Annual Report Summary for RECs in England April 2018 to March 2019

1. Purpose

To provide a management summary for the Health Research Authority (HRA) Board of the annual reports in respect of the Research Ethics Committees (RECs) in England. This summary will enable the Board to discharge its function to monitor the performance of the RECs against the requirements of Governance Arrangements for Research Ethics Committees (GAfREC: 2018 edition).

2. Background

GAfREC requires that the Health Research Authority as the Appointing Authority for RECs in England receives the annual reports for the individual Research Ethics Committees (RECs). This report provides a summary of those individual reports has been structured geographically by region.

Copies of the individual REC annual reports are available to the Board and will be published on the HRA website.

3. Introduction

Reports have been submitted for all 65 RECs operating during the reporting period in the nine regions. During the period each region, other than London, was served from a single HRA Office. Since the implementation of the new integrated approval process and new staff structure in April 2019, this is no longer the case and staff supporting RECs may be based in any HRA Office and are managed within a different structure.

Table 1: Number of RECs managed by regions as at 31 March 2019

Region	No. of RECs reporting	HRA Office
East Midlands	5	All managed from the Nottingham Office
East of England	5	All managed from the Nottingham Office
London	23	7 RECs managed from London 7 RECs managed from Bristol 7 RECs managed from Manchester

Region	No. of RECs reporting	HRA Office
		1 REC from Nottingham 1 REC from Newcastle
North East	4	All managed from the Newcastle Office
North West	8	All managed from the Manchester Office
South Central	7	All managed from the Bristol Office
South West	3	All managed from the Bristol Office
West Midlands	5	All managed from the Nottingham Office
Yorkshire & the Humber	5	All managed from the Newcastle Office

Head of Research Ethics Service (England) for reporting period, now Head of Approvals Support: Ann Tunley.

Director of Approvals Service for reporting period: Janet Messer.

4. Summary

Membership

Each Research Ethics Committee may have up to 18 members; however, the HRA optimum is 15. As a minimum, one third of members should be lay members. Deputies may also be appointed. A quorum comprises 7 members, including a REC Officer, an expert member and a lay member (for the review of CTIMPs this must be a lay+ member) and arrangements are made to co-opt members from other committees where a meeting would otherwise be inquorate to ensure that a valid ethical opinion can be given. Membership across the 65 RECs ranged from 8 to 16 members.

The recruitment of new members is by an open process and the constitution of the committee is set by GAFREC.

15 RECs were not correctly constituted as at 31 March 2019; of these RECs, 6 remain incorrectly constituted and recruitment is in progress to correct this. The incorrect constitution does not necessarily put meetings at risk of quoracy, it can be due to an imbalance of expert and lay members, for example. Arrangements were made to co-opt members to these RECs as necessary where meetings were at risk of being inquorate.

Reports show that a total of 162 members resigned or completed their term of office; this is an increase of 17 in the number of members t who left in 2017/18. The number of expert members leaving was 74 compared to 68 in the previous year. Of the expert members leaving, 29 were medically qualified doctors compared to 26 in

the last reporting period. The number of lay members leaving was 88, compared to 77 in the previous year.

During the reporting period 141 new members were recruited; this is a slight increase in recruitment from the last reporting period during which time 134 new members were recruited. Of the new members recruited, 62 are expert members, 19 of these are doctors as compared to 10 in 2017/18, and 79 lay members were recruited.

The total membership at the end of the reporting period was 824 compared to the optimum total membership of 975 (based on 15 members per REC), giving a shortfall of 151 members; this compares with a shortfall of 145 members in 2017/18.

Table 2: Research Ethics Committee Membership as at 31 March 2019

Region	No. of RECs	Total no. of members	Resigned/Left	Appointed
East Midlands	5	47	13	10
East of England	5	73	8	10
London	23	300	72	57
North East	4	46	16	10
North West	8	95	13	12
South Central	7	102	12	17
South West	3	42	4	9
West Midlands	5	56	3	4
Yorkshire & Humber	5	63	13	9
Total	65	824	162	141

The Support Division was established on 1 April 2019 to centralise and enhance oversight of REC membership, and its development and quality assurance. It Is responsible for the recruitment and appointment of members, identification of their learning and training needs, and processing their expenses. Whilst the work remains ongoing to improve recruitment processes generally, the dates for interview panels are now available on the website and the number of potential members awaiting interview has reduced significantly to 25 from 107. Between 1 April and 31 July 2019, 43 new members were appointed and a further 42 are still awaiting references or appointment to a suitable REC with an appropriate vacancy. Other work will continue over the next year, including a project looking at our recruitment material, identifying potential recruitment channels in a more targeted way where recruitment is particularly low and to attract more clinicians.

