NHS
Health Research Authority

SUMMARY PLAN OF ACTIVITY

December 2011 - March 2012

Author:	Janet Wisely
Dated:	01 December 2011
Version:	2.1
Status:	Final
Approved by:	Interim HRA Senior Management Group and HRA Interim Board (01 December 2011)
Distribution on approval:	HRA website (www.hra.nhs.uk)
Review date:	31 March 2012

CONTENTS

INTRODUCTION

The Health Research Authority (HRA) is a newly formed NHS organisation established on 01 December 2011 as a Special Health Authority (SpHA). The purpose of the HRA is to protect and promote the interests of patients and the public in health research. The Health Research Authority includes the National Research Ethics Service (NRES).

This Summary Plan of Activity describes the work the HRA will complete from establishment on 01 December 2011 through to the end of the financial year 31 March 2012.

The HRA will also support the Department of Health (DH) in taking forward the transfer of wider functions to the HRA and establishment of the HRA as a Non-Departmental Public Body. The DH-led work to develop the HRA is not included in these plans.

1. ESTABISHMENT OF THE HRA

1.1 HRA with NRES at the core

The initial phase of the Health Research Authority (HRA) includes the National Research Ethics Service (NRES), related ethics functions and the appointing authority functions previously held by the Strategic Health Authorities. Bringing these functions into one organisation provides immediate efficiencies to the operation of the NRES. Some functions previously provided by NRES are now HRA functions, including the Integrated Research Application System (IRAS) and provision of advice. The HRA will work closely with other bodies and with those with a regulatory function, including the Medicines and Healthcare products Regulatory Agency (MHRA), to create a unified approval process and with regulators and others, including the National Institute for Health Research (NIHR), to promote proportionate standards for compliance and inspection within a consistent national system of research governance.

The NRES Director, Janet Wisely, has been appointed as interim Chief Executive (CE) of the HRA, and the NRES Deputy Director, Debbie Corrigan, has been appointed as interim Deputy Chief Executive and Acting Director of Finance. The HRA CE is currently directly accountable to the Secretary of State for Health through the Department of Health (DH) R&D Sponsor. NRES will retain its identity as the National Research Ethics Service within the HRA.

1.2 Transferring other functions to the HRA

As a first step, the HRA will be established as a Special Health Authority (SpHA). The HRA's initial functions as a SpHA have been specified in more detail in Directions given to the body under Section 28 of the National Health Service Act, 2006. The Government intends to transfer other functions to the HRA and legislate to establish the HRA as a Non-Departmental Public Body (NDPB), with clauses to be published for pre-legislative scrutiny in the second session of this Parliament. The HRA will work closely with DH as this work is taken forward. The DH plans for the development of the HRA are not included in this summary of activity. The DH expects to transfer in the Secretary of State function for approving the use of patient information while the HRA is a Special Health Authority. DH will also be consulting on the future of the HFEA (Human Fertilisation and Embryology Authority) with the intention of transferring some of its functions to the HRA.

2. HRA PURPOSE

The purpose of the HRA is to protect and promote the interests of patients and the public in health research. The HRA functions include the National Research Ethics Service. The HRA will develop other mechanisms for delivery and will from establishment take on functions and lead collaboration that will support the development of a unified approval process and promote proportionate standards for compliance and inspection within a consistent national system of research governance in line with the overall objectives and mission for the HRA.

3. HRA GOVERNANCE

3.1 Accountability

The HRA sponsor at the DH is the Chief Medical Officer and the HRA CE is accountable through the R&D sponsor at DH to the Secretary of State for Health. The HRA has an Executive Board of the CE and Deputy CE and a NRES management team, which is also the interim senior management team for the HRA. The NRES Ethics Advisor is a clinician and provides clinical advice to the HRA Executive Board and is also a member of the NRES management team. The framework agreement which describes the relationship between the DH and the HRA was approved on 01 December 2011, along with other required statutory policies. The DH will begin the process to make substantive executive and non-executive appointments to the HRA early in 2012.

