Research Ethics Service for Scotland
Summary Annual Report

covering April 2021 – March 2024

Purpose of this combined annual report

This combined annual report covers the previous 3 years of work carried out by NHS Research Ethics Committees 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. GAfREC*** *(Governance Arrangements for Research Ethics Committees v2.1 July 2021)*

The Ethics 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 achievements and challenges that the service has faced over the past 3 years and what new challenges face the service going forward.

Standard Operating Procedures are agreed at a UK national level under the Health Research Authority and our remit and function is described in, 'Governance Arrangements for Research Ethics Committees, a UK policy document last updated in July 2021. (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/)

1. Introduction

The NHS Research Ethics Service in Scotland runs 12 research ethics committees (RECs) which are based across 4 regional centres. North of Scotland is run from NHS Grampian (2 RECs), East of Scotland from NHS Tayside (2 RECs), South East Scotland from NHS Lothian (4 RECs) and West of Scotland from NHS Greater Glasgow & Clyde (4 RECs).

The service is staffed by a Scientific Officer in each centre and REC Managers and Assistants who are all Health Board employees. The membership of each committee contains a mixture of both lay and expert members.

Please note that Scotland A REC (based in NHS Lothian) is split into 2 entities: Scotland A REC deals only with adults with incapacity (AWI) research applications and Scotland B REC deals with all other types of research applications. Essentially this is the same committee but working under two different governance structures. However, these two entities are counted as 2 RECs for the purposes of this report.

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.

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 4 Recognised RECs (including both Scotland A and Scotland B RECs) and the remaining 8 are classed as Authorised RECs. In addition, many of the RECs have flagged status which denotes a specific expertise and/or training that allows the REC to review specific types of research applications. Some of these are mandatory such as the (AWI) flag for Scotland A REC and others are recommendations only (**Table 1**).

The workload of the RECs is made up of a number of different work streams, the full Committee Meeting, the Proportionate Review Sub Committee Meetings, and the Sub Committee Meetings that review Amendments and responses from Applicants to Opinions given by the Committee.

Table 1: Committee Status and Flags in Scotland

REC	CTIMPs Phase I (1st in man)	CTIMPs Patients (not 1st in man)	Flags
East of Scotland REC 1			Research Tissue Banks, Qualitative, Prisons
East of Scotland REC 2		Yes	IRB registered, Paediatrics, CTIMPs, Prisons
North of Scotland REC 1		Yes	Children, Medical Devices, CTIMPs, Prisons
North of Scotland REC 2			Research Tissue Banks & Research Databases, IRB registered, Qualitative, Paediatrics, Prisons
Scotland A REC		Yes*	Adults with Incapacity (*and CTIMPs ONLY where there is AWI and the CI is professionally based in Scotland), Prisons
Scotland B REC	Yes		IRB registered, Gene Therapy, CTIMPS, Phase I CTIMPs(HV), Prisons
South East Scotland REC 1			Prisons
South East Scotland REC 2			Medical Devices, Prisons
West of Scotland REC 1	Patients only	Yes	IRB registered, Phase 1 CTIMPs (patients) CTIMPs, Paediatrics, Prisons
West of Scotland REC 3			Qualitative, Prisons
West of Scotland REC 4			Research Tissue Banks, Research Databases, Medical Devices, Paediatrics, Prisons
West of Scotland REC 5			Paediatrics, Prisons

2. Membership

The membership of each committee is composed of volunteers. The composition of the Committee has to include Expert Members and Lay Members. The definition of both member types can be found in the Clinical Trials Regulations and Governance Arrangements for Ethics Committees. Together the members provide a broad range of experience and expertise to give a balanced and independent review of a research study. Including the scientific value, ethical issues and protecting the dignity, rights, safety and well-being of all research participants.

Each Committee has up to 18 members, and at least one third of this membership must be lay and half of these should be Lay Plus members (for Recognised Committees) who have no background experience of clinical research and have never been a healthcare professional. **Table 2** provides an overview of the Committee Membership across Scotland in May 2024.

For a research ethics committee meeting 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.

To ensure that members retain and expand their knowledge, they 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.

The Scotland A REC has its own distinct membership and quoracy requirements, which are outlined in the Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002.

Table 2: Membership summary of Scottish ethics committees (May 2024)

REC	Total number	Expert	Lay
East of Scotland REC 1	15	8	7
East of Scotland REC 2	14	7	7
North of Scotland REC 1	14	5	9
North of Scotland REC 2	17	9	8
Scotland A/B REC	16	6	10
South East Scotland REC 1	14	7	7
South East Scotland REC 2	13	4	9
West of Scotland REC 1	16	10	6
West of Scotland REC 3	17	11	6
West of Scotland REC 4	16	10	6
West of Scotland REC 5	13	8	5

2.1 Membership Training & Development

Committee members as part of their terms and conditions of appointment are required to attend at least the equivalent of one day (approx. 5 hrs) of relevant training in each annual reporting period. Newly appointed members are expected to complete Induction Training. They must also complete Equality & Diversity (E&D) training. The training is recorded as credits which are accepted by a number of the Royal Colleges as the equivalent of CPD (Continued Professional Development)

points with 2 credits equating to 1 CPD point. This has been a useful arrangement for many of our expert members.

