Annual report for RECs in England 2020/21

Introduction

This report provides a management summary of the activity of the RECs in England to enable the Board to discharge its function to monitor the performance of the RECs against the requirements of the UK wide Governance Arrangements for Research Ethics Committees (GAfREC).

The introduction of lockdown following the start of the pandemic meant that face to face meetings were converted to virtual meetings in March 2020. After an initial settling period, members responded well to the technology and the new format with meetings continuing to be held virtually during the year; staff attended remotely to support the meetings. A number of members requested a break in service during this period, most of whom were experiencing significant work or family pressures due to the pandemic. We are enormously grateful to all the members for their dedication during this time.

A system was set up for the expedited review of urgent COVID-19 research and members across the country volunteered to support this work, attending additional ad hoc meetings set up for this purpose and reviewing some applications in as little as 24 hours. RECs also accepted applications at very short notice for review at their scheduled meetings.

A Specialist ad hoc REC with membership drawn from experienced REC members from across the UK was established to review COVID-19 studies involving a challenge methodology.

Building on this experience, a pilot of a Fast Track REC to review some types of clinical trials was piloted with a rotating membership drawn from experienced members around the UK. After an evaluation, this has now been implemented as business as usual and is being integrated with the combined process for CTIMPs (previously referred to as CWOW) working closely with the MHRA.

Biannual regional Chairs meetings continued to be held in a virtual format and were well attended by Chairs and other REC Officers.

During the year, and after an options appraisal, the decision was taken to close North West - Liverpool East REC due to low membership and a lack of REC Officers to support the Committee. Five of the members chose to join other RECs within the region. The remaining 64 RECs continued to operate during the reporting period.

1. Membership

The membership of the 64 RECs in set out in figure 1 below. Although up to 18 members may be appointed to each REC, 15 members is the operational target. Therefore, there was a shortfall of 135 members at the end of the reporting period. The constitution of the committee is set out in the Governance Arrangements for Research Ethics Committees (GAFREC), and requires a minimum of a third of the membership to be lay and for those RECs reviewing CTIMPs, half of the lay members should be unconnected with the conduct of clinical research and not be registered health and social care professionals.. In order to ensure sufficient clinical and expert input we try to ensure that at least 50% of the members of each REC are expert. Recruiting experts, particularly clinicians, has continued to be challenging during the year, but the development of new recruitment material and a recruitment drive in the autumn of 2020 through the Valuing our Volunteers programme successfully recruited 26 members, most of whom were lay members. A subsequent tailored recruitment campaign has recruited a further 14 expert members so far with others awaiting interview.

The recruitment of new members is by an open process. Interview panels are held on a regular basis and the move to virtual meetings has given greater flexibility to appoint members outside of their geographical location.

At the end of the reporting period the membership ranged from 8 to 15 members. Where meetings were in danger of not being quorate, this was managed by co-opting members from other RECs. A number of members have shown significant commitment and have been prepared to be co-opted on a number of occasions to support other RECs. Holding meetings virtually has given greater flexibility to allow more members to co-opt to meetings, often outside of their geographical location.

Figure 1: REC Membership

Number of REC members

Lay Plus - 223 (27%)

Lay - 196 (24%)

Expert - 406 (49%)

