Research Ethics Service

Annual Report for Scotland

April 2017 – March 2018

## 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.

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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.

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 3 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 three 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 |
| [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 | Yes | IRB registered, Gene Therapy, CTIMPS, Phase I CTIMPs(HV), Adults with Incapacity |
| [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 well being 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 health care 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 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/) | 13 | 8 | 5 | 2 |
| [North of Scotland REC 1](http://www.hra.nhs.uk/news/rec/north-scotland-research-ethics-committee-1/) | 15 | 8 | 7 | 5 |
| [North of Scotland REC 2](http://www.hra.nhs.uk/news/rec/north-scotland-research-ethics-committee-2/) | 17 | 9 | 8 | 5 |
| [Scotland A R](http://www.hra.nhs.uk/news/rec/scotland-research-ethics-committee/)EC | 19 | 10 | 9 | 2 |
| [South East Scotland REC 1](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-1/) | 14 | 7 | 7 | 3 |
| [South East Scotland REC 2](http://www.hra.nhs.uk/news/rec/south-east-scotland-research-ethics-committee-2/) | 15 | 7 | 8 | 3 |
| [West of Scotland REC 1](http://www.hra.nhs.uk/news/rec/west-scotland-rec-1/) | 15 | 9 | 6 | 4 |
| [West of Scotland REC 3](http://www.hra.nhs.uk/news/rec/west-scotland-rec-3/) | 16 | 10 | 6 | 4 |
| [West of Scotland REC 4](http://www.hra.nhs.uk/news/rec/west-scotland-rec-4/) | 18 | 12 | 6 | 4 |
| West of Scotland REC 5 | 15 | 7 | 8 | 5 |

Numbers shown in brackets indicate deputy members.

# 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 |
| 14/09/17 | Glasgow | UK wide REC members (mainly Scotland based) | Chairs Training Day | HRA | 20 | NHS GG&C |
| 6/10/17 | Glasgow | West of Scotland REC members ( available to other Scottish members on request) | Annual Ethics Members Training Day | WoSRES | 65 | NHS GG&C |
| 25/05/17 | Edinburgh | Open to Scottish REC members and all Investigators | Informed Consent: Legal & Ethical Issues in Consent (Adults) | WTCRF | 10 | Cost covered by relevant HB |
| 15/09/17 | Edinburgh | Open to Scottish REC members and all Investigators | Consent: Can we do it better | WTCRF | 10 | Cost covered by relevant HB |
| 6/09/17 | Edinburgh | Open to Scottish REC members and all Investigators | Helping you submit a successful REC application | WTCRF | 10 | Cost covered by relevant HB |
| 05/06/17 | Dundee | UK wide REC members (mainly Scotland based) | Training - Committee Members Induction | HRA | 23 | HRA |
| 20/06/17 | Aberdeen | North of Scotland REC members (available to other Scottish members on request) | Annual Ethics Members Training Day | NoSRES | 23 | NHSG |
| 17/11/17 | Dundee | East of Scotland REC members | Various presentations:  Informed Consent (Mild dementia patients); Basic statistics; Tayside Biorepository; participant experience in research | EoSRES | 34 | EoSRES |
| 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 researcher 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 Full or 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 2017 and March 2018, 370 studies were reviewed at full REC meetings across Scotland and the distribution of study type is given in (Table 4). 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 genetherapy (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 the three within Scotland.

The opinions given at first meeting are summarised in (Table 7), the majority of provisional opinions given at the first meeting were converted to favourable opinions after researchers respond 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 26 days (Table 8).

**Table 4: Applications for full ethical review by study type** (1st April 2017 to 31st March 2018)

|  |  |  |
| --- | --- | --- |
| **Study Type** | **UK Applications Reviewed** | **Scotland Applications Reviewed** |
| **Clinical Trial of Investigational Medicinal Product** | 962 | 42 |
| **Clinical investigation or other study of a medical device** | 295 | 30 |
| **Basic science study involving procedures with human participants** | 556 | 66 |
| **Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice** | 602 | 83 |
| **Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology** | 499 | 57 |
| **Study involving qualitative methods only** | 423 | 39 |
| **Study limited to working with data (specific project only)** | 109 | 14 |
| **Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)** | 84 | 10 |
| **Others** | 66 | 8 |
| **Research Database** | 84 | 13 |
| **Research Tissue Bank** | 53 | 9 |
| **Total** | 3744 | 370 |

**Table 5: Applications for full ethical review proportion in specialist area** (1st April 2017 to 31st March 2018)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study Area** | **UK** | **UK %** | **Scotland** | **Scotland %** |
| **All Full Reviews** | 3744 |  | 370 |  |
| **Commercial Studies** | 963 | 26% | 47 | 13% |
| **Paediatric Studies** | 592 | 16% | 53 | 14% |
| **Adults Unable to Consent** | 304 | 8% | 35 | 9% |
| **Prisoner** | 32 | 1% | 7 | 2% |