REC committee members can attend a range of training sessions delivered through a number of providers including the Health Research Authority, Scottish NHS Ethics Service, National Research Scotland, Universities and the MRC Regulatory Centre. Some of the Scottish regions run a face to face Annual Training Day which is generally popular with the members. Members are also encouraged to record their own relevant training through self-directed learning.

3. Investigator Training and Support delivered by the Ethics Service

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

Scientific Officers also 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 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.

4. Applications assigned to Full Research Ethics Committee during the reporting period

Research applications can be reviewed at full committee or sub-committee if they are suitable for proportionate review (PR). An assessment of the ethical risk of the

application is completed via an electronic triage through a series of booking questions when the Investigator submits their application. Where applications require full committee review, Investigators are given the choice of Committee they would like to go to. In the past this would often align with where the Chief Investigator was located, however now that REC meetings are virtual and the Investigator team can attend the meeting virtually then the majority of applicants will go to the first suitable meeting available to them across the UK. The number of studies reviewed is generally dictated by the local ethics service who will make slots available to be booked. Occasionally not all slots are booked across the UK and at the end of 2023 we did see a number of slots not taken up and this may be partially reflected on the slightly lower numbers for 23/24 when compared to the previous year (**Table 3**). **Table 3** shows the number and distribution of study types reviewed in Scotland during the 3 annual report years.

Table 3: Applications reviewed in Scotland at Full REC by study type (1st April -31st March)

Study Type	21-22	22-23	23-24
Clinical Trial of Investigational Medicinal Product	38	31	42
Clinical investigation or other study of a medical device	43	51	44
Basic science study involving procedures with human participants	74	68	63
Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice	55	58	58
Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology	45	57	44
Study involving qualitative methods only	36	42	50
Study limited to working with data (specific project only)	13	18	14
Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)	9	27	10
Others	3	6	5
Research Database	13	11	7
Research Tissue Bank	9	7	3
Total	339	379	341

Table 4 shows the numbers of studies in some specific areas for annual report year 23/24. The table shows the figures for the UK as a whole and Scotland only reviews for comparison. This is not reflective of research in Scotland as the reviews are not necessarily located in the same nation as they are reviewed, with the exception of AWI research and prison based research.

Table 4: Applications for full ethical review proportion in specialist areas (1st April 2023 to 31st March 2024)

Study Area	UK	UK %	Scotland	Scotland %
All Full Reviews	3034		341	
Commercially Sponsored Studies	937	31%	64	19%
Paediatric Studies	497	16%	47	14%
Adults Unable to Consent	232	8%	22	6%
Prisoner	29	1%	4	1%

Table 5 shows the total number of Clinical Trials of Investigational Medicinal Products (CTIMPs) reviewed in Scotland and the UK. These studies can only be reviewed by a Recognised Committee of which we now have four within Scotland. Scotland B REC is quite restricted in the numbers of CTIMPs it is able to review due to the members also covering Scotland A REC work. There are also numbers supplied for some specialist CTIMP studies including the commercial sector.

Table 5: CTIMP applications for full ethical review proportion in specialist area (1st April 2023 to 31st March 2024)

	UK	UK %	Scotland	Scotland %
CTIMP Reviews only	838		43	
Commercial CTIMP Studies	702	84%	31	72%
Phase I (Healthy Vol)	107	13%	0	0%
Adults Unable to Consent CTIMPs	31	4%	4	9%
Gene therapy	47	6%	0	0%

4.1 Ethical Review Outcomes

The opinions given at full REC meetings are summarised in **Table 6**. Favourable Opinions can involve some conditions of approval but no further ethical review of the application is required. The majority of applications are given a provisional opinion which requires the applicant to respond with further information or clarifications. 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. The numbers of unfavourable opinions are generally quite small across Scotland and the UK. An unfavourable opinion means that the research application cannot proceed through the approval system, however Investigators are clearly told what the ethical issues are and can then reapply with an updated application. There is also an appeal mechanism in place for researchers who feel they have been wrongly issued an unfavourable opinion.

Table 6: Opinions given at full meetings (1st April 2023 to 31st March 2024)

Opinion	UK applications	UK %	Scotland applications	Scotland %
Favourable Opinion (+ or – Additional Conditions)	614	20%	74	22%
Provisional Opinion	2315	76%	248	73%
Unfavourable Opinion	104	3%	17	5%
Total	**3033**		**339**	

Timelines for ethical review are closely monitored and reported on. Full applications are required to be reviewed within a target of 60 days. In the annual reporting period 2023/24, 99% of all Full REC reviews in Scotland were within target. Of the 4 studies outside of target 3 of these were due to issues outside of REC control. The target time for Proportionate review is 21 days and this was attained for 90% of studies with an average review time of 13.1 days. Although numbers of PR reviews are relatively small in Scotland our timelines are relatively good averaging 13.1 days against a UK average of 23.6 days (Table 7).