■ Expert ■ Lay ■ Lay Plus
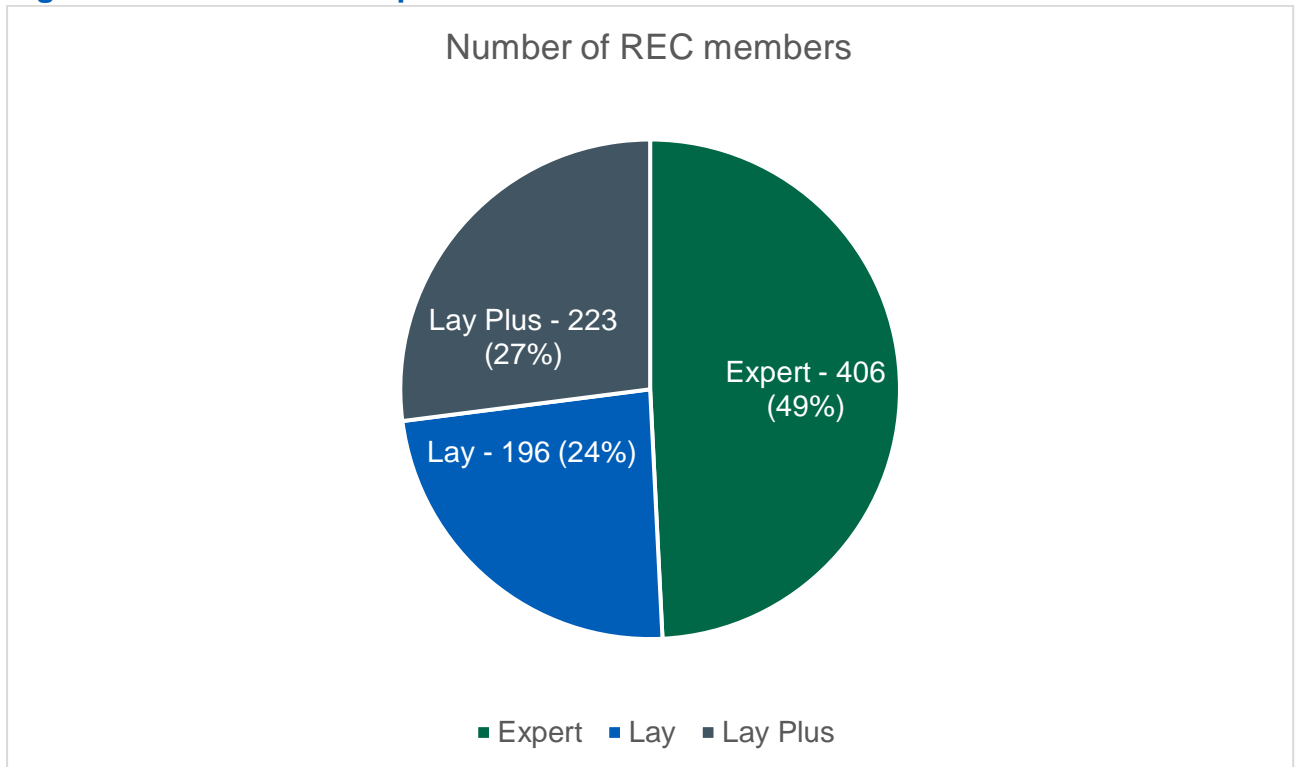
(Note: lay plus members are defined as people who are not, or never have been, a registered health care professional or been involved in the conduct of clinical research: expert members are defined as currently registered health care professionals, individuals with professional qualifications or experience in clinical research or a previously registered doctor or dentist.)

As shown in figure 2 below, significantly more members were recruited than left in the past year, addressing a historic shortfall in membership. This has helped to reduce the burden on the membership.

The term of office is 5 years, which may be renewed, with short-term extensions in exceptional circumstances to maintain the service. Given the commitment involved, we do not expect most members to renew their term of office and appreciate the service of those who have given long service. Members may also share membership which reduces the time and workload commitment of individual members.

Members left the service either as a result of coming to the end of their term (around 30% of leavers) or earlier for other reasons, such as workload commitments related to their job or for personal reasons.

Data on current and predicted vacancies is routinely collected to aid improved succession planning and targeted recruitment.

