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# **NATIONAL RESEARCH ETHICS SERVICE**

**YEAR IN REVIEW  
2010 - 2011**

**The National Research Ethics Service  
has a dual mission:**

- to protect the rights, safety, dignity and well-being of research participants; and
- to facilitate and promote ethical research that is of potential benefit to participants, science and society

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## OVERVIEW FROM JANET WISELY



Firstly a heartfelt thanks to all NRES staff and NRES committee members who have continued to provide the service on which many rely during what has been a challenging year for many within the service. We are truly indebted to all, as are the researchers and research sponsors who rely on the efficiency and predictability of the service, and the participants who are invited to take part in research that has been the subject of a robust review provided by the NRES.

This 'Year in Review' has seen announcements that have impacted on the very basis on which the NRES is established, with both the National Patient Safety Agency (NPSA), which hosts the head office function, and the Strategic Health Authorities (SHAs), who appoint (Research Ethics Committees (RECs), scheduled for

closure in 2012. This has created uncertain times and practical difficulties for the service as we waited for decisions on future arrangements. The summer saw the Academy of Medical Sciences (AMS) review of research regulation; NRES was able to respond very positively to describe the considerable achievements in recent years to transform the ethics service in the UK. It was with much pleasure and pride that we were able to reflect that the AMS report published early in 2011 gave a ringing endorsement for the changes we have delivered and recognition of the service improvements that have been achieved.

The subsequent announcements by the Government to set up a Health Research Authority with NRES at its core provide welcome clarity and genuine opportunity to bring together in a single home the collective parts of the service. It will mean more change, but change that will see the NRES established alongside other related functions with the opportunity to deliver the principles described by the Academy of Medical Sciences. To safeguard participants, facilitate high quality research to the public benefit, to be proportionate, efficient and coordinated and to maintain and build confidence in the conduct and value of clinical research. All principles that NRES has firmly embedded in its mission to protect the rights safety and dignity of research participants and to facilitate ethical research.

The next year is one to look forward to, it is a year that will see further change with transfer of structures to the new Health Research Authority. With the clarity on future arrangements it is also a year where I expect we can make considerable progress on our described plans for further service improvements, particularly with regard to proportionality, to build on our successes and grasp firmly the opportunities presented by the recent announcements for the NRES.

With thanks again to all working and contributing within the service.

## STATEMENT FROM ANDREW GEORGE



The last year has been a very difficult year for many involved with NRES, with considerable uncertainty about the future as well as continued closures and mergers of a number of RECs. However, the AMS review gave a strong endorsement to the work of the REC community, encouraging the current 'direction of travel'. The challenge of the next year will be to continue changes and improvements in the service, while implementing the alterations in governance – in particular participating in the establishment of the Health Research Authority.

As outlined in the report on the next page, the National Research Ethics Advisors' Panel (NREAP) have continued to provide guidance on ethical issues, as well as responses to reviews and reports. The NREAP is there to

support the work of RECs, and the guidance is there to help RECs make decisions but not there to tell RECs how to think. One of the welcome developments this year has been the 'NREA-hosted Chairs' Network meetings' which have allowed Chairs to discuss issues and to establish a dialogue between themselves and with the NREAs. NREAs have also participated in the training programmes. These developments should all improve the consistency and quality of REC decision making, without taking away from RECs their independence of thought.

For much of this year it has sometimes felt that mere survival in the face of change was a victory. However, in the next year we have great opportunities to continue improvements in the work that we do to protect research participants, while supporting ethical research. In particular, we are going to have to work out how best to improve proportionate review of projects that have few or limited ethical issues. The time and expertise of the members around the committee table is a precious resource, and we need to use that most effectively on the projects and questions that need detailed debate.

I would like to thank my fellow members of NREAP who have provided stimulating and challenging debates, and to acknowledge the excellent management support provided to the panel. It has been a challenging and interesting year, but we are now in a strong position to move forward. I look forward to continuing to work with all NRES staff and committee members to continue to improve the service we provide to researchers, as well, as most importantly, protecting research participants.

# NATIONAL RESEARCH ETHICS ADVISORS' PANEL

The past year has seen the NREAP getting to grips with a number of important issues most notably the formulation of a joint response to the AMS Review of the Regulatory and Governance Environment for Medical Research in the UK in conjunction with the Association of Research Ethics Committees (AREC). This was submitted to the Academy in May and the subsequent AMS report with its praise for NRES was warmly welcomed by the Panel. It is hoped that the coming year will see these recommendations implemented bringing to an end the period of uncertainty for NRES that has permeated 2010 and the beginning of 2011. This year has also seen the Panel debate and issue guidance and statements on a number of issues:

- NREAP/01 (22/4/2010): (i) Disclosing information about a research participant without consent and (ii) Appropriate action for a researcher when seeing poor practice.
- NREAP/02 (12/7/2010): Follow-up contact of potential participants who have not responded to an initial invitation to take part in research.
- NREAP/03 (29/11/2010): Addenda to participant information sheets.

The guidance produced so far appears to have been well received by the REC community with one REC member even declaring the statement on 'addenda' to be "absolute undiluted sense"! Currently the Panel are working on guidance on subjects as diverse as 'Conflict of Interest', 'Incidental Findings in Imaging Research'; 'Expert review of research and the role of RECs' and 'Participants who may have difficulties in adequate understanding of English'.

The Panel has also been involved in the introduction of 'NREA-hosted Chairs' Network meetings'. Whilst REC Chairs have been meeting regularly for many years in some areas, this was not routine everywhere and the introduction of the network meetings provides an opportunity for all Chairs to meet, share good practice and discuss issues of mutual interest which in turn will help to improve the consistency and quality of ethical review. NREAP guidance is discussed at the meetings and it is hoped that this will form part of an ongoing dialogue between Committee members and the Panel so that both published guidance and guidance under consideration will be informed by the wealth and breadth of experience present in the REC community.