**Table 6: CTIMP applications for full ethical review proportion in specialist area** (1st April 2017 to 31st March 2018)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **UK** | **UK %** | **Scotland** | **Scotland %** |
| **CTIMP Reviews only** | 955 |  | 42 |  |
| **Commercial CTIMP Studies** | 754 | 79% | 29 | 69% |
| **Phase I (Healthy Vol)** | 164 | 17% | 2 | 5% |
| **Adults Unable to Consent CTIMPs** | 37 | 4% | 3 | 7% |
| **Genetherapy** | 37 | 4% | 0 | 0 |

**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)** | 964 | 26 | 121 | 33 |
| **Provisional Opinion** | 2566 | 69 | 232 | 63 |
| **Unfavourable Opinion** | 187 | 5 | 12 | 3 |
| **Withdrawn** | 27 | 1 | 5 | 1 |
| **Total** | **3744** |  | **370** |  |

**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)** | 25.6 |
| **Reviewed within 60 days target** | 99.2% |

# 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. 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 applications go to PR subcommittee which are not suitable and require full review and in this situation a “NO OPINION” is given. In this case the application is transferred to a Full REC. 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 | 427 | 28 |
| Clinical investigation or other study of a CE marked medical device | 61 | 5 |
| Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice | 59 | 9 |
| Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology | 495 | 43 |
| Study involving qualitative methods only | 276 | 24 |
| Study limited to working with data (specific project only) | 202 | 21 |
| Study limited to working with human tissue samples (or other human biological samples) and data (specific project only) | 244 | 23 |
| Other | 38 | 4 |
| Total | **1799** | **157** |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Row Labels** | **UK applications** | **UK**  **%** | **Scotland**  **applications** | **Scotland %** |
| **Favourable Opinion (+ or – Additional Conditions)** | 816 | 45 | 68 | 43 |
| **Provisional Opinion** | 776 | 43 | 74 | 47 |
| **No Opinion - Refer to Full Committee** | 119 | 7 | 8 | 5 |
| **Unfavourable Opinion** | 32 | 2 | 4 | 3 |
| **Withdrawn** | 56 | 3 | 3 | 2 |
| **Total** | 1799 |  | 157 |  |

The average number of days for PR review in Scotland over the period is 15.1 days. This average has increased from the previous year by 3.5 days as the HRA has now given the service more time to validate and check the applications coming in with a view to improving the quality of applications presented to REC members.

# Scotland A REC

Scotland A REC is constituted by Scottish ministers as the only REC in the UK which can review studies taking place in Scotland involving adults who lack the capacity to consent for themselves, under the Adults with Incapacity (Scotland) Act 2000. In addition, Scotland A also reviews CTIMPs, and, moreover, where a trial is to be conducted at one or more sites in Scotland, *and* the Chief Investigator is professionally based in Scotland, it is also always allocated to Scotland A under Scottish law. If the Chief Investigator is based outside Scotland, the application may be allocated to any other recognised REC. Scotland A also has additional flags (as outlined in table 1). It does not consider proportionate review applications. The types of study reviewed at full application are given in tables 11 and 12.

In addition to the full new applications listed in tables 11 and 12, Scotland A also considers amendments to existing studies in a full meeting where a study wishes to add research on adults unable to consent for themselves for the first time in Scotland. In addition, specialist training is also provided within the meetings on the legal and ethical issues around the consideration of applications involving adults lacking capacity.

**Table 11: Study types of applications assigned to a full Scotland A Committee meeting**

|  |  |  |
| --- | --- | --- |
| **Type of study** | **Number** | **%** |
| Clinical Trial of Investigational Medicinal Product | 7 | 15.56 |
| Phase 1 | 2 | 4.44 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank (including renewals) | 0 | 0.00 |
| Research Database (including renewals) | 4 | 8.89 |
| Others | 32 | 71.11 |
| **Total Applications Reviewed** | **45** | **100** |

**Table 12: Study types of applications assigned to a full Scotland A Committee meeting**

|  |  |
| --- | --- |
| **Type of study** | **Number** |
| Number of student applications reviewed | 10 |
| Number of paediatric applications reviewed | 7 |
| Number of device applications reviewed | 1 |
| Number of prisoner applications reviewed | 0 |
| Number of applications involving adults unable to consent reviewed | 31 |
| Number of applications reviewed that are funded by the US DHHS | 1 |
| Number of qualitative applications reviewed | 6 |

# Numbers of Applications to UK Research Ethics Committees 2012 -2016

The tables below are divided into all applications going to Full and PR research ethics review across the Scottish RECs and across all UK RECs over the last seven years. These are measured over the calendar year January to December.