

Executive Summary for the Office for Research Ethics Committees Northern Ireland (BSO), HSC Research Ethics Committee's A and B for the Financial Year 1st April 2020 to 31st March 2021.



Left to Right: Committee member training day 2019. Dr Alastair Walker (Chair of HSC REC A), Mrs Julie Erskine (Chair of the BSO Board), Dr Anne Moorhead (Vice-Chair of HSC REC B), Dr Hugh Davies (Health Research Authority, Chair of the HRA Oxford A REC); Sue Trouton (Alternate Vice-Chair of HSC REC B), Dr Siobhan McGrath (Head of the ORECNI), Prof Patrick Murphy (Chair of HSC REC B)

Firstly a sincere thank you to all the volunteer Health and Social Care Research Ethics Committee (HSC REC) members from HSC RECs A and B who along with the support from the ORECNI staff 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 ORECNI continues 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.

This is the year when the critical importance of research was brought to the general public's attention during the COVID-19 pandemic. Some 800 new research studies for COVID-19 were ethically reviewed before patient involvement in the UK. (See). The committees had to provide ethical approval of COVID-19 research trials and other studies, some in emergency expedited timelines. The committee and staff also had to adapt to remote working during the past year.

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

% meeting present KPI target 95% 40 days or less	56	71.4	76.5	78	87.5	100	100	100	100	100	100
Amendments post approval KPI 95%											
% meeting legal timeline 35 days	100	100	100	100	100	100	100	100	100	100	100
% meeting present KPI target 95% 28 days or less	82.8	88	89.5	85.6	92.7	99.5	100	100	100	100	100
New studies by PRSC KPI 95%											
% meeting UK KPI 21 days	No PR	100	100	93	90	100	99	100*	100*	100*	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

HSC REC A

Annual Report

01 April 2020 - 31 March 2021

Part 1 – Committee Membership and Training

Name of REC:	HSC REC A
Type of REC:	Recognised, Type 1 and 3
Type of Flag:	Phase 1, RTBs, ALC (NI only), Medical Devices, Qualitative, Devices, Paediatrics, Combined ways of Working Pilot (CWoW)
Chair:	Dr Alastair Walker
Vice-Chair:	Dr Mary Murphy
Alternate Vice-Chair:	Mr Barry Mimmagh
REC Manager:	Mrs Tamla Ervine
PRS Manager:	Mrs Melissa Stewart
REC Assistant:	Mrs Fiona McNally
Committee Address:	Business Services Organisation Unit 4, Lissue Industrial Estate West Rathdown Walk, Moira Road Lisburn BT28 2RF
Telephone:	N/A
Email:	RECA@hscni.net

Chair's overview of the past year (period 01 April 2020 to 31 March 2021):

The year began with the first wave of the COVID 19 pandemic reaching its climax and, although there was some general relaxation during the summer of 2020, this did not alter the mode of work of the Committee which at that stage was meeting remotely through the medium of the PEXIP system. As the second wave developed during the autumn it was decided that the Committee would continue to operate remotely for the foreseeable future. However, the software used for meetings was changed to ZOOM and this has worked very satisfactorily.

The success of the remote meetings owes much to the excellence of the work of the ORECNI staff in co-ordinating the arrangements for meetings in a way that is suited to the medium and which now enables researchers to join the meeting by video for discussion of their proposals. This means that there is visual contact not just with researchers in Northern Ireland but also those in GB which is an advance on the pre-COVID situation. Smooth running of the meetings has been greatly assisted by the way in which all of the members have adapted to the new format. For a further year all of the Committee's Key Performance Indicators have been met in full.

The Committee had its full accreditation renewed in December 2020 following an audit by the Health Research Authority and the next audit will take place before June 2022. The "Combined Way of Working" system in which some clinical trial studies are considered simultaneously by the REC and the MHRA has continued and, for the most part, has worked well. On occasions the MHRA Part 1 Assessment has not arrived prior to a meeting and this has prevented the Committee from finalising its opinion until the contents of that assessment are known. This has the effect of reducing the Committee's ability to control the decision timescale to the same extent.

The impact of the pandemic was felt in the nature of the Committee's work as well as its mode of working in that there was a fast track procedure established by the HRA for COVID-related projects. The Committee successfully processed a number of such applications within the required time frame. The processing of applications raising few ethical issues through Proportional Review Sub-Committee Meetings continued with all targets being met thanks to the excellent support provided by the Proportional Review Manager Melissa Stewart.

