community will be the result of intellect, ideas, skills and diligence, and not the product of the ethically dubious preservation of restricted and privileged access to patient samples and information.
- c) *onCore UK will create an exemplary system that is scalable and transferable,* in part at least, as a model system for the management of biosample and information resources applicable to the study of other diseases.

6. The overall future benefits for the discovery and development of new interventions for the fight against cancer are

- a) *Research will be more efficient* with a compression of the time taken to generate results.
- b) *An increased number of interventions will be generated as a result of a more concerted and effective research effort* and this will in turn improve outcomes for patients.

- c) The environment will *encourage this type of cancer research to be conducted in the UK* as a preference with the consequential benefits to both the health and wealth of the country.
- d) Collaboration between agencies such as government, the NHS, universities, charities and industry on a research effort employing active patient involvement will *improve the effectiveness of the search for new interventions by shifting the focus from biological target driven research to clinical driven patient-centric research.*

How will NHS Trusts be optimally involved with onCore UK?

For this discussion, participants were asked to consider defining the opportunities and challenges facing NHS Trusts if they were to play their part in achieving the benefits recognised as resulting from the future success of onCore UK.

Opportunities:

- a) At present many NHS Trusts are unaware of appropriate benchmarks for best practice for most aspects of human biosample based research. onCore UK presents a timely opportunity for harmonisation of practice and procedures on a national scale and to set the expected quality benchmarks. If this could be achieved and effectively communicated, onCore UK would contribute a significant service to allowing NHS Trusts to more readily become involved in human biosample based research. A practical example of this might be in relation to best practice for obtaining consent for donation for research.
- b) Similarly, with the recent sensitivities and risks for individuals (patients or professionals) and organisations of participating in human biosample related activities, there is an opportunity for onCore UK to provide a standard and widely applicable model for managing those risks and restoring confidence and willing in all who want to be involved.
- c) NHS Trusts have many pulls on their resources, financial or otherwise. The creation of onCore UK presents an opportunity for Trusts to seek investment for the establishment and maintenance of an entirely new service for its portfolio. This may, as one example, provide a boost to staff morale and personnel capacity. This new service may also provide an opportunity for staff to feel that they are involved in something that is unprecedented anywhere else in the world, although other countries have intentions to do so. By contributing their individual experiences and efforts for the greater good in the development of a huge resource of samples linked to clinical outcome, staff have the chance to ensure that the NHS becomes the world leader in this type of service by 2010.
- d) The organ retention crisis highlighted chasms between the public, healthcare workers and researchers in their attitudes to human biosamples, largely resulting from a lack of mutual understanding and gaps in information. onCore UK could assist the entire community associated with the NHS if it were to take a lead on public relations to increase awareness, education and training for all involved in the care of patients, the donation of samples, the collection of information, the passage of samples and information to researchers, and the use of donated resources. Fostering of knowledge and understanding will lead to respect, cooperation and success for mutual benefit. This, in turn, may help restore trust in science and pathology in particular.
- e) onCore UK may provide a practical demonstration of how human biosample based research can be appropriately and successfully

conducted within the context of the Human Tissue Act 2004 and aid resolution of some of the reservations that exist in relation to the formation of the Human Tissue Authority.

- f) The linking of onCore UK's IT systems with those of the national programme for IT in the NHS provides an opportunity to maximise the use of routine clinical data to test clinical and laboratory hypotheses for the first time on this scale in the UK.
- g) NHS Trusts may generate additional income through the provision of "added value" services for onCore UK or its clients. The provision of such services may, in turn, be viewed as a measure of research and development performance and a valid criterion for funding allocation.
- h) Should donation of samples after death be required, this presents an opportunity to increase the number of post mortems being conducted in hospitals, which improves training, preserves skills and provides an important but declining aspect of clinical audit in addition to serving the need for tissues for research.