3.2 HRA establishment and NRES transfer

The establishment of the HRA has been managed through a DH Group Chaired by the NRES Director. Secretariat has been provided by NRES and DH and the NRES secretariat has been responsible for project management. There is a detailed implementation plan which has covered all aspects to successfully establish the HRA as a body fit for purpose to enable the NRES to transfer successfully and appropriately conduct business. NRES staff will transfer to the HRA in three phases: the initial phase completed on 01 December 2011 for previously hosted NPSA staff; phase 2 at the end of March 2012 for staff in hosts unable to continue support past the end of this financial year; and a final transfer of staff in remaining hosted arrangements is expected by the end of July 2012.

3.3 Patient and public involvement

The HRA will develop and implement a comprehensive plan for effective patient and public involvement. The HRA and DH have approached INVOLVE and the Association of Research Medical Charities (ARMC) for advice and support in developing this strategy and early discussions have taken place. The HRA will confirm plans for effective patient and public involvement before April 2012.

3.4 HRA staff partnership forum

The HRA Executive Board has approved initial proposals for the terms of reference of a HRA staff partnership forum and has asked for further consultation with staff to agree the final format of the forum. The forum is expected to meet for the first time in January 2012.

3.5 HRA as the appointing authority for RECs

Members have been advised that their membership will transfer from the Strategic Health Authority (SHA) to the HRA and updated appointment letters will be issued. The UKECA (United Kingdom Ethics Committee Authority) has been advised of the change to the appointing authority and recognition status for the purpose of updating clinical trial regulations. The HRA has approved previous operational frameworks to support

membership as HRA policies and these will be published on the HRA website. NRES will continue to provide the operational support to RECs and REC members.

3.6 HRA communications and stakeholder engagement

The HRA will work closely with DH to ensure communication plans are developed to effectively support the business of the HRA and the DH plans to further develop the functions of the HRA and to establish the HRA as a Non-Departmental Public Body.

3.7 HRA finance

The agreed budget for NRES for 2011/2012 is £10.1 million and this will transfer to the HRA. The HRA aims to meet its financial duties and all HRA activity needs to be affordable within this funding envelope.

The HRA final accounts, annual report and governance statement will be prepared for 2011/12 and published.

3.8 Equality and diversity

The HRA will meet the requirements of the Equality Act 2010. This will include the development of an Equality Policy and the provision of Equality training for staff and REC members to begin to address our general duty under the Act. The HRA will also address requirements to meet our public duty identified in Section 149(1) of the Act. This will include the collection and analysis of available data relating to our staff and REC membership and the engagement with appropriate local groups in order to develop measurable equality objectives.

The HRA will provide staff with a range of mandatory training to enable them to achieve competence and awareness within their role. This will include the requirement to undertake Equality and Diversity training.

3.9 HRA web-site

The HRA website was launched on 01 December 2011 (www.hra.nhs.uk) with basic corporate information, including details of the executive team and Board meetings. The website will be developed to include all required corporate information by end February 2012; during the transition information will be referred to on other sites, including the NRES website and the NPSA website as the transferring organisation.

3.10 Corporate functions to support the HRA

During the period from 01 December 2011 to the end of March 2012, the NPSA will continue to provide corporate functions to support the NRES, including IT, HR and financial systems. From 01 April 2012 these will move to the ALB (Arm's Length Bodies) shared service.

4. HRA FUNCTIONS

4.1 The integrated research application system (IRAS)

The HRA will provide IRAS on behalf of the DH and other review bodies, and will continue to develop the system in response to feedback and the needs of the IRAS partners. The HRA will make improvements now that will enable IRAS ultimately to provide a platform for a national registration of researchers. The HRA will also develop IRAS to enable greater access to advice, and to provide prompts where feedback indicates that applicants are less aware of guidance; for example, what is meant by active patient and public involvement in research.