There was no annual training day in this reporting period because of the pandemic restrictions but a number of members have availed of the online training provided by the HRA. Members also contributed to "Shared Ethical Debate 27" organised by the HRA. On this occasion the debate was a themed one, focusing on the particular situation faced by researchers carrying out studies involving emergency situations in which some adult participants lack the capacity to give informed consent.

Attendance at meetings, despite the challenges of the remote format, has been high and the commitment to provide an excellent service to ensure the highest ethical standards in research has been constant from all concerned. Particular recognition must go to the Vice Chair, Dr Mary Murphy and the Alternate Vice-Chair Barry Mimmagh who were unwavering in their support despite the heavy professional demands on them as a result of the pandemic. In particular their coverage during a period of absence by the Chair is greatly appreciated. The work of the Committee Manager, Tamla Ervine, has been outstanding throughout and has been the foundation on which the Committee has built its successful year.

HSC REC A Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Margaret Brady	Deputy Chief Education Welfare Officer Operations	Expert	17/02/2014	
Mr James Cooke	Student	Lay Plus	01/07/2019	
Ms Marie Fenton	Guardian Ad Litem, Social Worker	Expert	01/03/2018	
Dr Helen Harty	Academic Lecturer	Lay	18/02/2014	
Mrs Julie Howse	Barrister	Lay Plus	01/03/2018	
Ms Rosemary Kelly	Registered Nurse	Expert	01/07/2019	
Dr Lorna Lawther	Registered Midwife	Expert	01/03/2018	
Mrs Kathryn Logue	Barrister In Independent Practice	Lay Plus	01/03/2018	25.03.2021
Mr Godfrey Madill	Project Manager	Lay Plus	05/06/2017	26.10.2020
Ms Rejina Mariam Verghis	Junior Biostatistician	Expert	17/01/2017	
Dr Toni McAloon	Lecturer	Expert	17/02/2014	
Mr Barry Mimnagh	Pharmacist	Expert	17/01/2017	
Dr Andrew Moriarty	Cardiologist	Expert	29/01/2019	
Dr Charles Mullan	Consultant Radiologist	Expert	17/02/2014	
Dr Mary Murphy	Registered Nurse	Expert	18/02/2014	
Professor Mahendra Varma	Consultant Physician in charge of Cardiology and Diabetic Services (Retired)	Expert	17/02/2014	
Dr Alastair Walker	Retired Head of Education Services, CCEA	Lay Plus	17/02/2014	

HSC REC A: Deputy Members

Name	Profession	Status	Meeting date attended
n/a			

HSC REC A: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr John Edward Mone	Former Executive Director of Nursing (Retired)	Lay	24/11/2020

HSC REC A: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Margaret Brady	Designated Governor on the Board of Governors for De La Salle College Belfast	30/07/2020
Ms Marie Fenton	Connection to NIGALA.	27/05/2020
Mrs Julie Howse	No declarations of interest. Full Practising Certificate issued by Bar of Northern Ireland 1.5.20	14/01/2021
Mr Godfrey Madill	None	08/12/2020
Ms Rejina Mariam Verghis	None. Employee at Parexel International as Biostatistician II from 20 July 2020 as per DOI form 10.8.2020	11/08/2020
Dr Toni McAloon	None.	09/07/2020
Dr Charles Mullan	None. Although a list of activities or interest likely to be related to the conduct of research: Divisional Clinical Director Cancer Services + Diagnostics Western Health and Social Care Trust	27/05/2020
Professor Mahendra Varma	Chairman of the Governance Board N.I of Chest, Heart & Stroke.	27/05/2020

Meetings for Full Ethical Review 01 April 2020 - 31 March 2021:

Month	Date	Number of Members Present at Meeting
April	28/04/2020	14
May	26/05/2020	14
June	30/06/2020	12
August	25/08/2020	9
September	22/09/2020	11
October	20/10/2020	12
November	24/11/2020	10
January	26/01/2021	10
February	23/02/2021	9
March	23/03/2021	11

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2020 - 31 March 2021:

