

# NRES PROPOSALS AHEAD OF PLANNING FOR FURTHER SERVICE IMPROVEMENT AND EVALUATION

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Dated: 01 December 2011  
Version: Draft v. 2.1  
Status: Final for comment  
Approved by: NRES Management Group & HRA Interim Board (01 December 2011)  
Distribution on approval: HRA website ([www.hra.nhs.uk](http://www.hra.nhs.uk))  
Review date: 30 January 2012

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## 1. INTRODUCTION

The Health Research Authority (HRA) is a newly formed NHS organisation established on 01 December 2011 as a Special Health Authority. The purpose of the HRA is to protect and promote the interests of patients and the public in health research. The HRA has issued a [Summary of Activity Plan](#) for the four month period from establishment to the end of March 2012.

The HRA will also support the DH-led programme of work to transfer in additional functions to the HRA and establish the HRA as a Non-Departmental Public Body. The ambition for the HRA is real and vital, in working to establish a unified approval process and to promote proportional standards for compliance and inspection within a consistent national framework. The HRA will issue the first full year business plans in April 2012.

An early important objective for the HRA is the stabilisation of the National Research Ethics Service (NRES) as it transfers in to the HRA and to enable the NRES to respond to the challenges from the Academy of Medical Sciences (AMS) review. This welcomed the improvements that had been made to the ethics service in the UK and urged the NRES to continue with its programme of work to deliver further service improvements to address, in particular, proportionality and consistency of review. The proposals in this document are the NRES response, issued for comment and to be finalised and included in the HRA business plans for 2012-2013.

## 2. BACKGROUND

The National Research Ethics Service (NRES) reviews research proposals to protect the rights and safety of research participants and enables ethical research of benefit to science and society. The [Academy of Medical Sciences review](#) (AMS) acknowledged the considerable improvements that had been made to the system for ethical review in the UK. The principles that underpinned the recommendations from the AMS reflect the current strategic objectives for the NRES.

[The Plan for Growth](#) published with the Budget in March 2011, announced that the Government would create a health research regulatory body. The Health Research Authority was established on 01 December 2011 with NRES at the core of the new organisation.

The move to the HRA provides a robust platform from which NRES can deliver improvements to the service building on the work done to date to improve the ethics service that is timely, predictable and effective for researchers and robust and transparent to protect research participants. NRES has the opportunity to build on the system improvements and to do now what will set the pace for the further work to deliver the vision for the HRA as described in the Plan for Growth.

## 3. PURPOSE

The purpose of this document is to describe proposed strategic developments to the NRES, for pilot, testing and evaluation in 2012. These will be developments specifically to the NRES which will be tested in small pilot sites before wider implementation. Whilst they are NRES specific, they are also designed with the intention of enabling and informing further improvements across

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the systems for regulation and governance in the UK. The document should be read in conjunction to the [HRA Summary of Activity Plans](#) for December 2011 - March 2012.

#### 4. ABOUT THE NRES

The National Research Ethics Service comprises the NRES Research Ethics Committees in England, the National Research Ethics Advisors' Panel, the NRES members that serve on the committees and the NRES staff. NRES works in collaboration with colleagues in Scotland, Wales and Northern Ireland to provide a comprehensive service. The NRES currently has 81 committees in England, 1,200 committee members and 130 staff.

The fundamental principle underpinning the service is the requirement for independent review of research involving human subjects, to protect the rights, safety, dignity and well-being of research participants. These principles and standards are described within the Declaration of Helsinki and captured in statute within the UK. The Governance Arrangements for Research Ethics Committees (GAfREC) that describes the remit of ethics committees within the UK sits within the Research Governance Framework for Health and Social Care; the decisions made by ethics committees sit within the legal frameworks including the Mental Capacity Act, Human Tissue Act, UK Clinical Trials Regulations and EU Clinical Trials Directive.

