FOSTERING THE ROLE OF PATHOLOGY IN RESEARCH 2009

NCRI
National
Cancer
Research
Institute

EXECUTIVE SUMMARY

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Translational research is an area identified as a national priority and is dependent on effective cooperation and collaboration with pathologists. Pathologists contribute specialist expertise to underpin the quality of research, both in clinical research and animal models of human disease, and provide access to well characterised, high quality human biological samples. Despite many new opportunities to advance the understanding of disease and improve the diagnosis and treatment of patients, there are concerns regarding difficulties in engaging National Health Service (NHS) pathologists in research, compounded by severe shortages of academic pathology expertise. In response to this, the National Cancer Research Institute (NCRI) established a short-lived Task Force to explore the issues and identify areas where action can be targeted to best effect. While the Task Force was set up initially to respond to problems in cancer research particularly relating to histopathology, the issues affect other areas of medical research and the actions are expected to have benefits beyond the field of cancer and in other pathology sub-specialities.

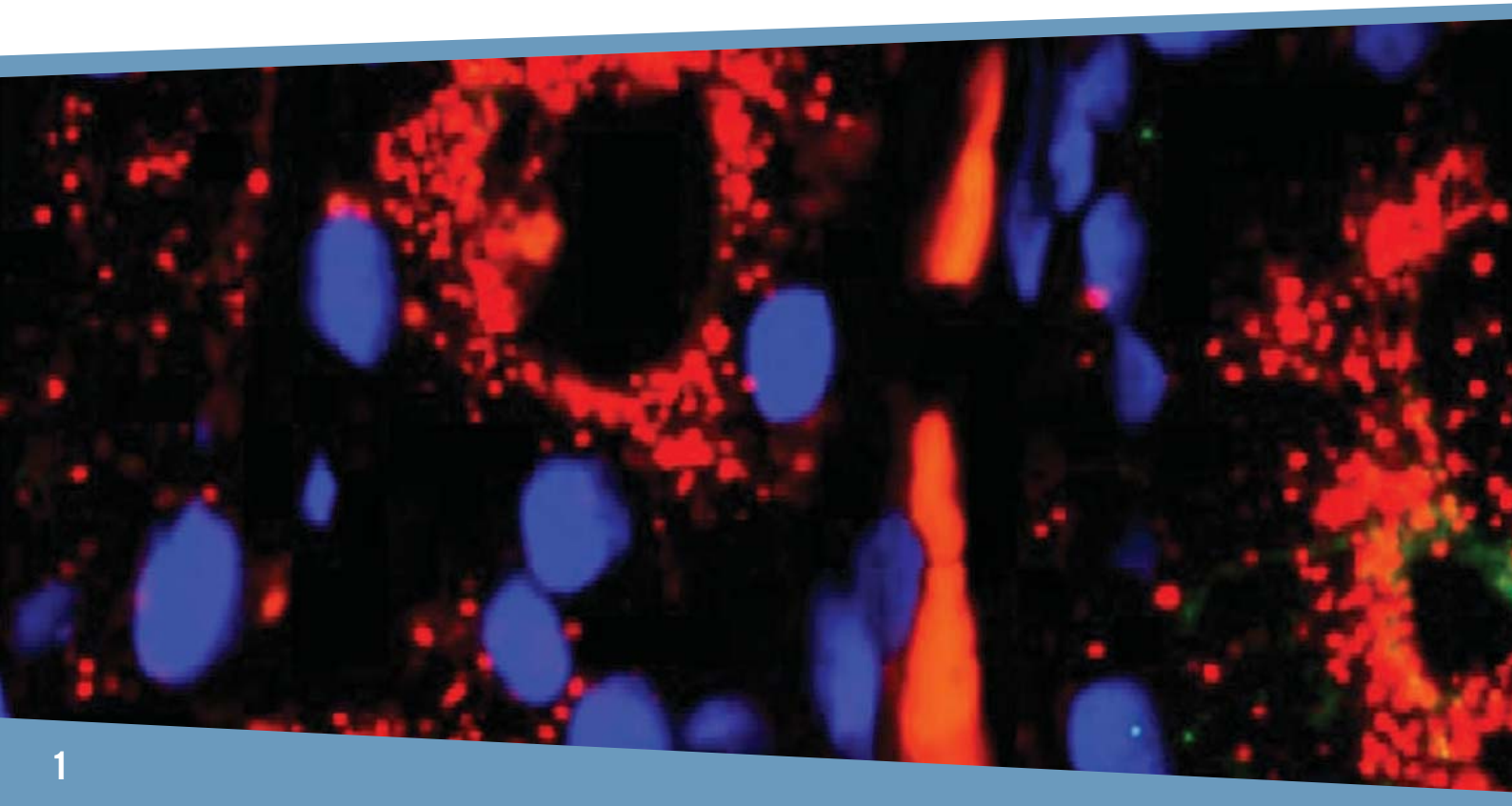
Many obstacles have combined to create a downward spiral that will not be reversed without intervention to create and sustain an environment that fosters research, in the interests of patients and the public. The Task Force agreed that action is needed in three areas in particular to:

