RES SOPs (Version 7.3) Summary of Changes, September 2018

How to use this document

This summary of changes document includes all of the revision from version 7.2 to version 7.3 of the Research Ethics Service Standard Operating Procedures (RES SOPs). The left hand column shows the wording which was present in version 7.2 and deletions are indicated by ~~strikethrough~~. The right hand column shows the wording which is now present in version 7.3 and additional text is indicated by underline.

General revisions			
Para	SOP 7.2	Para	SOP 7.3
	Data Protection Act 1998		Data Protection Act 2018
	Research Governance Framework		UK Policy Framework for Health and Social Care Research
	Staff intranet		HRA Hub
	HRA Director of Operations		Director of Approvals Service
	HRA Improvement & Liaison Manager		*All references removed and replaced with the relevant job title based on the particular activity.*
	National Research Ethics Service		Research Ethics Service
Introduction to RES SOPs			
Page	SOP 7.2	Page	SOP 7.3
17	Introduction to RES SOPs – version ~~7.0~~	17	Introduction to RES SOPs – version 7.3
18	~~The National Research Ethics Advisors' Panel (NREAP) is established by the HRA under GAfREC as~~	18	The Health Research Authority has established a National Research and Ethics Advisers' Panel to

	~~a resource to the UK Health Departments' Research Ethics Service and the appointing authorities of RECs within that service, to help optimise research ethics review and so improve the research environment in the UK.~~ The role of the NREAP includes advice to RES ~~on the development of operational policy, as well as advice and support to RECs and~~ their appointing authorities in exercising their responsibilities under GAfREC and the SOPs. The full terms of reference for the panel are available on the HRA website.		provide it with a transparent source of advice and expertise to enable it to fulfil its' statutory functions within an overall UK-wide framework for research ethics and broader research governance. The panel is a resource available to the UK Research Ethics Service and to the appointing authorities of the RECs within that service. The role of the NREAP includes advice to RES and their appointing authorities in exercising their responsibilities under GAfREC and the SOPs. The full terms of reference for the panel are available on the HRA website.
Glossary			
Page	SOP 7.2	Page	SOP 7.3
20	No wording	20	Anonymised - Anonymised in accordance with the Information Commissioner's Office anonymisation code of practice.
Section 1: New applications for ethical review			
Para	SOP 7.2	Para	SOP 7.3
1.9	Lists of flagged RECs are available on the HRA website ~~by using the 'Advanced search' tool on the 'Directory of RES Research Ethics Committees' page - these are updated from time to time.~~	1.9	Lists of flagged RECs are available from the REC Directory page of the HRA website.
1.69	REC Staff should complete as much of the validation process as possible before an application is transferred to a different REC, ~~i.e. when an application~~	1.69	For full applications, REC staff should complete as much of the validation process as possible before an application is transferred to a different REC. REC staff

	~~is received for a Proportionate Review meeting but is deemed unsuitable and transferred to a full REC meeting.~~ REC staff from the transferring REC should relay any information relating to the validation status of an application to the receiving REC. ~~Similarly, if a PR application is received and deemed to be invalid, REC staff should also undertake an assessment of PR suitability so that the applicant can be advised appropriately regarding resubmission of the application.~~		from the transferring REC should relay any information relating to the validation status of an application to the receiving REC. When an application is received for a Proportionate Review meeting but is deemed unsuitable and needs to be transferred to a full REC meeting, the REC Manager of the receiving REC should liaise with the applicant to arrange the transfer and should inform the second REC why the application is not suitable for Proportionate Review. The second REC is then responsible for validating the application. The receiving REC should transfer the application to the agreed full REC meeting and remove the application from the meeting as soon as possible in order to ensure Proportionate Review meeting slots are used as effectively as possible.
1.95	Research involving only staff of health or social care services, who are recruited by virtue of their professional role, and healthcare market research are generally excluded from the scope of REC review (see paragraphs 2.3.13 - 2.3.14 of GAfREC) and should not normally be accepted. An application may, however, be reviewed exceptionally by a REC where the Research Ethics Service agrees that the proposal raises material ethical issues. Responsibility for deciding whether such research should be reviewed rests with the Regional Manager. Where a researcher or research sponsor wishes to apply to a REC, they are encouraged to seek advice in writing from the REC	1.95	Research involving only staff of health or social care services, who are recruited by virtue of their professional role, and healthcare market research are generally excluded from the scope of REC review (see paragraphs 2.3.13 - 2.3.14 of GAfREC) and should not normally be accepted. An application may, however, be reviewed exceptionally by a REC where the Research Ethics Service agrees that the proposal raises material ethical issues. Responsibility for deciding whether such research should be reviewed rests with the Regional Manager. Where a researcher or research sponsor wishes to apply to a REC, they are encouraged to seek advice in writing from the REC