Attendance
Member attendance at meetings is generally good with the majority of members meeting the two thirds attendance requirement, combining attendance at full meetings with participation in Proportionate Review Sub-Committees. Where individual shortfalls were identified these were addressed through the member management policy.

Training
Attendance at training is generally good.

In addition to attendance at face to face courses, attendance at regional Chairs meetings is recorded as training, and a number of local and regional training events were held to meet the specific needs of members. Additionally, further e-learning packages have been developed and rolled out. Training needs relating to REC flags were identified and relevant training was highlighted and targeted to members of flagged RECs where possible.

REC activity
Timelines for Research Ethics Committee Decisions

Meeting statutory timelines for the review of new applications and substantial amendments is excellent across the service with a significant number of RECs meeting 100% of all statutory timelines. The timelines for Proportionate Review (PR) are slightly down during this reporting period year with an overall 84% compliance with the target compared to 87% in 2017/18.

5. Research Ethics Committees' meeting and member attendance

To maintain competency Research Ethics Committees should meet at least ten times per year and should aim to review between four and six applications at main meetings; one meeting may be used as a training meeting. To meet terms and conditions of appointment members are required to attend two thirds of main REC meetings or may combine this with participation in PR Sub-Committees.

Table 3: Number of Research Ethics Committee meetings held

Region	No. of RECs	Full REC	Proportionate Review Sub-Committee	Sub-Committee
East Midlands	5	50	51	131
East of England	5	51	49	127
London	23	226	211	644
North East	4	38	43	125
North West	8	78	79	206

Region	No. of RECs	Full REC	Proportionate Review Sub-Committee	Sub-Committee
South Central	7	66	69	265
South West	3	30	29	80
West Midlands	5	48	56	113
Yorkshire & Humber	5	52	49	132
Total	65	639	636	1823

In 24 cases scheduled meetings were cancelled due to low numbers of applications or because it was not possible to achieve a quorum. In other cases, co-opting was used to achieve a quorum. However, 8 meetings were held which were inquorate either just before or during the meeting, relating to 21 applications. These applications were managed in line with standard operating procedures to ensure that a valid opinion was given after re-review at a quorate meeting.

Requests to co-opt members to achieve quoracy have been higher during the reporting period than the previous year. Co-option has been required to ensure that meetings are quorate both in terms of the numbers present, but also in terms of expert and lay members, and is particularly important to support RECs where the membership is lower than the ideal.

6. Summary of REC activity

The opinion rates for the individual IRAS study types are shown below. The favourable opinion rates are higher for studies limited to the use of tissue and data or data only; many of these applications involve non-identifiable tissue and/or data only. Research tissue banks and research databases are renewed on a 5 yearly basis and this accounts for the higher favourable opinion (FOSC and FOAC) rates.

Table 4: Applications reviewed at full committee meetings

Study type	No. of apps	% Favourable Opinion with standard conditions	% Favourable Opinion with additional conditions	% Provisional Opinion	% Unfavourable Opinion
CTIMP	747	3.8	12.7	81.7	1.8
Clinical investigation of a medical device	199	3.1	13.0	79.2	4.7

Study type	No. of apps	% Favourable Opinion with standard conditions	% Favourable Opinion with additional conditions	% Provisional Opinion	% Unfavourable Opinion
Combined CTIMP/device	6	0.0	0.0	100	0.0
Other clinical trial	497	2.8	20.4	71.6	5.2
Basic science involving procedures with humans	464	5.2	19.3	70.6	4.9
Questionnaires/interviews or mixed qual/quant methods	305	3.6	15.7	71.8	8.9
Qualitative methods only	270	3.5	18.8	72.0	5.7
Limited to tissue samples and data	77	17.2	17.3	62.1	3.4
Studies involving data only	61	49.3	20.3	26.1	4.3
Research tissue bank (including 5-year renewals)	41	11.8	27.5	58.7	2.0
Research database (including 5-year renewals)	52	33.8	7.7	53.9	4.6
Other	42	8.2	14.3	73.4	4.1
Total/Average	**2761**	**5.1**	**15.4**	**75.2**	**4.3**