Figure 2: Number of Members appointed and leaving the service during 2020/21

Number of REC Members Appointed and Leaving

	Expert	Lay	Lay plus
■ Number joining	78	49	49
■ Number leaving	57	32	33
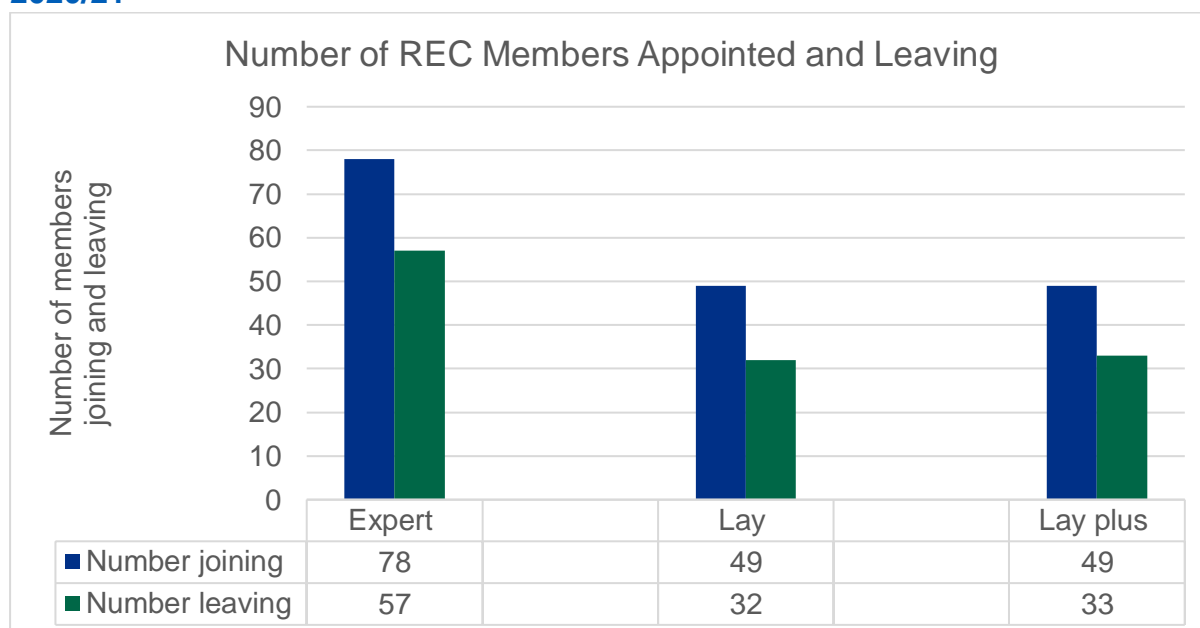
2. Reviews undertaken

Applications reviewed at full REC meetings

The number of applications reviewed in 2020/21 was less than the previous year (2736) due to an overall reduction in research activity resulting from the pandemic. However, there was an increase in the intensity of the review of fast-tracked studies and an increase in complex innovative study design of COVID-19 studies. For this reason, there was a wider range of time to final opinions, with COVID-19 and urgent public health research being prioritised.

The data for CTIMPs includes combined review applications which may affect the timelines as there is no clock stop when applicants want flexibility to submit before the usual REC submission window, or whilst applicants prepare their response to requests for further information (this sometimes takes longer that the requested 14 days). MHRA and HRA are exploring the potential to offer applicants additional flexibility whilst retaining relevant performance figures for the combined review service.

Type of study	Number reviewed	Median time to final opinion	Reviewed in less than 60 days
CTIMP*	733	31 days	92.2%
Non-CTIMP	1812	28 days	96.3%
Total applications	2545	29 days	95.1%

(* Timeline for REC in legislation is 60 days. Data includes combined review pilot)

Applications reviewed by Proportionate Review Sub-Committees

The number of applications reviewed in 2020/21 is significantly less than the previous year (1149), this is mainly related to the suspension of non-COVID-19 research and a reduction in student research in particular. Student applications were halted during the pandemic, but new criteria are being introduced from September 2021.

Applications

Number reviewed	Median time to final opinion
772	20 days

Substantial amendments

The number of substantial amendments reviewed increased over the previous year (6613). This may in part be due to amendments to existing research to mitigate pandemic circumstances or to incorporate research aspects relating to COVID-19. Amendments related to urgent COVID-19 and urgent public health research were fast tracked.

Type of study	Number reviewed	Median time to opinion	Reviewed in less than 35 days
CTIMP	4614	20 days	83.7%
Non-CTIMP	2812	17 days	88.1%
Total	7426	19 days	85.4%

Modified amendments

These are modified amendments submitted after an unfavourable opinion of a previous substantial amendment and have a 14 day timeline.

Modified amendments

Number reviewed	Median time to opinion
24	10 days

Section 30 amendments

These are amendments to include adults lacking capacity in the study for the first time and have a 60-day timeline.

The number of section 30 amendments reviewed in 2020/21 increased from the previous year (9), this is related to the inclusion of adults lacking capacity in ongoing research impacted by COVID-19.

Section 30 amendments

Number reviewed	Median time to final opinion
15	18 days

Fast Track REC

The Fast Track REC ran as a pilot from January to March 2021. Details of the activity for this period are in the table below:

Type of study	Number reviewed	Median time to final opinion
Applications*	43	13 days
Substantial amendments	1	1 day

*includes a specific group of CTIMPs and Phase 1 studies

Generic Review Committee

This is a small committee of 3 members set up to review generic recruitment documents for Phase 1 trials. This year has also seen several organisations submitting generic Covid-19 related materials for review by the GRC. As well as new submissions, the GRC also receives amendments to previously approved submissions.