Month	Date	Number of Members Present at Meeting
April	06/04/2020	3
June	01/06/2020	3
August	10/08/2020	3
September	07/09/2020	3
October	05/10/2020	3
November	02/11/2020	3
January	11/01/2021	3
February	08/02/2021	3
March	08/03/2021	3

9 proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2020 - 31 March 2021:

Month	Date	Number of Members Present at Meeting
April	02/04/2020	2
April	21/04/2020	2
April	27/04/2020	2
May	11/05/2020	2
May	20/05/2020	2
June	01/06/2020	2
June	03/06/2020	2
June	09/06/2020	2
July	04/07/2020	2
July	23/07/2020	2
August	10/08/2020	2
September	01/09/2020	2

September	09/09/2020	2
September	28/09/2020	2
October	12/10/2020	2
November	02/11/2020	2
November	11/11/2020	2
November	20/11/2020	2
December	08/12/2020	2
December	21/12/2020	2
January	14/01/2021	2
February	04/02/2021	2
February	16/02/2021	2
February	22/02/2021	2
March	10/03/2021	2
March	29/03/2021	2

26 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held:01 April 2020 - 31 March 2021

Date	Reason	Action taken
n/a		

Attendance of Members at full committee meetings:01 April 2020 - 31 March 2021

Name	Number of Meetings Attended
Ms Margaret Brady	5
Mr James Cooke	9
Ms Marie Fenton	7
Dr Helen Harty	9
Mrs Julie Howse	2
Ms Rosemary Kelly	9
Dr Lorna Lawther	6
Mrs Kathryn Logue	5
Mr Godfrey Madill	2
Ms Rejina Mariam Verghis	7
Dr Toni McAloon	6
Mr Barry Mimmagh	5
Mr John Edward Mone (co-opted from HSC REC B for meeting 24/11/2021)	1
Dr Andrew Moriarty	9
Dr Charles Mullan	3
Dr Mary Murphy	9
Professor Mahendra Varma	9
Dr Alastair Walker	9

Attendance of Members at proportionate review sub-committee meetings: 01 April 2020 - 31 March 2021

Name	Number of Meetings Attended
Ms Margaret Brady	3
Mr James Cooke	4
Ms Marie Fenton	1
Dr Helen Harty	2
Ms Rosemary Kelly	3
Dr Lorna Lawther	1
Mrs Kathryn Logue	3
Dr Toni McAloon	1
Dr Mary Murphy	8
Dr Alastair Walker	1

Attendance of Members at sub-committee meetings: 01 April 2020 - 31 March 2021

Name	Number of Meetings Attended
Ms Margaret Brady	1
Mr James Cooke	7

Ms Marie Fenton	1
Dr Helen Harty	2
Ms Rosemary Kelly	6
Dr Lorna Lawther	4
Mr Godfrey Madill	1
Dr Toni McAloon	2
Mr Barry Mimmagh	6
Dr Mary Murphy	6
Dr Alastair Walker	16

Training 01 April 2020 - 31 March 2021

Name of Member	Date	Event(s) attended
Ms Margaret Brady	29/05/2020	Training pack from HSC Annual Training Day Feb 2020
Ms Margaret Brady	07/12/2020	Introduction to Equality, Diversity and Human Rights
Ms Marie Fenton	03/07/2020	HSC REC Training Day
Ms Marie Fenton	19/01/2021	Research Tissue Bank Training
Ms Marie Fenton	24/02/2021	Prisons Research
Ms Marie Fenton	04/03/2021	Prison Research (focused discussion)
Dr Helen Harty	27/10/2020	Disability Training
Dr Helen Harty	28/10/2020	Equality Training
Mrs Julie Howse	09/07/2020	HRA REC Training Day - Epac
Mrs Julie Howse	17/01/2021	Confirmation of Completing refresher training
Mrs Julie Howse	05/02/2021	Adults Lacking Capacity CTIMP non-CTIMP NI
Mrs Julie Howse	14/02/2021	Equality Diversity and Human Rights
Ms Rosemary Kelly	15/09/2020	'Shared Ethical Debate (ShED) Exercise 27' training on Adults Lacking Capacity in emergency research
Ms Rosemary Kelly	08/10/2020	Research in ALC - Focus on Emergency Situations
Ms Rosemary Kelly	08/10/2020	Research in ALC - Learning Resources
Ms Rosemary Kelly	08/10/2020	Research on Pandemics
Ms Rosemary Kelly	21/01/2021	Research Tissue Banks - an Introduction - eLearning
Ms Rosemary Kelly	05/02/2021	Adults Lacking Capacity CTIMP/ non-CTIMP Northern Ireland Webnair
Ms Rosemary Kelly	22/03/2021	How to ethically review a Research Tissue Bank - eLearning
Dr Lorna Lawther	05/02/2021	Adults Lacking Capacity CTIMP non-CTIMP NI
Mrs Kathryn Logue	06/08/2020	Introduction to Phase 1
Mrs Kathryn Logue	24/01/2021	Ethical Review of a Research Tissue Bank
Mrs Kathryn Logue	24/01/2021	An introduction to Research Tissue Banks
Mrs Kathryn Logue	05/02/2021	Adults Lacking Capacity - Principles and Frameworks
Ms Rejina Mariam Verghis	07/12/2020	Introduction to Equality and Diversity & Human Rights
Dr Toni McAloon	29/04/2020	Equality and Diversity Training
Dr Toni McAloon	07/07/2020	HRA REC Training Day - Epac
Mr John Edward Mone	02/07/2020	BSO Equality & Diversity