This year also saw the addition of a new NREA, Caroline Harrison, a practising Barrister in the field of clinical negligence and complex personal injury law with expertise in medical research, and the ethical, legal and social implications of human genetic research. Her appointment has greatly added to the Panel's expertise.

Other notable contributions made by the Panel this year include a response to the Nuffield Council on Bioethics consultation document 'Human Bodies in Medicine and Research' and advising on and endorsing NRES on the 'Ethical review of student research: guidance for students, supervisors and RECs'.

The past year has been a challenging one with the Panel finding its feet, exploring its role and starting to issue guidance and advise NRES on a range of strategic and ethical issues all against a backdrop of major changes in the research governance environment. No matter what the future brings the Panel will continue to strive to always achieve the high standard of "absolute undiluted sense".

## POLICY

### Revision of the NRES Standard Operating Procedures

NRES undertook a major review of the Standard Operating Procedures (SOPs) for RECs during 2010-11. In August 2010 a summary of issues to be addressed in the review was published on the NRES website, together with an invitation to all stakeholders, including RECs, researchers, sponsors and other research bodies, to contribute comments and suggestions. Meetings were held at all NRES REC centres to brief staff, discuss the main issues and invite feedback. Consultation also took place with REC managers in Scotland, Wales and Northern Ireland; the Social Care REC; and the Appointing Authority for Phase 1 RECs, all of which adopt the NRES SOPs.

Following the Department of Health's Arm's Length Bodies Review, it was proposed that the Gene Therapy Advisory Committee (GTAC) should also move to become fully supported by NRES following adoption of the SOPs. Meetings took place with GTAC and its Secretariat to discuss what adaptations would be needed, in particular to take account of the specific provisions in the Clinical Trials Regulations relating to applications to GTAC.

Version 5.0 of the SOPs is expected to be issued early in 2011-12.

### Governance Arrangements for Research Ethics Committees

Governance Arrangements for Research Ethics Committees (GAfREC) is the Department of Health's (DH) policy framework governing the remit, composition, appointment, management and operation of RECs. During the year, the four UK Health Departments (UKHDs) evaluated responses to its consultation on an updated, harmonised UK-wide edition of GAfREC, with advice and

drafting support from NRES. At the end of the year, a final draft of GAfREC had been prepared for issue early in 2011-12.

### Review of the European Clinical Trials Directive

Following an initial consultation during 2009-10, the European Commission continued to explore and consult on ideas for revision of Directive 2001/20/EC to streamline and harmonise the regulation of clinical trials of investigational medicinal products within the Community. It also continued with a comprehensive revision of guidelines on the existing Directive. NRES represented the United Kingdom Ethics Committee Authority (UKECA) on the relevant Commission Working Group and contributed to the development of UK policy on the Directive led by the Medicines and Healthcare products Regulatory Agency (MHRA).

### Collaboration with other regulators

NRES aims to collaborate closely with other research regulators where studies are reviewed in parallel by RECs and other bodies, in order to clarify roles and responsibilities, minimise duplication, streamline procedures, share relevant information and ensure a consistent approach to common issues.

Detailed discussions were held with the National Information Governance Board (NIGB) and the Administration of Radioactive Substances Advisory Committee (ARSAC) during the year. It is expected that Memorandums of Understanding with both bodies will be concluded early in 2011-12 and relevant procedures incorporated in the NRES SOPs.

NRES continued to collaborate closely with the MHRA and the Human Tissue Authority (HTA) under existing agreements.

## Other developments

**Human tissue** – A successful series of workshops for researchers and RECs on issues with consent for use of human tissue in research was held in conjunction with onCore UK, the HTA and the NIGB.

**Mental capacity** – An on-line toolkit was released to provide guidance to Committee members, researchers and sponsors on the requirements for including adults lacking capacity in research under the Mental Capacity Act 2005 and the Clinical Trials Regulations. The toolkit was commissioned by NRES from a team at the Universities of Leicester and Bristol.

**Research databases** – NRES was represented on a NIGB working group to review existing guidance on the establishment and operation of research databases, and make recommendations for new guidance. A meeting was held with members of the flagged RECs for research databases applications. The working group's recommendations were accepted by the NIGB.

**Radiation** – In light of feedback and queries from researchers and commercial sponsors, NRES re-convened the Ad Hoc Working Group on Radiation in Research to review existing guidance in consultation with other regulators and the radiation professional bodies. NRES also assisted DH in arranging an industry workshop in March 2010 to consult on emerging proposals for streamlining approval procedures. A revised version of the guidance will be issued in 2011-12.

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## OPERATIONS

It has been a busy year for NRES Operations with good progress made towards the implementation of the Strategic Direction which was launched in September 2009. The timetable for implementation has slipped in some areas due to factors associated with changes in the wider NHS but we are hopeful that objectives will be completed during the coming year.

The restructuring of the operations management team was finalised with the proposal taken forward for two Regional Managers, supported by Centre Managers and Senior Co-ordinators implemented.

We have seen the establishment of new REC centres in Leeds and Bristol and new accommodation provided for the staff in Nottingham and Cambridge. Work is underway to establish two REC centres in London with increased space at the Northwick Park and Charing Cross sites. We have standardised the Service Level Agreement we hold with our host organisations and were pleased to sign new agreements with the Leeds NHS Partnerships and the University of Bristol NHS Foundation Trusts. We have significantly reduced the number of host employers and consolidated staff into REC centres. We are grateful to all our host employers for the support which is given to NRES.

