National Research Ethics Service

NHS Health Research Authority

STANDARD OPERATING PROCEDURES FOR RESEARCH ETHICS COMMITTEES IN THE UNITED KINGDOM

Version:	Version 5.0 dated September 2011
Change:	Amendment No. 1
Date of issue:	16 March 2012
Date of implementation:	1 April 2012
Purpose:	Take account of the establishment of the Health Research Authority and the winding up of the Appointing Authority for Phase 1 Research Ethics Committees (AAPEC). Include other minor changes and clarifications to the SOPs Correct typographical errors, update weblinks, etc

Summary of changes

1. A summary of all substantive changes in this version of the SOPs is available in the Annex to this document.

2. The changes are incorporated into Version 5.1 of the SOPs, available as a PDF on the NRES website at http://www.nres.nhs.uk/news-and-publications/publications/standard-operating-procedures/. A separate PDF is available showing all tracked changes from version 5.0.

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ANNEX

Amendment no. 1 to version 5.0 of the NRES SOPs – summary of changes

Topic / issue	***Reference***	***Details of changes***
Health Research Authority (HRA)	Front cover Introduction Glossary	The SOPs are now issued by NRES within the Health Research Authority.
The Appointing Authority for Phase 1 Ethics Committees (AAPEC) has been wound up.	Glossary 1.6 1.22-1.23 1.90 4.26 7.17, 7.19-7.20 13.37	Consequential changes have been made to remove all references to AAPEC, AAPEC RECs and the Business and Operations Manager for AAPEC. Those former AAPEC RECs that remain operational have been re-constituted as NRES RECs within the HRA and continue to work within the NRES SOPs.
Submission deadlines for applications submitted through the Proportionate Review Service	Summary page for Section 1 8.16	Electronic booking and submission for all applications is to be introduced later this year. Version 5.0 of the SOPs stated that, in the interim, the previous SOPs continue to apply under which a complete paper copy of a new application must be submitted to the REC within **4 days** of the booking. The change relates to applications submitted through the Proportionate Review Service. These should reach the REC within **2 days** of the booking. Researchers will be advised about this by REC office staff at the time of booking. These arrangements will be superseded when e-submission from IRAS is introduced. Further information will be made available in due course.

Applications relating to sub-studies	1.3	Where a separate application is submitted for a sub-study, it is recommended this is submitted to the same REC as the parent study where possible.
Recognition to review CTIMPs	1.17	A note of clarification is added to paragraph 1.17. This confirms for avoidance of doubt that RECs which are no longer recognised to review new applications for CTIMPs continue to be recognised by UKECA to act as the main REC for studies of which they previously gave a favourable opinion. This means they have authority to review any substantial amendments, safety reports etc and undertake any other business associated with the trial until it has closed.
Cancellation of REC meetings	2.38	Where it is proposed to cancel a planned meeting, the Co-ordinator should seek the agreement of the REC operational manager at an early stage.
RECs acting as referee to another REC	2.45A 2.46	A new paragraph 2.45A is added giving guidance on requests from a REC for referee's advice from another REC. Such requests have been made in the past and RECs are encouraged to work together and share expertise where this would be of benefit to the ethical review. The guidance provides for RECs to seek referee's advice either from an individual member of another REC (e.g. a member with particular expertise such as a statistician) or from the REC collectively (e.g. where it is flagged and has experience of reviewing certain types of research). The request should be made via the Co-ordinator of the REC concerned. The response to the main REC should indicate clearly whether the advice is from an individual member or the REC collectively; if the latter, it should be agreed by sub-committee. A consequential amendment is made to paragraph 2.46.
Consideration of advice from referees	2.50	Paragraph 2.50 has been reworded to clarify the guidance to the REC on how it may draw on a referee's advice in framing its opinion while maintaining the referee's confidentiality.