The HRA will, through IRAS, develop a unified approval process which provides a single application route as an option alongside further improved individual and parallel applications, as currently provided through IRAS. The HRA will also consider coordinated messaging on status and approval of applications to IRAS partners. The work to develop these enhanced systems and a unified approval process has begun, with delivery later in 2012.

Key issues for IRAS in the coming months:

- implementing interfaces to allow electronic submission of forms and supporting documentation to review bodies, once they have compatible systems in place, streamlining procedures and reducing use of paper;
- developing proposals to provide a unified approval option;
- developing proposals to enable linked messaging on application and approval status;
- developing proposals to bring trial registries in as IRAS partners;
- reviewing the datasets to ensure all questions are relevant, and to indicate where responses are provided to partners for review or information;
- enabling different levels of registration with appropriate functionality (investigator, approver and training sites);
- prompts to guidance in IRAS.

4.2 Collaboration with research regulators and other organisations

The NRES has a good history of forming effective partnerships and collaborations. The HRA will maintain and build on these relationships and continue to work closely with other regulators and organisations to facilitate sharing of information, consistent guidance and streamlining of application and review procedures. The HRA will use these partnerships and collaborative groups to develop further improvements to the regulatory and governance systems in the UK, with early proposals for consideration including a national registration and assurance framework for researchers and development of integrated reporting systems.

These relationships will provide a platform for the HRA in working with partners towards its role in promoting proportionate standards for compliance and inspection.

These bodies include:

- UK Health Departments;
- MHRA Clinical Trials;
- MHRA Devices Division;
- Care Quality Commission;
- Human Tissue Authority (HTA);
- Human Fertilisation and Embryology Authority (HFEA);
- National Information Governance Board for Health and Social Care (NIGB);
- Administration of Radioactive Substances Advisory Committee (ARSAC);
- National Offender Management Service;
- R&D community, including the National Institute for Health Research (NIHR) and Clinical Research Network Coordinating Centre (CRN CC);
- Ministry of Defence.

4.3 Advice from the HRA

The NRES currently provides responses to queries through the NRES queries line, often providing advice or links to guidance on matters broader then the core remit of NRES, as well as those fundamental to it. NRES will continue to provide responses to queries, which will be repositioned as an HRA advice service and which will be developed through the coming months to provide a comprehensive service for advice on all HRA relevant business. This will be supported by development of additional guidance and through effective links with others able to provide expert advice, not least the MHRA which will remain the direct and appropriate source of advice as the competent authority under the clinical trials directive.

4.4 The National Research Ethics Service

NRES is the NRES Research Ethics Committees in England, the National Research Ethics Advisors' Panel (NREAP), the NRES members, who serve on these committees, and the NRES staff. NRES works in collaboration with partners in Scotland, Wales, Northern Ireland and the Social Care Institute of Excellence (SCIE) to provide a comprehensive service for ethical review of clinical, health services and social care research in the UK.

The NRES has 81 committees in England (May 2010), around 1,200 independent volunteer members and 130 staff. NRES is committed to enabling and supporting ethical research to maximise the benefits of research in the UK. NRES has a duty to provide an efficient and robust ethics review service that maximises UK competitiveness for clinical research and maximises the return on investment in the UK.

4.5 The NRES mission statement

The National Research Ethics Service (NRES) mission is to protect the rights, safety, dignity and well-being of research participants and to facilitate ethical research which is of potential benefit to participants, science and society.

NRES does this by:

- providing robust and responsive ethical review of research through the NRES Research Ethics Committees (RECs);
- providing ethical guidance to the NRES RECs;
- providing and delivering a managed structure to support NRES RECs;
- delivering a quality assurance (QA) framework;
- delivering a training programme;
- working with colleagues across the UK to maintain a UK-wide framework for ethical review;
- working with colleagues in the wider regulatory environment to streamline the processes for approving research;
- promoting and supporting transparency in research.

4.6 NRES Internal communications

NRES will continue to build on current initiatives to ensure information is shared effectively within the organisation. NRES is aware of the views of REC members within NRES, and the diverse views in terms of required method and detail of information shared by NRES.