The fall in the total number of applications received is now steady at around 5%, much can be associated to NRES initiatives to more readily identify and review only research projects and the consolidated applications for research tissue banks and databases. NRES received just over 6,000 applications in 2010 which were reviewed on average between 33 and 39 days.

NRES has continued to rationalise the number of RECs to ensure that capacity is matched to the demand for its service and achieved its target of 80 RECs.

We received appeals against 24 unfavourable opinions of which 14 proceeded to appeal; 9 were asked to resubmit revised applications and 1 application was resolved prior to appeal. At the end of these processes only 3 of the applications continued to have an unfavourable opinion.

We received 13 complaints of which 6 were upheld and from which we learned with additional staff training provided; changes to local procedures and one change to national processes put in place.

meetings and training events and a waiting room for researchers.

The Centre currently serves 6 committees of which 4 are currently piloting Proportionate Review. The new structure has definitely improved the working lives of the Co-ordinators and assistants who now work as a fully supported team. The REC Centre achieved full accreditation status in February 2011 and the team are very proud. The REC Centre model is a key component of the NRES strategic direction.

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## EAST MIDLANDS REC CENTRE

The East Midlands successfully re-located to new offices in Nottingham on 1st September 2010 'The Old Chapel'.

The Chapel was built in 1855 as part of the Nottingham General Hospital (built in 1782) and which discharged its last patient in 1992, before moving to a new site. The accommodation comprises of small offices, an



open-plan office with the original arched stained glass window, a meeting room for REC



## QUALITY ASSURANCE

A continued key strategic objective for NRES is our commitment to quality assurance (QA) to ensure ethical review is supported by robust systems and compliant procedures. QA has worked to retain ISO 9001 certification for QA functions and develop QA processes to ensure they meet the needs of a changing organisation, present value for money and are sustainable for the future. QA continues to work as a paperless service where all documentation is sent and stored electronically. When taking forward the development of functions QA has revised working practices to deliver functions where possible by electronic means to save costs without compromising the quality of the service. QA has also put emphasis on working with colleagues in all countries to ensure QA functions are taken forward uniformly across the UK.

### NRES Accreditation Scheme

QA has completely revised and piloted a new approach to the accreditation of RECs building on the success of our previous scheme. The audit of all RECs under the old scheme and the completion and management of action plans arising from audits was undertaken during 2010. This gave NRES a good baseline from which to launch a new scheme based on a remote, desktop audit of the Research Ethics Database (RED) account (including the newly-developed members information) of each REC supported by a review of the previous audit report, action plan and quality control (QC) conducted during the audit period, as well as a telephone discussion with the coordinator of the REC. This approach has enabled QA to develop an evidence-based method of audit while avoiding the expensive site visits to individual RECs across the UK required by the previous scheme. It has also enabled QA to utilise functions such as QC conducted by operational management teams to provide

NRES with a more integrated, comprehensive approach to quality management.

QA has introduced a small number of onsite audits of the newly created REC centre offices as part of the revised Accreditation scheme. This is to verify that there are good systems in place to run an effective business unit to manage RECs based at the centre as well as taking forward NRES operational systems and responsibilities at the local site.

### QA involving our product: ethical review

QA continues to support the NRES Ethics Advisor by taking forward the management of the shared ethical debate process to collect audit findings from application based Shared Ethical Debates (ShEDs), as well as managing and reporting on single issue debates based on a key and supplementary debate questions chosen to illustrate key ethical themes.

In addition QA has developed and is piloting a tool to manage and review applications falling within the scope of the Mental Capacity Act with the aim of providing a framework to help RECs address the requirements of the Act.

### Taking forward quality management within NRES

QA has undertaken *ad hoc* audits on request within NRES, as well as developing processes to support NRES functions according to a QA developed template to ensure a consistent approach.

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## USER FEEDBACK

QA manages and reports on feedback from users of our service. During the year, QA has continued to develop ways of collecting and reporting on feedback, as well as continuing to collect feedback from the self-selecting group of users who choose to report back via the feedback form on the NRES website. QA now targets users and seeks feedback. One meeting of each REC per year is selected at random and all the applicants who had an application reviewed at that meeting are emailed a copy of the feedback form and asked to complete it and return it to a confidential email account managed by QA. This approach has increased both the volume and scope of feedback received. QA has also reconsidered how feedback is reported so that full use can be made of all feedback received while continuing to meet our guarantee to users that their feedback is confidential. QA now produces two feedback reports; one public report which presents trends in feedback and a management report that brings to the attention of NRES managers comments made by users that highlight concerns that should be addressed to improve our service. These are reported confidentially and the name of the REC involved, but not the user, is released to individual managers on request if it is required to address an issue. It is hoped in this way to address the needs of applicants and use their experience to continually improve the service we offer.

Reports are reviewed by the NRES Management Group and referred to the NREAP if there are issues that fall within their remit to provide ethical guidance to RECs. NRES Operational Managers report on how issues raised through comments made in feedback are addressed and this is reported within the feedback report on the NRES website.