##### ***NRES protecting participants, an example***

*The REC stated that the main ethical issue remains whether it is ethical to switch off the patient notifier found on the study device. The committee did not consider the research questions justified switching off the alert feature for twelve months in half the patients, with the attendant risk that the detection of battery or device failure would be delayed.*

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 from investment in the UK. Specifically NRES provides a service that delivers:

- One NRES ethics approval for the UK
- Predictable, managed and efficient timelines
- Robust and quality assured ethical review
- A transparent service that underpins public confidence in clinical research.

NRES collects and monitors a comprehensive set of management information to inform the management and development of the service.

NRES has managed a change programme which has transformed the ethics service in England from a starting point of a fragmented service of some 200 committees with no management framework, coordination, quality framework and little training to an internationally recognised system for ethics review. In 2004 the service had 200 RECs and cost £12 million and provided little more than secretariat support to the committees. The service now is comprehensive in

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providing a standard operating framework, guidance, training, transparency and accountability, quality control and quality assurance. The cost for the comprehensive service is currently £10 million so significant savings have been realised, as well as releasing funding for the development of the service.

## 5. TAKING THE NRES FORWARD AT THE HRA

The principles underpinning the suggested developments are greater transparency; greater efficiency; proportionality; quality and consistency of ethical review; greater integration across the regulatory and governance frameworks; and maintenance of the UK-wide system for ethical review.

In considering and delivering these further improvements, the intention is to be more efficient. It is also to enable RECs to focus time and energy on the issues it is uniquely positioned to consider with greater support from the structures within NRES.

## 6. THE POTENTIAL FOR EFFICIENCY – THE PROPOSALS

The NRES has a good history of delivering service improvements that lead to efficiencies whilst protecting the robust service provided. Examples include: one NRES REC approval for the UK; the requirement for funding before ethics submission; tissue bank applications and; database applications.

Proportionate review of low risk studies has introduced efficiencies within the system by referring these through sub-committee and this is one example where a greater efficiency can be made by further reducing the dataset required on such low risk studies. *NRES proposes a structured evaluation of the dataset and information required by NRES to make robust decisions on low risk studies.*

We also need to look at where there are common elements within applications and avoid duplication. Approved models for studies could be published so that applicants can be confident that elements of a design will meet the requirement of ethical review by choosing approved ‘templates’ within an overall study design and application. We may be able to develop robust models for programme-based rather than project-based approvals. For example, enabling health services researchers to obtain approval for a programme of activity in a defined area and approved methodology, with individual projects then being notified and agreed as being within the programme approval rather than requiring individual approval. *NRES proposes that options for template approved elements within study designs and programme based approvals are developed and evaluated.*

Other opportunities lie in use of decision-making options and the potential benefit of providing further assessment and advice earlier in the process. The 2010-2011 NRES annual report data showed that of the 5,567 full applications reviewed: 25% of applications received a favourable opinion or favourable with additional conditions; 68% of applications received a provisional opinion, with almost all provisional opinions moving on to a favourable opinion. Could some of these provisional opinions be favourable opinions if advice was provided earlier? Is there benefit in assessing applications to improve the quality of applications submitted through to review?

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Would this be welcomed by applicants? What we do know is that if a provisional opinion is provided, a further response is required by the applicant and a second decision is needed. The administration to support this decision-making is significant and it increases the actual timelines from submission to decision. Of course, this is a valid and valuable route where it is appropriate, but could efficiencies be introduced so that use of this option is required less? *NRES proposes that a new ethics and assurance function is evaluated that will provide early assessment and advice to applicants and facilitate the review process for the REC.*

The proposals are for NRES, we need to consider how they impact and benefit within the service and on the service provided. In evaluating, we also need to consider how they impact on others who approve research and assess how this could reduce duplication or improve confidence in the ethical review by, for example, Trust R&D. We also need to consider developments by others, for example the MHRA work on proportionality. It is a time of change for many and the proposals come at a time when NRES has moved to the HRA and needs to settle in to the new operating framework. The proposals are also significant and implementation may require policy changes. *In recognition of these factors, NRES proposes that these service improvements are tested and evaluated in defined areas before they are considered for implementation.*

## 7. PROPOSED SERVICE IMPROVEMENTS

### 7.1 Proportionality

The NRES has successfully implemented a proportionate review service (PRS) where studies declared and agreed as falling within the framework for proportionate review, detailed in the [No Material Ethical Issues Tool](#), are allocated for review at sub-committee. The process is now well established and will be available from all NRES offices by the end of March 2012. The PRS is efficient in that it delivers shorter timelines for researchers, with a current average of 13.2 calendar days for a decision to be given. It is also efficient in that only three REC members review the application and most are reviewed electronically and avoid associated meeting costs.

