



Health Research Authority

Jarrow HRA Office Annual Report Summary April 2015 to March 2016

Purpose	To present a summary of the annual reports from Research Ethics Committees (RECs) managed from the Jarrow HRA Office. The reports cover the activity between April 2015 and March 2016 and copies of the full reports are available on the HRA website.
Recommendations	That the annual reports be received and noted.
Presenter	Mark Ryan-Daly Research Ethics Service Manager (England) mark.ryandaly@nhs.net
Contact RECs	<p>Research Ethics Service Manager (England): Mark Ryan-Daly Regional Manager: Leigh Pollard leighpollard@nhs.net Deputy Regional Manager: Neil McCaffery neil.mccaffery@nhs.net</p> <p><u>London – Camden & Kings Cross</u> REC Manager: Christie Ord Email: nrescommittee.london-camdenandkingscross@nhs.net</p> <p><u>North East – Newcastle & North Tyneside 1</u> REC Manager: Gillian Mayer Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net</p> <p><u>North East – Newcastle & North Tyneside 2</u> REC Manager: Hayley Henderson Email: nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net</p> <p><u>North East – Tyne and Wear South</u> REC Manager: Kathryn Murray Email: nrescommittee.northeast-tyneandwearsouth@nhs.net</p> <p><u>North East – York</u> REC Manager: Gillian Mayer Email: nrescommittee.northeast-york@nhs.net</p> <p><u>Yorkshire & The Humber – Bradford Leeds</u> REC Manager: Katy Cassidy Email: nrescommittee.yorkandhumber-bradfordleeds@nhs.net</p> <p><u>Yorkshire & The Humber – Leeds East</u> REC Manager: Katy Cassidy Email: nrescommittee.yorkandhumber-leedseast@nhs.net</p>

	<p><u>Yorkshire & The Humber – Leeds West</u> REC Manager: Christie Ord Email: nrescommittee.yorkandhumber-leedswest@nhs.net</p> <p><u>Yorkshire & The Humber – Sheffield</u> REC Manager: Kathryn Murray Email: nrescommittee.yorkandhumber-sheffield@nhs.net</p> <p><u>Yorkshire & The Humber – South Yorkshire</u> REC Manager: Helen Wilson Email: nrescommittee.yorkandhumber-southyorks@nhs.net</p>
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INTRODUCTION

The Health Research Authority (HRA) is a Non Departmental Public Body, established initially as a Special Health Authority on 1 December 2011. Its purpose is to protect and promote the interests of patients and the public in health research. The HRA does this by supporting and promoting a robust and efficient regulatory and governance framework in the UK and providing the Research Ethics Service (RES).

The Research Ethics Service in England is part of the Operations Directorate within the HRA and has a dual mission:

- to protect the rights, safety, dignity and well-being of research participants; and
- to facilitate and promote ethical research that is of potential benefit to participants, science and society.

We do this by:

- providing robust and responsive ethical review of research by Research Ethics Committees (RECs);
- providing ethical guidance and management support to RECs;
- delivering a quality assurance framework for the research ethics service;
- delivering a training programme;
- working with colleagues across the UK to maintain a UK-wide framework for ethical review;
- working with colleagues in the wider regulatory environment to streamline the processes for approving research; and
- working with colleagues to promote transparency in research.

The HRA is the Appointing Authority for RECs in England and is required by the Governance Arrangements for RECs (GAfREC) to receive and adopt the REC Annual Reports.

Update on changes since 2014/2015 Summary of Annual Reports

As a result of geographical reconfiguration of the committee's across the five HRA offices, administrative support for the following committee's changed during the reporting period. They continued to meet in the same locations and the transfers were achieved with minimal disruption.

- East of England – Cambridge and Hertfordshire: transferred to HRA Nottingham from HRA Jarrow
- Yorkshire & The Humber – Sheffield: transferred to HRA Jarrow from HRA Manchester

Annual Reports

As the Appointing Authority, the HRA is responsible for the establishment, appointment, support and training of Research Ethics Committees. The HRA also takes full legal liability for the actions of those members in the course and performance of their duties subject to compliance with terms and conditions of service.

Research Ethics Committees are required to submit Annual Reports to the Appointing Authority no later than 30 September. Copies of the full reports are available upon request.

The Governance Arrangements for Research Committees (GAfREC, harmonised edition – DH 2011) requires annual reports to include the following minimum information.