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

Each of these areas is summarised below:

Area for action 1:
Rejuvenate and enable histopathology research in medical schools, higher education institutes and the NHS

There has been a dramatic decline in the academic pathology workforce and there is now a fundamental lack of capacity for pathology research. The need for urgent action to reverse this decline is recognised by NCRI partners and also by industry, as evidenced by the recently published Life Sciences Blueprint[1]. In response to the need for capacity building and recognising the needs identified by the NCRI Task Force, the MRC has announced a £3.7m programme for fellowships in clinical pathology and pharmacology. This is a valuable step which will need to be one of a package of measures, if the problem is to be fully addressed. The

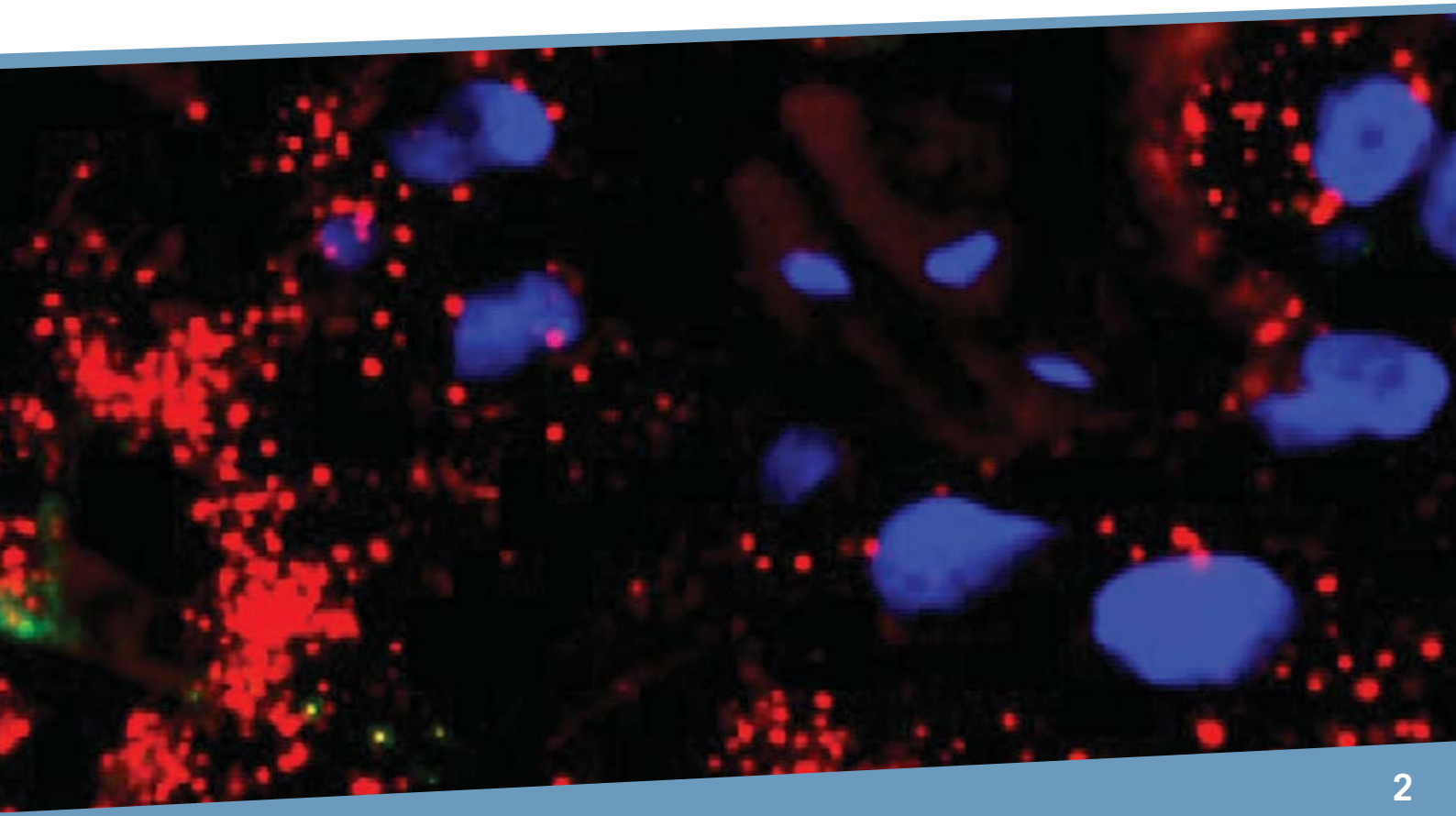


National Institute for Health Research (NIHR) will be reviewing their existing Academic Clinical Fellowships and Clinical Lecturer opportunities to determine whether pathology specialities need increased support at these levels. Recognition of the need to re-build academic capacity in histopathology is widening across the UK, and further developments are expected to follow. NCRI partners are among those actively considering additional action and how best to coordinate efforts across the sectors involved.

New entrants need to be attracted into academic pathology if research is to be successful in the longer term. The low profile of basic science and pathology teaching in undergraduate medical curricula needs to be addressed to attract academically able students into the field, as well as ensuring an appropriate knowledge base for new doctors. The Royal College of Pathologists (RCPath) will continue to lobby for change. Graduates proceeding along a pathology career path have, in recent years, had little exposure to research during their specialist training. The RCPath Advisory Training Team for Histopathology has recently agreed a series of proposals to begin to address this issue which will contribute to promoting academic career development. In those trainees who go on to develop service careers, it will engender greater appreciation of the valuable role they can play in collaborative research.

While many pathologists working in the NHS wish to participate in research, they are under considerable service pressures and their contribution is dependent on availability of time and appropriate reimbursement of costs. Principal Investigators in other disciplines who collaborate with pathologists must ensure that the pathology component of their research is adequately costed and provided for. In particular, clinical research networks and experimental medicine centres need to ensure that the service support costs of pathology activities within their research portfolios are clearly defined and met by the established funding mechanisms. To this end, the NIHR Comprehensive Local Research Networks are providing around £2.7m of key service support funding to pathology departments in England during 2009/10. While this is a significant step forward, difficulties in opening trials and meeting trial requirements remain in some networks. The NIHR Clinical Research Network Coordinating Centre is working with NCRI to develop national guidance on service support funding for pathology. The value of similar guidance for use in the Devolved Administrations will be explored and regular surveys conducted across the UK to assess progress.