*The NRES proportionate review service is now a formal review option for NRES, as described in [Standard Operating Procedures for Research Ethics Committees in the United Kingdom v5.0](#) issued in September 2011. The metrics from April 2011 to end October are:*

- **391** applications have been reviewed through PRS
- **71%** of applications received a **favourable opinion** or a **favourable opinion with additional conditions**
- 2% of applications received an unfavourable opinion
- 6% of applications received a no opinion and were referred to a full REC for review

*The main types of studies reviewed via PRS during this period were questionnaire research (41%), interview / focus group research (29%) and anonymous tissue / data*

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However, NRES recognises this will not be a truly proportionate process until the information required for the PRS is greatly reduced. The NRES therefore proposes to test and evaluate further developments: (i) the option for researchers to apply for ‘programme approval’ for a set of projects within a defined programme, which then only require individual notification on a minimal data set; (ii) the option for template approval of specified elements of study design that could then be selected and included into research protocols by researchers; and (iii) to test and evaluate the review through PRS on a greatly reduced dataset.

(i) *Programme approval for a defined programme of research with individual project notification*

NRES will explore the possibility of developing a procedure to provide researchers with the opportunity to describe a programme of activity; for example, health services research in a defined area with identified methodology, which would be submitted for REC approval – at full committee – and then enable individual projects to be notified on minimal additional information. The approval of the individual project would be taken by an officer to the REC and given on the basis that the project falls within the defined, and approved, programme of activity. A framework for the approach will be developed in consultation with researchers and REC community, before testing in one area and potential implementation. This model builds on current options for approval of research tissue banks and research databases. The true value of this approach also depends on the acceptance of global assurance on suitability of researchers and sponsors as proposed in Section 5 of this strategic plan.

(ii) *Templates for study design*

NRES will explore the possibility of developing elements that can be included within an overall study design as an approved template. Application would still be required and the REC would need to judge the applicability of the chosen template. But this could greatly improve consistency and take what may be guidance now on to a firmer footing and reduce duplication of review and duplication of effort in study design.

(iii) *Reducing the volume of information required for PRS*

The information required by NRES is a dynamic dataset depending on the type of study proposed, and the dataset is generated from the responses to the initial filter questions on IRAS. The dataset will be much smaller for, say, a questionnaire-based study than a clinical trial of a medicinal product, but NRES recognises the need to respond to feedback from researchers and REC members to greatly reduce the volume of information required on some very low risk studies. Caution is required in taking this forward, to not reduce the number of studies actually accepted for review at PRS as this would reduce current efficiency.

The NRES therefore proposes to test and evaluate in one NRES centre. During the test and evaluation stage, NRES will conduct a controlled evaluation of information required to make decisions on proportionate review applications.

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## 7.2 Providing advice from the HRA on the requirement for NRES ethical review

The NRES has provided much advice to applicants and sponsors, on legislation, policy and ethical aspects of the application, before submission and as part of the application process. NRES receives positive feedback on such advice and the support it provides. The HRA will continue to look at effective mechanisms for providing such advice. The centrally provided general and pre-application guidance has become an HRA function from 01 December 2011, in recognition of the value of this service and the broad range of queries the NRES has provided responses to historically. Application-specific advice will remain within the NRES and these plans also propose to enhance this locally-provided service.

