Research Ethics Service

Annual Report for Scotland

April 2018 – March 2019

## Purpose of this combined annual report

This annual report for the Scottish Research Ethics Service provides a short summary of the NHS Research Ethics Service in Scotland. The main objective of the service is to:

* protect and promote the interests of patients and the public in health and social care research.

The service in Scotland consists of four regional centres and 11 ethics committees. Over 180 voluntary members give considerable time, effort and expertise to provide consistent and thorough review of the applications made by researchers.

This report provides data on the number and type of applications reviewed together with the key performance indicators of the service and gives an overview of the opinions made by the committees. The report also looks at some of the challenges and difficulties that the service is currently faced with.

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# Introduction

The NHS Research Ethics Service in Scotland runs 11 research ethics committees (RECs) which are based across 4 regional centres. North of Scotland is run from NHS Grampian (2), East of Scotland from NHS Tayside (2), South East Scotland from NHS Lothian (3) and West of Scotland from NHS Greater Glasgow & Clyde (4). The service is staffed by a Scientific Officer in each centre and REC Managers and Assistants who are Health Board employees. The membership of each committee contains a mixture of both lay and expert members. Please note that just beyond the period of this review Scotland AREC split into 2 parts, AREC dealing with AWI research applications and B REC dealing with all other applications. Essentially this is the same committee but working under two different governance structures. This is further discussed in Section 7c below.

There are two types of NHS ethics committees; ‘Recognised’ which are legally recognised by the UK Ethics Committee Authority (UKECA) to give an ethical opinion on a clinical trial of an investigational medicinal product (CTIMP) and ‘Authorised’ which are established under GAfREC and cover all other types of clinical research requiring NHS ethical review. In Scotland there are three Recognised RECs and the remaining 8 are classed as Authorised RECs. In addition many of the RECs have a flagged status which denotes a certain expertise and/or training that allows the REC to review certain types of research applications. Some of these are mandatory such as the AWI flag for Scotland AREC and others are recommendations only.

All of the RECs in Scotland are subject to audit by the Health Research Authority (HRA) every two years and must gain Full Accreditation to continue as UK RECs.

**Table 1: Status of Committees and Flags**

|  |  |  |  |
| --- | --- | --- | --- |
| REC | C TIMPs Phase I  (1st in man) | C TIMPs Patients  (not 1st in man) | Flags |
| [East of Scotland Research Ethics Service REC 1](http://www.hra.nhs.uk/news/rec/east-scotland-research-ethics-service-rec-1/) |  |  | Research Tissue Banks, Qualitative |
| [East of Scotland Research Ethics Service REC 2](http://www.hra.nhs.uk/news/rec/east-scotland-research-ethics-service-rec-2/) |  | Yes | IRB registered, Children, CTIMPs |
| [North of Scotland Research Ethics Committee 1](http://www.hra.nhs.uk/news/rec/north-scotland-research-ethics-committee-1/) |  |  | Children, Medical Devices |
| [North of Scotland Research Ethics Committee 2](http://www.hra.nhs.uk/news/rec/north-scotland-research-ethics-committee-2/) |  |  | Research Tissue Banks, IRB registered, Qualitative, Children |
| [Scotland A Research Ethics Committee](http://www.hra.nhs.uk/news/rec/scotland-research-ethics-committee/) |  | Yes\* | Adults with Incapacity (\*and CTIMPs ONLY where there is AWI) |
| [Scotland B Research Ethics Committee](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-1/) | Yes |  | IRB registered, Gene Therapy, CTIMPS, Phase I CTIMPs(HV) |
| [South East Scotland Research Ethics Committee 1](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-1/) |  |  | None |
| [South East Scotland Research Ethics Committee 2](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-2/) |  |  | Medical Devices |
| [West of Scotland REC 1](http://www.hra.nhs.uk/news/rec/west-scotland-rec-1/) | Patients only | Yes | IRB registered, Phase 1 CTIMPs (patients) CTIMPs, Children |
| [West of Scotland REC 3](http://www.hra.nhs.uk/news/rec/west-scotland-rec-3/) |  |  | Qualitative |
| [West of Scotland REC 4](http://www.hra.nhs.uk/news/rec/west-scotland-rec-4/) |  |  | Research Tissue Banks, Research Databases, Medical Devices, Children |
| West of Scotland REC 5 |  |  | Children |