		Training
Mr John Edward Mone	04/03/2021	Focused discussion of Application-Prison Research
Dr Charles Mullan	30/05/2020	Discovering Diversity Programme
Dr Charles Mullan	29/08/2020	Shared Ethical Debate (ShED) Exercise 27
Dr Charles Mullan	05/02/2021	Adults Lacking Capacity CTIMP & Non-CTIMP
Dr Mary Murphy	20/07/2020	Podcast 2 What is the role of the Data Monitoring Committee in CID trials
Dr Mary Murphy	20/07/2020	Podcast 3 Transparency and Publication of finished arm data
Dr Mary Murphy	20/07/2020	Video - Consent, Assent, Dissent
Dr Mary Murphy	20/07/2020	Video - Should Children be Involved in Research
Dr Mary Murphy	20/07/2020	Why Research in Children is Important
Dr Mary Murphy	20/07/2020	Equality, Diversity and Human Rights - eLearning
Dr Mary Murphy	20/08/2020	Podcast 1 What is a Complex Innovative Design and why do them
Dr Mary Murphy	19/09/2020	Shared Ethical Debate (ShED) Exercise 27' training on Adults Lacking Capacity in emergency research
Professor Mahendra Varma	30/07/2020	Introduction to Equality Diversity and Human Rights Presentation 2019
Professor Mahendra Varma	16/09/2020	Shared Ethical Debate (ShED) Exercise 27' training on Adults Lacking Capacity in emergency research
Professor Mahendra Varma	19/01/2021	Research Tissue Bank Training
Dr Alastair Walker	08/07/2020	HSC Discovering Diversity Training
Dr Alastair Walker	19/09/2020	Shared Ethical Debate (ShED) Exercise 27' training on Adults Lacking Capacity in emergency research

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	7	16.67
Phase 1	10	23.81
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.76
Research Database (including renewals)	0	0.00
Others	23	54.76
Applications Reviewed	42	100
Applications via Combined Ways of Working – Clinical Trial of investigational Medicinal Product / Phase 1	8	
Overall Total Applications Reviewed	50	

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	6
Number of student applications reviewed	7
Number of paediatric applications reviewed	5
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	1

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	4	9.52
Favourable Opinion with Additional Conditions	4	9.52
Unfavourable Opinion	0	0.00
Provisional Opinion	34	80.95
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	42	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	29	69.05
Further Information Favourable Opinion with Additional Conditions	4	9.52
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	9.52
Favourable Opinion with Additional Conditions	4	9.52
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.38
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	42	100

Summary of applications reviewed during the reporting period – submitted via combined ways of working pathway (CTIMP studies reviewed jointly by HSC REC A & MHRA and where appropriate HRA as part of UK Pilot

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	8	n/a

Table 5: Applications assigned to a proportionate review sub-committee within the reporting period

Total Applications Reviewed	18
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	2
Number of paediatric applications reviewed	1
Number of device applications reviewed	1
Number of qualitative applications reviewed	4

