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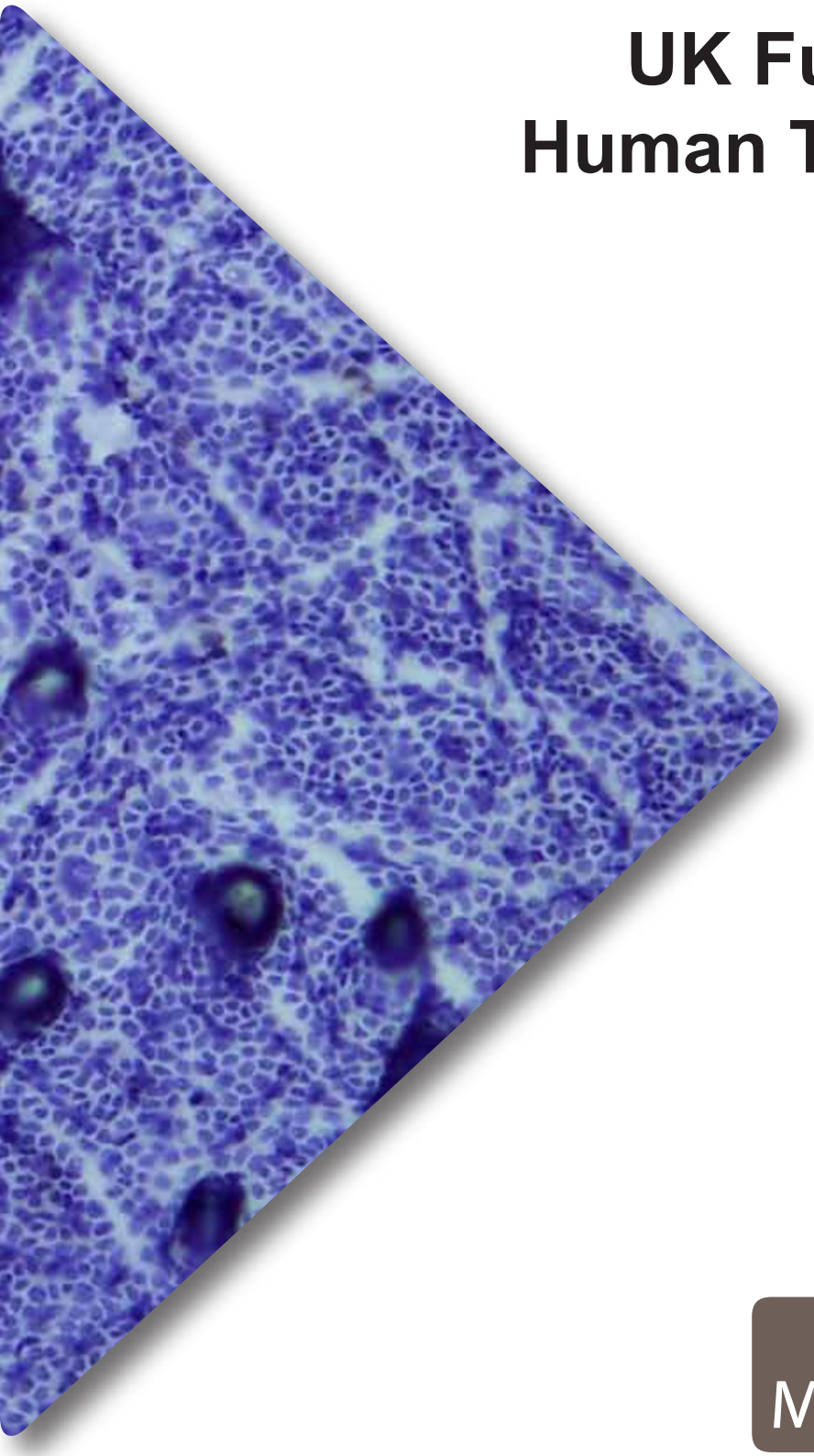

# UK Funders' Vision for Human Tissue Resources

**September 2011**

MRC Medical Research Council

NCRI National Cancer Research Institute

# Contents



This report is the result of a project undertaken by Medical Research Council (MRC) and National Cancer Research Institute (NCRI) staff overseen by the UK Clinical Research Collaboration (UKCRC) Experimental Medicine Funders Group and the NCRI's Board Sub-group on Clinical and Translational Research. The report presents a coordinated vision for human tissue resources that is shared by the UK funders of these resources and describes associated areas in which they will take action to move towards this.

The vision, underlying principles and actions are now presented for wider comment and will be reviewed in early 2012. Please send any comments to info@rsc.mrc.ac.uk by 2nd January 2012.

Cover image: Esther Arwert, Cancer Research UK Cambridge Research Institute.

# Executive summary

i. Human tissue and linked data held from routine health care and from clinical research (trials, cohorts etc) are a necessary and valued resource for public and private sector research. During the past decade, legislative and other changes have driven increased standards of sample management, and the UK is well placed to build on this strong base to support academic and commercial research using human tissue. Research centres, professional groups, funders and industry have led various initiatives to improve the UK's effectiveness in collecting and using tissue. However, these have not been closely coordinated and there are continued risks of duplication of effort, neglected areas and of disparate policy solutions that do not join up.

ii. To help identify where and how greater harmonisation will fully realise the potential of human tissue resources, the UK Funders of this research have agreed a common vision to inform their action in this area over the next five years. This vision is intended to encompass both free-standing tissue collections (sometimes referred to as 'biobanks') and sample collection which is integral to a self-contained research project designed to test a clear hypothesis.

***"Funders aim to maximise the value of human tissue samples and resources while minimising duplication of effort. This requires better characterisation of tissue samples, asking for generic consent, and increased linkage to accurate clinical data. Sample collections must then be made more easily discoverable and accessible for use in high quality, ethical research."***

iii. In order to achieve their vision funders will now require applicants to:

- justify the need for new human tissue sample collections and consider opportunities to link sample collection to existing studies or trials collecting high quality clinical data;
- seek generic consent or to justify why this would not be appropriate;
- describe how their collection and storage of samples complies with existing good practice; and
- make appropriate arrangements for access and register collections in a publicly accessible directory.
- and require existing awardees, where collections have not been depleted, to:
- have an access policy in place;
- register collections in a publicly accessible directory; and
- be able to provide existing sample metadata on request.

iv. These requirements will be defined in a joint policy statement and incorporated as appropriate into UK Funders' existing policies. In parallel, to further support applicants, funders will:

- Highlight these policies to their funding boards/panels, emphasising the importance of this area in their assessments.
- Maintain and promote existing tools, such as Medical Research Council (MRC) e-learning on Research and Human Tissue Legislation[1] and MRC Data and Tissues Tool Kit[2] that provide education on the legislation to facilitate wider access.
- Support joined up training on human tissue regulatory requirements, working with the UK Clinical Research Collaboration Regulatory and Governance Training Coordination group to lead coordination of training between organisations including the National Research Ethics Service, Human Tissue Authority, Scottish Chief Scientist Office, National Institute for Health Research and others.

v. To build on these policy changes over the next 1-2 years, funders will take the following actions:

- Actively develop and promote detailed guidance on seeking generic consent, incorporating views of patient and public groups.
- Work towards a common set of good practice requirements for tissue collection and storage and associated mechanisms for assessing compliance.
- Provide practical mechanisms for potential users to discover the existence of human tissue collections and basic details about them.
- Develop practical guidance on access, consolidating that which already exists, and addressing practical issues of acknowledging the contribution of investigators who generate collections.
- Review programmes of funding to ensure that support for collection of, or linkage to, robust clinical data is adequate.
- Establish minimum requirements for existing resources to be more discoverable and accessible in proportion to their value.