Table 7: Review times for Scotland and UK reviews (1st April 2023 to 31st March 2024)

	No of Studies Reviewed with outcome in 2023/24	Average Review Time in days	% Reviews within target
Full Review Scotland	335	26.7	99
PR Review Scotland	41	13.1	90
CTIMP only Scotland	41	35.4	93
Full Review UK	2966	31.3	98
PR Review UK	953	23.6	58
CTIMP Review UK	816	34	97

5. Applications assigned to Proportionate Review subcommittee meetings during the reporting period

Applications are electronically assigned to Proportionate Review (PR) following a number of questions the applicant completes. PR applications are always assigned to the first available REC in the UK, although further triage by ethics staff is often required to ensure the appropriate applications go to PR Review. As a result, approximately 50% of applications are triaged out of PR and promoted to Full Review. This can cause delays for the Investigator and additional work for ethics staff.

Table 8 shows the numbers and types of PR applications reviewed in Scotland over the previous 3 years. Complex clinical trials are not suitable for PR and therefore the categories include only certain study types. Numbers are generally dictated by slots made available by the staff and studies deemed suitable for PR by the ethics staff and not generally indicative of the numbers of applications in the system.

Table 8: Scottish Proportionate Review Applications by year

Type of study	21-22	22-23	23-24
Basic science study involving procedures with human participants	13	4	6
Clinical investigation or other study of a CE marked medical device	0	0	1
Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice	0	1	0
Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology	16	8	7
Study involving qualitative methods only	3	5	13
Study limited to working with data (specific project only)	7	9	5
Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)	14	9	8
Other	0	0	1
Total	**53**	**36**	**41**

In **Table 9** we can see the decisions given at first review and as you would expect there are a higher percentage of PR studies gaining a Favourable Opinion at this stage than the more complex studies getting Full committee review. However, this is not reflected in the UK figures which may be due to higher levels of triage in Scotland.

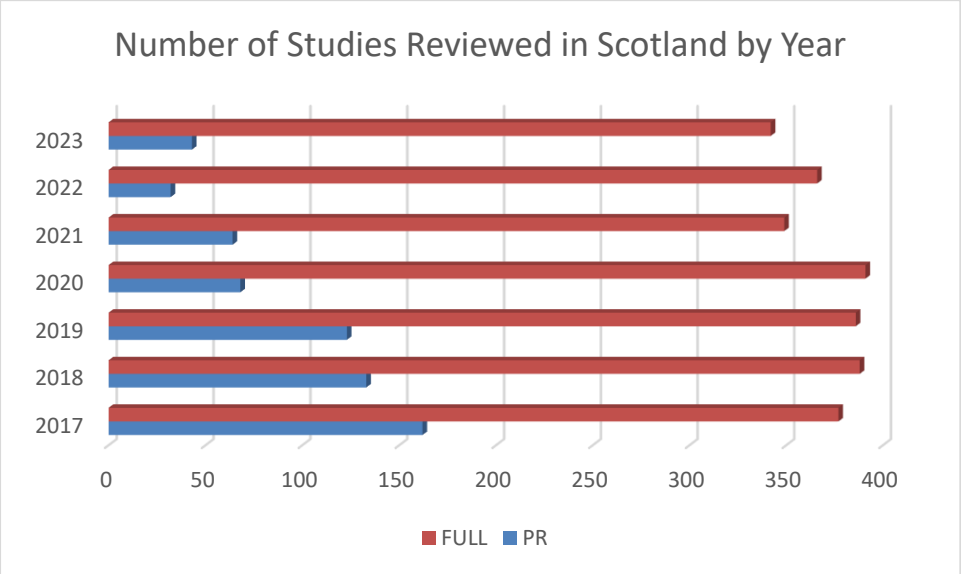
Table 9: Decision at 1st meeting for PR applications (1st April 2023-31st March 2024)