Challenges:

- a) The success of a partnership between an NHS Trust and onCore UK will be dependent on the willingness of the staff of the Trust to take on additional activities, alter current workflows and perhaps also change clinical practices. Consultant body "buy-in" and participation is often a barrier to change, especially in the absence of obvious effective incentives - this is potentially true for all staff involved in any Trust. A related issue is the need for involvement across multi-disciplinary teams. This may result in lack of lead and ownership with inevitable failure, unless one of the team members takes the lead seeing that it offers a personal advantage of some sort. It might be advantageous if the team recognised such activities as part of their duty of care to the patient-donor and took responsibility for the activity as they do for other aspects of patient care.
- b) Pathologists are natural participants in the chain of custody of donated samples from the donor to onCore UK. They also have particular expertise in the handling of tissue specimens. Unfortunately, they have also often been accused of exerting a controlling influence over the movement of samples that extends beyond that necessary for patient care. In addition, they have also become very cautious about their involvement in the release of samples for research in the wake of organ retention scandals. onCore UK will need to work with professional bodies to find ways of rekindling the necessary participation of this important group of staff.
- c) Personnel capacity and capability issues exist within Trusts for patient information and consent, medical records and data handling, pathology, informatics and IT integration and sometimes also in R&D management. Where there are personnel required, there is also usually additional non-human infrastructure required. onCore UK will need to work with Trusts to

identify, resource and probably train staff according to the local needs of the Trust and assist with investment in infrastructure.

- d) The administrative burden experienced by a Trust is likely to be considerable and a disincentive for Trusts to seek partnership unless onCore UK provides assistance to lighten the burden and help make this activity an acceptable part of core NHS workload. This burden especially relates to setting up the NHS Trust/onCore partnership, ensuring costs are accurately estimated, ensuring that funding is ring fenced and properly utilised, managing performance against contract, managing risk and governance issues, managing resource conflicts with priority services, etc. Even then, it might remain unattractive where there is a lack of perceived benefit, especially in smaller Trusts. In the early days, competition between Trusts may conspire to lead some managers to conclude that the effort to tender for partnership may not be worthwhile.
- e) In Trusts that house research-active personnel who require access to resources but find them difficult to acquire, becoming involved with onCore UK may be perceived as an attractive opportunity. However, those Trusts housing pre-existing collections/resources may find it difficult to gain the cooperation of staff who will perceive an internal conflict developing over tissue sharing and an inevitable dilution of their own access to the resource, with loss of personal competitive advantage in the research community.
- f) Until the Human Tissue Authority is fully operational and Trusts can understand how it affects their operations, the lack of clarity still surrounding the Human Tissue Act will be a barrier to early willingness to participate.
- g) Data collection, collation and transfer, IT capability, fears over breaches of confidentiality and data protection remain as significant weak points in most Trusts and could interfere with the recruitment of partner Trusts or the performance of Trusts against onCore UK's expected standards.
- h) The fact that onCore UK exists purely to service cancer research to the exclusion of other diseases will remove the opportunity for partnership from many potentially willing Trusts.
- i) The challenge of maintaining effective communication with the diverse groups of stakeholders that most Trusts naturally have to consider will take considerable planning, resources and time. Indeed, this might adversely affect the time to implementation of a partnership and the timing of introducing donation via onCore UK to patients.

What are the critical ethical and regulatory considerations at this time?

In this discussion the participants were asked to define the critical ethical and regulatory considerations that will need to be observed, addressed, or resolved for onCore UK to succeed and realise the potential future benefits.