1. MRC Regulatory Support Centre, 2010. *Research and human tissue legislation e-learning module*. Available at: http://www.rsclearn.mrc.ac.uk/ [Accessed 08 August 2011].

2. MRC. *Data and Tissues Tool Kit*. Available at: http://www.dt-toolkit.ac.uk/ [Accessed 08 August 2011].

- Consult their relevant boards and committees to identify if lack of adequately powered studies is an issue and, if necessary, suggest actions to address it.

vi. Finally, funders recognise the need to work with other professional groups and the public to:
    - understand more about public and patient views on research use of tissues;
    - make better use of diagnostic tissue collected in the NHS; and
    - understand the tissue resources that are required to support research.

vii. The main body of this report provides a more detailed description of each of these areas for action and includes an overview of the environment for human tissue resources in the UK which has informed the development of this vision.

# Introduction

1. Human tissue[3] and linked data held from routine healthcare and from clinical research (trials, cohorts, etc) are a necessary resource for public and private sector research – such as studies of normal and pathological tissue functions, disease genetics, disease stratification and research into new treatments and diagnostics. As a result, biobanking and organised tissue collection has risen in importance for the UK during the past decade.

2. It is accepted that in order to maximise the scientific potential of human samples, they need to be well collected and managed, and used in high quality, ethical research. As a consequence of human tissue legislation[4], the standards of sample management have increased, and the UK is well placed to build on this in a co-ordinated fashion. Research centres, professional groups, funders, and industry have led various initiatives to improve the UK's effectiveness in collecting and using tissue. These communicate with each other but are not very closely coordinated – the coverage varies, the range of effectiveness and issues tackled varies and there are risks of duplication of effort, and of separately inventing policy solutions that do not join up.

3. This project, undertaken by Medical Research Council (MRC) and National Cancer Research Institute (NCRI) staff overseen by the UK Clinical Research Collaboration (UKCRC) Experimental Medicine Funders Group and the NCRI's Board Sub-group on Clinical and Translational Research, was tasked with identifying areas that would benefit from the development of common policy for the UK funders of research using human samples, taking account of previous and current work in the area. Its report presents a coordinated vision for human tissue resources that is shared by the UK funders and describes associated areas in which they will take action to move towards this. This vision is intended to encompass both free-standing tissue collections (sometimes referred to as 'biobanks') and sample collection which is integral to a self-contained research project designed to test a clear hypothesis. Funders who support either one or both of these activities are invited to embrace the vision

4. This vision cannot be achieved by funders alone; investigators, regulators, the NHS and the patients and members of the public who donate their samples will all need to be involved. However, there are some important areas where funders can make progress by co-ordinating and harmonising their requirements for grant awards and providing additional guidance to researchers. This report also summarises areas that, while still important, would require longer-term work by a wider group of organisations.

5. The findings that informed the vision and resulting policy can be found in the Environment Scan document at Annex A. The project methodology and list of consultees can be found in Annex B.

3. The terms human tissue and samples are used interchangeably and refer to all human biosamples, including fluids that do and do not contain cells, but not cell lines. Where relevant, the principles can be applied to DNA, although it is appreciated that storage of DNA is not legislated and DNA is not a depleting resource.

4. The human tissue legislation is different in Scotland than the rest of the UK. The Human Tissue Act 2004 applies in its entirety to England, Wales and Northern Ireland, and the section on DNA analysis to Scotland. The Human Tissue Scotland Act 2006 applies only to Scotland.

***"Funders aim to maximise the value of human tissue samples and resources while minimising duplication of effort. This requires better characterisation of tissue samples, asking for generic consent, and increased linkage to accurate clinical data. Sample collections must then be made more easily discoverable and accessible for use in high quality, ethical research."***

**Maximising value and minimising duplication of effort**

6. Maximising value requires action at several levels in the collection, management and use of samples. Donors expect that the samples they provide will be used for productive research; the value or potential for medical research of samples that are stored unused for long periods of time is not maximised. To avoid prolonged storage or wasteful destruction – and provided the value of the samples justifies the cost of providing access – samples collected for a particular purpose should be made available for further uses once that purpose is achieved. Similarly, unnecessary duplication of sample collection fails to maximise the value of funders' investment in human tissue resources; wherever possible and cost effective, investigators should make use of existing resources rather than collecting new samples.

***Action 1:*** *Funders will now require researchers proposing to make use of human tissue to consider whether existing resources would meet their needs and to justify why any new collection is necessary.*

7. It is recognised that not every piece of tissue that may be collected is of equal value and the value may not be known at the outset depending on whether the tissue was collected for a particular piece of research or not. The value of a sample will depend on the scarcity or otherwise of the particular tissue or disease type and on its potential to support high quality research. This in turn depends on the conditions and consent under which the material is collected and on the availability of high quality data on both the tissue and the donor.

**Seeking generic consent**

8. The Human Tissue Authority, in line with MRC and the National Research Ethics Service, advises that consent for the use of tissue in research should be generic (broad in time and scope, also referred to as broad and enduring consent) and not purely project based[5]. This facilitates the widest use of valuable samples in all research and is open and transparent for the donor. Funders will encourage the use of generic research consent in future collections by requiring applicants intending to collect human tissue to either state that they will seek such consent or justify why this is inappropriate.

9. Consent for research uses of samples should be separated from the primary consent for treatment or diagnosis. As well as details of any specific studies planned for samples, it is important that the process of obtaining generic research consent includes information or discussion about the range of potential uses to which samples may be put, in particular where these may be sensitive or emotive to the donor. Examples include: genetic analysis, use in research involving animals, and sharing with academic or commercial collaborators in the UK and abroad. Systems must also be in place to allow donors to withdraw their consent in future and to make clear what withdrawal would mean. For example, identifiable or coded samples could be disposed of, but not those that have been irreversibly anonymised; and it should be clear whether data that had been derived from the samples would continue to be used or otherwise.

10. Where collection is for a research tissue bank, consent should be generic as managing complex caveats is not conducive with the purpose of the bank. When collection is primarily for a specific study investigators are still expected to seek generic consent. They may, however decide to seek consent in two phases - firstly for the specific project and secondly for generic future use. The approach taken will depend on whether dissent to generic research use is anticipated from the study population and thus will compromise recruitment to the initial study.

11. Whatever the strategy for seeking consent, investigators should ask for generic consent, both to facilitate the widest use of tissue resources in line with ethical and legal obligations and to meet donor expectations that their samples are used in productive research. To assist investigators with meeting this requirement, funders will prepare guidance on seeking generic consent, incorporating the views of patient and public groups.

***Action 2:*** *Funders will now require researchers proposing to collect human tissue to seek generic consent or to justify why this would not be appropriate.*

***Action 3:*** *Funders will develop common guidance on the issues to consider when seeking generic consent.*

5. Human Tissue Authority, 2009. *Code of Practice 9: Research*. Available at: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm [Accessed 08 August 2011].

**Improving the characterisation of tissue resources to understand their quality**

12. There is no absolute standard for sample quality; the requirements in each case will depend on the intended use of the tissue. Nor is there a single, 'best' method for sample collection or storage. It would be inappropriate for funders to prescribe specific protocols for sample collection or preservation and this would be impractical given the range of types and purpose of collections. A range of good practice guidance already exists and so it is possible for funders to require proposed collections to show evidence that their protocols will comply with good practice in key areas. Areas that funders can practically assess are the existence of appropriate standard operating procedures, the availability of relevant pathology expertise and plans to record metadata relevant to proposed use of the samples.