# Membership

The membership of each committee is made up of volunteers and should provide a broad range of experiences and expertise to allow for a balanced review of the scientific value of the study and dignity, rights, safety and wellbeing of the people who are likely to take part. The membership can include up to 18 members and at least one third of the membership must be lay with half of these being, what is called, Lay + whereby the member has no background experience of clinical research and has never been a healthcare professional. An overview of the membership is shown (Table 2)

In order to be quorate seven members are required to be present in person (including live media link) at a meeting and at least one Lay member (Lay+ for Recognised Recs) and one Expert member. Members are required to attend at least two thirds of all meetings and attendance is monitored as part of compliance processes. The Research Ethics Service as a whole should reflect the diversity of the adult population of society, taking account of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. This applies to both the lay and expert membership.

**Table 2: Membership summary of the Scottish ethics committees**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| REC | Total number | Expert | Lay and lay+ | Lay + |
| [East of Scotland REC 1](http://www.hra.nhs.uk/news/rec/east-scotland-research-ethics-service-rec-1/) | 14 | 9 | 5 | 2 |
| [East of Scotland REC 2](http://www.hra.nhs.uk/news/rec/east-scotland-research-ethics-service-rec-2/) | 15 | 9 | 6 | 3 |
| [North of Scotland REC 1](http://www.hra.nhs.uk/news/rec/north-scotland-research-ethics-committee-1/) | 15 | 7 | 4 | 4 |
| [North of Scotland REC 2](http://www.hra.nhs.uk/news/rec/north-scotland-research-ethics-committee-2/) | 17 | 10 | 4 | 3 |
| [Scotland A R](http://www.hra.nhs.uk/news/rec/scotland-research-ethics-committee/)EC | 18 | 10 | 8 | 3 |
| [South East Scotland REC 1](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-1/) | 15 | 7 | 8 | 2 |
| [South East Scotland REC 2](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-2/) | 14 | 7 | 7 | 3 |
| [West of Scotland REC 1](http://www.hra.nhs.uk/news/rec/west-scotland-rec-1/) | 16 | 10 | 6 | 4 |
| [West of Scotland REC 3](http://www.hra.nhs.uk/news/rec/west-scotland-rec-3/) | 16 | 8 | 8 | 6 |
| [West of Scotland REC 4](http://www.hra.nhs.uk/news/rec/west-scotland-rec-4/) | 16 | 9 | 7 | 4 |
| West of Scotland REC 5 | 14 | 7 | 7 | 4 |

# Training and development for committee members

REC committee members can attend a range of training sessions delivered through providers including the Health Research Authority, NHS Ethics Service, Universities and the MRC Regulatory Centre. Local annual training days provide essential training on specific themes and enable members to discuss ethical issues within a supportive environment. A summary of training available is shown (Table 3). REC members are required to attend the equivalent of one day of relevant training per year and new members are asked to attend an Induction Training Day. On top of this members are asked to complete Equality & Diversity (E&D) training at the start of each term of office. The following face to face events were held for members within Scotland but there are also a number of online training courses available to members through the HRA and some Health Boards and this include E&D training. Other HRA training courses held in England are open to Scottish members but costs of travel and accommodation (when required) can be prohibitive.