Ethical considerations

- a) It is increasingly accepted that patient consent to donate samples can be wide-ranging (“blanket”) and cover a range of uncertain future research uses. However, there is no widely adopted standard to achieve this in practice and research ethics committees sometimes object to this approach. The challenge remains as to how to make this a common practice and how to make it sufficiently “informed”. It would be preferable if the discussions on a standard method for obtaining wide ranging consent would be national with relatively little opportunity or need to alter the standard at the local level. It would be preferable to use a nationally agreed and Department of Health centrally approved consent form that includes donation for research to help secure the adoption of wide-ranging consent as required by research tissue banks.
- b) In order to collect samples, NHS Trusts and onCore UK should deal with the ethics application as a process wide approval to minimise the costs and bureaucratic burden on healthcare workers who have no personal interest in the research conducted on the samples.
- c) Processes should be put in place to preserve the integrity of the donors’ consents and the ethics approval along the entire supply chain to prevent drifts (restrictions or widening) of scope occurring further along the chain of custody and remotely from the originating sources.
- d) The ethical issues associated with access control need to be debated to ensure that it is sound ethics that dictates the priorities for access, as exists in transplantation, and not predominately the opinions of “esteemed scientists”. There is an ethical imperative to make optimum use of samples willingly donated and, although restricting access may be necessary for rare samples, it is not as ethically defensible for more common samples. Rules for governing supply and demand issues that are firmly rooted in ethics and not in competition between scientists are required.
- e) The issue of access by public sector researchers versus commercial researchers requires resolution. Access decisions should include aspects regarding likely patient benefit of the research rather than decisions based solely on scientific merit or on financial criteria. The choice could be offered to donors during the consent process, but this would require a very balanced and impartial information process at the point of consent to ensure a balanced and informed decision by the donor.
- f) There is a widely held perception that Research Ethics Committees (REC’s) have been inconsistent in their approaches and opinions to human

biosample collection and research in the past. This has sometimes resulted from lack of sufficient expertise and experience in assessing the issues inherent in this area. Common guidance is needed for RECs to ensure that common standards are recognised and to ensure fairness and consistency around the country. Specifically, REC's should have a responsibility to consider donor's wishes and not impose undue requirements that donors themselves did not need (e.g. project - specific consent).

- g) National standards for ethically acceptable protection of patient confidentiality within the research setting are required.
- h) A means of establishing the standards on intellectual property rights, particularly ownership of data collated by tissue resources such as onCore UK need to be established and adopted as integral to all consent processes, all partnership agreements between Trusts and onCore UK and all contracts between onCore UK and end users.
- i) When in custody of samples and information, onCore UK should have a duty of care to the donors and accommodate contact that allows feedback where necessary and revocations of consent when desired.

Regulatory Considerations

- a) Standard model contracts that are binding on all parties should be produced to minimise the risks for Trusts of breaching regulation through partnership with onCore UK.
- b) When Trusts are required to form a partnership with onCore UK, they should be asked to do so via an agreement that makes the relationship robust, meaningful and worthwhile for the Trust to alter its procedures and hire or train staff. Under such formal arrangements, there should equally be no scope for opt-out by Trusts.
- c) Contracts between Trusts and onCore UK should determine where responsibility rests for resourcing all activities associated with regulatory compliance and best practice.
- d) Trusts and researchers should be able to rely on national, coordinated, standardised guidance on legal, ethical, and quality systems aspects and these could perhaps be coordinated by onCore UK. This would include coordination of guidance from regulatory agencies e.g. Human Tissue Authority, Royal College of Pathologists, COREC, Data protection commissioner, MHRA, etc.
- e) onCore UK could deliver a "package" of protocols that will ensure legal, ethical and safe standards to its partner Trusts as a service to the community. This package should recognise that legal compliance is a minimum standard that may differ from meeting ethical standards which

may be more optimal. The package should facilitate Trust level governance (R&D) approval and compatibility with professional standards, infection control and audit requirements.

- f) Compliance with regulation will be assisted by the use of robust, accessible and co-ordinated IT systems between onCore UK and Trusts.
- g) Regulation by competent authorities such as the Human Tissue Authority should be transparent, consistent and comprehensible.

What are the key issues related to patient involvement and confidentiality and access by users to samples and data?

Information about patients:

- a) A good system of fully informed consent will be required to inform donors of what information will be sought, what the purpose is and what will happen to the data. The creation of national standards for such documentation would be useful.
- b) onCore UK's new sample and information management system will need to be able to easily interface with existing procedures and data management systems.
- c) Information systems will need to robustly handle security/confidentiality and consent issues, including anonymisation.
- d) A system will be required to ensure the real time accuracy and quality of data through curation. It might be desirable to involve patients in data submission and curation wherever possible to engage them in the process.
- e) The system should ensure that the data stored is available for use and not confined to an impenetrable or obsolete data black hole.
- f) The system should provide an opportunity for patients to look at the work of onCore UK and see the contribution they are making (collectively) to the results of the research.
- g) Careful consideration should be given to where the considerable skilled personnel and IT resources are coming from to ensure that the system can run smoothly and not falter.