13. Examples of existing international good practice include:
    - National Cancer Institute (NCI) Office of Biorepositories and Biospecimen Research (OBBR) Biospecimen Best Practices[6]
    - Organisation for Economic Cooperation and Development (OECD) Best Practice Guidelines for Biological Resource Centres[7]
    - International Society for Biological and Environmental Repositories (ISBER) Best Practices for Repositories[8]

14. Funders will consider other mechanisms for assessing compliance with good practice. For example, meeting the criteria for accreditation under schemes such as the one under discussion by the NCRI's Confederation of Cancer Biobanks. It is recognised that this would not be necessary or suitable for all, awardees will need to consider other schemes or guidance to determine the most appropriate.

***Action 4:*** *Funders will consider and implement practical ways by which their boards and committees can evaluate how well a proposed tissue collection will comply with existing good practice in the collection and storage of samples.*

***Action 5:*** *Funders will work towards a common set of good practice requirements and associated mechanisms for assessing compliance.*

**Linkage to clinical information**

15. Associating samples with high quality clinical information about the donor (including history, diagnosis, treatment and outcomes) is fundamental for research and will be crucial to realising the potential of stratified medicine. Obtaining high quality clinical information may require significant effort; either for extracting this from existing records or, where these are insufficient, collecting information separately. Obtaining such data should become easier as data linkage initiatives are developed.

16. Sample collections that are associated with a clinical trial or other highly clinically phenotyped study obtain these data as part of the study protocol. It is therefore important that such well-characterised samples are used to their full potential; and that, where possible, additional samples for future research use are taken and stored in these studies (see below).

17. Additionally, funders should encourage investigators to consider how collection of tissue samples might be combined with studies that are already generating high quality clinical data, reducing the marginal cost of collecting samples linked to high quality clinical information. Such collection would require justification in its own right (with strong evidence of demand, need or value) and should fit with funders' policies on tissue collection. Achieving this would require funders to ensure that appropriate mechanisms are in place to evaluate the proposed needs and demands for such collections and promote existing funding streams for such work (such as that available through Cancer Research UK's Clinical Trials Awards and Advisory Committee (CTAAC)). To enable researchers to extend trials/collections in this way, it is vital that funding mechanisms for long-term storage and curation are considered.

***Action 6:*** *Funders will encourage researchers to consider opportunities to combine sample collection with studies or trials collecting high quality clinical data. Such collection must be justified and linked to a plan for how samples would be used or made available.*

***Action 7:*** *Funders will review programmes of funding to ensure that support for collection of or linkage to, robust clinical data is adequate.*

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6. National Cancer Institute, 2007. *National Cancer Institute Best Practices for Biospecimen Resource*s. Available at: http://biospecimens.cancer.gov/practices/ [Accessed 08 August 2011].

7. Organisation for Economic Co-operation and Development, 2007. *OECD Best Practice Guidelines for Biological Resource Centres*. Available at: http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html [Accessed 08 August 2011].

8. International Society for Biological and Environmental Repositories, 2008. *Best Practices for Repositories*. Available at: http://www.isber.org/bp/ [Accessed 08 August 2011].

**Access to collections**

18. Maximising the value of collections means ensuring that they are available for a range of uses, either immediately after collection or once they have served the primary purpose for which they were collected. Unless the tissues collected will be depleted during any planned primary study a clear plan for when and how access will be provided should be in place. Although the majority of funders already have policies requiring this, implementation varies and researchers may not have the resources or support required to allow sharing[9].

19. In order to encourage sharing, funders must ensure:
    i. That collections can be discovered and their suitability for use in a particular study assessed (i.e. that collections are discoverable).
    ii. There are adequate arrangements for access.
    iii. There is clear guidance on how the interests of investigators who invest time and effort in sample collection are recognised.

20. Mechanisms to enable access to collections must be supported by systems that allow potential users to discover their existence. This could be achieved by requiring those receiving an applicable grant, supporting well characterised tissue collection and further access, to register the details of the collection in one or more publicly accessible directory(ies). Currently there is no single suitable directory (although there are domain and topic specific directories such as the NCRI Cancer Biosample Directory[10], Institute of Cancer Research prostate cancer repository[11], and the catalogues prepared by the Biobanking and Biomolecular Resources Research Infrastructure project[12]). Funders might extend the existing directories or provide new options, for example through the UKCRC Experimental Medicine resources website. To ensure that the information in directories remains relevant, simple mechanisms for curation will need to be developed.

21. Quality control and maintenance of the data will be important to ensure that such registries advertise well-characterised collections, and reflect the true status of each collection and the samples that are available.

***Action 8:*** *Funders will require that those receiving funding to create a tissue collection, and provide access to this, to register the collection in a publicly accessible directory.*

***Action 9:*** *Funders will provide mechanisms for making collections discoverable.*

22. A range of guidance on the topic of access to collections has been prepared by funders and other bodies. However, this diversity may cause confusion, hindering rather than supporting sharing. Access to resources would benefit from the development of joint guidance on the appropriate governance arrangements (similar to that provided for clinical trial data access committees and guidance under development for cohort studies) and on practical aspects of enabling such access, for example encouraging researchers to lodge collections with institutional biorepositories or other tissue banks once the initial study is complete to reduce the administrative burden on individual research groups or organisations. Such guidance should also address issues of decision-making and prioritisation (given that samples are a depleting resource), how to acknowledge the contribution of investigators who collect and characterise samples and how to maintain a chain of custodianship when investigators move between or collaborate across institutions. Guidance should also require applicants to consider whether collection of additional tissue, to enable greater sharing, is appropriate and to justify the approach they use. In addition to existing resources, such as the NCRI Template for Access Policy Development[13], access policies from UK Biobank[14] (once fully developed), and Generation Scotland[15] may inform such common funder guidance.

***Action 10:*** *Funders will develop practical, joint guidance, consolidating that which already exists, to assist collectors of human tissue in enabling access and to drive standardisation of approaches across collections. This guidance will also address practical issues of acknowledging the contribution of investigators who generate collections.*

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9. Sharing can be collaborative or with unknown third parties, each will require different management strategies.

10. NCRI Informatics Initiative, 2010. *Oncology Information Exchange Resource Catalogue*. Available at: http://www.ncri-onix.org.uk/portal/#S103a [Accessed 08 August 2011].

11. Institute of Cancer Research, 2010. *UK Prostate Cancer Sample Collection Database*. Available at: http://prostatedatabase.org.uk/ [Accessed 08 August 2011].

12. Biobanking and Biomolecular Resources Research Infrastructure, 2011. *Catalog of European Biobanks.* Available at: http://www.bbmri.org/index.php/catalog-of-european-biobanks [Accessed 08 August 2011].

13. NCRI, 2009. *Template for Access Policy Development.* Available at: http://www.ncri.org.uk/default.asp?s=1&p=8&ss=9 [Accessed 08 August 2011].

14. UK Biobank, 2011. *Draft Access Procedures*. Available at: http://www.ukbiobank.ac.uk/procedures/ [Accessed 08 August 2011].

15. Generation Scotland, 2010. *Generation Scotland Access Policy.* Available at: http://www.generationscotland.co.uk/index.php?option=com_content&view=article&id=22&Itemid=25 [Accessed 08 August 2011].

**Regulatory training and education**

23. Regulatory and ethical constraints are frequently cited as reasons not to share tissue resources, but this is often based on misunderstanding. Further education (in particular increased promotion of existing tools) on the requirements of the human tissue legislation for researchers, NHS staff and ethics committee members is required. Education and communication will also be required to assist these groups in understanding changes to the regulatory environment in light of the Department of Health's Arm Length Bodies review[16] and the recommendations of the Academy of Medical Sciences review of the regulation and governance of health research[17].