- The REC's name, address and other contact details.
- The type of REC, including details of any recognition by UKECA and/or designation by the Research Ethics Service for review of certain types of research proposal.
- Details of the officers and staff of the REC.
- Details of the membership of the REC, including for each member and deputy member their occupation, expert/lay status, initial date of appointment, and where applicable the date on which the term of membership expired or the member resigned.
- The current register of members' interests.
- The attendance record of each member and deputy member during the year.
- A list of full meetings held during the year and the number of members attending.
- The training record of each member and deputy member.
- A list of the applications reviewed during the year, including the final decision reached on each application and the time taken to complete the review (or the current status of the review).
- A report by the Chair on the REC's work during the year.

Ten Committees have submitted reports for the year 1 April 2015 to 31 March 2016:

- London – Camden and Kings Cross
- North East – Newcastle and North Tyneside 1
- North East – Newcastle and North Tyneside 2
- North East – Tyne and Wear South
- North East – York
- Yorkshire and The Humber – Bradford Leeds
- Yorkshire and The Humber – Leeds East
- Yorkshire and The Humber – Leeds West
- Yorkshire and The Humber – Sheffield
- Yorkshire and The Humber – South Yorkshire

Membership as at 31 March 2016

Each Research Ethics Committee may have up to 15 full members. As a minimum, one third of these should be Lay members. Deputies may also be appointed. A maximum of two members may be co-opted per meeting, from other Research Ethics Committees, where the meeting would otherwise be inquorate.

Recruitment of new members is by an open process and appropriate screening and interviewing takes place in line with GAfREC 4.2.5

REC	Total Number	Expert	Lay	Resigned in period	Appointed in period
London – Camden & Kings Cross	17	8	9	3 expert, 2 lay	1 expert, 2 lay
North East – Newcastle & North Tyneside 1	15	9	6	1 lay	1 expert
North East – Newcastle & North Tyneside 2	15	9	6	1 expert	1 expert, 1 lay
North East – Tyne & Wear South	17	8	9	3 expert, 3 lay	2 lay
North East – York	15	10	5	2 expert, 2 lay	2 expert, 1 lay
Yorkshire & The Humber – Bradford Leeds	15	8	7	1 expert, 3 lay	1 lay
Yorkshire & The Humber – Leeds East	15	8	7	2 expert, 1 lay	1 expert
Yorkshire & The Humber – Leeds West	16	10	6	2 lay	0
Yorkshire & The Humber – Sheffield	15	10	5	1 expert, 1 lay	1 expert
Yorkshire & The Humber – South Yorkshire	15	9	6	1 expert, 1 lay	1 expert, 2 lay

Quorum

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 101 scheduled meetings, one had to be cancelled in advance due to member availability. The cancelled meeting was for the North East – Newcastle and North Tyneside 2 REC. In addition, one meeting of the Yorkshire & The Humber – South Yorkshire committee was not quorate and the discussion and decisions ratified at an additional meeting in line with Standard Operating Procedures.

Research Ethics Committees' meetings

- To maintain competency, the HRA recommends that Research Ethics Committees should meet at least ten times per year and should aim to review six studies at main per meeting. Of the ten committees covered by this summary, only nine held 10 meetings. One committee (North East – Newcastle and North Tyneside 2) met on nine occasions.
- In addition to full Committee meetings, the RECs covered in this summary held a total of 322 Sub-Committee meetings and 111 Proportionate Review Sub-Committee meetings

Summary of activity for all RECs administered from the HRA Jarrow office operating during 2015/16

Numerical information for REC workload and outcomes contained in the individual annual reports has been summarised below.

Applications for review at full Committee meetings

REC	FOSC	FOAC	UFO	PO	POPC	Total	SSB
London – Camden & Kings Cross	2	10	2	43	0	57	0
North East – Newcastle & North Tyneside 1	2	5	6	39	0	52	0
North East – Newcastle & North Tyneside 2	1	12	3	30	1	47	0
North East – Tyne & Wear South	3	7	1	44	0	55	0
North East – York	5	6	3	29	0	43	1
Yorkshire & The Humber – Bradford Leeds	2	5	3	40	0	50	0
Yorkshire & The Humber – Leeds East	3	5	1	48	0	57	0
Yorkshire & The Humber – Leeds West	0	3	8	37	0	48	0
Yorkshire & The Humber – Sheffield	4	6	3	45	0	58	0
Yorkshire & The Humber – South Yorkshire	1	0	4	41	0	46	0
TOTAL	23	59	34	396	1	513	1

Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
UFO	Unfavourable opinion
PO	Provisional opinion
POPC	Provisional Opinion Pending Consultation with Referee
SSB	Number of studies sent back to full committee meeting for final opinion