Type of application	Number reviewed
New submissions	84
Amendments	79

3. REC meeting decisions

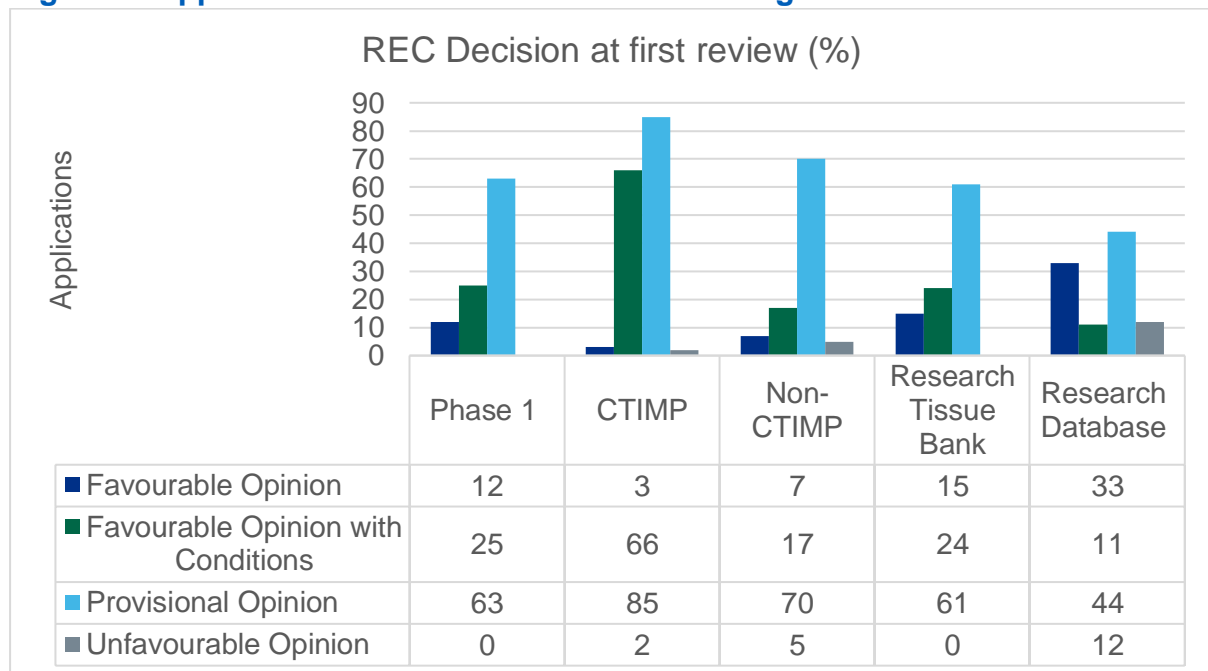### Figure 3: REC meeting decisions – decision at first review

Study type	Favourable Opinion	Favourable Opinion with Conditions	Provisional Opinion	Unfavourable Opinion	No Opinion (transferred to full REC Review – PR only)
CTIMP	22 (3%)	66 (9%)	591 (85%)	17 (2%)	-
Phase 1	11 (12%)	23 (25%)	57 (63%)	0	-
Research Tissue Bank *	5 (15%)	8 (24%)	20 (61%)	0	-
Research Database*	19 (33%)	6 (11%)	25 (44%)	7 (12%)	-
Non-CTIMP (full review)	96 (7%)	216 (17%)	905 (70%)	68 (5%)	-
Non-CTIMP (Proportionate Review)	222 (28%)	91 (12%)	415 (53%)	9 (1%)	48 (6%)

*Includes renewals

The data for CTIMP and Phase 1 studies includes applications submitted through the Combined Review process.

The decision rates for each study type are roughly comparable with those applications reviewed in 2019/20.