***Action 11:*** *Funders will maintain and promote existing tools such as MRC e-learning on Research and Human Tissue Legislation and MRC Data and Tissues Tool Kit.*

***Action 12:*** *The UKCRC Regulatory and Governance Training Coordination group will discuss leading the continuation of joined up training between organisations like National Research Ethics Service, Human Tissue Authority, Chief Scientist Office, NIHR and others.*

**Promoting high quality research**

24. Maximising the value of tissue resources requires ensuring that the research carried out using these resources is of high quality and that funding decisions include peer review. One particular concern has been that some studies making use of human tissue resources are not adequately powered to produce statistically robust results. In some cases this may be because the number of suitable samples available is insufficient. In order for collections to be combined to provide sufficient numbers, decisions need to be based on the appropriate information about the donor and sample. In addition, funders may wish to consider ways of ensuring that studies using tissue samples are appropriately powered (for example by requiring statistical review of proposals for biomarker studies).

***Action 13:*** *Funders will consult their relevant boards and committees to identify the scale of this problem and, if necessary, suggest actions to address it.*

**Ensuring compliance**

25. In addition to making common guidance available to applicants, it will be important for funders to develop appropriate mechanisms to review and evaluate compliance with this guidance. It is unlikely that funders have the resources to monitor compliance, but their importance can be highlighted to funding boards and past compliance should be reviewed when applications for renewal of funding are received. It should be noted that requiring higher standards of tissue collections is likely to increase their overall cost to funders.

***Action 14:*** *Funders will highlight these policies to their funding boards/panels, emphasising the importance of this area in their assessments.*

**Existing collections**

26. Retrospectively applying new guidance to existing collections would require significant effort and may not be desirable or possible. However, there are areas in which custodians of existing collections (which will not be depleted in the funded study) can work towards these standards at minimal cost. In particular, they should ensure that:
    - collections are registered in a publicly accessible directory,
    - an access policy is in place; and
    - they can provide basic metadata about the samples that they hold.

27. Beyond this, funders should consider existing collections when requests for further funding are made, requiring applicants to comply with new guidance as far as is practical. Additional funding requests for individual collections to comply with these new standards might be considered on a case-by-case basis if received. Individual funders may also choose to review specific existing collections (for example, those of particular strategic importance) to ensure compliance with this new guidance, either in whole or in part.

***Action 15:*** *Funders will require existing grant holders to register collections on a publicly accessible directory, have an access policy and, where possible, be able to provide existing sample metadata on request.*

16. Department of Health, 2010. *Liberating the NHS: Report of the arms-length bodies review*. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117691 [Accessed 08 August 2011].

17. The Academy of Medical Sciences, 2011. *A new pathway for the regulation and governance of health research*. Available at: http://www.acmedsci.ac.uk/index.php?pid=47&prid=88 [Accessed 08 August 2011].

## Areas for broader action

28. There are a range of other areas where action would help to achieve the funders' vision for tissue resources but which would require work by a broader set of organisations or over a longer period. Funders should consider how and when action in these areas might be possible.

**Understanding the views of patients and the public**

29. It is important to understand the views of patients and the public about the use of tissues collected from living donor and post-mortem. To begin to address this, and the level of information required for potential donors to make a decision, a small focus group of patients and healthy volunteers is being considered as part of this project.

30. There is a strong feeling within the cancer community that patients are willing to allow (and indeed expect) samples to be used for research, the evidence for this is largely circumstantial and it is not clear whether the same extends beyond cancer. It is difficult and expensive to properly survey public opinion but it should be possible to draw together indirect evidence, for example the recruitment figures for projects such as UK Biobank, work in the NHS on routinely taking consent and consent rates for additional uses of tissue collected in trials. A piece of work to bring this evidence together and assess its strength would be helpful, both directly and to inform future work in this area.

**Making better use of diagnostic tissue collected by the NHS**

31. The NHS is often cited as one of the UK's unique differentiators for research and potentially provides a vast number of diagnostic samples that might be used for research. Providing access to tissue collected routinely during NHS care requires action in a range of overlapping areas from capacity and workforce building (particularly in pathology services but also in other areas) through to mechanisms for routinely obtaining and recording consent for research uses of surplus tissue. These issues have been identified in the past and the challenges will not be reiterated here. Several are the subject of ongoing initiatives, for example: the actions agreed by the NCRI Task Force on Pathology Research; numerous examples of taking routine consent for research in trusts or health boards throughout the UK; and Cancer Research UK's Stratified Medicine Initiative.

32. Although it is likely that greater use of routinely collected NHS samples could reduce the need for other types of collection, there is an alternative view that only samples collected with the intention to carry out research will be of value. Should funders wish to pursue this beyond the existing initiatives it would be necessary to understand the potential uses of routinely collected samples and their limitations.

**Understanding what tissue resources are required to support research**

33. Although funders have put considerable resources into tissue collection, it is not clear what types of samples and collection arrangements are of most value in supporting research. Without such information, it is impossible to ensure that efforts are directed towards the most useful samples and collections; to know how useful opening up surplus NHS diagnostic material for research may be; or to focus conversations with regulators on how regulation can better enable research.

34. Gathering such information is not easy as the requirements for different sample types will change as new technologies and research areas develop. It should be possible to learn from the experiences of existing biobanks (both the number and types of samples released and the requests that they are not able to fulfil), from the published literature, from potential users of the samples and from funding the boards and committees who consider applications requiring tissue samples. In addition it is important to understand more about the value of large physical biorepositories versus smaller collections that operate under similar governance arrangements; such work might include a cost/benefit analysis.

# Annex A - Environment for tissue resources in the UK

35. This document summarises the current environment for tissue resources in the UK, based on discussions with a range of academics (both users and creators of resources), funders, regulators and industry representatives during July, August and September 2010.

36. The detailed narrative which follows sets out elements that are viewed as working well and less well, together with the major ongoing initiatives. From this, certain key issues emerged as follows:

    i. There is a proliferation of types of study collecting and using human tissue, conducted under varying conditions. Standards and systems are established based on anticipated usage, and it is often very difficult or excessively costly to retrospectively revisit existing collections to widen access. When results are reported, important information about samples is often missing, making comparisons difficult or impossible.

    ii. Validated and widely accepted protocols for processing and storing samples are not available and so each collection prepares its own. Efforts to harmonise protocols have failed through lack of incentives and evidence to guide process development. Such variation makes it more difficult to combine collections or compare results.

    iii. Samples often lack annotation with metadata describing how they have been collected, processed and stored, and lack sufficient information about the donor; therefore it is not possible to assess their suitability for a particular purpose. There is an impression that many samples currently in tissue resources are of poor quality; without accurate annotation it is impossible to judge this.

    iv. There is no easy mechanism to obtain details of existing collections that are available for wider access (e.g. biosample registries), so existing resources are not fully exploited.

    v. Sharing of samples requires significant infrastructure and ongoing effort. Research groups may not have the willingness or resources to achieve this and custodians of collections are often unrecognised for the work involved, reducing the incentive to share. Where sharing does occur there is duplication in developing agreements and processes, particularly for academic-industry collaborations.

    vi. Regulatory and ethics constraints are frequently cited as reasons not to share tissue resources, but this is often based on misunderstanding. Further education (in particular increased promotion of existing tools) on the requirements of the human tissue legislation for researchers, NHS staff and ethics committee members is required.

    vii. A number of research funders throughout the UK have established programmes to facilitate tissue banking and encourage sharing of resources within their field or geographical area. These initiatives, whilst having similar aims, could be better coordinated.

    viii. There is a lack of standardisation of cost-recovery models, and a lack of cost-benefit analysis of different approaches (in particular of the value of large physical biorepositories) to successfully inform policy making in the field.

    ix. Constraints on NHS resources limit opportunities for surplus tissue to be routinely accessed for research. There are barriers to obtaining consent (both due to capacity and, reported in some cases, a paternalistic attitude that it is best for the patient if the care team assumes dissent) and to accessing existing tissue. In particular in the NHS, availability of pathology expertise is a limiting factor, as support for research tissue resources or releasing samples from diagnostic archives must compete with health service and other research requirements.

    x. We have little direct evidence for the public's views on the use of tissue resources or awareness of the value of tissue resources. What indirect evidence we have suggests support for the use of surplus tissue.