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## BUSINESS UNIT ACHIEVEMENTS AND HIGHLIGHTS

The last 12 months have seen significant changes and achievements within the Business unit including:

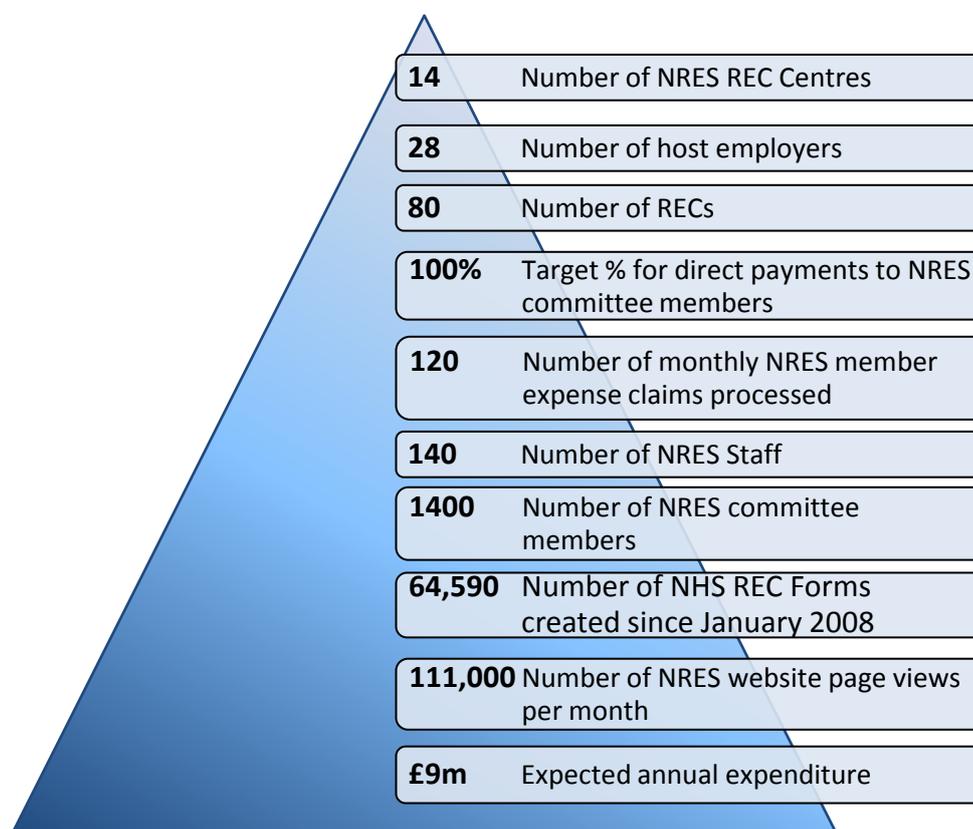
- implementing the NRES-wide [Information exchange](#), with monthly information exchange slides now disseminated to all RECs updating on key NRES news;
- launch of the extranet for NRES staff and members;
- refresh of the NRES website, which is used by circa 21,000 visitors each month;
- responsibility for the former RECs in the News, now known as [Staying Informed](#);
- careful management of the number of emails sent out in recognition of the impact on our valued NRES committee members and feedback from members to take care with email volume;
- facilitating the increased use of webinar meetings to support NRES-wide information sharing with NRES staff and members;
- monthly refresh of the NRES Forum (through Research Ethics Database) to enable information sharing with all NRES staff;
- business support for the change management programme linked to the ALBs Review and the Health and Social Care Bill which is impacting on our hosts, including the transition towards the abolition of the NPSA, the SHAs and PCTs and the establishment of the Health Research Authority;
- two consultations undertaken with staff to ensure robust structures in place to support NRES business;
- publication of research summaries following review by a central panel and the Ethics

- Advisor, and also the publication of the record of opinion;
- ongoing support to member and staff training days;
- efficient responses to circa 3,500 emails to the NRES queries line and the Integrated Research Application System (IRAS). queries line with over 90% being answered within 4 working days;
- successful support provided to enable NRES-wide risk management;
- successful financial management support during a challenging year;

- proactive and vigorous approach to reducing cost of venue hire at our NRES training days;
- maximising use of internal NRES trainers at NRES training days with an associated 66% reduction in daily cost.

### NRES in numbers and resources

NRES has once again lived within its means financially and met its statutory obligations. The figure below shows the key resources used and services delivered throughout the year



# INTEGRATED RESEARCH APPLICATION SYSTEM

The NRES has taken a leading role in delivering one of the major streamlining efforts of recent years - the Integrated Research Application System (IRAS). IRAS was conceived in direct response to the need to streamline the process for completing the regulatory and governance applications in the four UK nations. It is the result of a partnership between the bodies involved in the regulation and governance of health research and, as one of the IRAS partners, NRES led on the delivery of the IRAS and continues to host the system on behalf of all of the IRAS partners.

IRAS is an intuitive web-based system for applying for permissions and approvals for health and social care/community research in the UK. It provides a single dataset, which is tailored to the particular research activities of a study and encompasses all the information needed for the regulatory and governance applications for that study. As a result, applications are simultaneously completed without duplication. The system is also designed to complement and support other activities to simplify and standardise processes, particularly those around NHS R&D permissions.

In the last year there have been a number of additions to IRAS that are particular noteworthy, including:

- *Addition of application for the National Offender Management Service (NOMS):* this means that applications for research taking within NOMS can now be prepared in IRAS.
- *All forms for notification of substantial amendments are now available in IRAS:*
  - IRAS now includes both the EudraCT Annex 2 form for Clinical Trials of Investigational Medicinal Products (CTIMP) studies and the NRES Notice of Substantial Amendment form for non-CTIMP studies. It also includes a customised version of the NRES Amendment Form for Research Tissue Banks and Research Databases.
  - *Introduction of completion tracking and check your form option:* these two complementary pieces of functionality, which are optional to use, have been introduced to provide a simple mechanism for researchers to check which fields in the dataset have been completed. The *completion tracking tool* consists of a tick icon next to each question, which is clicked once the researcher is satisfied that the question is completed. This in turn enables: a simple visual check for which questions have been completed whilst the researcher is using the navigation pane view of the dataset; as well as allowing the researcher to use the *check your form* button to check entire dataset is complete before submitting their application.
  - *Functionality improvements:* several of the additions made to IRAS in the last twelve months were in direct response to user feedback. Examples include:
    - Enabling users to change their login details and regular reminders to change their password.
    - Allowing multiple students and/or multiple academic supervisors to be named in a single project.
    - Adding search functionality and further sorting options to contacts lists.
    - Creation of an authorisation history section so that a user can keep a record of all the projects they have electronically authorised.
  - *Full electronic submission of applications:* during the last year IRAS has been

developing a mechanism to allow researchers to submit application forms and supporting documentation to the review bodies. This functionality will be rolled out over the coming months.