Figure 4: Applications reviewed at full REC meetings

REC Decision at first review (%)

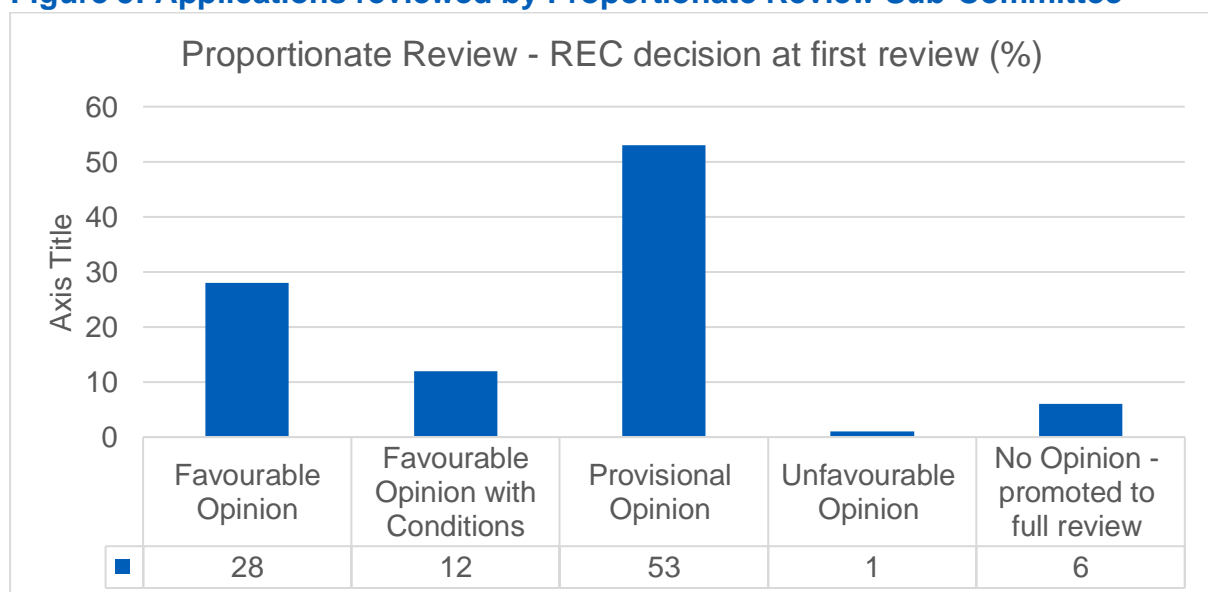|	Phase 1	CTIMP	Non-CTIMP	Research Tissue Bank	Research Database
■ Favourable Opinion	12	3	7	15	33
■ Favourable Opinion with Conditions	25	66	17	24	11
■ Provisional Opinion	63	85	70	61	44
■ Unfavourable Opinion	0	2	5	0	12

Favourable opinion – no outstanding ethical issues and no changes needed

Favourable opinion with conditions – no outstanding ethical issues, minimal specific changes not requiring further review by the REC

Provisional opinion – ethical issues to be addressed or further information needed to enable the REC to make a decision

Unfavourable opinion –significant, unresolved ethical issues

## Figure 5: Applications reviewed by Proportionate Review Sub-Committee

Proportionate Review - REC decision at first review (%)

	Favourable Opinion	Favourable Opinion with Conditions	Provisional Opinion	Unfavourable Opinion	No Opinion - promoted to full review
■	28	12	53	1	6

An unfavourable opinion may be given when the application is of poor quality

4. Accreditation

The constitution of the REC and the meeting attendance, declarations of interest and relevant training undertaken by members is audited biennially as part of the accreditation scheme. Planned face to face training events were held virtually during the period complementing online training to ensure that training requirements continued to be met.

No committees failed to achieve accreditation. For those committees that had to complete an action plan before achieving accreditation the most common actions related to indemnity arrangements, constitution, member attendance and the management of minutes. The number of issues raised per REC significantly decreased from the previous year and also during the reporting period.