**Findings of the environment scan**

***Models for tissue resources***

37. A wide variety of types of tissue resources exist in the UK. These range from collections of samples that support a specific hypothesis-led study or trial; to institution level 'biorepositories', which host a variety of collections in shared infrastructure; and larger collections which aim to provide a resource to any suitable study. Beyond this, multiple resources may be linked as networks that share some common infrastructure elements or scientific aims. Each type of collection has its merits and weaknesses with varying standards and systems which were established according to the tissues required and the anticipated usage. Therefore a single approach seems unlikely to suit all circumstances.

38. An important distinction is between directed collection, which starts from the needs of a particular study and sets out to fulfil these, and service collections, generated as a resource to meet a potentially unknown future demand. Directed collection is based around needs for a particular study which makes it likely that samples will be used and allows tailoring of protocols to the needs of each study. However, such freedom has resulted in a proliferation of studies conducted under varying conditions, making comparisons difficult. Sample collection takes time, and the creation of a new collection will be slower than access to an existing resource. For some rare sample types, directed collection may not be feasible. In contrast, service collections can provide a readily accessible set of samples collected and stored in a comparable fashion but suffer from the difficulty of predicting demand for samples, inevitably leading to some unused samples. It is difficult to assess the number of samples that go unused as, although many collections publish data on the studies that are making use of samples, detailed metrics of number of samples accrued and the number used are not available.

39. Collection and curation of samples requires a range of skilled personnel (to take consent, process samples and ensure compliance with regulation) and appropriate infrastructure (such as physical storage facilities, IT systems and governance arrangements). There are clear economies in sharing such capabilities rather than creating them afresh for each collection. Recognition of this has led to the creation of institutional level repositories and hosting arrangements between new collections and existing resources. Some aspects of infrastructure (particularly IT and governance arrangements) may be shared across multiple resources to form a single virtual collection while holding samples locally to the point of collection.

*Networking and co-ordination*

40. There are a number of communities attempting to co-ordinate tissue resources in the UK and internationally. In the UK, the two most obvious networks are the NCRI's Confederation of Cancer Biobanks (CCB)[18] and the MRC-led UK Brain Banks Network[19]. Networks have the potential to improve the quality of resources and reduce duplication through spreading best practice, co-ordinating activity and supporting members in solving specific problems.

41. The CCB has been successful as a forum for communication and networking amongst its members, holding a range of workshops and training events. However, limited progress has been made towards the Confederation's goal of 'harmonised standards for the operation of cancer biobanks' beyond agreement to high-level guiding principles and making operating procedures from some banks available to other members. Brain banking is a smaller community and the network is at an earlier stage of development (established in June 2009) but there is already an impression that the clear funder drive is giving researchers a strong incentive to join. Eventually, the UK Brain Banks Network aims to streamline operational issues and governance arrangements in order to facilitate access to the networked banks.

42. A wide variety of international initiatives are also attempting to co-ordinate tissue resources. The International Society for Biological and Environmental Repositories (ISBER)[20] aims to act as an international forum that addresses the technical, legal, ethical, and managerial issues relevant to repositories of biological samples. The Public Population Project in Genomics ($P^3G$)[21] focuses on the resources required for population genomics. These are both communities of resources that try to support, co-ordinate and harmonise activity. The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)[22] is more ambitious, funded under an EU FP7 grant for a preparatory phase to plan for a pan-European biobanking infrastructure. This initial funding ended in April 2010 and a plan is now being developed for the establishment of a BBMRI European Research Infrastructure Consortium.

***Establishing tissue resources***

43. Using existing tissue collections for new research rather than collecting duplicate samples benefits funders, researchers and donors. Deciding whether an existing collection will meet the needs of a specific study is not straightforward and a range of information is required. In general, it must be possible to identify existing collections that may be suitable, obtain information about the donor and the nature and quality of tissue holdings and finally gain access to the required samples. Sample quality and access are addressed in more detail below, but one major barrier to the reuse of existing collections seems to be the lack of publicity of existing collections that are available for sharing.

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18. NCRI, 2011. *Confederation of Cancer Biobanks*. Available at: http://www.ncri.org.uk/ccb/ [Accessed 08 August 2011].

19. MRC, 2010. *The UK Brain Banks Network*. Available at: http://www.mrc.ac.uk/Ourresearch/Resourceservices/UKBrainBanksnetwork/ [Accessed 08 August 2011].

20. International Society for Biological and Environmental Repositories, 2011. *International Society for Biological and Environmental Repositories*. Available at: http://www.isber.org/ [Accessed 08 August 2011].

21. Public Population Project in Genomics, 2010. *Welcome to P3G*. Available at: http://www.p3g.org/ [Accessed 08 August 2011].

22. Biobanking and Biomolecular Resources Research Infrastructure, 2011. *BBMRI during the transition phase*. Available at: http://www.bbmri.eu/ [Accessed 08 August 2011].

44. One initiative that aims to address this is the NCRI Cancer Biosample Directory and the related Cancer Clinical Trials Biosample Directory[23]. Each of these aims to provide a catalogue of existing resources that may be searched by tumour and sample type and containing information on access arrangements and contact details. These directories replace an earlier CCB sample search portal which aimed to provide more detailed results (numbers of samples of a particular type) but which was poorly updated and used.

*Regulation*

45. It is critical that the public supports the use of human tissue in research. To maintain public confidence and trust, all tissue used must be obtained lawfully and with appropriate consent, and be handled and used sensitively and responsibly by researchers. The Human Tissue Act (2004) regulates activities concerning the removal, storage, use and disposal of human tissue. The Act applies in full in England, Wales and Northern Ireland, but it does not apply in full in Scotland where separate legislation has been enacted. The Scottish Human Tissue Act only applies to tissue from the deceased.

46. The general opinion of those consulted was that the UK has a clear and proportionate regulatory framework for conducting research on human tissues. In England, Wales and Northern Ireland the Human Tissue Act (2004) is felt to have driven consolidation of collections and improved standards in areas such as recording of consent, and the Human Tissue Authority (HTA) is viewed as doing a good and difficult job. The National Research Ethics Service (NRES) system for generic approval of research tissue banks has now approved approximately 120 banks and has been welcomed by the community.

47. Differences in legislation across the UK (for example, between the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006) can complicate matters; and a misunderstanding of the legislative requirements can be cited as a reason for preventing access to established collections. To ease the issue, NRES leads on guidance for the UK working with Scotland, Wales and Northern Ireland. The generic tissue bank approval operates across the UK, despite the differing regulatory contexts.

48. NRES currently flags those ethics committees with experience of tissue banking resources but researchers are free to use any committee they choose. NRES is considering reducing the number of flagged committees and making it mandatory to use one of these. This could allow standardisation of guidance as well as collection of information and monitoring of issues/patterns.

49. Interviewees felt that more education for researchers would assist them in navigating the regulatory framework. In particular, a better understanding of when and how tissue collections might be shared could help reduce duplication. Some resources do exist in this area, for example the MRC Regulatory Support Centre's Human tissue e-learning module and the MRC Data and Tissues Tool Kit. In addition to these, a series of educational workshops for researchers and Research Ethics Committee members have been run by onCore UK, NRES and the HTA. It is not felt that more material is needed, but better access to and communication of existing guidance would be helpful. Although generally seen as reasonable, meeting the necessary standards for the Human Tissue Act requires resource and is a lengthy process.