Table 5: Applications reviewed at PR Sub-Committee meetings

Study type	Total Apps	% Favourable Opinion with standard conditions	% Favourable Opinion with additional conditions	% No Opinion	% Provisional Opinion	% Unfavourable Opinion
Medical device	59	32.2	13.6	6.8	45.7	1.7
Other clinical trial	46	28.3	8.7	17.4	41.3	4.3

Study type	Total Apps	% Favourable Opinion with standard conditions	% Favourable Opinion with additional conditions	% No Opinion	% Provisional Opinion	% Unfavourable Opinion
Basic science involving procedures	327	24.5	16.8	9.8	47.7	1.2
Questionnaires/interviews or mixed qual/quant methods	413	29.8	15.0	6.1	45.2	3.9
Qualitative methods only	230	28.3	18.3	7.8	43.0	2.6
Limited to tissue samples and data	226	45.6	13.7	4.9	34.9	0.9
Studies involving data only	170	68.8	6.5	2.4	20.5	1.8
Other	20	10.0	30.0	20.0	30.0	10.0
Total/Average	**1491**	**35.0**	**14.7**	**7.1**	**40.8**	**2.4**

7. Timelines for Research Ethics Committee decisions

New applications presented to the committees should be given an opinion within 60 calendar days (with clock stop for any request for correction or clarification) and Substantial Amendments within 35 calendar days; these timelines are only mandatory for CTIMPs though have routinely been applied to all applications. Proportionate Review Applications should be reviewed within 21 calendar days.

Table 6: Decisions given by RECs broken down by region

Region	No. of Full apps	% of full apps reviewed within 60 days	No. of Proportionate Review apps	% of Proportionate Review apps reviewed within 21 days	No of Substantial Amendments	% of Substantial Amendments reviewed within 35 days
East Midlands	195	100	97	88	602	99

Region	No. of Full apps	% of full apps reviewed within 60 days	No. of Proportionate Review apps	% of Proportionate Review apps reviewed within 21 days	No of Substantial Amendments	% of Substantial Amendments reviewed within 35 days
East of England	197	99	96	72	604	99
London	998	99	527	86	2610	90
North East	165	100	116	94	488	100
North West	364	99	169	76	950	97
South Central	306	98	175	84	988	97
South West	127	99	76	83	252	99
West Midlands	192	100	120	76	443	100
Yorkshire & Humber	217	100	115	90	438	99
Total	2761	99	1491	84	7375	96

8. Appeals and complaints

The Board receives separately an annual report of appeals and complaints.

4 complaints relating to RECs or REC review were received in 2018/19; 2 were upheld, 1 was partly upheld and 1 was not upheld.

6 appeals against an unfavorable opinion were made in relation to full applications, all of which were allowed; 4 were given a favourable opinion after a request for further information, 1 opinion was varied to favourable opinion on receipt of additional information and 1 received a further unfavourable opinion.

5 appeals against an unfavourable opinion were received in relation to substantial amendments, 3 of these were resubmitted as a modified amendment and received a favourable opinion, 1 received a favourable opinion and 1 received a further unfavourable opinion.

9. Accreditation of Research Ethics Committees

The HRA Quality Assurance Department audits RECs on a three year rolling programme.

Table 7: Outcomes of accreditation audits during reporting period

Region	RECs achieving accreditation at first review	Number of RECs achieving accreditation having completed an action plan
East Midlands	No audits completed in period	
East of England	Cambridge East	Cambridge South Essex
London	Camden & Kings Cross Brighton & Sussex Social Care Harrow Surrey	Stanmore Queen Square
North East	No audits completed in period	
North West	GM East	Liverpool East GM South Preston
South Central		Hampshire B
South West	Central Bristol Cornwall & Plymouth	Frenchay
West Midlands	Edgbaston Solihull Black Country	
Yorkshire & the Humber	South Yorkshire Bradford Leeds	

All other RECs hold accredited status and will be re-audited as scheduled.

10. Recommendation

In accordance with GAfREC the Board of the Health Research Authority is required to receive the Annual Reports for the RECs in England.

11. Acknowledgements

The Health Research Authority acknowledges the contribution made by its volunteer members, staff and managers in providing an effective and robust ethical review service and expresses its appreciation for their commitment to providing high quality ethical review.