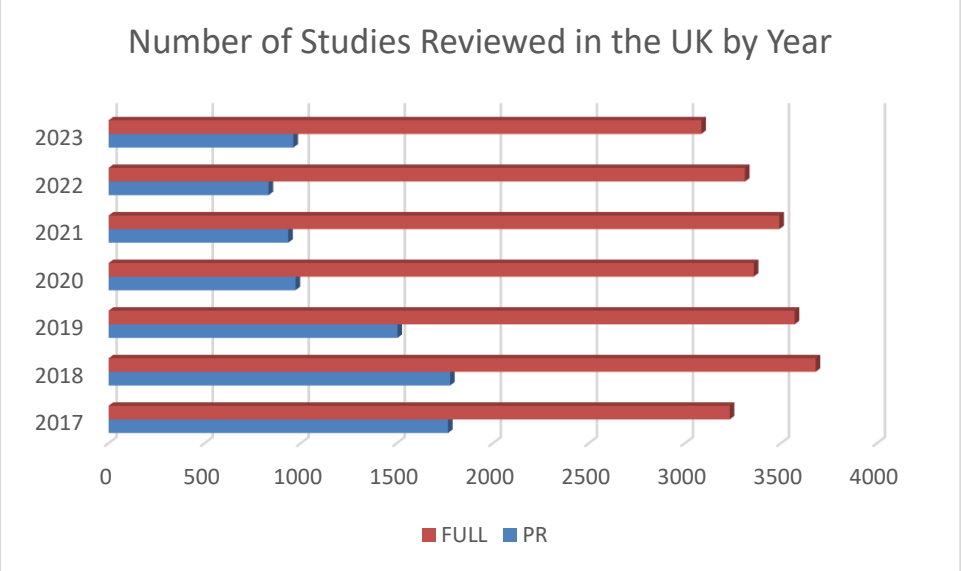
Opinion	UK applications	UK %	Scotland applications	Scotland %
Favourable Opinion (+ or – Additional Conditions)	308	32%	25	61%
Provisional Opinion	579	60%	10	24%
No Opinion - Refer to Full Committee	67	7%	5	12%
Unfavourable Opinion	13	1%	1	2%
Total	968		41	

The Sub Committees that review the PR applications are generally held in between the monthly full REC meetings. These subcommittees consist of three to four members who communicate via secure email and the HRA Assessment Review Portal (HARP) . 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 approval time for a project.

In Figures 1 & 2 below we can see the total number of applications reviewed in Scotland and in the UK over a 7 year period. This includes the change in practice from face to face meetings to virtual meetings which took place when COVID took hold in 2020.

Fig.1&2 Ethical Reviews by Scottish & UK RECs





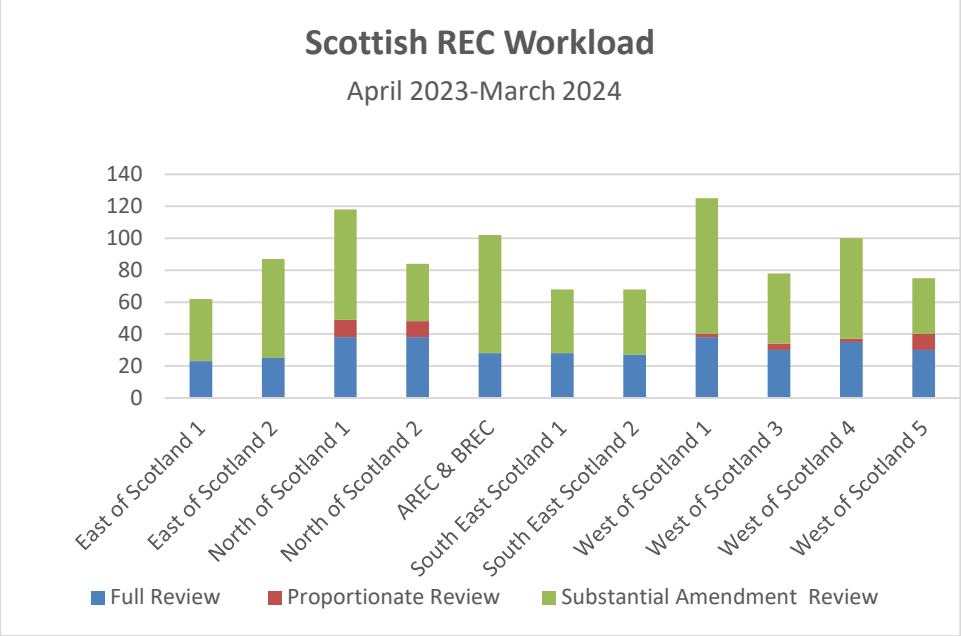
6. Subcommittee work (Substantial Amendments, Breaches, Safety Reports)

A large part of the ethics service work deals with substantial amendments to ongoing studies. An amendment is defined as a change made to a research study after

approval has been given. The categorisation of the amendments determine if they are to be reviewed by a subcommittee of the main REC. This categorisation is confirmed by the Sponsor of the Study. Substantial amendments include, changes to the design or methodology of the study, to procedures undertaken by the participants and can include anything that may have a significant impact on the safety, physical or mental integrity of the participants or to the risk/benefit assessment of the study.

These are dealt with via subcommittees of the main REC along with other business such as replies to Provisional Opinion, safety reports and breaches which creates substantial extra work for REC members. **Figure 3** gives an indication of the work done on a per REC basis. As you will see the Recognised RECs deal with more Substantial Amendments due to the complex nature of Clinical Trials.

Fig.3 Scottish REC Workloads



7. HRA Quality Assurance Audit

A Quality Assurance audit is undertaken by the Health Research Authority (HRA) QA Department for all RECS in the UK. This ensures that UK RECs are operating to the required standard. Currently all of the Scottish RECs hold full accreditation.