### *NRES advice*

*NRES guidance and advice is welcomed by many, particularly in complex areas of legislation. Frequently, researchers propose to recruit participants who may lack capacity and many within the NRES are willing and able to provide support and guidance to researchers. This happens currently but not in any nationally organised way.*

*To quote a response: "With regards to the Mental Capacity Act, thank you for the attached documentation. I can confirm that I understand and will discharge my responsibilities as a researcher under the Act."*

*The NRES move to the HRA provides an opportunity to give routine and formal sources of advice for researchers.*

NRES believes there is one specific area in which the central HRA provided advice service could be significantly improved. This relates to queries on whether an activity is research and whether it falls within the remit of NRES requiring review from a NRES REC. The decision lies ultimately with the research sponsor and, under the current framework, the NRES (centrally through HRA from 01 December 2011) will initially reference that the decision does not sit with the HRA and refer to relevant guidance ( a model that has been followed within NRES for some time). NRES is currently putting in place mechanisms to capture locally provided advice where Chairs and others provide this advice from the NRES centres. From the NRES Business Unit queries line data, we know we receive around 40-50 queries per week of this nature which we refer to guidance and invite to come back with more detail for further advice. We know that nearly all do come back for further advice, despite the initial reply explaining it is not within our remit to provide definitive guidance in this area. NRES believes it is timely, with the move to the Health Research Authority, to explore with research sponsors, including NHS R&D Departments, the extent to which they would welcome a service from the HRA which could provide definitive advice on whether an activity requires review from an NRES research ethics committee, with the same authority the MHRA can advise if a study is a clinical trial of a medicinal product. NRES recognises the need to carefully frame such decisions so that activity is appropriately approved, University REC and/or R&D Trust approval for example, even where NRES approval is not required.

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### ***NRES support***

*REC members may be able to provide particular early advice to applicants, for example helping other members in an academic team to prepare an ethics application and to focus on the ethics of the research at this early stage in areas frequently addressed by the committee, such as considering a patient's perspective, anonymity and de-identification of samples and patient details. This happens currently, but not in any nationally organised way.*

### **7.3 Extending validation to preliminary assessment**

NRES has recognised for some time that the level of provisional opinions needs to reduce to improve absolute timelines for ethical review. A provisional opinion is a good decision option, but NRES believes that more could be done to reduce when it is required. There has been a target to reduce provisional opinion rates in previous business plans and NRES is disappointed that these have not been delivered, even with the introduction of the option to give a favourable opinion with additional conditions. Reducing provisional opinions would also introduce further administrative efficiencies as a considerable amount of coordinator time is taken in managing the process through from provisional to favourable opinion. Data shows that very few applications receive a provisional and then an unfavourable opinion; this is almost exceptional, although some studies are withdrawn after a provisional opinion.

Some issues lie with the RECs and the appropriate use of decision-making options and NRES is addressing these through internal review and training. A fundamental and underlying issue is that currently applications are submitted and progress through to committee review on the basis of them being valid. Some assessment and advice is provided from current coordinators, but there is no formal and consistent assessment on the suitability of the application prior to progress through to committee review. This means applications are received by committee which could have benefited from early advice, and then receive provisional opinions for reasons that could have been addressed much earlier in the process. For example, incorrect use of the IRAS filter to declare the study type so the application dataset is incorrect; technical changes to information sheets to address typing and spelling mistakes; justification of scientific validity; as well as general issues around quality of the application and it being ready for review by committee.

NRES proposes introducing a new function as an extension to the current validation process and that within this function there would be early correspondence with the researcher and sponsor to seek assurance that measures will be taken; for example to correct information sheets; and to request further information that the officer determines will be required by the committee, for example further evidence of scientific review.

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NRES recognises that this new approach will need to be tested for acceptability to both researchers and RECs, and that great care would need to be taken to ensure that the assessment is not seen as approval and that RECs do not become overly reliant on the assessment. This approach will be piloted and evaluated in two NRES centres. There is also opportunity to learn from the scientific officer model in Scotland.