Access by users:

- a) Robust, fair, transparent and accountable systems should be developed to manage access to samples and information about patients. This should not be over complicated and should not give overemphasis to the opinions of individuals, other than donating patients, who have a vested interest in controlling access.
- b) The system must derive a means of fairly assessing competing requests for material/ resources that are in short supply.
- c) Conditions should be attached to the supply of samples and information from the resource to ensure that they are only used for the original approved purpose, for a defined duration of storage by others and with limitations on onward supply or sub-contracting. There should be a condition that benefits are returned in some way to the community. e.g.

publication of results, data sharing via return to onCore UK's or NCRI Informatics Initiative's databases.

- d) Access rules should include provisions that places responsibilities on users that encourages sharing between their own collections and those accessed via onCore UK. This could encourage acknowledging sources of samples, some form of reward for professional contributors to the resource if they are subsequently accessed by another user, or a condition on users to share samples from their own collections if appropriate.
- e) The policies and procedures for access should ensure transparency of the conditions of access and how they are applied. The creation and application of the rules should be subject to some form of appropriate external review.
- f) To encourage wide public benefit from the resource, onCore UK should ensure that its communications strategy includes frequent and clear publicity to allow researchers to learn about the onCore UK service and avoid access being restricted not through a restricted access policy, but through the operation of a "well kept secret".

Willingness of participants to recommend that their NHS Trust becomes a working partner of onCore UK

In order to track the changes in perceptions of participants about the establishment, mission, values and likelihood of success of onCore UK, they were asked on three occasions during the workshop to score their willingness to recommend that their own local NHS Trust should seek to become a partner of onCore UK and contribute to the future benefits for cancer care.

Participants were asked to score their willingness on a linear scale from 1 (no interest at present) to 10 (ready to commit to participation). They were asked to provide their scores after a session in which an introduction to onCore UK was presented, after two topics had been discussed and at the end of the workshop.

Perhaps not surprisingly given the voluntary nature of the registration process for participants, at the beginning of the day there were few individuals who had little or no interest in participating with onCore UK. This changed little as the day progressed. At the start of the workshop, most participants were neutral about recommending partnership of their Trust with onCore UK. A small number were more interested in recommending partnership. As the workshop progressed, despite minor shifts in the perceptions, there was no overall significant change in the pattern of willingness to recommend partnership, despite the very active engagement by participants in discussion with many positive benefits and opportunities being identified. It would appear that the barriers that were identified remain significant in the minds of participants who remain moderately interested in the success of this new organisation, but need to be convinced that the barriers can be effectively overcome.

The considerable participation of workshop attendees contributed many suggestions for where onCore UK might focus its efforts to overcome the barriers and create an environment where willingness to form working partnerships with onCore UK would be improved.

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Sarah Dart diligently provided all aspects of the organisation and secretariat for this workshop as well as assistance with the preparation of this report.

Matthew Moffatt and the staff of the Thistle Hotel Marble Arch, London provided an excellent venue, catering and attentive service in support of the event.

Cathy Ratcliffe and Julie Howard provided advice and assistance in the preparation of this report.