The HRA also request user feedback from applicants and this includes written comments on their experience of the REC. The overall return rate is quite low at

around 20% and most remain anonymous. Where applicants do make themselves known the feedback is directed back to the service.

Here are some of the comments received that can be attributed to Scottish RECs over the previous annual report period.

- *Incredibly helpful and courteous service (WoSRES REC 4)*
- *Communication was clear, suggestions were understandable, and straightforward to respond to (Scotland A REC).*
- *Very professional and to the point discussion (EoSRES 1).*
- *Chair was warm and approachable. Questions were reasonable and explained. The panel showed a genuine interest in the research and seemed pleased to talk to us (SEoSRES 2).*
- *Excellent, clear and very quick (NoSRES REC 1)*

8. Current Challenges, Issues and Developments for the Scottish NHS Research Ethics Service

8.1 Membership

Recruitment of voluntary REC members remains challenging for several categories of membership, particularly lay plus, those with no experience of health care research, and expert members who are health care professionals, such as doctors, dentists, nurses etc. The former may be due to a lack of knowledge of the research ethics service and the latter due to increased time pressures, commitments within the health service and difficulty in arranging protected time to attend the REC meetings. These challenges will be influenced by the revised Clinical Trials Regulations, anticipated implementation early 2026, following a 12-month introductory period.

The revised regulations will have the largest impact on REC member classification and REC constitution. Member classification is anticipated to change from the current three designations Lay, Lay Plus and Expert member, to five designations, REC member, Health & Social Care (HSC), Research, Ethics and Lay member. While quoracy requirements will change from the current Officer, Expert and Lay/Lay Plus member to requiring an Officer, HSC member and Lay member. However, fewer REC members will fit into the new HSC and Lay member categories, categories which will be required for full meeting quoracy and are currently challenging member groups to recruit.

To meet the ongoing challenge of recruiting Expert and Lay Plus members, while ensuring that the Scottish REC service is prepared for the implementation of the revised Clinical Trials regulations, the Scottish REC service must:

- Implement strategies to raise awareness of the REC system with the public.
- Request that supporting Health Boards facilitate, where possible, designated time for HSC members to attend REC meetings.
- Proactive forward planned recruitment, to gradually increase the number of Registered HSC members and Lay Plus members currently on Committees.

Our members generally find their time on the REC to be rewarding and productive. Members review a wide range of applications and study types, and research active members in particular find it beneficial in informing their own studies.

8.2 Record on Accreditation & Timelines

Accreditation

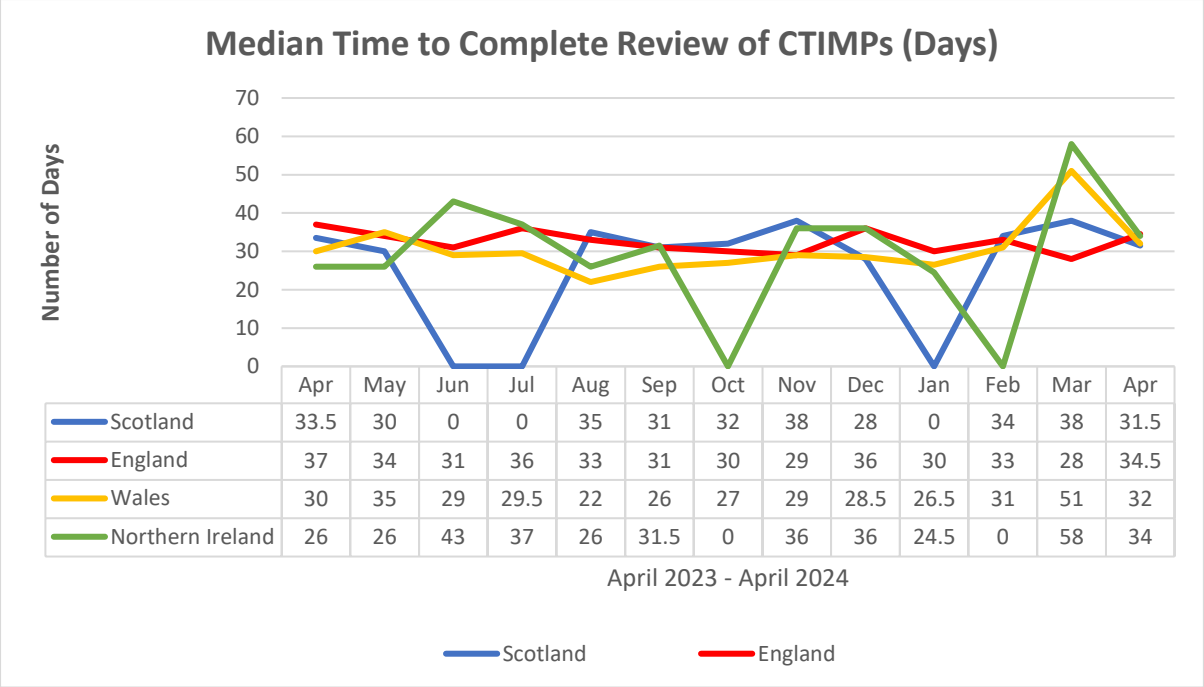
Scottish Research Ethics Committees (RECs) provide a nationwide service and adhere to the Standard Operating Procedures (SOPs) and the Governance Arrangements for Research Ethics Committees (GAfREC). To ensure consistency across the UK, all RECs undergo an accreditation process, which was established in 2007 to audit RECs against the above standards. This involves the Quality Assurance Department of the HRA scrutinising the daily operations of the Committees to ensure compliance. All Scottish RECs have successfully passed this accreditation, with credit going to the staff within each Ethics Region for ensuring high standards are maintained across the service.