***Operation of tissue resources***

*Variation in procedures and protocols*

50. There is significant variation in the protocols followed by tissue resources in the collection and curation of their samples. A part of this variation will be due to the differing requirements of the studies that they support. However, much of the variability is because the collection and curation of tissue resources to support modern translational research is at an early stage of development. This area of research, known as biobanking science, is a new field and optimal methodologies for collection, storage and access are not known. Combined with a lack of research funding in this area, knowledge development is slow.

51. Established protocols are not available and so each collection prepares it own procedures based on the experience of the investigators involved. This variation hinders comparison of results or combination of samples across collections and generating new protocols leads to wasteful duplication of effort.

52. Efforts to agree harmonised procedures across resources (for example those of the CCB) have generally been unsuccessful. Such efforts have struggled against a natural resistance to changing procedures in the absence of strong evidence that such a change would be beneficial. One promising example of progress is the resource being established by the Breast Cancer Campaign. Here, four existing resources are joining together to create a new collection, requiring standardised collection and processing. The approach taken has been to begin by establishing a common core of procedures already in use by each resource. For other areas, work is underway to agree standard operating procedures that ensure consistency while allowing for local variability where this is appropriate. These procedures are not set in stone but will be assessed by the bank and improved where

23. NCRI Informatics Initiative, 2010. *Oncology Information Exchange Resource Catalogue*. Available at: http://www.ncri-onix.org.uk/ [Accessed 08 August 2011].

possible. This approach appears to have made more progress than others through being funder driven but led by the researchers running the resources, who see a clear need to harmonise.

*Quality and sample metadata*

53. There is a perception that many samples currently held in tissue resources are of poor quality, although this may be partly due to a lack of harmonised procedures. In the US, the National Cancer Institute has highlighted a 'critical and growing shortage of high-quality, well-documented human biospecimens for cancer research' and in response is creating a new standardised, national tissue resource.

54. Even where samples are of lower quality, they may still be useful for some applications but it is still essential for collection and storage data to be known. A reported barrier to reuse is that many samples lack annotation with metadata describing how they have been collected, processed and stored. Without such annotation some samples may turn out to be useless. While there is a huge range of potential metadata that might be collected there are no agreed standards for which data items should be collected (a lack of evidence means that it is not always clear which are important) or how these should be defined. This means that what collection of metadata does occur is inconsistent and may not be comparable.

55. Whether or not samples are suitable for use, the perception of variable quality, which is linked to a lack of harmonisation of procedures and failure to collect metadata on samples, is a barrier to the reuse of existing collections. Additionally, there is a general failure to report sample metadata when results are reported, making it difficult to judge their quality and relevance.

56. Quality specifications such as ISO 9001 have been adopted by some banks. These do drive continual improvement in quality but are not specific to tissues resources. Specific guidance on managing tissue resources is available from the Organisation for Economic Co-operation and Development, ISBER and the US National Cancer Institute. These do not necessarily cover all UK requirements and not all elements are applicable to the UK but, in general, these are a good guide for UK resources. The CCB intends to begin work on an accreditation scheme for members in late 2010. This may provide an opportunity to drive both improvements in quality and harmonisation of procedures.

*Annotation with clinical data*

57. In addition to the provision of data on a sample's history, annotation with clinical data about the donor is important to achieve maximum benefit. Ideally such information would cover both the donor's medical history prior to giving the sample or receiving a particular treatment and their health, drug treatments and outcome since. Balancing the value of such linkage with protecting donor confidentiality can be challenging – this is an area where custodians of tissue resources must also be familiar with the information governance requirements for processing patient information. Where arrangements are in place to link to medical records, it has been reported that disease and death registers are not always sufficiently complete or the data may be inaccurate, leading to duplication of effort as data must be collected again.

58. There was a strong feeling that samples associated with clinical trials currently represented the best option for obtaining well characterised and clinically annotated samples. Linkage to high quality clinical data should become easier in the future with the development of new systems and data linkage mechanisms, but in the meantime it might be beneficial to seek further opportunistic ways to obtain well-characterised samples.

59. The linkage of samples to high quality clinical data will be vital to the development of stratified medicine. Cancer Research UK is currently planning a major initiative in stratified medicine, beginning with the Experimental Cancer Medicine Centres but with the aim of eventually rolling this out across the NHS. This initiative will need to address the issues raised above and the mechanisms that will be put in place to support this may well benefit other tissue resources.

***Pathology input***

60. The skills provided by pathologists are vital to the success of tissue resources. However pathology time is extremely scarce within the NHS and support for tissue resources must compete with health service and other research requirements. Tissue resources have had some success where they have been able to provide additional support to free up pathologists' time.

61. Recognising the importance of pathologists to translational research and the problems in this area, the NCRI established a Pathology Task Force which reported in late 2009. The Task Force agreed that work was required in three areas: (1) Rejuvenate and enable histopathology research in medical schools, higher education institutes and the NHS; (2) Create a clear and practical pathway through the regulatory and governance framework; (3) Promote and create enhanced recognition of the patient benefits arising from pathology research. Actions in each of these areas are being pursued by NCRI partners and others but, after initial progress, delivery against the agreed actions has been slow.

*Post mortem samples*

62. For tissues such as brain (and for control tissues), post mortem collection can be an important source. This raises a range of additional issues around consent, ensuring that tissue can be taken wherever and whenever people die, including engagement with coronial or equivalent systems, and covering the costs involved with movement of bodies for autopsy. The UK Brain Banks Network is making good progress in sharing best practice in these areas between members.

*Sustainability*

63. Where tissues are accessed from a service collection or secondary uses are made of collections created for a specific project, there is generally an expectation that the tissue resource will charge users on a cost recovery basis. However, there is very little information on the true costs of tissue collection, making it difficult for potential users to estimate their costs in grant proposals and for resources to justify the level of charges that would be required for them to become self-supporting. Often a lower charge is made to academic than industry users, suggesting either that academic users are cross-subsidised by industry or that these samples are provided at lower than the true cost.

64. Most service resources are supported through a mixture of programme funding and charging for distributed samples. Collections funded as part of project or programme grants frequently have potential for wider use and the sustainability of these beyond the initial funding also needs to be considered early (for example through hosting in an existing repository). There is a lack of cost-benefit analysis of different approaches (in particular of the value of large physical biorepositories) to successfully inform policy making in the field.

***Access to existing collections***

65. Most major funders have policies in place requiring that resources are shared but aspects of the current competitive academic environment may actively discourage sharing. The creators of directed tissue resources invest significant effort into the collection and characterisation of the samples and may view unfettered access by competing researchers as unjust. Simply supplying materials to a study is not usually considered sufficient intellectual contribution to justify authorship of publications. It is not always clear where on the spectrum from simple supply of material to full collaboration the supply of well-characterised human tissue samples falls and the custodians' contributions may be unrecognised. Beyond this, sharing of samples requires significant effort and appropriate infrastructure, and research groups may not have the resources to achieve this. In general 'independent' collections are seen as more willing to share than those linked to a particular clinical study.

66. Despite a widely shared feeling that best use is not made of existing samples and that effort is wasted in duplicate collection, funders have not reported receiving complaints from researchers who are unable to access particular resources. This does not necessarily mean that access to resources is not a problem: a lack of awareness of what exists, concerns over quality, over-complicated application procedures and other perceived high barriers to access may discourage attempts to reuse existing collections. There is a general impression (from both academics and funders) that funders have done little in the past to enforce the terms of grant funding related to sharing and that metrics for the success of tissue collections (for example how many samples are used) are not established or tracked. Duplication of tissue resources due to lack of reuse of existing collections also raises ethical concerns. Stronger policies and enforcement from funders around open access would be welcomed by ethics committees.