Since IRAS was launched, the separate forms and systems for applications to the various review bodies that existed before IRAS have been gradually phased out. This means that IRAS is now the only system for preparing applications to most of the review bodies in the UK and the preferred system for the remainder. Therefore it is more important than ever that IRAS continues to respond to both user feedback and changes in the regulatory and governance environment and systems.

In 2010 the AMS was invited by Government to review the regulation and governance of health research. The resulting report, *A new pathway for the regulation and governance of health research*, was published in early 2011 and stated "IRAS is generally considered to have been successful in streamlining the application process for regulatory and governance assessments". The AMS went on to underline the continued role for IRAS in the future in the report's recommendation to create a new health research agency, with IRAS placed at the heart of the information system, to provide a single point of entry for applications to undertake research.

IRAS can be accessed at [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk).

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## THE NRES EXTRANET

### **An online resource for all NRES committee members and staff – enhancing communication, efficiency and consistency**

In March 2011 the newly-expanded staff and members' extranet area went fully 'live'. This resource has been developed to enhance staff and members' online presence and to provide a central repository for documents and information. Developments for the NRES extranet began with a pilot in April 2010, which helped shape and expand this central resource for staff and committee members. At first, the extranet brought together operational guidance, operational management email alerts and update information relating to the Research Ethics Database (RED) for staff. It has steadily expanded and now includes useful resources for the entire NRES.

### **Why the Extranet?**

The extranet is intended to provide staff and members with quick and easy access to up-to-date core business information. This tool will be invaluable for enhancing consistency of communication and practice, improving efficiency and increasing flexibility for staff and members; for example, members can now gain access to many useful documents and information independently of their Co-ordinator.

A single log-on allows staff and members access to all parts of the extranet. Resources are grouped in discrete areas for staff and members, although access is not restricted to either. Staff pages contain operational resources, corporate policies, tools to facilitate the Co-ordinator's role, training information and quality assurance guidance. Information

provided under the members' pages supplies committee members with a host of resources to complement their membership on a REC; for example, induction materials, role descriptions, training information and expense claim procedures.

A number of pages within the extranet have **RSS Feeds** ('Really Simple Syndication') which is a great way to be alerted to changes or new issues of interest.

The extranet features a section called **Staying Informed** which replaces the previous 'RECs in the News' publication. The Staying Informed page of the extranet is designed to alert members and staff to a range of pertinent news items and papers published in the biomedical literature. Article headings are displayed in a clear table and electronic links signpost users to the full text. The majority of

articles can be accessed free of charge, or require an NHS Athens user name and password, which is available to all staff and members. A routine publication, *Clinical Research Advisor*, is accessible in electronic format via the extranet. This newsletter provides the latest news and information on clinical research, quality assurance, and changes in regulation, guidelines and more. Users have the option to subscribe to the **Staying Informed** RSS feed if they wish, enabling quick access to recently added news items.

NRES invites **feedback** from users in order to enhance features of the extranet. There is a feedback form at the bottom of selected pages to enable users to rate whether they found it useful.

*Welcome page of the members section of the NRES Extranet*

The screenshot shows the NRES Extranet members' area. At the top, there is a navigation bar with links for 'Site map', 'Accessibility', and 'Text size: Smaller | Normal | Larger'. Below this is a search bar and the NHS logo. The main heading is 'National Patient Safety Agency National Research Ethics Service'. A secondary navigation bar includes links for 'About us', 'News and publications', 'Training', 'Applications', 'Patients and the public', 'NRES Resources', 'Useful links', and 'Contact us'. A large banner reads 'Facilitating and promoting ethical research'. Below the banner is a breadcrumb trail: 'Home » NRES Resources » NRES extranet - registration and Login » NRES Extranet » NRES Area for Logged-in Committee Members'. The main content area is titled 'Welcome Testerman' and 'Welcome to the NRES Committee Members' Area'. It states: 'This is a secure area for all NRES Committee Members. The purpose of this secure area in the first instance is to make available to NRES Committee Members all procedures, processes, guidance, associated forms and documents which may be necessary or useful in performing their duties as a committee member. All documents issued here should be considered the current controlled version. Areas currently available are: Being an NRES Committee Member, Training days for NRES Committee Members - forthcoming days, NRES Organisational Structure. (pdf, 60KB), Staying Informed, NRES Committee Members' Discussion Forum (The Discussion Forum is currently undergoing testing and will be made open to Committee members soon), NRES Staff area.' A 'Featured Item' section highlights a 'Public consultation on a concept paper on the revision of the 'Clinical Trials Directive' 2001/20/EC.' and provides a link to 'Download the paper in pdf format (94 KB)'. A sidebar on the left lists 'NRES Extranet' and 'NRES Area for Logged-in Committee Members' with sub-links for 'Forum', 'Staying informed', 'Being an NRES Committee Member', 'REC member feedback', 'Information Exchange', and 'NRES area for logged in Staff'.

# TRAINING

The NRES remains committed to its training programme. The review of research must command the respect of public patients and researchers if it is to be effective. That respect will rest on consistent and appropriate process and the skills of the members. Training is therefore central and crucial.