	Manager prior to completing an application.		Manager prior to completing an application. Market research may be undertaken by professional market researchers, e.g. for public health research or on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the principles set out in the Market Research Society Code of Conduct or with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review, except where otherwise required by law, e.g. if it requires approval under the Mental Capacity Act.
1.96	Under paragraph 2.3.7 of GAfREC, RECs may agree to consider applications in respect of activities preparatory to research. Applications relating to the establishment of research tissue banks and research databases in the UK are voluntary but are welcomed by the Research Ethics Service. The application should normally be accepted under the procedures in Sections 11 and 12. If a REC feels unable to review the application, the REC Manager should make arrangements to transfer it to a REC willing to review it. Requests for review of non-study specific pre-trial advertising and screening should be submitted to the Generic Document Review Group via phase1.advertreview@nhs.net.	1.96	Under paragraph 2.3.7 of GAfREC, RECs may agree to consider applications in respect of activities preparatory to research (e.g. the establishment of research databases or tissue banks, or pre-trial advertising and screening for healthy volunteers). Applications relating to the establishment of research tissue banks and research databases in the UK are voluntary but are welcomed by the Research Ethics Service. The application should normally be accepted under the procedures in Sections 11 and 12. If a REC feels unable to review the application, the REC Manager should make arrangements to transfer it to a REC willing to review it. Requests for review of non-study specific pre-trial advertising and screening should be submitted to the Generic Document Review Group via phase1.advertreview@nhs.net.

1.97	Paragraph 2.3.7 of GAfREC also allows a REC to review other research not requiring review under the policy and legal requirements set out in GAfREC. Where such research involves human participants and raises material ethical issues, it is desirable as a matter of public policy that it is ethically reviewed. If the researcher does not have access to ethical review from another source, e.g. a university REC or an ethics committee established by a professional body, the REC is encouraged to accept the application and give an ethical opinion on a voluntary basis. It is a matter for the Chair to decide whether the application should be reviewed. Applicants are encouraged to seek the advice of the REC prior to completing the application. Where the Chair agrees to review the application, it should be reviewed in accordance with standard operating procedures. ~~In responding to the applicant following the meeting, SL25 should be used.~~ Where the Chair declines to review the application, the RES Manager should decide whether or not to invite another REC to consider the application.	1.97	Paragraph 2.3.7 of GAfREC also allows a REC to review other research not requiring review under the policy and legal requirements set out in GAfREC. Where such research involves human participants and raises material ethical issues, it is desirable as a matter of public policy that it is ethically reviewed. If the researcher does not have access to ethical review from another source, e.g. a university REC or an ethics committee established by a professional body, the REC is encouraged to accept the application and give an ethical opinion on a voluntary basis. It is a matter for the Chair to decide whether the application should be reviewed. Applicants are encouraged to seek the advice of the REC prior to completing the application. Where the Chair agrees to review the application, it should be reviewed in accordance with standard operating procedures. Where the Chair declines to review the application, the RES Manager should decide whether or not to invite another REC to consider the application.
Section 2: Full meetings of a Research Ethics Committee			
Para	SOP 7.2	Para	SOP 7.3
2.28	Subject to paragraph 2.30, the quorum for meetings of a REC is seven members, including at least the following: · The Chair or, if unavailable, the vice-Chair or	2.28	Subject to paragraph 2.30, the quorum for meetings of a REC is seven members, including: • The Chair or if unavailable, the Vice-Chair or

	alternate vice-Chair · One lay~~+~~ member ~~as defined in GAfREC must be in attendance~~ · One expert member.		Alternate Vice-Chair • One expert member • One lay member <u>(where CTIMPs will be reviewed at the meeting, a lay+ member as defined in the Clinical Trial Regulations must be present for the meeting to be quorate).</u>
Section 10: Monitoring of research given a favourable opinion			
Para	SOP 7.2	Para	SOP 7.3
10.78	Where a REC receives information other than from the sponsor (or sponsor's representative) suggesting that a serious breach may have occurred in relation to an application for ethical review or the conduct of research, ~~the Chair or REC Manager should pass the information confidentially to the HRA Improvement and Liaison Manager (delegated to the Operations Business Manager) in writing.~~ If the REC concerned is not the main REC for the study, a copy should also be sent to the main REC ~~and its Regional Manager.~~	10.78	Where a REC receives information other than from the sponsor (or sponsor's representative) suggesting that a serious breach may have occurred in relation to an application for ethical review or the conduct of research, <u>the Chair or REC Manager should email the information to breaches.nres@nhs.net</u> . If the REC concerned is not the main REC for the study, a copy should also be sent to the main REC.
10.79	In some cases, information may initially be received directly by REC Manager or by other staff within RES (including through the HRA Queries Line). ~~Such information will be passed to the HRA Improvement and Liaison Manager via breaches.nres@nhs.net~~	10.79	In some cases, information may initially be received directly by <u>the</u> REC Manager or by other staff within RES (including through the HRA Queries Line).
10.80	The REC Manager should ~~notify the HRA Improvement & Liaison Manager of all reports received.~~	10.80	The REC Manager <u>or relevant staff member should send the details of any possible serious breaches received to breaches.nres@nhs.net</u>