Studies undertaken primarily for educational purposes	3.16	The amendment to 3.16 clarifies that correspondence should be addressed to the student (or the first named student on the application if more than one is involved) and copied to the CI if this is a different individual. This reflects current REC practice.
Definition of a research site	4.21	Paragraph 4.21 has been slightly modified so that the definition of a Participant Information Centre (PIC) is consistent with that in the NIHR Clinical Research Co-ordinating Centre Operating Manual. There is no substantive change to the definition of a research site.
Site-specific assessment (SSA) for non-NHS sites	4.43	A minor clarification has been made to paragraph 4.43 so that it is consistent with the general guidance in Section 6 of SOPs on minuting of sub-committee business conducted by correspondence.
Notices of substantial amendment (NOSA)	Summary page for Section 5 5.12-5.13	The summary page has been updated to clarify that both the European Commission NOSA form (for use with CTIMPs) and the NRES NOSA form (for non-CTIMPs) are available within IRAS. The summary page and paragraphs 5.12-5.13 have been amended to clarify that any notice of substantial amendment (or modified amendment) must be authorised or co-authorised by a representative of the sponsor. This reflects the existing policy on the requirements for a valid NOSA in paragraph 5.22(c).
Amendments which may require a new application	5.60 5.62A	The guidance in paragraph 5.60 has been redrafted to emphasise the need for a proportionate approach. A new application should only be required where a proposed amendment would <u>fundamentally</u> alter the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants. Where an amendment is rejected on this basis, the REC should give reasons to the applicant with reference to the criteria in paragraph 5.60. These criteria now include a proposed sub-study with a different Chief Investigator and/or an intention to publish the results separately from the parent study.

		Paragraph 5.62A adds further guidance to RECs on cases where the concerns arise from the apparent complexity and extent of the changes but do not fundamentally alter the nature of the research. It is open to the REC to review such NOSAs at a meeting of the full committee and to invite the Chief Investigator and/or sponsor to attend.
Sub-committee business in correspondence – responsibilities of the Co-ordinator	6.32	Minor changes have been made so that the summary of the Co-ordinator's responsibilities in paragraph 6.32 is consistent with the guidance on minute-taking (paragraph 6.22) and destruction of written comments from members once the minutes have been ratified (paragraph 14.8).
Annual progress reports – due date	9.12	SOPs have previously required submission of the annual progress report to the REC on the anniversary of the favourable opinion. This made it difficult for sponsors to provide complete data for the reporting year. Paragraph 9.12 has therefore been amended to allow 30 days from the end of the reporting year for the report to be provided. If the report is not received, a reminder will be sent by the REC office at the 30 day point under paragraph 9.17.
Reports by the sponsor of serious breaches of the protocol or GCP	9.110	Guidance has been included to deal with situations where it may not be appropriate for serious breach reports from the sponsor to be referred to the original main REC, for example because the study has closed. In such cases, paragraph 9.110 allows for the report to be referred to the HRA for further consideration.
Other spontaneous reports of possible serious breaches	9.114	Where such reports contain insufficient information, paragraph 9.114 allows the NRES Head of Operations to refer the matter to the HRA, which may then write to other bodies to request further information about the circumstances of the reported breach.
Research databases – renewal of approvals	10.36	Minor clarifications have been made to the process for 5 year renewal of generic approvals for research databases.

Research databases – terminology	10.36 10.38	The term “Data Controller” was adopted in version 5.0 of SOPs to refer to the person who is the applicant and manager of the research database team. Amendments have been made so that this terminology is used consistently throughout this section of the SOPs.
Specific projects involving human tissue	11.11	Under paragraph 11.11, project-based approvals for research involving human tissue are valid only for the duration of the project. A minor clarification has been added to confirm that the project may continue beyond the projected end date to complete the procedures described in the application and the protocol. This is consistent with the general policy on the duration of a project in paragraphs 9.10-9.11.
Research tissue banks – renewal of approval	11.35	Minor clarifications have been made to the process for 5 year renewal of generic approvals for research tissue banks / biobanks.