#### ***NRES facilitating research, an example***

*The Participant Information Sheet in a research study on Alzheimer's patients which was very onerous talked about the (fairly high) risks of being involved in the stud; however, the REC discussed with the sponsor that those risks were actually present as part of standard care and not associated with the research element. Changes were requested as it was felt this would facilitate and improve recruitment rates.*

#### **7.4 Researcher and representative attendance at meetings**

Researchers are routinely invited to attend the REC meeting and are strongly advised to do so. Sponsor representatives may also attend the REC meetings. NRES recognises the value of the opportunity for the REC to discuss the application with the researcher and sponsor representatives. REC feedback is that this is a valuable part of the process, although there is agreement that sometimes there are few remaining issues to discuss with the researchers. Researchers report that, although attendance is often worthwhile, it can present a significant investment of time and resource for travel and NRES has received requests for the options of attendance by telephone or videoconferencing. There are limitations on technical resources to enable videoconferencing, although RECs are asked to support requests for teleconferencing. However, the feedback from RECs is that the face-to-face interaction can be very valuable where there are significant issues to explore with the researcher.

NRES therefore proposes that there is early discussion with the applicant on the need for attendance in person, making an early judgement from the nature of the study and issues the committee may wish to discuss. This will enable an informed decision to be made on attendance in person or availability by teleconference. NRES will also look to provide videoconferencing options for some REC meetings.

The discussion on attendance in person will be piloted and evaluated in two NRES centres.

#### **7.5 Prior assessment and approval on some aspects of the ethical review**

NRES proposes that there are some aspects to the current ethical review which could adequately, efficiently and robustly be provided by a suitably trained and qualified individual on behalf of the REC, such as the suitability of the researcher, the sponsor, insurance provision and funding. This would mean the REC would not normally need to consider these aspects of the application; however, there would be room for exceptions

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and discussion but the REC would normally rely on the assurance provided by the prior assessment.

The greater potential of this proposal is that, if the REC can accept the prior assessment, there is potential for the assurance to become a global check rather than application specific. For example, a researcher could apply to be registered as approved in a particular area – health services research, or clinical research in a particular discipline – and a further assessment would not be required unless a study was proposed outside of this registration. If the assessment could be linked to IRAS registration, then the opportunity for efficiency is considerable and the current IRAS filter options and individual application declaration could be used to ensure the system is robust.

There are also benefits that an early assessment may provide others with a greater assurance that aspects, such as insurance, have been consistently reviewed and it will enable the volunteer membership to focus on the core non-administrative aspects of the ethical review.

The potential is considerable. The first step is to test if RECs are able to take an assurance from a suitable individual on some aspects of the ethical review. This approach will be piloted and evaluated in two NRES centres.

## **7.6 Advice to the REC to support consistent and robust review**

RECs make independent decisions on the ethical aspects of research applications. They do not make legal decisions but they make ethical decisions within a complex policy and legal framework. As well as the potentially complex setting, there is much relevant guidance to consider when looking at an individual application. NRES has introduced Shared Ethical Debate, which takes one application to a number of committees and enables reflection on decisions taken compared to others. NRES also has the National Research Ethics Advisors' Panel which offers further guidance to RECs. NRES believes further assessment and advice to the REC of relevant legislation, policy or guidance, and to brief the REC on previous similar applications or discussion of similar issues, would greatly improve the quality and consistency of decision-making. This assessment would provide assurance to the RECs that they are looking at all the relevant issues and in the appropriate context in undertaking their independent assessment of the application.

There is also opportunity to strengthen the review of substantial amendments, with prepared briefings, bringing together the previous history of the study for the sub-committee members reviewing the amendment. This is reported as being a valuable part of the Scientific Officer role in Scotland.

NRES accepts that careful consideration will be needed to look at how prior assessment and briefing fits with the current roles, particularly the lead reviewer, coordinator and Chair. There is opportunity to learn from the Scientific Officer role in Scotland.

This additional assessment will be piloted and evaluated in two NRES centres.

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## 7.7 The Research Ethics Committee meeting

The Research Ethics Committee meeting is very much focussed on review and approval of applications. There may be related business on the agenda, but this will be limited and current viability of committees is based on assessment of workload where RECs are expected to meet 11 times a year and review, typically, 6-8 applications a meeting with a per meeting average of 6 applications being considered a reasonable workload.