**Table 3: Ethics Member Training Delivered in Scotland**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date | Location | Open to | Event | Organised by | Numbers | Cost for event |
| 14/09/18 | Glasgow | UK wide REC members (mainly Scotland based) | Members Induction Training | HRA | 20 | NHS GG&C |
| 12/10/18 | Glasgow | West of Scotland REC members (available to other Scottish members on request) | Annual Ethics Members Training Day | WoSRES | 65 | NHS GG&C |
| 23/05/18 | Aberdeen | North of Scotland REC members (available to other Scottish members on request) | Annual Ethics Members Training Day | NoSRES | 25 | NHSG |
| 27/03/19 | Dundee | UK wide REC members (mainly Scotland based) | Members Induction Training | HRA | 23 | NHS Tayside |
| 28/03/19 | Dundee | UK wide REC members (mainly Scotland based) | Advanced Research Ethics Training Day | HRA | 29 | NHS Tayside |
| 26/04/19 | Dundee | East of Scotland REC Members (available to other Scottish members on request) | Various courses: Paediatric assent/consent, Prisoner research, Qualitative research | EoSRES | 23 | NHS Tayside |
| 14/03/19 | Edinburgh | South-East Scotland REC Members (available to other Scottish members on request) | Annual Ethics Members Training Day | SESRES | 45 | NHS Lothian |
| various | Edinburgh | REC members | In-meeting training (eg consent, AWI) | SESRES |  | Cost covered by relevant HB |
| various | Edinburgh | Open to Scottish members & all Investigators | Various courses:  Consent; R&D and Ethics Training; PPI (patient-public involvement); data | Wellcome Trust CRF |  | Cost covered by relevant HB |
| various | Glasgow | Open to Scottish members & all Investigators | Various courses:  Devices Training, Ethics Training, Informed Consent | Glasgow CRF |  | Cost covered by relevant HB |

# Training and support delivered by the Ethics Service for researchers

The Ethics Service also has an educational role to play and in particular the Scientific Officers in each regional service organise and take part in training sessions across relevant NHS Health Board and University sites.

Scientific Officers provide workshops and seminars at numerous events and courses where knowledge of the ethics service and in particular how to put together an ethical research proposal is required. Audiences include NHS researchers, Doctoral students, student supervisors and University researchers. The staff in regional offices and committee chairs also attend meetings with and liaise with NHS Research and Development Departments, local researchers, and representatives of other organisations involved with research and clinical governance such as the Public Benefit and Privacy Panel, clinical effectiveness teams and Health Protection Scotland so that they can support researchers in conducting quality ethical research.

The regional offices provide an advice service for sponsors and researchers on the types of ethical review required, accessing the service and linking researchers to guidance.

# Full applications assigned to committee during the reporting period

Applications are ethically reviewed by Full Committee or given a Proportionate Review by subcommittee depending on an assessment of the ethical risk of the application. Studies are triaged initially by the Central Booking Service which is run by the HRA through a series of questions which are asked when an Investigator is ready to submit their application for ethical review. Further checks are completed by ethics staff in each centre to ensure studies are suitable for PR review. For Full review Investigators get the choice of committee they would like to go to and this usually aligns with where the Chief Investigator is working but time constraints can mean that applicants will come to Committees outside of their own geographic area. This means that the research studies going through the RECs in Scotland does not fully align with the research originating in Scotland although the majority of research projects requiring Full review are dealt with by a local REC. Studies reviewed by Full Committee require quorate membership and for the committee to meet at a specified time usually face to face, however some committees also allow members to attend via telephone or video conferencing. Between April 2018 and March 2019, 393 studies were reviewed at full REC meetings across Scotland and the distribution of study type is given in (Table 4). The numbers are very similar to the previous year with no significant changes in any of the study types or the overall study numbers. The figures for the whole of the UK are given for the same time period as a comparison. The annual figures have also been separated out for a number of specific types of studies which may be of interest giving the percentage of commercial trials reviewed, paediatric, adults lacking capacity, prisoners and gene therapy (Table 5). In Table 6 the reviews of Clinical Trials of Investigational Medicinal Products (CTIMPs) have been separated out. These studies can only be reviewed by a Recognised Committee and we have three within Scotland.