There are anecdotal concerns that research funding does not always cover the costs of associated pathology activities. The need for greater transparency of the costs of supporting clinical research (whether service support costs, treatment costs or direct research costs) will increase if tariffs for pathology service work are introduced as a result of the Second Phase of the Review of NHS Pathology Services in England[(2)]. Developments in this area will be monitored by onCore UK, with a view to advising NCRI partners and other



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stakeholders on the need for national guidance on a costing process for histopathology activities supporting clinical research.

Area for action 2:
Create a clear and practical pathway through the regulatory and governance framework

The regulatory and governance environment pertaining to human tissue-based research is complex and the diversity of guidance available is confusing[3]. This leads to time-wasting, uncertainty and delay, and is a disincentive for pathologists and biomedical scientists to engage in research. The MRC has agreed to further develop and promote the MRC Data and Tissues Tool Kit which provides route maps and sign-posting to good guidance via a single portal and was originally developed in close consultation with a number of regulators. onCore UK will work with the MRC to establish a diverse user group to review and help develop the content. Many of the regulators and other research governance organisations in this area such as the Human Tissue Authority (HTA), the National Research Ethics Service (NRES) and the NHS R&D Forum already work closely together and will continue to contribute to the further development of the Tool Kit.

Samples collected for routine diagnostic purposes are probably the greatest resource available nationally to support translational research and many patients expect their samples to be used to maximum effect to benefit others. A number of actions can improve access for research:

- Some hospitals have incorporated processes for prospective, generic and enduring consent for research into routine NHS practice, and action is required to take this forward at national level. Opportunities are now being actively explored in both Scotland and England to enable detailed consideration of the issues involved. It will be important to ensure that NHS IT systems are able to record the research consent status of diagnostic samples.
- Although many diagnostic samples have not been collected with donor consent for research use, they can be used provided the research is ethically approved and the tissue is anonymised to the researcher. While this is a valuable provision, there is a need to clarify the principles and criteria used by Research Ethics Committees when reviewing applications of this type. onCore UK and NRES will jointly promote information and debate on this topic to the wider community.
- Research tissue banks are able to apply for ethical approval such that tissue can then be distributed and used without the need for each individual research project to be ethically reviewed, provided the tissue in the banks is stored on HTA-licensed premises. NRES has reviewed the application form and guidance to make it clear that the same process can be applied to diagnostic archives to facilitate research and a number of enquiries have already been received. An HTA licence will be required by those archives that seek to use this facility.

Area for Action 3:
Promote and create enhanced recognition of the patient benefits arising from pathology research

The contribution that pathologists make to research is not widely appreciated, either by researchers from other disciplines or more broadly in the NHS. Pathologists should be regarded as valued collaborators from the beginning of the research process, to realise their intellectual contribution and to identify practical issues and costs that should be built into grant applications. Research funders can encourage such interactions by requiring evidence of the engagement of pathologists in grant applications and by including pathology expertise in grant review processes, where appropriate. An exemplar is provided by the Biomarkers and Imaging Discovery and Development Committee, within Cancer Research UK, which expects a pathologist to be involved in all biomarker projects involving human samples to help ensure the quality and feasibility of the research proposal.

True engagement is unlikely to be achieved by process changes alone and a wider cultural shift is needed. A joint communications programme to promote the role of pathology in high quality translational research and in achieving clinical excellence is required; the Royal College of Pathologists and the Pathological Society have agreed to take this forward.

The Report of the Second Phase of the Independent Review of NHS Pathology Services in England, while not making a specific research recommendation, recognised that as pathology services are re-configured to meet growing and changing demands it is essential to build in measures that facilitate translational research and the promotion of innovation in pathology[4]. NCRI has held a number of productive meetings with the National Clinical Director for Pathology and looks forward to greater partnership working with the diagnostic service, both in England and the Devolved Administrations.