The number of RECs has reduced, predominantly because of efficiencies that have been introduced to the service such as removing duplicate review, requesting that funding is in place before an application is submitted and the database and tissue bank approval options. The proportionate review service has also reduced the number of full applications at committee. With the removal of the low risk studies from the main agenda, and the increase in sub-committee work, NRES has recognised that RECs should not routinely review more than 6 studies and member attendance requirements will also more formally recognise the contribution to sub-committee work. Proposals for programme approvals and early assessment to improve the readiness of the application for review will further reduce the volume of sub-committee business.

Some further reduction in REC numbers is inevitable. However, NRES proposes that the reduction in application-based business at REC meetings is an opportunity to use committee meeting time for local training. Potentially, it could also to enable REC members to contribute to the development of guidance and to reflect on previous decisions in light of progress of the application and the study. This process would be facilitated for the committee allowing, for example, National Research Ethics Advisor's Panel (NREAP) guidance to be more widely discussed and grounded within views of RECs. With this additional use of committee time, numbers of new applications may reduce to 4-6 per meeting.

### ***NRES contribution to training***

*NRES has an extensive training programme. NRES training is primarily for REC members but the collaborative approach of NRES has enabled many events to be mixed audience to provide guidance and debate across sectors.*

*The expertise and willingness of staff and REC members to contribute has enabled NRES to provide training in many complex policy areas and on topics requiring advanced knowledge of ethical issues. The wider contribution of those within the service should not be underestimated and the experience and expertise within the NRES significant, with membership including those leading in a particular area of expertise, busy clinicians working alongside the valuable contribution of the lay membership to provide a comprehensive service to applicants, and support to those working in related fields.*

NRES will develop models for additional use of committee time, alongside a review of the NREAP terms of reference and management of the Panel as NRES moves to HRA.

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## 7.8 Providing the additional assessment and advice from NRES

The strategic plan proposes new functions within NRES to advise and support applicants and to facilitate the REC review. The pilot and evaluation of the new function will need to examine not only the acceptability and value of the additional role – to researchers and RECs – but also where this function may ultimately sit within current structures and what new roles would be required. For example, the proposed extension of validation to preliminary assessment could almost certainly sit within revised job descriptions for coordinators.

There are some working assumptions, the person doing the early assessment would not be a member of the committee, but they would need to attend committee meetings to present the advice to the committee. They would make an initial presentation to the committee and then not take part in the committee deliberation, unless by invitation of the Chair or to intervene if the REC was leading itself to an incorrect course of action. The current responsibilities of the Chair would remain with the Chair, but there would be opportunity for local or case-by-case delegation; for example, a busy Chair may delegate that the officer sign off the decision notice to the researcher.

*There is significant work to do to examine how best to provide this additional resource within the service and this will be determined in the pilot and evaluation phase of the proposals.*

## 7.9 Evaluation

The NRES accepts that some or indeed much of the new function may sit, ultimately, within existing structures. However, to effectively test the acceptability and value of the new function to researchers and NRES, additional resource will need to be provided during a pilot and evaluation phase.

Pilot areas have been identified: for the new assessment and advice function, the NRES centres in Jarrow and Nottingham; and the proportionality pilot will be based in the NRES centre in Manchester. Secondment / fixed-term appointments will be made to 'NRES ethics and assurance officer' posts that will provide the new function during this evaluation phase, working alongside the existing staff and in collaboration with the RECs in those areas. The pilot will be formally evaluated before decisions are taken on wider implementation. The evaluation is being supported by an expert advisory group. The plans for the pilots and evaluation will be published in April 2012.

## 7.10 Affordability

Any strategic plan needs to be affordable and to present the opportunity to realise further efficiencies and savings. NRES has undertaken the necessary modelling to enable confidence that the proposals as presented, subject to evaluation of benefit and acceptability, would deliver efficiencies within NRES and for applicants to NRES and would also have the potential to inform further efficiencies across the wider framework of regulation and governance.