Timelines

Scotland has always tried to achieve Ethical Approval for all studies under 30 days. The Clinical Trials Regulations states that Ethics Committees have 60 days to approve applications and this also applies to non-Clinical Trial Studies.

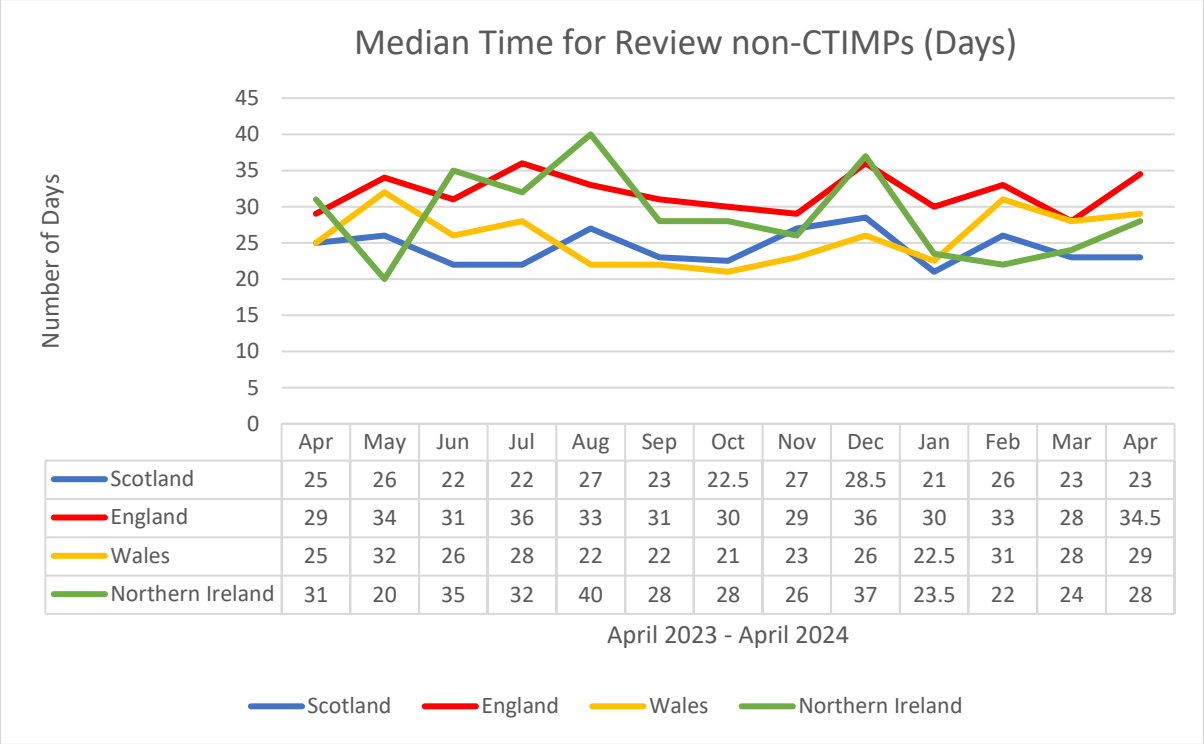
Proportionate Review applications are applications that have no material ethical issues and therefore require less time for review, these applications should be reviewed within 21 days.

The Graphs below show the median timelines for approval of applications to the Ethics Committees across the United Kingdom for Clinical Trials of Investigational Medicinal Products (CTIMPs), non-CTIMPs and PR applications. From April 2023 – April 2024.