In addition, NRES provides systems that will allow members to receive papers electronically and securely. The scheme will remain optional as it is rolled out over the next few years but this is an initiative that will be actively progressed over the coming months.

4.7 NRES REC operation

NRES will continue to work within the agreed Standard Operating Procedures and Governance Arrangements for RECs (GAfREC). Further substantive changes to these are not expected or planned at this time. The key issue will be to maintain delivery, to address current variation in use of decision options (favourable, favourable with conditions and provisional) and to complete the roll out of proportionate review. There are no programmes for closures or mergers or RECs, although decisions will be made on a case-by-case basis where RECs would need further support to remain viable. Further development to the operational systems are subject to the review and implementation of the HRA NRES proposals issued on 01 December 2011 for comment.

4.8 NRES Phase 1 Advisory Group

The previous NRES / AAPEC Phase 1 Advisory Group will continue to meet under revised membership as AAPEC (Appointing Authority for Phase 1 Ethics Committees) closes and functions move to NRES at the HRA.

4.9 NRES service improvement

Further service improvements are described and subject to consideration within the HRA NRES proposals. These include additional functions within NRES to further support the assessment and review of applications, and for provision of further support and advice to applicants.

i) *Proportionate review*

The proportionate review service will be available from all NRES centres by the end of this financial year. Further review will be undertaken to extend the remit of the proportionate review service and the information required for proportionate review is a key element to evaluate under the strategic development of NRES.

ii) *National Research Ethics Advisors' Panel (NREAP)*

The National Research Ethics Advisors' Panel comprises 13 independent and unpaid members who were recruited and appointed on behalf of the UK Health Departments. The NREAP will continue to provide advice and support NRES on its strategic direction, but under the new accountability arrangements for NRES the focus will be ethical guidance to RECs. The move to the HRA provides an opportunity to review the format for advice and guidance and the strategic plans for NRES include facilitating greater feedback to the panel from RECs.

Individual members of the NREAP will continue to host regular meetings with groups of REC Chairs in order to share best practice, improve the quality and consistency of ethical review and build stronger relationships within NRES.

4.10 Consistency: the NRES Quality Assurance (QA) agenda

The NRES QA division received ISO9001 certification status in October 2009 and this has continued to be and will be maintained. The move to the HRA provides opportunity to expand the scope of the certification and plans are being developed to support this.

NRES has an extensive QA programme of ongoing and planned work to assess and improve compliance with governance requirements and Standard Operating Procedures (SOPs) and to audit and influence the consistency and quality of ethical review and decision-making within the REC system.

i) *Accreditation*

The scheme will continue with the re-audit programme of RECs in September 2010 according to agreed schedules.

ii) *Shared ethical debate exercise*

NRES has successfully established a framework and programme for shared ethical debate. This will continue and topics undertaken recently include confidentiality in research, Phase 1 research, qualitative research and CTIMPs conducted in children, which also involved participation from outside the UK.

iii) *Feedback from applicants*

NRES routinely invites feedback from applicants to the service and will continue to do so; communications will encourage feedback to be provided. Findings will continue to be published and considered when identifying priorities for training, development and improvement to the service.

iv) *Analysis of appeals and complaints*

NRES will continue the routine monitoring and analysis of appeals and complaints to ensure that lessons learned can be used to inform and improve the service.

4.11 NRES consistency and compliance: Training

NRES provides an extensive programme of training for REC members and researchers in order to optimise ethics review and so improve the research environment in the UK. All confirmed training dates are published on the NRES website. Members are also encouraged to use the NRES extranet and other resources made available by NRES to support members. NRES will develop a further strategy for training for 2012-2013.