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	2	11.11
Favourable Opinion with Additional Conditions	2	11.11
No Opinion transfer to full committee for review	2	11.11
Provisional Opinion	12	66.67
Unfavourable Opinion	0	0.00
Total	18	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	4.20
Number of completed applications for full ethical review	42
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	2.38%
Number of days taken to final decision – average (mean)	22
Number of completed proportionate review applications for ethical review	16
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	0
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	93
Number of substantial amendments reviewed via combined ways of working pathway	12
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	34
Number of substantial amendments received for information	2
Number of substantial amendments received for new	9

sites/PIs	
Number of annual progress reports received	66
Number of safety reports received	23
Number of Serious Adverse Events received	0
Number of final reports received	18

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
20/NI/0051	Brain Diabetes main study	22
20/NI/0054	Hypoglycaemia among people with diabetes and their family members	22
20/NI/0055	A Single Dose Intravenous ADME Study in Healthy Volunteers (QSC202874)	20
20/NI/0085	Non-invasive detection of anaemia in pregnancy V0.2	24
20/NI/0101	Temperature monitoring using urinary bladder catheter in children	23
20/NI/0102	M19-747: ABBV-184 in Subjects with Previously Treated AML and NSCLC	23
20/NI/0103	NIS793 (+/- spartalizumab) with SOC chemotherapy in first-line mPDAC	23
20/NI/0104	Safety, tolerability and pharmacokinetics of inhaled GSK3923868	24
20/NI/0108	An evaluation of ARBI Residential Rehabilitation Service in NI	18
20/NI/0114	STUDY TO ASSESS THE PK OF CANNABIDIOL PRODUCTS IN HEALTHY SUBJECTS	18
20/NI/0115	INDUCT	18
20/NI/0127	Safety Tolerability & PK Study of Inhaled Murepavadin in Healthy Subj	24
20/NI/0128	WO41554 A Study of GDC 0077 in patients with HR-Positive Breast Cancer	26
20/NI/0131	WO41994-Atezo with Chemo after progression with immunotherapy in Renal	20
20/NI/0135	Absolute Bioavailability and ADME study of Savolitinib (QSC204066)	24
20/NI/0136	OSPREY	24
20/NI/0137	CONVERT	29
20/NI/0142	VRAMMT Study	23
20/NI/0152	Clinic Versus Home Spirometry (COMPAIR)	23
20/NI/0158	Safety, Tolerability, PK and PD of anle138b in Patients (QSC203925)	22
20/NI/0159	Bioavailability and ADME study of GDC-9545 in healthy females (204283)	21
21/NI/0010	Northern Ireland Motor Neurone Disease Biobank	23
21/NI/0031	Late Anthracycline induced Cardiotoxicity- Childhood Cancer Survivors	35
21/NI/0035	Decision making processes in learning disability services- in whose BI	23
21/NI/0037	Deprescribing in older people receiving palliative care in hospice	27
21/NI/0041	IMPROVE-HCM	25
21/NI/0043	PREP Plus	27
21/NI/0060	STEERING Asthma	25
21/NI/0061	Exploring African-Caribbean people's experiences of inpatient services	25

Further Information Favourable Opinion (continued)

Summary of applications reviewed during the reporting period – submitted via combined ways of working pathway (CTIMP studies reviewed jointly by HSC REC A & MHRA and where appropriate HRA as part of UK Pilot)

REC Reference	Title	Number of Days on Clock
20/NI/0045	ADHERE	63
20/NI/0053	ADHERE+	57
20/NI/0086	CA41705 THE EFFICACY AND SAFETY OF OBINUTUZUMAB IN PATIENTS WITH LUPUS NEPHRITIS	70
20/NI/0070	BRIOChe	53
20/NI/0100	PIVOT-12	63
20/NI/0145	RSV challenge study to evaluate efficacy of MVA-BN RSV vaccine	47
20/NI/0148	ABACUS-2	61
20/NI/0005	Efficacy and Safety of Benralizumab with an OLE in NCFB (Mahale)	42
<i>This is a pilot and the timelines represent the joint total timeline of ethics committee and MHRA & where appropriate HRA review. Timeline aim for the pilot is 60 days.</i>		

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0076	The CoPS study [COVID-19]	8
21/NI/0012	ICE BAT	44
21/NI/0019	The Northern Ireland Biobank (NIB): 2021-2026	25
21/NI/0063	Home Spirometry	24