The opinions given at the first meeting are summarised in (Table 7). The majority of provisional opinions given at the first meeting were converted to favourable opinions after researchers responded to the feedback and submitted revised or additional documents for a final decision by the chair or a subcommittee. Provisional Opinions do involve longer review periods overall and therefore good preparation of applications before presentation to an ethics committee should result in reduced review timelines with a higher ratio of applications gaining a favourable opinion on initial presentation.

Timelines for ethical review are closely monitored with over 99% of the applications reviewed within the target of 60 days after the application was submitted to the service. The average review time across all of the committees and applications was 25.5 days (Table 8).

**Table 4: Applications for full ethical review by study type** (1st April 2018 to 31st March 2019)

|  |  |  |
| --- | --- | --- |
| **Study Type** | **UK Applications Reviewed** | **Scotland Applications Reviewed** |
| **Clinical Trial of Investigational Medicinal Product** | 899 | 39 |
| **Clinical investigation or other study of a medical device** | 245 | 25 |
| **Basic science study involving procedures with human participants** | 624 | 85 |
| **Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice** | 632 | 81 |
| **Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology** | 433 | 59 |
| **Study involving qualitative methods only** | 357 | 53 |
| **Study limited to working with data (specific project only)** | 90 | 20 |
| **Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)** | 93 | 10 |
| **Others** | 54 | 9 |
| **Research Database** | 70 | 9 |
| **Research Tissue Bank** | 58 | 3 |
| **Total** | 3555 | 393 |

**Table 5: Applications for full ethical review proportion in specialist area** (1st April 2018 to 31st March 2019)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Area** | **UK** | **UK %** | **Scotland** | **Scotland %** |
| **All Full Reviews** | 3555 |  | 393 |  |
| **Commercially Sponsored Studies** | 904 | 25% | 55 | 14% |
| **Paediatric Studies** | 567 | 16% | 56 | 14% |
| **Adults Unable to Consent** | 307 | 9% | 33 | 8% |
| **Prisoner** | 30 | 1% | 7 | 2% |

**Table 6: CTIMP applications for full ethical review proportion in specialist area** (1st April 2018 to 31st March 2019)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **UK** | **UK %** | **Scotland** | **Scotland %** |
| **CTIMP Reviews only** | 899 |  | 39 |  |
| **Commercial CTIMP Studies** | 723 | 80% | 33 | 85% |
| **Phase I (Healthy Vol)** | 128 | 14% | 0 |  |
| **Adults Unable to Consent CTIMPs** | 32 | 4% | 1 | 3% |
| **Genetherapy** | 43 | 5% | 5 | 13% |

**Table 7: Opinions given at full meetings** (1st April 2017 to 31st March 2018)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Opinion** | **UK applications** | **UK**  **%** | **Scotland**  **applications** | **Scotland %** |
| **Favourable Opinion (+ or – Additional Conditions)** | 818 | 23% | 116 | 30% |
| **Provisional Opinion** | 2564 | 72% | 256 | 65% |
| **Unfavourable Opinion** | 173 | 5% | 21 | 5% |
| **Total** | **3555** |  | **393** |  |

**Table 8: Time taken for Full Review applications.**

Time from valid application received to issue of final opinion letter (time from issue of Provisional Opinion to receiving further information is not included)

|  |  |
| --- | --- |
| **Number of days to review mean (SD)** | 25.5 |
| **Reviewed within 60 days target** | 99.7% |

# Proportionate review applications assigned to meetings during the reporting period

Applications triaged to receive a Proportionate Review are assigned by CBS to the first available REC in the UK therefore applications are likely to come from anywhere in the UK. The first line triage results in approximately 25% of PR studies being incorrectly assigned to PR therefore further checks on suitability for PR are carried out by the REC staff and unsuitable studies transferred to an appropriate Full REC. This can cause delays and duplication of effort and further work is required to get these studies correctly assigned in the first instance.