Applications reviewed at Proportionate Review Sub-Committee meetings

REC	FOSC	FOAC	NOT	PO	UFO	Total
London – Camden & Kings Cross	17	3	4	3	1	28
North East – Newcastle & North Tyneside 1	19	7	1	2	0	29
North East – Newcastle & North Tyneside 2	11	2	2	7	0	22
North East – Tyne & Wear South	20	5	2	3	1	31
North East – York	15	3	3	8	1	30
Yorkshire & The Humber – Bradford Leeds	25	4	3	5	0	37
Yorkshire & The Humber – Leeds East	23	1	3	4	0	31
Yorkshire & The Humber – Leeds West	16	2	4	6	2	30
Yorkshire & The Humber – Sheffield	10	4	4	11	0	29
Yorkshire & The Humber – South Yorkshire	23	0	1	1	0	25
TOTAL	179	31	27	50	5	292

Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
NOT	No Opinion, transfer to Full Committee for review
PO	Provisional Opinion
UFO	Unfavourable Opinion

Summary of workload after REC favourable opinion

REC	NOSA	MOD	INFO	PI	MIN	SR	SAE	APR	FR	SSA
London – Camden & Kings Cross	70	1	0	0	60	0	14	43	7	7
North East – Newcastle & North Tyneside 1	127	0	0	33	76	37	0	126	44	8
North East – Newcastle & North Tyneside 2	110	2	0	18	75	23	27	61	19	5
North East – Tyne & Wear South	110	0	0	27	104	50	1	54	17	9
North East – York	79	0	0	14	68	21	3	54	46	12
Yorkshire & The Humber – Bradford Leeds	51	1	0	0	30	1	4	63	43	0
Yorkshire & The Humber – Leeds East	150	1	4	57	103	53	0	77	17	23
Yorkshire & The Humber – Leeds West	112	0	3	33	111	39	9	89	22	4
Yorkshire & The Humber – Sheffield	114	4	0	16	96	31	1	78	54	17
Yorkshire & The Humber – South Yorkshire	68	0	0	0	56	0	0	70	45	10
TOTAL	981	9	7	198	779	255	59	715	314	95

Key

NOSA	Notice of Substantial Amendment
MOD	Modified Amendment
INFO	Substantial Amendment received for information only
PI	Substantial Amendment received for new sites/PIs
MIN	Minor Amendment
SR	Safety Report
SAE	Serious Adverse Event
APR	Annual Progress Report
FR	Final Study Report
SSA	Site Specific Assessment

Timescales for Research Ethics Committee Decisions

All new studies presented to the committees should be given an opinion within 60 calendar days, Substantial Amendments within 35 calendar days, and Proportionate Review Applications should be reviewed within 14 calendar days. Site Specific Assessments (SSAs) are now being carried out by the main REC.

The RES is working towards achieving the following KPIs (Key Performance Indicators), 95% of applications to full committee to receive a final decision within 40 calendar days, 95% of proportionate review applications to receive a final decision in 14 days and 95% of amendments to receive a decision within 28 calendar days.

Performance

513 studies were reviewed by full Committee of which 100% were given an opinion within the 60 day timeline, and 96% within the 40 day timeline. 292 studies were reviewed by Proportionate Review Sub-Committees of which 98% were given an opinion within the 14 day timeline. Of the 981 Substantial Amendments reviewed, 100% were given a final opinion within the 35 day timeline and 97% within the 28 day timeline. There were 54 Section 30 applications reviewed during the reporting period.

REC	% of full applications reviewed within 60 days	% reviewed meeting the 40 day KPI	% of Substantial amendments reviewed within 35 days	% reviewed meeting the 28 day KPI	% of PR applications reviewed within 14 days
London – Camden & Kings Cross	100%	96%	100%	94%	100%
North East – Newcastle & North Tyneside 1	100%	98%	100%	100%	98%
North East – Newcastle & North Tyneside 2	100%	89%	100%	99%	100%
North East – Tyne & Wear South	100%	100%	100%	98%	100%
North East – York	100%	98%	100%	97%	100%
Yorkshire & The Humber – Bradford Leeds	100%	98%	100%	100%	97%
Yorkshire & The Humber – Leeds East	100%	93%	100%	97%	100%
Yorkshire & The Humber – Leeds West	100%	96%	100%	96%	85%
Yorkshire & The Humber – Sheffield	100%	98%	100%	88%	100%
Yorkshire & The Humber – South Yorkshire	100%	96%	100%	99%	100%
Average for Centre	100%	96%	100%	97%	98%

Accreditation of Research Ethics Committees

The HRA accreditation scheme aims to ensure that RECs are operating according to guidance set down by the Department of Health.