67. A variety of models for access to collections are possible, ranging from providing samples directly to studies based on scientific merit, requiring collaboration with the original creator of the collection, through to conducting analysis on behalf of applicants and providing only the resulting data. While each collection is slightly different, the overarching principles to be considered are very similar. Based on a belief that effort was being duplicated in generating policies on access to collections, NCRI has published a 'template for access policy development' to assist custodians in preparing appropriate policies. This is one of multiple pieces of guidance from funders on access to tissue resources and this diversity may cause confusion, hindering rather than supporting sharing. Such guidance does not always distinguish the minimum requirements for complying with funding conditions from best practice that may not be required in all cases, which may make sharing of small collections appear more difficult than necessary.

68. Transfer of tissues and the associated data should be covered by an appropriate agreement between the parties involved. Agreements in use vary considerably in complexity and, particularly when commercial organisations are one of the parties, considerable effort may be involved in establishing these.

*Access to NHS pathology archives*

69. NHS pathology archives are a potentially valuable but underexploited resource. To try to increase their use the HTA and NRES issued a joint statement in July 2009 explaining the regulatory arrangements for the use of diagnostic tissue archives operating as research tissue banks. Although this provides a clear mechanism for the research use of such archives, this still places an additional burden on NHS pathology services.

70. In most cases tissue obtained from a diagnostic archive will not have consent for research and will be used in an anonymised form, but as long as it was taken from the living, and the research project has NHS REC approval these can be legally used for research. It would be preferable if patients undergoing procedures likely to generate surplus material were routinely asked to give consent for research use of excess tissue. Work in Scotland and elsewhere is testing various models of routinely seeking consent to identify effective and ethical approaches. This needs to overcome a range of barriers including issues of capacity in pathology services and other services, and, in some cases, a paternalistic culture in which it is considered best for the patient if the care team simply assumes dissent. The results of this should inform future work in this area.

***Public opinion***

71. The continued availability of tissue resources is dependent on the willingness of the public to donate their tissues and allow them to be used in research. The importance of maintaining public trust was clearly illustrated by the reaction to events at Alder Hey and the Bristol Royal Infirmary. Despite this, we have little evidence for the public's views on tissue resources. The evidence that we do have, and the experience of population-based resources like the Wales Cancer Bank and clinical trials where tissue is collected, suggests a willingness to donate tissues if asked. In some cases the reaction is surprise that surplus tissues are not already used in this way. There is also a lack of knowledge about the importance of human tissue to research.

72. It has been suggested that the required cultural change in the way that sample donation for research is viewed by many in the NHS could be driven by a public right to be given the opportunity to donate samples for research.

# Annex B - Project methodology and contributors

Human tissue and linked data held from routine healthcare and from clinical research (trials, cohorts etc) is a necessary resource for public and private sector research – such as studies of normal and pathological tissue functions, disease genetics, disease stratification and research into new treatments and diagnostics.

Research centres, professional groups and funders have led various initiatives to improve the UK's effectiveness in collecting and using tissue. These communicate with each other but are not very closely coordinated – the coverage varies, the range of effectiveness and issues tackled varies and there are risks of duplication of effort or of separately inventing policy solutions that do not join up. Funders may in the past have been part of the problem through giving different steers and remits to different initiatives.

**Objectives**

This project was established following discussions at the NCRI Board Sub-Group on Clinical and Translational Research and the UKCRC Experimental Medicine Funders Group. The aim was to develop a cross-disease vision for what the UK should be doing to realise the value of tissue resources for medical research over the next five years; setting out high-level expectations advocated and shared by the major funders.

The potential benefits of such a stretching and attractive vision for the area include:

- A consistent strategy across diseases, rather than risking silo formation.
- Policy level alignment between various streams of work.
- Consistent funder "push" based on expectations for quality, alignment, access and sharing, built into funding processes.
- Operational alignment between projects, avoiding wasted effort and unnecessary gaps. One main benefit would be to ensure that systems that evolve are consistent and compatible.
- Greater sharing of samples and data leading to less unnecessary duplication.

The project aimed to identify areas where greater harmonisation between UK funders would help realise the potential of tissue resources, as well as barriers that need to be overcome to achieve this and areas where harmonisation would be unproductive. The vision itself does not attempt to prescribe solutions to these issues in detail but should form the basis for further work by the funders and others.

The vision has been informed by the opinions of the creators of tissue resources, researchers and sample donors and agreed by the major funders. It is purposefully cross-disease and UK-wide and, where appropriate, it takes into account international initiatives such as BBMRI. The vision focuses on research tissue resources and does not cover the challenges of patient cohorts, research databases or clinical trials, except where these directly impact tissue resources.

**Methodology**

A project board consisting of representatives from MRC, Wellcome Trust, National Cancer Research Institute (NCRI) and the NIHR Office for Clinical of Research Infrastructure (NOCRI) was established to give strategic direction and oversight to the work, which was conducted jointly by MRC and NCRI.

The approach to the project can be broken down into three phases:

1. An initial scoping exercise to understand current issues for tissue resources; what is working well and where there is room for improvement and greater co-ordination. This was also an opportunity to understand the other initiatives in this area and to learn from what has and hasn't worked in the past. The output from this phase is an overview of current thinking regarding tissue banking in the UK, included at Annex A.

   This work was informed by a consultative exercise including MRC's Forum of Designated Individuals and Tissue Managers in March 2010, and a series of telephone interviews between July, and September 2010 with representatives of different groups: academics (both creators and users of tissue resources), professional managers of tissue resources, pathologists, research funders, regulators and industry representatives. The list of participants is included below. We also took the opportunity to canvass the views of the wider community at the MRC's Human Tissue Sharing conference in September 2010.
2. Development of the vision and a set of practical actions to move towards it. To ensure that the vision and approach were in line with funders' expectations, updates were provided at the NCRI Board Sub-Group on Clinical and Translational Research and the UKCRC Experimental Medicine Funders Group and feedback taken on board.
3. Discussion and iteration of the vision document with funders to agree the areas in need of action and plans for how a subset of these issues should be addressed. Review of the proposals with the NCRI's Consumer Liaison Group.

**People consulted during the project**

***MRC Forum of Designated Individuals and Tissue Managers***

| | |
|---|---|
| Oke Avwenagha | MRC Prion Unit, London |
| Karen Chamberlain | MRC Human Nutrition Research, Cambridge |
| Keith Gardner | MRC Lifecourse Epidemiology Unit, Southampton |
| Hazel Inskip | MRC Lifecourse Epidemiology Unit, Southampton |
| Polly Page | MRC Human Nutrition Research, Cambridge |
| Joachim Payne | MRC National Institute for Medical Research |
| Sue Ring | MRC-funded cohort, ALSPAC, University of Bristol |
| Kathryn Robson | Weatherall Institute of Molecular Medicine, Oxford |
| Claire Troakes | MRC London Brain Bank for Neurodegenerative Diseases |
| Rachel Smith | MRC Regulatory Support Centre |
| Heather Coupar | MRC Regulatory Support Centre |
| Rachel Robertson | MRC Regulatory Support Centre |

***Interviewees***

| | |
|---|---|
| Lucy Allen | NIHR Office for Clinical Research Infrastructure (NOCRI) |
| Chris Birkett | Human Tissue Authority |
| Brian Clark | onCore UK |
| Cyril Clarke | Association of British Pharmaceutical Industries (ABPI) |
| Julie Corfield | AstraZeneca |
| Stuart Griffiths | Breast Cancer Campaign |
| Barry Gusterson | University of Glasgow |
| Bernadette Hannigan | Public Health Agency, Northern Ireland |
| David Harrison | University of Edinburgh |
| Leon Hooftman | Chroma Therapeutics |
| James Ironside | University of Edinburgh/UK Brain Banks Network |
| Jackie James | Queen's University Belfast |
| Anne Johnson | University College London |
| Louise Jones | Cancer Research UK |
| Keith Lloyd | National Institute for Social Care and Health Research (NISCHR) |
| Alan McNair | Chief Scientist Office Scotland |
| David Neal | National Research Ethics Service |
| Polly Page | MRC Human Nutrition Research, Cambridge |
| Alison Parry-Jones | Wales Cancer Bank |
| Mary Perkins | NHS R&D Manager, University Hospitals Bristol |
| Phil Quirke | University of Leeds |
| Sarah Rudkin | Arthritis Research UK |
| Paul Stewart | University of Birmingham |
| John Williams | Wellcome Trust |
| Chris Womack | AstraZeneca / University of Manchester |
| Martin Yuille | University of Manchester / UK DNA Banking Network |