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*These plans are issued for comment, please send feedback, questions or suggestions to NRES  
via the project manager Steve Tebbutt by 30 January 2012*

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01 December 2011

FOR COMMENT

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## GLOSSARY

<b>Amendment</b>	A change made to the terms of the REC application, the protocol or any other supporting documentation after the study has started. A study is normally considered to start with the commencement of any protocol procedures
<b>Appointing Authority</b>	The body responsible for the establishment and support of RECs
<b>Appeal</b>	Following the issue of an unfavourable opinion, the submission of the application without revision to another REC for a second ethical opinion
<b>Approval conditions</b>	Conditions to be met by the applicant prior to the start of the research. Approval conditions are issued by the REC in the final letter confirming a favourable ethical opinion. <i>(Note: Approval conditions are distinct from the further information or clarification requested from the applicant when issuing a provisional opinion.)</i>
<b>Care organisation</b>	The organisation(s) responsible for providing care to patients and/or users and carers participating in the study. Care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study
<b>Chair</b>	The member of a REC appointed to be Chair by the appointing authority. Where the Chair is unavailable for any reason, his/her duties may be performed by the vice-Chair or alternate vice-Chair
<b>Chief Investigator (CI)</b>	The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI
<b>Clinical Trials Regulations</b>	The Medicines for Human Use (Clinical Trials) Regulations 2004
<b>Clock</b>	The period allowed for the ethical review of a new application or substantial amendment. The clock starts on receipt of a valid application
<b>CTIMP</b>	Clinical trial of an investigational medicinal product (any other type of research is known as a non-CTIMP)
<b>DH</b>	Department of Health
<b>EU Directive</b>	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

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<b>EudraCT</b>	The European Clinical Trials Database administered by the European Medicines Agency on behalf of the European Commission
<b>Favourable opinion</b>	When giving a favourable opinion, the REC may specify any conditions to be met <i>prior to the start of the study</i> (or the start at each site). The conditions must be met in order for the favourable opinion to be in place once the study starts. It is the responsibility of the sponsor to ensure that the specified conditions are met.
<b>GAfREC</b>	The UK Health Departments' Governance Arrangements for Research Ethics Committees
<b>HRA</b>	Health Research Authority (Special Health Authority established from 01 December 2011)
<b>IRAS</b>	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 ( <a href="http://www.myresearchproject.org.uk">http://www.myresearchproject.org.uk</a> )
<b>MHRA</b>	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
<b>Minor amendment</b>	An amendment which is not a substantial amendment, not requiring review by a REC
<b>NDPB</b>	Non-Departmental Public Body
<b>NIHR</b>	National Institute for Health Research
<b>NRES</b>	National Research Ethics Service
<b>NRES Director</b>	The senior manager with overall responsibility for management of the National Research Ethics Service
<b>Participant</b>	Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a study. (Under the Clinical Trials Regulations, participants in CTIMPs are referred to as "subjects".)
<b>Protocol</b>	A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study
<b>Provisional opinion</b>	A decision reached by a REC on an application, subject to the receipt of further information or clarification from the applicant (including

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	revisions of documentation) and/or further consultation with a referee. The 60 day time period is suspended until information requested from the applicant is received
<b>REC</b>	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
<b>RED</b>	The Research Ethics Database used by the REC system
<b>Recognised REC</b>	A REC legally recognised by UKECA to give an ethical opinion on a clinical trial of an investigational medicinal product (CTIMP) to be undertaken
<b>Research site</b>	The organisation or unit responsible for conducting any of the research procedures in a study at a particular locality
<b>Scientific officers</b>	Staff appointed by the Health Boards in Scotland to provide expert advice to RECs and R&D offices on the review of research proposals and manage REC centres
<b>Single ethical opinion</b>	The ethical opinion given by a REC on a research study, with application to the whole of the UK. An ethical opinion may be either favourable or unfavourable
<b>SOPs</b>	The Standard Operating Procedures for Research Ethics Committees
<b>Sponsor</b>	The person who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a research study
<b>Substantial amendment</b>	Under the Directive and the Clinical Trials Regulations, an amendment to a CTIMP that must be notified to both the ethics committee and the competent authority; it requires a favourable opinion from the main REC and/or a notice of no objection from the MHRA before it can be implemented. In the case of non-CTIMPs, a substantial amendment requires the issue of a favourable opinion from the main REC except where it only involves adding a new site or PI at a NHS site
<b>UKECA</b>	United Kingdom Ethics Committee Authority