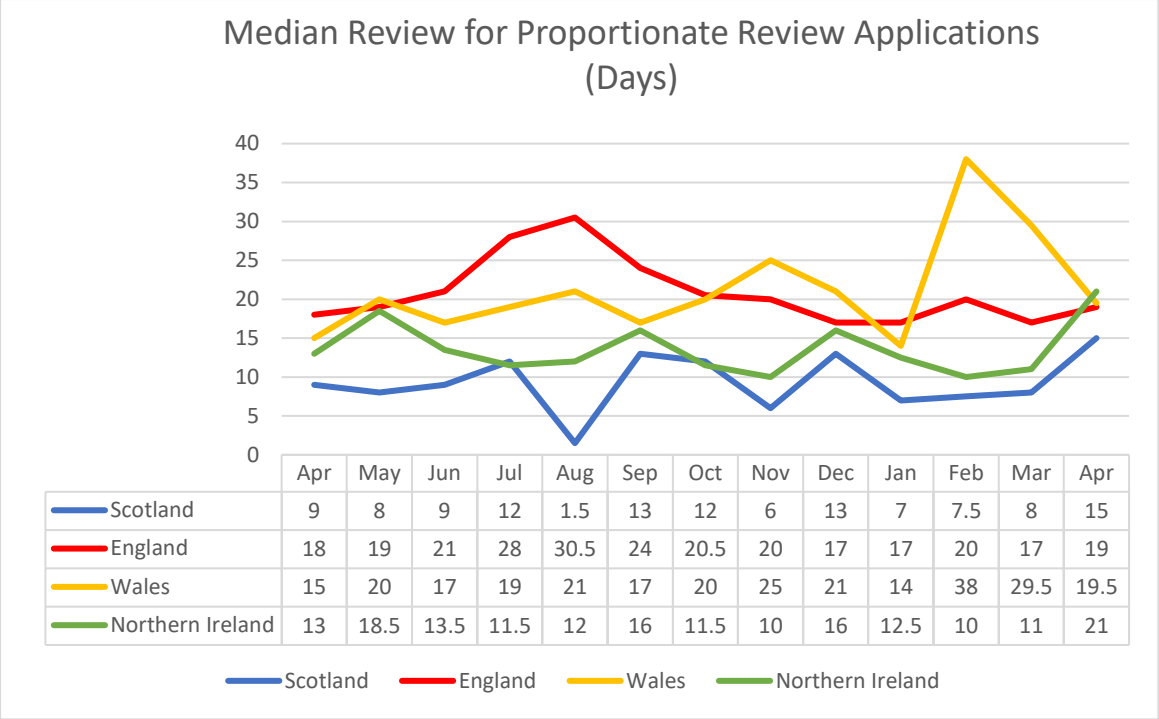


	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Scotland	33.5	30	0	0	35	31	32	38	28	0	34	38	31.5
England	37	34	31	36	33	31	30	29	36	30	33	28	34.5
Wales	30	35	29	29.5	22	26	27	29	28.5	26.5	31	51	32
Northern Ireland	26	26	43	37	26	31.5	0	36	36	24.5	0	58	34

NB: The data points for Scotland in June & July were due to a technical error in the system.



	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Scotland	25	26	22	22	27	23	22.5	27	28.5	21	26	23	23
England	29	34	31	36	33	31	30	29	36	30	33	28	34.5
Wales	25	32	26	28	22	22	21	23	26	22.5	31	28	29
Northern Ireland	31	20	35	32	40	28	28	26	37	23.5	22	24	28



	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Scotland	9	8	9	12	1.5	13	12	6	13	7	7.5	8	15
England	18	19	21	28	30.5	24	20.5	20	17	17	20	17	19
Wales	15	20	17	19	21	17	20	25	21	14	38	29.5	19.5
Northern Ireland	13	18.5	13.5	11.5	12	16	11.5	10	16	12.5	10	11	21

In summary, the high standards maintained by the Ethics Teams and the diligence of the Ethics Committees are key factors contributing to the nation consistently achieving its timelines.

8.3 Quality Standards

The Quality Standards were introduced in September 2023 and became a mandatory requirement in December 2023. The Quality Standards followed an initiative by the HRA called, “Think Ethics” which concluded early in 2023 with the, “Quality Standards” and the, “Design and Review Principles” emerging from this.

The purpose of these documents is to develop better quality participant information, created with meaningful public involvement which should result in more efficient and inclusive participant recruitment and retention. This also gives RECs clear criteria on how they should review participant information to ensure consistency across RECs and increase the possibility of a favourable opinion.

Scottish RECs have found the clear criteria very useful and all applications are now expected to have appropriate public and patient involvement in place. In general, we have seen a much improved uptake of public and patient involvement in the planning and review of research applications which has been well received by our ethics committees.

8.4 Combined Review

The regulatory (MHRA) review and ethics review are now carried out in parallel and a single decision is issued to the study Investigator. This year the MHRA launched a revised notification scheme for low-risk clinical trials, where checks of the trial criteria for low-risk studies are made without a regulatory assessment. This is all part of further streamlining the approval of clinical trials in line with the O'Shaughnessy Review (May 2023). This has meant that clinical trials are now being reviewed by the regulator within the required timelines and has allowed the overall Combined Review to be completed within the required 60 days.

8.5 Combining Ethics & Governance Review (Future Challenge)

The HRA have a combined governance and ethical review process for all English and Welsh clinical research studies. This covers all types of NHS clinical research and has been put in place to help streamline the review process for research applicants and sponsors.. A similar combined process is being planned for Scotland which should introduce some advantages of efficiency and timing of the overall approval process. It will also be a requirement of a new integrated application system which is currently under development and expected to be fully up and running by 2026. NHS Research Scotland are currently looking at how the combined ethics and governance process can be achieved within our current structures across Scotland, which may lead to future structural change so that we can align with HRA processes.