The Quality Assurance Department audit RECs every 3 years to check that they are interpreting procedures and standards correctly in order to maintain a consistent ethical review process across the UK. One REC in HRA Jarrow was audited during the reporting period.

To supplement the audit process RES Operations undertakes quality control checks of each committee every six months.

RECs Achieving Full Accreditation at first review

REC
Yorkshire & The Humber – Bradford Leeds

RECs who have received full accreditation having completed an action plan

REC
None

Appeals received between April 2015 and March 2016

No appeals were received for studies managed from HRA Jarrow.

Complaints received between April 2015 and March 2016

No complaints were received for studies managed from HRA Jarrow.

Conclusion and Acknowledgements

The Research Ethics Committees managed from HRA Jarrow continue to provide valuable independent advice to researchers, sponsors and employers whilst protecting the dignity, rights, safety and wellbeing of actual and potential participants. The office achieved a high level of performance and the work of the local management and staff is acknowledged.

The Research Ethics Service continues to look at how best to support the Research Ethics Committees across the country and to ensure that each is able to maintain its expertise. The REC members contribution to the performance of the RECs in the Centre is acknowledged and the services of our volunteer members is greatly appreciated.

Mark Ryan-Daly
Research Ethics Service Manager (England)
17 September 2016

Appendix A

% Opinion rates for each REC

Applications reviewed at Full Committee meetings

REC	FOSC	FOAC	UFO	PO	POPC	Total
London – Camden & Kings Cross	3.51%	17.54%	3.51%	75.44%	0.00%	100.00%
North East – Newcastle & North Tyneside 1	3.85%	9.61%	11.54%	75.00%	0.00%	100.00%
North East – Newcastle & North Tyneside 2	2.13%	25.53%	6.38%	63.83%	2.13%	100.00%
North East – Tyne & Wear South	5.45%	12.73%	1.82%	80.00%	0.00%	100.00%
North East – York	11.63%	13.95%	6.98%	67.44%	0.00%	100.00%
Yorkshire & The Humber – Bradford Leeds	4.00%	10.00%	6.00%	80.00%	0.00%	100.00%
Yorkshire & The Humber – Leeds East	5.27%	8.77%	1.75%	84.21%	0.00%	100.00%
Yorkshire & The Humber – Leeds West	0.00%	6.25%	16.67%	77.08%	0.00%	100.00%
Yorkshire & The Humber – Sheffield	6.90%	10.34%	5.17%	77.59%	0.00%	100.00%
Yorkshire & The Humber – South Yorkshire	2.17%	0.00%	8.70%	89.13%	0.00%	100.00%
Average for Centre	4.49%	11.47%	6.85%	76.97%	0.21%	100.00%

Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
UFO	Unfavourable opinion
PO	Provisional opinion
POPC	Provisional Opinion Pending Consultation with Referee
SSB	Number of studies sent back to full committee meeting for final opinion

Applications reviewed at Proportionate Review Sub-Committee meetings

REC	FOSC	FOAC	NOT	PO	UFO	Total
London – Camden & Kings Cross	60.71%	10.71%	14.29%	10.71%	3.58%	100.00%
North East – Newcastle & North Tyneside 1	65.52%	24.13%	3.45%	6.90%	0.00%	100.00%
North East – Newcastle & North Tyneside 2	50.00%	9.09%	9.09%	31.82%	0.00%	100.00%
North East – Tyne & Wear South	64.52%	16.13%	6.45%	9.67%	3.23%	100.00%
North East – York	50.00%	10.00%	10.00%	26.67%	3.33%	100.00%
Yorkshire & The Humber – Bradford Leeds	67.57%	10.81%	8.11%	13.51%	0.00%	100.00%
Yorkshire & The Humber – Leeds East	74.19%	3.23%	9.68%	12.90%	0.00%	100.00%
Yorkshire & The Humber – Leeds West	53.33%	6.67%	13.33%	20.00%	6.67%	100.00%
Yorkshire & The Humber – Sheffield	34.48%	13.79%	13.79%	37.94%	0.00%	100.00%
Yorkshire & The Humber – South Yorkshire	92.00%	0.00%	4.00%	4.00%	0.00%	100.00%
Average for Centre	61.23%	10.46%	9.22%	17.41%	1.68%	100.00%

Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
NOT	No Opinion, transfer to Full Committee for review
PO	Provisional Opinion
UFO	Unfavourable Opinion