Efficiencies may have dictated that our venues are more functional but we hope the standard and content (of the training rather than the sandwiches) have not fallen. Judging by feedback they have not

Next year we will provide a similar programme, and we have sought views to ensure we provide what RECs need. Let us know if there is a gap!

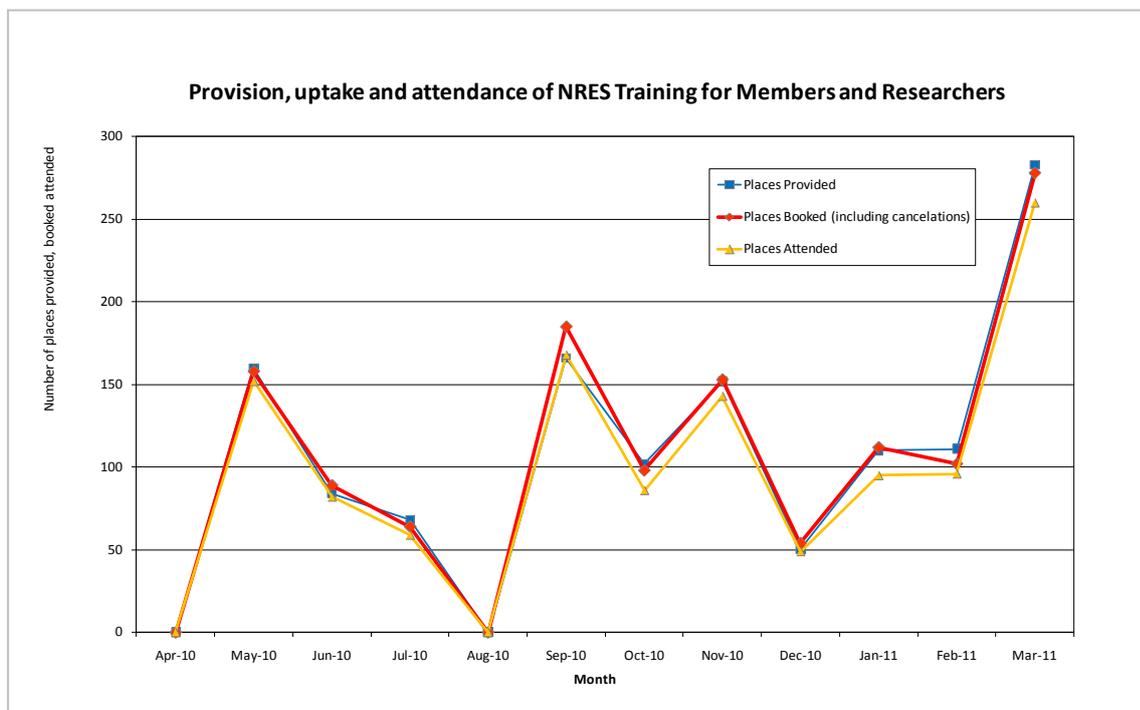
We have continued to develop our training for new members and we hope now that the majority are able to attend the one day induction course within the target of 3 to 6 months from appointment. It is an important part of our welcome and an opportunity for us

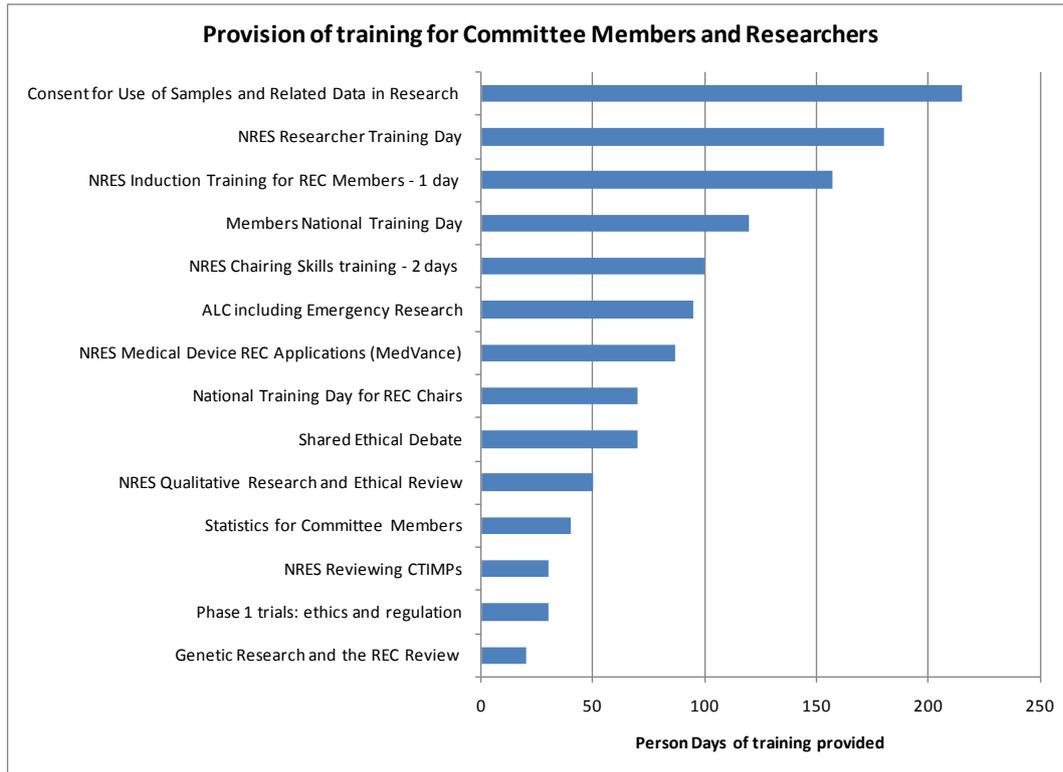
to say thank you for joining our endeavour. We do recognise the necessary commitment and are delighted that so many take up an opportunity to be on an REC. If we are to continue to improve research, the RECs will play an important part.