Figure 6: Audit outcomes
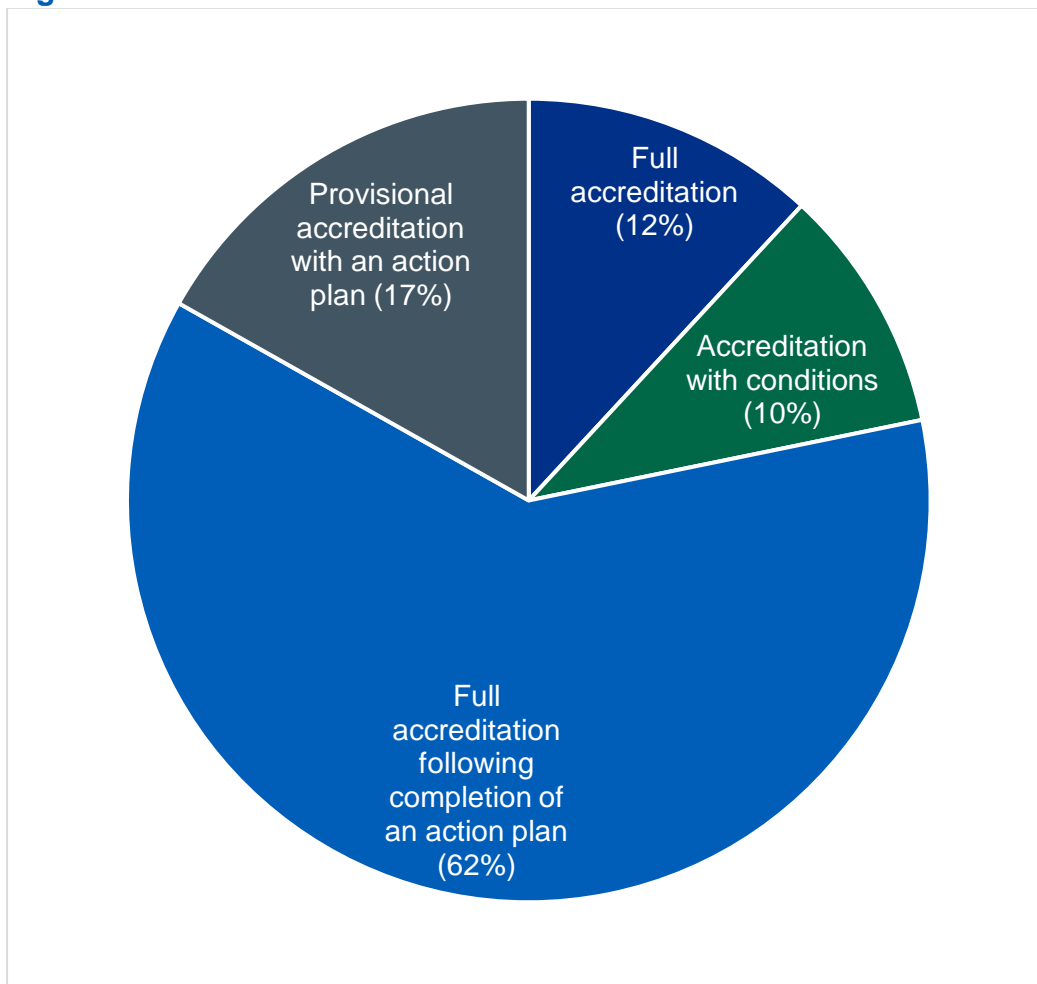
5. Appeals

Six appeals against an unfavourable opinion for applications were received; all were allowed resulting in the following outcomes:

- Two further information favourable opinions, one further information unfavourable opinion, one unfavourable opinion, one favourable opinion and one application was withdrawn by the applicant.

Four appeals against an unfavourable opinion for substantial amendments were received; all were allowed resulting in the following outcomes:

- Three were resubmitted as modified amendments and given a favourable opinion and one was withdrawn by the applicant.

6. Complaints

Two complaints relating to the Research Ethics Service or RECs, one was upheld and the other was resolved locally.

7. Conclusion

The Research Ethics has adapted well to the challenges of working in different ways. These include rapidly switching to virtual meetings and many members joined ad hoc meetings set up to review urgent research, where they provided expert advice on consent issues among other ethics matters. As a result of this and following a survey of REC members, under the auspices of the Ethics Review Programme, the decision was taken to move on a permanent basis to virtual meetings where applications are reviewed. The survey demonstrated that social interaction is important to members and regular Development Days from April 2022 onwards are in planning, with input from members. These will give opportunities for social interaction between members, as well as valuable opportunities for shared learning.

The move to virtual meetings and the establishment of a Fast Track REC built on lessons learnt during the year and were also part of the part of the Ethics Review Programme which will continue its work on making ethics review even more innovative, efficient, proportionate and trusted, with input from members.

Members have not only continued to deliver an excellent service in challenging circumstances, but have generously given their time to support colleagues on other RECs where the availability of members has been impacted by their clinical commitments during the pandemic and to join ad hoc meetings. They have worked with colleagues across the country, and at very short notice to review urgent research. Our work in the HRA to attract and recruit new members with an emphasis on increasing diversity and maintaining a balance of expertise will continue, as we seek to make the most of member's valuable time, while aiming for a research ethics review service that is more reflective of the population it protects.