A summary of objectives and actions to address the major issues identified by the NCRI Pathology and Research Task Force is provided in Table 1 below. Researchers, research funders, NHS staff, regulators, patients and others are already engaged in a range of discussions aimed at resolving the issues highlighted in this report. The continuing commitment of all stakeholders is needed to ensure that this early progress is sustained. The NCRI Secretariat and onCore UK will continue to monitor the actions and ensure that benefits are delivered. Brief update reports will be published on the NCRI website from time to time. We are grateful to those who gave their time and effort to the production of this report.

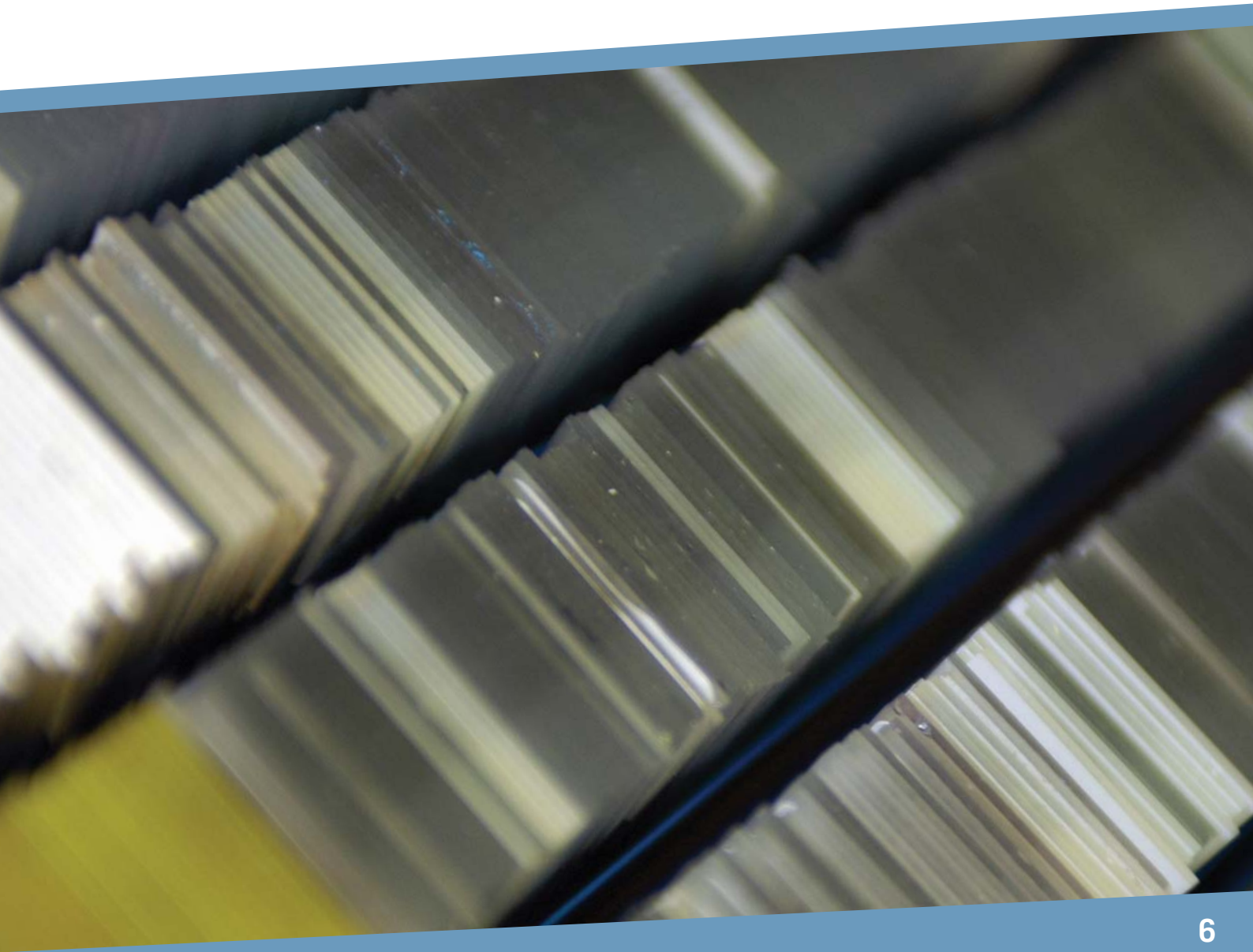
Table 1: Objectives, actions and timelines