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0057	Determining the lipid lowering effect of fenugreek seed tea	31
20/NI/0073	An observational study on the effects of repeat testing in COVID-19 [COVID-19]	6
20/NI/0082	QT Study to Evaluate the Effect of VT-1161 in Healthy Adult Females	17
21/NI/0013	Study of IV NPJ5008 and DANTRIUM IVÂ® in Healthy Volunteers(QSC204721)	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
20/NI/0060	ETD002 - first doses in humans	15
20/NI/0074	Cognitive Processes in Psychosis (CPIP)	7
20/NI/0081	ADME Study of [14C]-S-600918 in Healthy Male Volunteers (QSC203293)	17
21/NI/0049	Safety, Tolerability, and PK Study of INE963 (QSC204132)	20

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
20/NI/0061	SPARTAN	n/a

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
20/NI/0109	The early detection of primary liver cancer	12

20/NI/0111	AT100-01: AAV8 NAb Seroprevalence in Late Onset Pompe Disease	17
20/NI/0138	Exploration of care for people with diabetic foot disease- Version 1.0	9
20/NI/0157	Understanding health services delivery for fibromyalgia	10
21/NI/0015	Non-clinical evaluation of HemoClear blood filter in Intrapartum Care	8
21/NI/0033	Remote Isolation of Skin microbiome_v1	8
21/NI/0059	Sodium balance in dialysis patients	11

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0056	AFiRM Study v1.0	11
21/NI/0017	BOO, Residual Volume Of Urine & Bladder Cancer Risk	17
21/NI/0056	Experiences Before Surgery for Infection	18

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
21/NI/0014	PD-L1 (SP263) ESCC CDx Study for BeiGene Phase II BGB-A317-A1217-	16

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0078	Assessment of the properties of splicing kinase inhibitors - Version 1	7
21/NI/0038	Investigating biologic therapy initiation on asthma medication use	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0155	Mass spec analysis of metabolites in blood from Covid-19 patients	6
21/NI/0058	Stability of blood ammonia at ambient temperature (version 1)	7

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock
21/NI/0034	INFORM mi: TBI	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/NIR01/41/AM11	The role of Anaerobic Bacterial Infection in Cystic Fibrosis	Amendment 8	19/02/2020	27
10/NIR01/5/AM05	Predicting the risk of post-operative delirium. Version 1.			11
10/NIR01/5/AM07	Predicting the risk of post-operative delirium. Version 1.	1	26/10/2020	9
13/NI/0072/AM13	C25006 Ph4 of Brentuximab Vedotin in Patients with Large Cell Lymphoma			12
14/NI/0076/AM04	"Retinal ischaemia in diabetic retinopathy"	Substantial Amendment 6.0	06/04/2020	7
15/NI/0127/AM23	Open-label Extension Study of ALN-AT3SC in Haemophilia Patients			19
15/NI/0127/AM24	Open-label Extension Study of ALN-AT3SC in Haemophilia Patients			19
15/NI/0127/AM25	Open-label Extension Study of ALN-AT3SC in Haemophilia Patients			22
15/NI/0127/AM26	Open-label Extension Study of ALN-AT3SC in Haemophilia Patients			10
15/NI/0127/AM27	Open-label Extension Study of ALN-AT3SC in Haemophilia Patients			12
15/NI/0128/AM07	DSC/11/2357/44 extension study - Givinostat in patients with cMPN			21
15/NI/0128/AM09	DSC/11/2357/44 extension study - Givinostat in patients with cMPN			13
15/NI/0128/AM11	DSC/11/2357/44 extension study - Givinostat in patients with cMPN			23
15/NI/0145/AM18	GO29365 - Phase Ib/II Study of Polatuzumab Vedotin in r/r FL or DLBCL			19
15/NI/0145/AM19	GO29365 - Phase Ib/II Study of Polatuzumab Vedotin in r/r FL or DLBCL			26
16/NI/0030/AM03	The Northern Ireland Biobank (NIB)	SA03	24/04/2020	3
17/NI/0055/AM01	Developing a blood- based method to montior chemotherapeutic response			8
17/NI/0148/AM10	Optimal choice of targeted therapies in inflammatory bowel			13