Each REC is asked to run a PR subcommittee each month and there can be up to four applications looked at by the subcommittee. In general these subcommittees of the full REC are held on different dates to the full meetings and consist of three to four members that communicate using the secure web site for REC members, the HARP Portal, and e-mail. Face to face meetings are usually not required for PR applications. Occasionally unsuitable applications which are not triaged before REC review go to PR subcommittee and in this situation a “NO OPINION” is given and the application is transferred to a Full REC. This can significantly affect the overall approval times for a project.

Not all of the Scottish RECs run PR subcommittees.

**Table 9: PR applications by study type**

|  |  |  |
| --- | --- | --- |
| Type of study | **Applications Reviewed by UK REC** | **Applications Reviewed by Scottish REC** |
| Basic science study involving procedures with human participants | 369 | 23 |
| Clinical investigation or other study of a CE marked medical device | 72 | 2 |
| Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice | 51 | 3 |
| Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology | 461 | 35 |
| Study involving qualitative methods only | 243 | 11 |
| Study limited to working with data (specific project only) | 193 | 16 |
| Study limited to working with human tissue samples (or other human biological samples) and data (specific project only) | 271 | 23 |
| Other | 27 | 4 |
| Total | **1687** | **117** |

**Table 10: Decision at 1st meeting for PR applications**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Row Labels** | **UK applications** | **UK**  **%** | **Scotland**  **applications** | **Scotland %** |
| **Favourable Opinion (+ or – Additional Conditions)** | 839 | 50% | 40 | 34% |
| **Provisional Opinion** | 692 | 41% | 58 | 50% |
| **No Opinion - Refer to Full Committee** | 116 | 7% | 17 | 15% |
| **Unfavourable Opinion** | 40 | 2% | 2 | 2% |
| **Total** | 1687 |  | 117 |  |

The average number of days for PR review in Scotland over the period is 13.2days with 96% of reviews within the KPI of 21 days.

# Challenges Faced by the Scottish NHS Research Ethics Service

There are a number of areas where the REC service in Scotland is currently facing new and significant challenges and these are discussed in this section of the report in no particular order.

1. **Combined Ways of Working (CWOW)**

CWOW is a process of combining all of the approvals an Investigator/Sponsor requires in order to gain approval for a Clinical Trial of Medicine. It aligns with the requirements of the EU Clinical Trial Regulation 536/2014, preparing for the future regulatory landscape. This integrated process is being piloted under the conditions that are expected to be in place when the UK moves across to this process, whether this is within a European context or a system aligned with Europe. From the applicant perspective this should be a streamlined single application incorporating the MHRA Clinical Trial Authorisation, the Research Ethics Committee opinion and the study wide governance review. The reviews are carried out independently but the outcome of the reviews are co-ordinated to ensure requests for further information or changes are compatible with a single co-ordinated communication going out to the applicant.

The main consideration for the participating ethics committees is that they are asked to work in parallel with the MHRA and governance approval in order to fully approve the study within a 60 day period including any requests for further information which will take place as a single request from all of the bodies involved. This puts pressure on staff but also means that the ethics committees are working to tight deadlines for complex CTIMPS. To further complicate these studies the IRAS form is not available for review which means review of these complex studies becomes more onerous for Lay members in particular. The IRAS form is a tool that ethics committees rely on as it clearly states how recruitment will take place and what is additional to routine treatment and should generally be written in lay language. For the CWOW process the ethics members must work from the protocol alone which can be quite a challenge for large commercial CTIMP studies.

During the period of this annual report two of the Recognised Recs in Scotland, East of Scotland REC 2 and West of Scotland REC 1 have worked through a number of dummy pilot projects to train the REC members and staff on the processes and also to help refine the overall UK combined working practices. WoSREC1 has gone on to look at live pilot studies from volunteer sponsor bodies and EoSREC 2 is about to start.