10.95	If the trial is terminated early, the sponsor should notify the REC within 15 days of the date of termination. An explanation of the reasons for early termination should be given.	10.95	If the trial is terminated early, the sponsor should notify the REC within 15 days of the date of termination. An explanation of the reasons for early termination should be given. <u>If the trial has been terminated early for safety reasons it should be registered with immediate effect even if a registration deferral has been allowed by the HRA (see paragraph 3.21).</u>
Section 12: Research involving human tissue			
Para	SOP 7.2	Para	SOP 7.3
12.13	No wording.	12.13 (i)	<u>Research involving analysis of human DNA extracted from acellular material.</u>
Section 13: Research involving adults unable to consent for themselves			
Para	SOP 7.2	Para	SOP 7.3
13.41	~~An on-line toolkit on research involving adults lacking capacity, which was developed for RES by a joint team from the University of Leicester and the University of Bristol, is available via the HRA website.~~	N/A	Paragraph removed.
13.42	The Medical Research Council ~~and the British Psychological Society~~ has published detailed practical guidance for researchers on the inclusion of adults unable to consent for themselves. ~~Additional~~ Guidance for social scientists has been developed by SCIE and is available on the SCIE ~~and HRA~~ website~~s~~.	13.42	The Medical Research Council has published detailed practical guidance for researchers on the inclusion of adults unable to consent for themselves. Guidance for social scientists has been developed by the Social Care Institute for Excellence (SCIE) and is available on the SCIE website.

Annex G: Insurance, indemnity and compensation			
Para	SOP 7.2	Para	SOP 7.3
19	Guidance on 'Insurance and compensation in the event of injury in Phase 1 clinical trials' ('industry guidance') has been developed by industry bodies19 in consultation with DH and RES and is published at ~~http://www.bioindustry.org~~. The guidance is also available ~~on the Guidance page of the HRA website under 'Phase 1 trials'.~~	19	Guidance on 'Insurance and compensation in the event of injury in Phase 1 clinical trials' ('industry guidance') has been developed by industry bodies in consultation with DH and RES and is published on the Association of the British Pharmaceutical Industry (ABPI) website. ~~http://www.bioindustry.org~~. The guidance is also available via the Phase 1 section of the HRA website.
20	The industry guidance applies specifically to commercially sponsored Phase 1 trials. It applies principally to trials in 'healthy volunteers' but also extends to 'patient volunteers' without the target disease (see paragraph 24 below). It supplements the existing guidance on compensation within the ABPI Guidelines for Phase 1 Clinical Trials ('the ABPI Phase 1 Guidelines'), ~~2007~~ 2018 edition, available at ~~http://www.abpi.org.uk/our-work/library/guidelines/Documents/phase1-trial-guidelines.pdf~~	20	The industry guidance applies specifically to commercially sponsored Phase 1 trials. It applies principally to trials in 'healthy volunteers' but also extends to 'patient volunteers' without the target disease (see paragraph 24 below). It supplements the existing guidance on compensation within the ABPI Guidelines for Phase 1 Clinical Trials ('the ABPI Phase 1 Guidelines'), 2018 edition, available at: https://www.abpi.org.uk/about-us/resources/publications-library/guidelines-for-phase-i-clinical-trials-2018-edition/

ANNEX K: The Social Care Research Ethics Committee			
Para	SOP 7.2	Para	SOP 7.3
1.	It is part of the ~~National~~ Research Ethics Service (RES), and its membership, expertise and procedures have been developed to reflect the social care context.	1.	It is part of the Research Ethics Service (RES), and its membership, expertise and procedures have been developed to reflect the social care context.

3.	Researchers unsure about their options for seeking ethical review should seek guidance from the Social Care REC ~~Coordinator.~~	3.	Researchers unsure about their options for seeking ethical review should seek guidance from the Social Care REC Manager.
6.	~~Bookings are made directly to the REC Manager email nrescommittee.social-care@nhs.net~~		
Index			
			Addition of market research