***UKCRC Experimental Medicine Funders Group***

*Members*

| | |
|---|---|
| Declan Mulkeen (Chair) | MRC |
| Cyril Clarke | ABPI |
| Mike Wood | Bioindustry Association |
| Peter Weissberg | British Heart Foundation |
| Sally Burtles | Cancer Research UK |
| Alison Spaull | Chief Scientist Office, Scotland |
| Bernadette Hannigan | Public Health Agency, Northern Ireland |
| Keith Lloyd | NISCHR |
| Catherine Elliott | MRC |
| Louise Wood | Department of Health (England) |
| Helen Campbell | Department of Health (England) |
| John Williams | Wellcome Trust |
| William Rosenberg | NOCRI |

*In attendance*

| | |
|---|---|
| Lucy Allen | NOCRI |
| Julie Corfield | AstraZeneca |
| Sarah Jones | ABPI |

Others, as required, for specific items of business

***NCRI Board Sub-group on Clinical and Translational Research***

*Members*

| | |
|---|---|
| Declan Mulkeen (Chair) | MRC |
| Alison Armour | AstraZeneca |
| Sally Burtles | Cancer Research UK |
| Helen Campbell | Department of Health (England) |
| Jane Cope | NCRI |
| Steve Dewar | Marie Curie Cancer Care |
| David Grant | Leukaemia & Lymphoma Research |
| Russell Hamilton | Department of Health (England) |
| Bernadette Hannigan | Public Health Agency, Northern Ireland |
| Miriam Harris | Consumer member |
| Leon Hooftman | Chroma Therapeutics |
| Allison Jeynes-Ellis | ABPI |
| Kate Law | Cancer Research UK |
| Keith Lloyd | NISCHR |
| Xin Lu | Ludwig Institute for Cancer Research |
| Alan McNair | Chief Scientist Office, Scotland |
| Peter Rainey | Consumer member |
| Chris Watkins | MRC |

*In attendance*

| | |
|---|---|
| Stuart Bell | NCRI Informatics |
| Brian Clark | onCore UK |
| Mitch Dowsett | Biomarkers and Imaging Clinical Studies Group |
| Malcolm Mason | Confederation of Cancer Biobanks |
| Tim Maughan | NCRI Clinical & Translational Radiotherapy Research Working Group |
| Matt Seymour | National Cancer Research Network |

Others, as required, for specific items of business

***Members of the NCRI Consumer Liaison Group***
In particular those who commented in detail on the proposals:

Christine Allmark
David Ardron
Helen Bulbeck
Sheila Burns
April Ann Matthews
Alf Oliver
Ann Russell
Maggie Wilcox
Roger Wilson

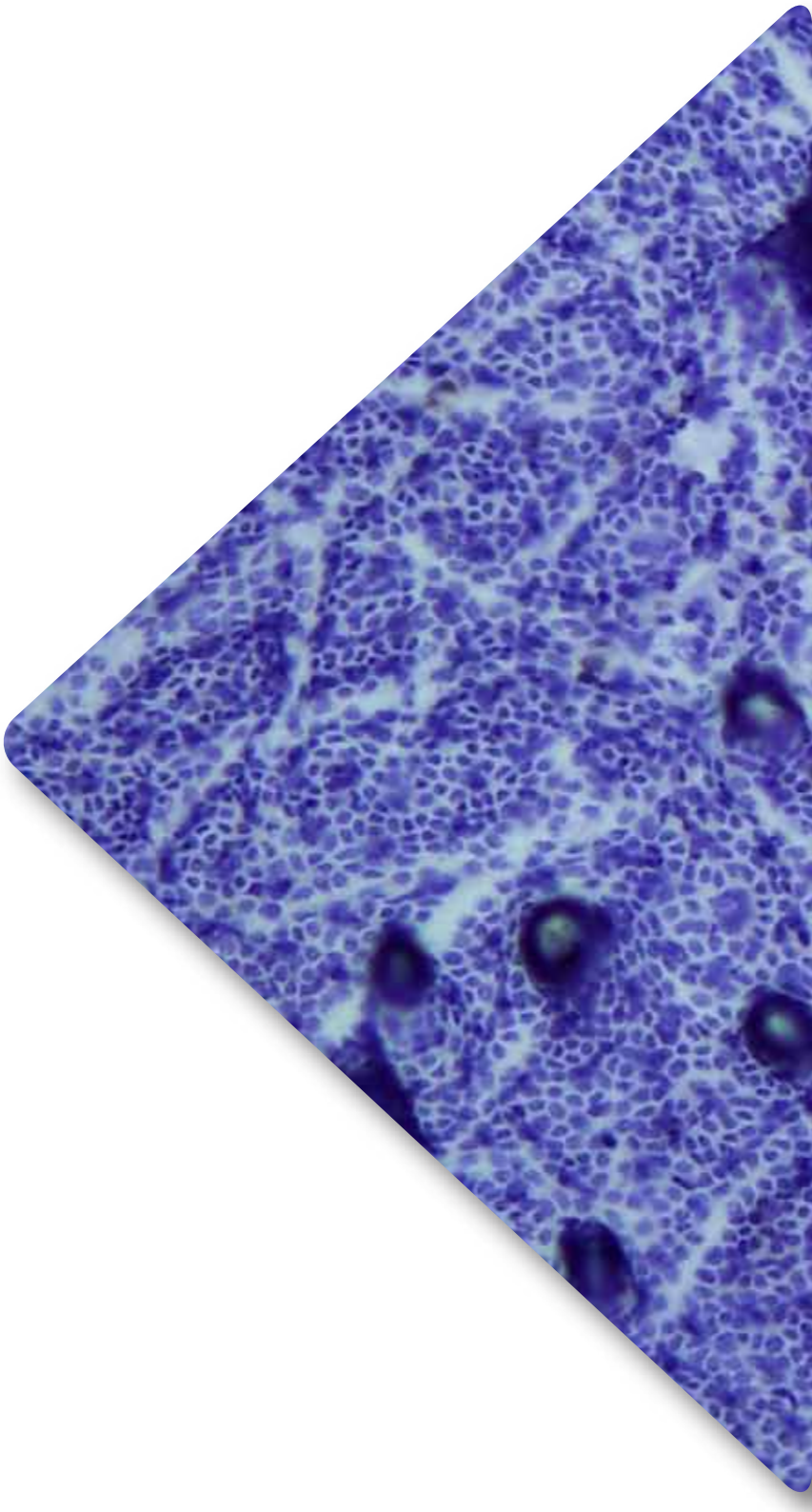
***Attendees at MRC Human Tissue Sharing conference, September 2010***
http://www.rscconference.mrc.ac.uk

***Project team***

| | |
|---|---|
| Michael Chapman | NCRI |
| Paula Clements | MRC |
| Sarah Dickson | MRC Regulatory Support Centre |

***Project Board***

| | |
|---|---|
| Kathryn Adcock | Wellcome Trust |
| Lucy Allen | NOCRI |
| Jane Cope | NCRI |
| Catherine Elliott (Chair) | MRC |
| James Ironside | University of Edinburgh/UK Brain Banks Network |
| Louise Jones | Cancer Research UK |
| William Rosenberg | NOCRI |
| John Williams | Wellcome Trust |



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