1. **HRA Restructuring and Achieving a Seamless UK wide Process**

Towards the end of the year the HRA embarked on a major restructuring of their staff to help work towards a single ethics and governance review which they call HRA Approval. This has meant very significant changes to staff roles in England although the actual ethics committees have remained the same. The changes that have resulted from this are an HRA governance review and an ethical opinion which is carried out independent of the sponsor body and the host institution. The challenge for Scotland is to work out how we can still have a UK wide review system with two different structures in place. The Scottish REC staff are now working more closely with HRA Assessors who will carry out the governance review for English and Welsh studies. A single review process is not yet in place for studies dealt with by Scottish Recs or for Scottish studies. The challenge will be how we respond to the changes in a way that allows smooth working relationships across the UK and ideally looking to a single governance and ethical review process for all UK applications.

1. **Adults With Incapacity & Scotland A REC**

The Scotland A Research Ethics Committee (SAREC) was set up by Scottish ministers to consider applications involving adults who lack the capacity to consent to research for themselves (AWI) in line with the Adults with Incapacity (Scotland) Act and associated statutory instruments. As such, it predates the other ethics Committees and the current regulatory environment and associated bodies including the Health Research Authority (HRA). A review of governance arrangements by the Scottish Government in 2018-2019 led to the withdrawal of SAREC’s other flags such as CTIMPs (unless these studies also involve AWI). A second Committee, Scotland B, has beenconvened to enable the continued oversight of existing studies (including amendments, queries and progress reports) which are no longer able to be reviewed by SAREC (such as CTIMPs, Phase 1 and Gene Therapy). Whilst this review was underway, it was not possible for Scotland A to review studies involving AWI, leading to delays for researchers. Indeed, one of the chief challenges for Scotland A is that it is the only Committee which is able to review AWI studies, leading to a lack of Scotland-wide operational flexibility and potential delays. The stipulations of Scottish AWI legislation are also far more restrictive regarding, for example, Committee quoracy, than those which govern other Committees, again leading to operational difficulties and associated delays for researchers.

1. **Social Care Research**

Since the publication of the UK Framework for Health and Social Care Research in 2017 there has been debate as to any requirements the inclusion of social care has on the NHS research ethics service. Scotland has not had a specific ethics committee in place to review social care based projects and work is ongoing to scope out whether there is a requirement for such an ethics committee or whether some small adjustments to the system already in place will be adequate to cover any identified gaps. It is currently unknown how many social care research projects are ongoing and whether these projects are being appropriately reviewed for ethical and governance considerations. This may be through University processes and ethics committees or the equivalent within local councils. Work ongoing across the CSO and NRS will hope to identify if there is a need and is also looking at models already in place in Northern Ireland.

1. **Membership and Recruitment**

Member recruitment is usually achieved through advertising and calls for applications via health board internal and external websites, patient and staff newsletters, posters placed in wards, staff areas, GP practices, other NHS services and clinics, local libraries and via email distribution through local and national volunteering organisations and other relevant sources. Some REC services additionally undertake face-to-face promotion and engagement in staff and patient areas. Member recruitment may also occur through word of mouth recommendation from current or past members. Recruitment is via written application, references are required and members are interviewed prior to appointment. As part of this recruitment process, applicants are strongly advised to attend and observe a REC meeting to get a clear idea of the type of work involved. During the recruitment process, applicants are informed of workload expectations and are advised to discuss their application with their line manager (expert and other working members) prior to submission.

The recruitment of expert REC members in particular has become increasingly challenging, with the number of expressions of interest from prospective applicants versus the number of submitted applications growing progressively disproportionate. Prospective applicants who have subsequently decided against applying cited workload, time commitment required and lack of manager support as primary reasons against application.