8.6 AWI Reforms and Social Care Research (Future Challenge)

When the Adults with Incapacity (Scotland) Act 2000 was introduced, it was regarded as a ground-breaking piece of legislation. For the first time, Scotland had a comprehensive regime to protect the welfare and rights of people lacking capacity. Now with 25 years' experience in operating the legislation, and recognising ongoing developments in international human rights law, it is important that Scotland's law remains fully fit for purpose. The Chief Scientist Office (CSO) within the Scottish Government has been working with stakeholders including researchers, service users and Scientific Officers to explore what changes need to be made to legislation to ensure that it remains workable and continues to protect the rights and dignity of adults unable to consent for themselves. In July 2024 a consultation on proposed

legislative changes was published. This consultation was supported by outreach work led by CSO, including webinars to explain the background to the proposed changes and provide the research community with an additional opportunity to provide suggestions and feedback to these proposals.

The most pertinent part of this consultation for the ethics service and wider research community was Part 8, which contained proposals aiming to modernise and update how the AWI Act supports incapacitated adults to participate in research. In summary, the proposed changes were as follows:

- Establishing more than one ethics committee that is capable of reviewing research proposals involving incapacitated adults in Scotland.
- Permitting adults with incapacity to be included in research studies without consent for those types of studies where consent is already not required from adults with capacity.
- Affording adults with incapacity the opportunity to participate in research studies that investigate conditions other than those responsible for their incapacity.
- Permitting waivers of consent to be applied in emergency situations to involve adults with incapacity in research in cases where it is not reasonably practical or feasible to seek consent from the individual's guardian, welfare attorney or nearest relative.
- Expanding the list of individuals permitted to provide consent for adults with incapacity to take part in research.

Responses to this consultation has helped bolster the evidence base the Scottish Government will use to support legislative reform in the future. The consultation analysis was published in January 2025 and is available to read here.

The original legislation and resulting statutory instruments allows for only one ethics committee to review AWI studies in Scotland. Issues heard from the research community indicate that this provision reduces service resilience and prevents the right of appeal for researchers. Whilst allowing more than one committee should help to mitigate these factors, any potential challenges for the ethics service that this change should introduce, such as consistency of review between committees and member training, should be properly considered.

The proposed changes found in the consultation would also remove some inconsistencies between different types of study. For example, there are some studies which can only take place in Scotland if they are classed as a Clinical Trial (CTIMP), as at present waivers of consent and consent by a professional can only be used in such studies in Scotland. There are also currently some studies which can take place in England, Wales or Northern Ireland that cannot take place in Scotland. This leads to the arguably inequitable situation whereby potential Scottish participants are unable to take part in a study which would be possible elsewhere in

the UK, and also that Scottish patients in general are potentially benefitting from treatments developed in studies in which Scottish participants lacking capacity could not have taken part.

It is also possible that the way that adult social care research is reviewed may change in Scotland. Recent changes to the ethical review process in England and Wales means that Scottish RECs may receive such applications from England and Wales and it is important that the committees have sufficient expertise and training to review such studies. In England and Wales there are currently three committees which are flagged to review social care research, and, whilst there is no formal requirement for specific expertise on these committees, it is considered good practice to have at least 2-3 members per committee with the relevant expertise. The proposed changes to REC membership categorisation outlined above should help to clarify membership and identify potential gaps in expertise. Whether any Scottish RECs will also seek social care flags (and if so, how many of them) is currently under consideration.

There is some overlap between social care research and that involving adults lacking capacity - for example, social care research conducted in care homes might involve those currently unable to consent for themselves due to conditions such as dementia. Given an ageing population and, potentially, a shift towards enabling those without capacity to participate in research, there is the potential for an increase in these types of study coming for review by Scottish RECs.

9. Summary & Conclusions

The Scottish Research Ethics Service has continued to deliver a first class service to the research community over the last three years and we are pleased to report that our membership levels remain healthy with a small but steady turnover of members throughout the year. Currently there are more than 175 members serving across the 12 research ethics committees in Scotland. As ever we are indebted to our volunteer workforce who give us a huge amount of time and dedication for the benefit of patients and clinical research. We are also fortunate to have a skilled and dedicated workforce that juggle the difficult job of managing Investigators, research applications and their committee members to ensure applications are efficiently and professionally dealt with throughout their approval journey.

There have been some challenges bringing in the new Quality Standards but they are already fully embedded in our system. We continue to work closely with the Chief Scientist Office and the HRA to ensure that all the new developments which

are taking place along the clinical research approval pathway are able to function efficiently within our Scottish service. The system is continually developing and changing and it is important that we, as a Scottish ethics service, are able to contribute to and help shape its future development.

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