

Executive Summary of Annual Report for the Business Services Organisation (BSO): Office for Research Ethics Committees Northern Ireland (ORECNI) for the Financial Year 2017 to 2018

Firstly a sincere thanks to all the ORECNI staff and the volunteer Health and Social Care (HSC) committee members from HSC RECs A and B who have continued to provide the service on which many research customers rely. I am obliged to all, as are the researchers and research sponsors who rely on the efficiency and predictability of the service, and the participants who are invited to take part in research that has been the subject of a robust review provided by the ORECNI service.

The average workload per meeting per committee is equivalent or greater than other UK jurisdictions. The service has been delivered within budget and financial savings required.

It was with much pleasure and pride that I am able to report that both HSC RECs A and B continue to have the most efficient Key performance indicators in the UK exceeding the KPI targets on ethical decision timelines in all areas.

The ORECNI will continue to work with the other UK ethics partners in England, Scotland and Wales and the Business Services Organisation (BSO) to support its mission statement and corporate objectives as follows:

ORECNI 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

The RECs considered during the financial year in total of 196 new research proposals involving human subjects (their tissue or data), and which took place within the HSC and/ or wider NHS. Each REC is made up from members of the general public as well as social care and healthcare professionals, who provide a voluntary service to protect the rights, dignity and safety of research participants by ensuring that these research projects conform to generally accepted ethical principles and standards.

The range of research involved included clinical trials of medicinal products or drugs, trials of medical devices or other interventions. Also research involving vulnerable subjects such as patients /services users with learning difficulties, mental impairment, 'looked after' children. The research involves social care and medical research using both quantitative and qualitative methods. The range of research is diverse and includes sponsorship from the HSC, from charities, commercial companies and universities.

Of the new studies reviewed 111 had significant material ethical issues (and were reviewed by a full REC) and 60 had less significant ethical issues (and were reviewed by a sub-committee of the full REC known as a Proportionate Review Sub-committee (PRSC)). In addition the service considered a total of 183 substantial amendments to studies which have received ethical approval as well as 209 minor amendments. The following tables give an overview of workload; timelines and Key performance indicators achieved by the service and demonstrate the service improvement year on year.

The full individual annual reports for the RECs are enclosed.

Yours sincerely

Dr Siobhan McGrath

(Head of the ORECNI)

Date: 25th June 2018

Table 1 Comparison over last 7 financial years of timeline service improvement for different work-streams

Financial Year	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-7	2017-18
New studies Full REC: KPI 95%								
% meeting legal timeline 60 days	99.4	100	100	100	100	100	100	100
% meeting present KPI target 40 days or less	56	71.4	76.5	78	87.5	100	100	100
Amendments post approval KPI 95%								
% meeting legal timeline 35 days	100	100	100	100	100	100	100	100
% meeting present KPI target 28 days or less	82.8	88	89.5	85.6	92.7	99.5	100	98.3
New studies by PRSC KPI 95%								
% meeting UK KPI 14 days	None	100	100	93	90	100	99	100*

KPI aim is 95% we have achieved this and more in all areas.

*- national timeline for PRSC changed from 14 to 21 days in the financial year 2017-18

Table 2 Workload Comparison over last 7 financial years

Year	2009-10	2010-11	2011-12	2012-13	2014-15	2015-16	2016-17	2017-18
Nos. of New studies	176	179	175	159	171	195	196	171
Nos. of Substantial Amendments	182	159	182	114	151	168	195	183