Additionally, retention of existing expert members is proving more challenging. REC workload requires reading several applications a month for both full and proportionate review meetings in addition to documentation pertaining to amendments, safety reports, breaches and other sub-committee work. Most applications consist of a lengthy protocol (for CTIMPs this can run to hundreds of pages) of varying complexity depending on study type and several appendices (participant materials, brochures etc.). Expert members have reported that the time required for REC work comprises one or two full working days or several evenings a week, placing significant strain on both clinical and other work commitments and family life. Attending training days and maintaining mandatory online training can be problematic for expert members given that this requires additional time away from clinical work and because they are also required by their health boards to complete mandatory online training as part of their daily role. Expert members have also reported that the requirement to work to REC deadlines (e.g. with regards to submission of Lead Reviewer forms and other responses) can leave them feeling pressured and in some cases has not been feasible or achievable. In 2019, there have been a number of resignations from Pharmacist members with most citing withdrawal of support from line managers and colleagues, lack of capacity to work to REC deadlines and impact of workload on family and childcare commitments as reasons for resignation. As reviews of CTIMPs require the involvement of a qualified Pharmacist, it is imperative that measures are taken to encourage these professionals to undertake and continue to engage in REC work.

Expert members also stated that support from NHS and clinical line managers had diminished significantly over time or had been withdrawn, leaving members increasingly reliant on the goodwill of clinical colleagues to cover absences and clinical workload to allow for attendance at meetings and the conduct of other REC work. Members believe that poor understanding of and lack of value for REC work among NHS management and clinical line managers in addition to increasing pressures on NHS staff resources as core factors in the lack of support for clinical staff to engage in REC work even for those employed in teaching hospitals with strong links to research. Expert members also report lack of recognition or merit for undertaking REC work as problematic both in terms of maintaining motivation to continue membership and with regards to recommending REC membership to colleagues.

REC recruitment and retention creates challenges for REC staff. Expert members are prone to cancel with short notice due to clinical commitments requiring REC staff to co-opt members from an alternative committee on occasion from committees out with the region to maintain quoracy. This can place significant pressure on REC Managers, most of whom are juggling increasing workloads and some who are additionally undertaking new types of work (e.g. CWOW reviews). Inquorate meetings require an additional meeting to issue a decision placing yet more pressure on expert members to find this time. REC staff can feel uncomfortable and frustrated with chasing expert members for responses, especially as most are aware of the challenges faced by experts, but feel compelled to do so to meet HRA deadline requirements. REC member recruitment is a time- and labour-intensive activity not just in regards to appointment but also to induction, training and providing support to new members. Changing membership can unsettle and destabilise Committees and it also makes succession planning for Chairs and Vice Chairs extremely difficult therefore REC staff strive to appoint candidates that are likely to stay in post long-term.

Expert members strongly advise that remedial measures are required to promote the value of REC work and incentivise other clinical colleagues to engage in this activity. Some believe that formal recognition or merit would suffice whilst others suggest that formal negotiation of clinical time at senior management level would be required. Pharmacist members recommend relaxation of membership SOPs to allow two deputies for each full Pharmacy member therefore allowing for distribution of workload. Further discussion and consideration of measures to address these issues is essential and urgent. Without expert members, NHS RECs cannot continue to operate.

# Summary

Overall the Ethics Service in Scotland has had a successful year with numbers of reviews remaining at the level of previous years and meeting all of our timelines and KPIs for Full, PR and amendment reviews. The major issues are those facing us in the future and these have been discussed in Section 7. It is clear that 2019 to 2020 will see a lot of change and new challenges and it is important that we work together as a unit within Scotland to ensure that the excellent service we have provided up to now is maintained. Further horizon scanning brings up the issues of large data driven studies and new innovation work within the NHS particularly with the increased interest and use of Artificial Intelligence in diagnostic practice. Study design is also changing with precision medicine meaning that there are often many different arms and stages to a study and these may significantly change over the lifetime of the study which makes them far more complex to understand and review. How we can ensure that appropriate and robust review is in place will be a challenge as the pace of change in study design is accelerating quickly.