Similarly 'topic based training' and chairs' training continues but while repeating the programme with relevant modifications, and providing many similar training days, we haven't missed the opportunity to innovate.

A new initiative is to develop training material that those who attend meetings can take back to their RECs. In this way we hope that all on RECs can share the learning. If you have been to one of our training days, please put it on your committee's agenda. Knowledge, like muck, is no good unless it's spread!

We will also shortly have a 'Research Ethics' CD that will be available to members who wish one. It has been a major piece of work to pull all the material together and once this is complete, we will consider how to put it on our website. Perhaps this could link into one other initiative to foster local, REC based training.





This year we have been working with our QA team to develop the training potential of our Shared Ethical Debates. We see this as a way for us all to share our views and experience and also develop consistent review that matches current guidance. We have run successful debates on prison research, shortly to be published in Research Ethics Review, on phase 1 research which is laying foundations for further training in this area and now one exploring qualitative research. Others are planned and we may even go 'international'. We have also run some debates on issues currently causing concern in RECs. Reports will be available on the extranet area of our website. Members are warmly invited to attend the workshops that support this process and to contribute to the debates. Training is a priority for NRES, it is leaner now but of maintained and increasing quality. If, in conclusion, we take a step back and take a longer view we can see that training is no longer the prerogative of a few RECs. When there was first an identified national training resource, more than ten years ago NRES estimates that less than 5% of members

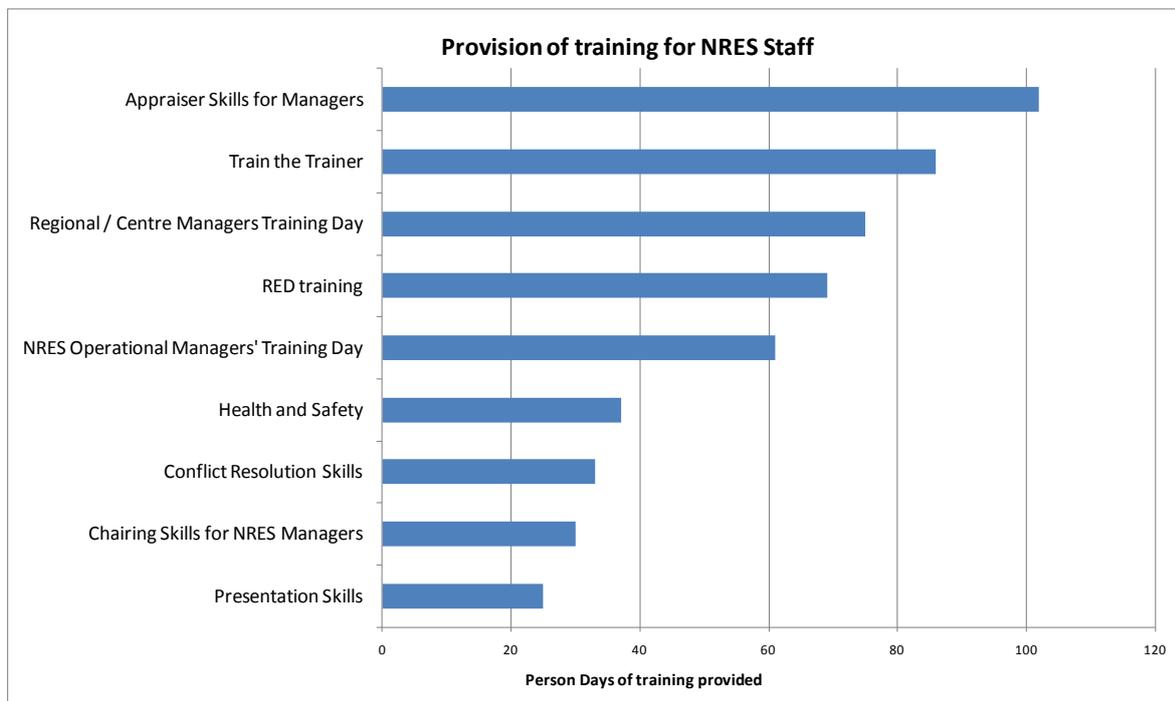
received training and no Chairs received specialist guidance on how to do the 'job'. Now the picture is very different and NRES believes we can confidently say RECs have available training to ensure they can conduct their business effectively, efficiently and robustly.

### Learning and Development

'2010-11 has been a busy year for staff training under the umbrella of 'Learning and Development'. We have delivered a comprehensive management training programme, Centre Training Days to encourage sharing of skills, knowledge and expertise, and, for the first time, training on topics such as Mental Capacity Act and Human Tissue Act targeted specifically at Co-ordinators so they can support committees to work within the required frameworks. In addition induction and appraisal documentation has been updated and new introductory modules written for new Co-ordinators on minute taking and letter writing.

In September 2010 we launched bespoke Training Modules on NRES SOPs, designed and written by the Training and Development Manager in conjunction with REC Co-ordinators. Each module covers a different section of the SOPs, and includes case studies and an assessment of knowledge. This work has been complex and extensive, and continues with valuable input from co-ordinators and managers. The training on this important core aspect of NRES work is delivered locally by Centre Managers.

In January 2011 we also started delivering mandatory minute taking training in-house. This has evaluated very well and provides a valuable opportunity to make sure 'hot topics' can be covered as they arise. In addition we have provided more staff with core presentation and training skills, to support delivery of NRES-specific training by NRES staff as far as possible. It has been good to use REC centres as training venues as they have become available, and we will build on this in the coming year.