Attending Participants

Allen	Stephanie	Miss	Research Governance Coordinator	St George's Healthcare NHS Trust
Ball	Angela	Ms	R&D Manager	Christie Hospital NHS Trust
Barnett	Christian	Mr	Acting R&D Co-Ordinator - Commercial	Mid Essex Hospital Services NHS Trust
Bartle	Gillian	Miss	Research Technician	The Royal Orthopaedic Hospital
Belcher	John	Mr	Patient	
Brazel	Jeff	Mr	Assistant R&D Manager	Guy's & St Thomas Hospital NHS Foundation Trust
Bulley	Sue	Mrs	R&D Manager	East Somerset NHS Trust
Campbell	Helen	Dr	Portfolio Manager for Cancer Research	Dept of Health
Cassery	Shelia	Ms	Assistant Director	NCRN Co-ordinating Centre
Clark	Brian	Dr	CEO	onCore UK
Cole	Trevor	Dr	Consultant Clinical Geneticist	West Midlands Regional Genetic Service
Cope	Jane	Mrs	Administrative Director	NCRI
Cross	Martine	Ms	R&D Manager	Portsmouth NHS R&D Consortium
Dart	Sarah	Miss	Office Manager	onCore UK
Davidson	Jean	Mrs	Data Protection Manager	Northampton General Hospital
Dennison	Jane	Mrs	Research Governance Co-Ordinator	Bradford Teaching Hospitals NHS Foundation Trust
Enright	Susan	Mrs	Research Governance Manager	Queen's Medical Centre Nottingham
Grimer	Robert	Mr	Consultant Orthopedic Surgeon	Royal Orthopaedic Hospital
Hair	Jane	Ms	BioBank Manager	North Glasgow University Hospital NHS Trust
Harness	Nigel	Mr	Biomedical Scientist 3 - Laboratory Manager	Histopathology Dept
Harrison	Shirley	Mrs	Cancer Patient and Member (Facilitator)	Human Tissue Authority
Hauptmannova	Iva	Miss	R&D Coordinator	North West London NHS Trust
Htay	U HLA	Mr	Carer	QRD, Alzheimer's Society
Issac	John	Dr	Assistant R&D Director	Ashford & St Peter's Hospital NHS Trust
MacKay	James	Dr	Consultant Clinical Genetic Oncologist	The North East Thames Regional Regional Genetic Service

Mager	Rachel	Miss	Policy and Programme Co-Ordinator	NTRAC
Marsh	Sally	Mrs	Senior Clinical Research Nurse	Northampton General Hospital
McGrath	Christine	Ms	R&D Manager	United Bristol Healthcare NHS Trust
Messer	Janet	Ms	Manager	NHS R&D Forum
Moore	Helen	Mrs	Senior Research Sister	Clinical Trial Unit, Dept of Oncology
O'Brian	Eamon	Mr	Facilitator	CR&C Consulting
Pandha	Hardev	Dr	Consultant Medical Oncologist	Department of Oncology
Parry-Jones	Alison	Dr	Manager	Wales Cancer Bank
Pavelin	Colin	Mr	Facilitator	Policy Manager
Ratcliffe	Cathy	Miss	Communications Manager	NTRAC
Roberts	Fiona	Dr	Cancer Trust Unit Manager	South Devon Healthcare NHS Trust
Rooney	Paul	Dr	R&D Manager	National Blood Service
Russell	Matthew	Mr	Senior Biomedical Scientist Histopathology/Tissue	Nottingham City Hospital
Scott	Julie	Miss	Acting R&D Co-Ordinator - Non- Commercial	Mid Essex Hospital Services NHS Trust
Sharplin	John	Mr	Cancer Patient	Black Country PACT
Shaw	Howard	Dr	Director of R&D	UHCW NHS Trust
Sneddon	Peter	Dr	Head of Research Programme	Dept of Health
Stainthroe	Andy	Dr	R&D Lead	Salisbury/S Wilsts R&D Office
Strachen	Ray	Mr	Patient	
Surr	Gillian	Miss	R&D Manager	UHCW NHS Trust
Thomas	Geraldine	Dr	Principal Scientist Wales Cancer Bank	Wales Cancer Bank
Tourette	Mary Anne	Ms	R&D Coordinator	St George's Healthcare NHS Trust
Vora	Abhi	Dr	The UK Multiple Sclerosis Tissue Bank	Division of Neuroscience and Mental Health
Wade	Kay	Ms	Voluntary Worker	Cherub
Wallace	William	Dr	Consultant Histopathologist	Royal Infirmary of Edinburgh
Warnes	Alan	Dr	Research Co-ordinator	Mark's Hospital/NWLH Trust
Whittal	Hugh	Mr	Facilitator	Human Tissue Policy and Regulation
Wilson	Julie	Mrs	R&D Manager	Northampton General Hospital

Womack	Chris	Mr	Consultant Pathologist and Facilitator	Peterborough Hospitals NHS Trust
Woodward	Wendy	Ms	Research Governance Manager	Nottingham City Hospital