Objective 1	**Increase capacity for histopathology research to enable pathologists to lead and contribute to multidisciplinary research**
	Actions • NCRI partners and others will decide a package of measures (2010) with new investment coming on stream in 2011 onwards. • MRC call for outline proposals (2009), full proposals and awards made (2010) for clinical pharmacology and pathology fellowship programmes. • RCPath will continue to lobby to raise the profile of pathology in undergraduate medical curricula and foundation training (ongoing). • RCPath Advisory Training Team for Histopathology will implement proposals to increase the profile of research and molecular biology in specialist training (2010). • NIHR will be reviewing the level of support to be provided after 2010 for research training of clinical trainees in academically-vulnerable specialities including pathology (2010).
Objective 2	**Ensure appropriate reimbursement to enable pathologists, biomedical scientists and pathology services to support research led by others**
	Actions • The NIHR Clinical Research Network Coordinating Centre will take the lead on developing guidance for the NIHR Clinical Research Network on service support funding for pathology in England (2010). NCRI will ask the Devolved Administrations to consider whether there is a need for guidance in the other countries of the UK. • onCoreUK will determine the feasibility of producing national guidance on costing histopathology research activities (2010). • NCRI will ask research funders to raise awareness among grant applicants of the importance of identifying and providing for pathology costs (2010).

Objective 3	**Provide an easily accessible, authoritative guidance resource to enable those conducting and contributing to tissue-related research to understand and comply with regulatory and governance requirements**
	Actions • MRC will further develop and promote the MRC Data and Tissues Tool Kit, in consultation with other regulators (2011). • onCore UK will establish a user group to identify gaps and inform development of the Tool Kit (2010).
Objective 4	**Promote processes for obtaining generic and enduring consent for research into routine NHS practice to increase the opportunity for patients to contribute to research**
	Actions • The Department of Health will commission a project to provide data on current NHS consent practices, including the extent to which consent for use of tissue for research is sought and to identify associated barriers (2010). • The short-life working group set up to advise the Scottish Government on the feasibility of national collection of tissue and consider, in conjunction with patients and other key stakeholders, the issues surrounding consent, storage, and access will report (2010).
Objective 5	**Streamline the regulatory and governance processes relating to access of tissue in diagnostic archives for research**
	Actions • onCore UK will host an event, in collaboration with NRES, to clarify the ethical principles relating to when consent is or is not required for use of anonymised samples in research. Information and educational materials will be produced and at least one public dissemination event will be held (2010). • A joint HTA/NRES statement will be published, clarifying the licensing requirements for diagnostic archives operating as research tissue banks and that applications may be made for ethical review (completed 2009). NRES will revise the application form and guidance in the Integrated Research Application System (IRAS) to make it more suitable for applications from diagnostic archives (2009). First applications reviewed (2010).

Objective 6	Create increased awareness of the role of pathology-based research and expertise in bringing benefits to patients and the NHS
	Actions • The RCPath and the Pathological Society will form a partnership to develop a joint communications programme (completed). Examples of activites include (a) formation of a team of senior pathologists offering public lectures on pathology topics of current general interest, (b) organisation and participation in the RCPath Annual National Pathology Week, (c) organisation of collaborations between Pathology Departments and Public Science Centres / Museums, and (d) commissioning and promoting books (ongoing). • onCore UK will host 3 regional events to publicise the work of the Task Force, disseminate information on ongoing activities and receive feedback on issues (2010).

The full report can be downloaded from www.ncri.org.uk and hard copies can be requested from info@ncri.or.uk



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