## INTRODUCTION TO PROPORTIONATE REVIEW

Proportionate review is for research studies which present 'no material ethical issues', i.e. there is minimal risk, burden or intrusion for the participants. Applications eligible for proportionate review are reviewed by a sub-committee made up of three REC members, one of whom must be lay and the aim is to review the application within 14 days. If the sub-committee finds that an application does contain material ethical issues and issues a 'no opinion', it will be sent for review by the full REC and a decision will be issued within the normal 60 day time-limit.

More information on proportionate review, including which studies are eligible, is available via the [NRES website](#)

### Pilot areas

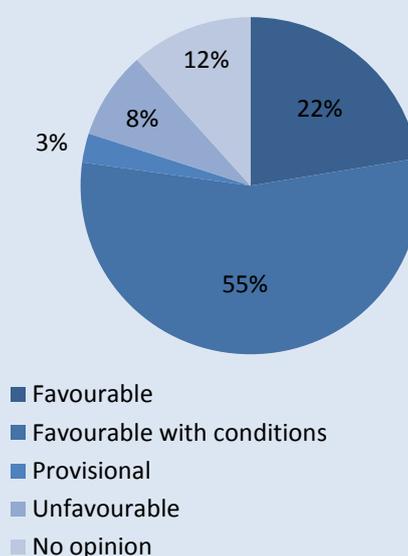
NRES launched the proportionate review pilot in London in September 2009 and this was expanded to the East Midlands REC centre in March 2010 and the North East REC centre in October 2010. Between January 2010 and December 2010, a total of 250 applications were reviewed via proportionate review.

**Figure 1** below shows over three quarters of all applications reviewed during this period receiving a favourable opinion or a favourable opinion with conditions. The aim to provide a decision within 14 days initially produced mixed results with approximately only 50 percent of studies reviewed within 14 days from January to December 2010. However, as RECs and coordinators became more experienced and as more RECs became involved, a higher percentage of studies were reviewed within the 14 day time period.

**Figure 2** shows that two thirds of studies were

reviewed on time between October 2010 and January 2011 and this figure will rise as experience levels increase and more RECs become involved. **Figure 3** shows the types of studies reviewed between October 2010 and January 2011. The chart demonstrates that the most studies reviewed by proportionate review were questionnaire and interview based studies, with over three quarters of the total number reviewed from these groups.

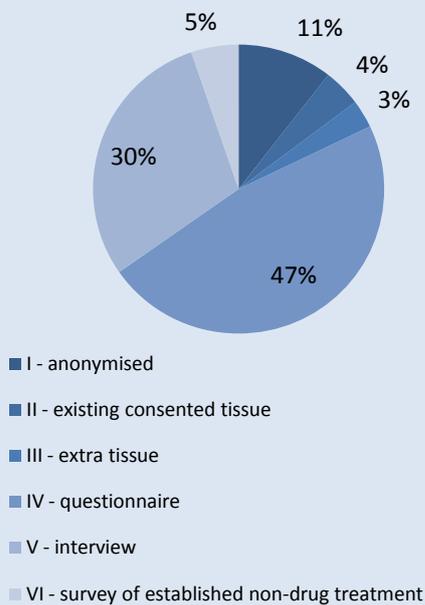
**FIGURE 1.**  
Proportionate review decisions  
(January to December 2010)



**FIGURE 2.**  
Length of time to issue a decision  
(October 2010 to January 2011)



**FIGURE 3.**  
**Types of studies reviewed**  
**(October 2010 to January 2011)**



For more information on types of studies reviewed please visit the [Proportionate Review](#) section of the NRES website.

## Future plans

An evaluation of the three pilot regions has been conducted with the best ways of working identified. This will be used to determine how proportionate review will be conducted in practice. Over the coming year, proportionate review will be rolled out to all REC centres, with the North West and East of England REC centres next to implement the service. Work is also being undertaken to identify other studies which may be suitable for proportionate review to continue to provide a service, as recommended by the AMS Review, which is proportionate to the risks and benefits to the individuals involved and society as a whole.

## GLOSSARY

<b>ALB</b>	Arm's-Length Bodies
<b>AMS</b>	Academy of Medical Sciences (AMS)
<b>AREC</b>	Association of Research Ethics Committees
<b>ARSAC</b>	Administration of Radioactive Substances Advisory Committee
<b>CTIMP</b>	Clinical Trials of Investigational Medicinal Products
<b>DH</b>	Department of Health
<b>GAfREC</b>	Governance Arrangements for NHS Research Ethics Committees
<b>GTAC</b>	Gene Therapy Advisory Committee
<b>HTA</b>	Human Tissue Authority
<b>IRAS</b>	Integrated Research Application System
<b>MHRA</b>	Medicines and Healthcare products Regulatory Agency
<b>NIGB</b>	National Information Governance Board
<b>NOMS</b>	National Offender Management Service
<b>NPSA</b>	National Patient Safety Agency
<b>NREA</b>	National Research Ethics Advisor
<b>NREAP</b>	National Research Ethics Advisors' Panel
<b>NRES</b>	National Research Ethics Service
<b>PCT</b>	Primary Care Trust
<b>PRS</b>	Proportionate Review Service
<b>QA</b>	Quality Assurance
<b>QC</b>	Quality Control
<b>REC</b>	Research Ethics Committee
<b>RED</b>	Research Ethics Database
<b>SHA</b>	Strategic Health Authority
<b>ShED</b>	Shared Ethical Debates
<b>SOPs</b>	Standard Operating Procedures
<b>UKECA</b>	UK Ethics Committee Authority
<b>UKHD</b>	UK Health Department