4.12 NRES transparency

A priority for NRES is to promote transparency in research; the arguments to demonstrate that duplication of research is unethical and may lead to unnecessary harm are well rehearsed. The role for NRES is to challenge researchers to register trials and publish results, and RECs have a legitimate role to ask if trials have been registered and, if not, why not. However, registration is not a condition of the favourable ethical opinion. NRES also has a role to ensure appropriate publication and dissemination of research findings; RECs consider plans for publication as part of the ethical review. The ongoing work will continue through to end April and this is an area that NRES expects to take a greater role from the HRA and will develop further plans for 2012-2013.

i) *Research summaries*

NRES will continue to develop its web-based publication of research summaries, with applicant agreement, of research reviewed by NRES and given a favourable ethical opinion at a full REC meeting.

ii) *Summary of REC opinion publication*

NRES will implement a programme to publish the summary of the ethical opinion to sit alongside the research summary. This will meet requirements under the Freedom of Information Act 2000 and further provide a transparent ethics service to build confidence in clinical research.

iii) *Trial registration and publication*

Few would disagree that unregistered and unpublished research is unethical. RECs have a legitimate role in seeking assurance from applicants on the intention to register and publish research. NRES will put further mechanisms in place to facilitate this role, including capturing data on registration and seeking publication details after study closure.

4.13 NRES performance indicators

Extensive management information is published on the NRES website to describe current performance. NRES will continue to publish management information as appropriate and will monitor the delivery of the Business Plan objectives against performance indicators including timelines, decisions, complaints, appeals and activity.

5. SUMMARY

This is a plan for the first four months of the New Health Research Authority, for the activity to be undertaken by the HRA. It does not include the work that will be led by the Department of Health in developing and transferring in other functions to the HRA. However, it does include activity that will be taken initially to build the plans to achieve the aims for the HRA in delivering a unified approval process and introduction of proportionate standards for compliance and inspection. The first full year plans for the HRA will be published in April 2012.

An important early function for the HRA was the stabilisation of the NRES. This summary plan should also be read in conjunction with the HRA issued document NRES proposals ahead of planning, which is issued now for comment and will be included in the first full year comprehensive business plan for the HRA in April 2012.

Janet Wisely
Interim Chief Executive
Health Research Authority
Director of NRES
01 December 2011

GLOSSARY

AAPEC	Appointing Authority for Phase 1 Ethics Committees
AMRC	Association of Medical Research Charities
Appointing Authority	The body responsible for the establishment and support of RECs
ARSAC	Administration of Radioactive Substances Advisory Committee
CRN CC	Clinical Research Network Collaborating Centre
Clinical Trials Regulations	The Medicines for Human Use (Clinical Trials) Regulations 2004
CTIMP	Clinical trial of an investigational medicinal product (any other type of research is known as a non-CTIMP)
DH	Department of Health
EU Directive	Directive 2001/20 EC of the European Parliament and the Council of the European Union relating to the implementation of good clinical practice in the conduct of clinical trials of medicinal products for human use
GAfREC	The UK Health Departments' Governance Arrangements for Research Ethics Committees
HFEA	Human Fertilisation and Embryology Authority
HRA	Health Research Authority (Special Health Authority established from 01 December 2011)
HTA	Human Tissue Authority
IRAS	Integrated Research Application System, the on-line application system used to apply for most permissions and approvals for research in health and social care in the UK (
MHRA	Medicines and Healthcare products Regulatory Agency. MHRA (Medicines) is the competent authority for the UK in relation to the EU Directive and the Clinical Trials Regulations. MHRA (Devices) is the competent authority for the UK in relation to the Medical Devices Regulations 2002
NDPB	Non-Departmental Public Body
NIGB	National Information Governance Board for Health and Social Care
NIHR	National Institute for Health Research

NRES	National Research Ethics Service
NRES Director	The senior manager with overall responsibility for management of the National Research Ethics Service
REC	A Research Ethics Committee established in any part of the UK in accordance with GAfREC and/or recognised by the UKECA under the Clinical Trials Regulations
SCEI	Social Care Institute for Excellence
SOPs	The Standard Operating Procedures for Research Ethics Committees
SpHA	Special Health Authority
Sponsor	The person who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a research study
UKECA	United Kingdom Ethics Committee Authority