	disease			
17/NI/0244/AM01	SOLITUDE			20
18/NI/0093/AM05	Monitoring cognitive health using the BrainWaveBank platform, v1.1			7
18/NI/0117/AM02	Optometric versus ophthalmic follow up of cataract surgery in N.I			17
18/NI/0148/AM03	Extraction of circulating nucleic acids from human blood from SNBTS			27
18/NI/0174/AM04	Unravelling patient predictors of ex vivo stem cell expansion			22
18/NI/0188/AM10	LUM0001			22
18/NI/0191/AM13	MedEx-UK: Mediterranean diet, exercise and dementia risk in UK adults			21
18/NI/0211/AM03	Improving engagement with Cardiac Rehabilitation			8
18/NI/0233/AM07	STIFLE			22
19/NI/0009/AM02	Peripheral nerve stimulation for Tremor			15
19/NI/0032/AM06	Study of safety and efficacy of Betalutin & rituximab in pts with FL			21
19/NI/0049/AM02	Adjunctive NaBen treatment of schizophrenia in adults			16
19/NI/0086/AM03	Disentangling Emotional Processing from Regulation in Bulimia Nervosa			8
19/NI/0086/AM04	Disentangling Emotional Processing from Regulation in Bulimia Nervosa			19
19/NI/0090/AM01	Posttraumatic Growth among survivors of the Northern Ireland Troubles			13
19/NI/0090/AM02	Posttraumatic Growth among survivors of the Northern Ireland Troubles			13
19/NI/0091/AM03	Development of a questionnaire for AYAs (14-39 years) with cancer			15
19/NI/0091/AM05	Development of a questionnaire for AYAs (14-39 years) with cancer			25
19/NI/0121/AM03	An fNIRS study to examine executive function in children: Version 1			21
19/NI/0126/AM04	SMALL Trial Version 1.0, 10-May-2019			19
19/NI/0130/AM01	Implementation of an exercise intervention for ovarian cancer patients			26
19/NI/0140/AM04	304_A phase 3 study to investigate if Fezolinetant helps			22

	reduce VMS			
19/NI/0140/AM05	304_A phase 3 study to investigate if Fezolinetant helps reduce VMS			28
19/NI/0155/AM02	Evaluate safety & efficacy of AZD2811 as Monotherapy or as Combination			10
19/NI/0155/AM04	Evaluate safety & efficacy of AZD2811 as Monotherapy or as Combination			9
19/NI/0162/AM06	IB1001-203			20
19/NI/0162/AM07	IB1001-203			7
19/NI/0175/AM02	Sexual wellbeing resources in cancer care v2			4
19/NI/0175/AM03	Sexual wellbeing resources in cancer care v2			11
19/NI/0175/AM04	Sexual wellbeing resources in cancer care v2			23
19/NI/0179/AM02	PROSPER: observational study on patients with plaque psoriasis			11
19/NI/0183/AM02	FALCON			14
19/NI/0183/AM03	FALCON			14
19/NI/0192/AM01	Healthy Habits in Pregnancy and Beyond pilot RCT	1.1 tracked	21/07/2020	16
19/NI/0200/AM01	Randomized, FIH, SAD/MAD, Safety PK Study in Healthy Adult Subjects.			8
19/NI/0200/AM02	Randomized, FIH, SAD/MAD, Safety PK Study in Healthy Adult Subjects.			14
19/NI/0202/AM01	Comparative PK Study of ENZ201 Teriparatide and Forsteo			7
19/NI/0202/AM02	Comparative PK Study of ENZ201 Teriparatide and Forsteo			5
19/NI/0202/AM05	Comparative PK Study of ENZ201 Teriparatide and Forsteo			13
19/NI/0202/AM06	Comparative PK Study of ENZ201 Teriparatide and Forsteo			6
19/NI/0206/AM02	Mental Health Care: (Eastern European) Migrants' Perspectives.			5
20/NI/0005/AM02	Study of PF-06741086 in Hemophilia A or B With or Without Inhibitors			7
20/NI/0005/AM03	Study of PF-06741086 in Hemophilia A or B With or Without Inhibitors			14
20/NI/0007/AM04	TREE; Tumour Reactive Lymphocytes: Evaluation and Enhancement			26
20/NI/0007/AM06	TREE; Tumour Reactive Lymphocytes: Evaluation and Enhancement			21
20/NI/0007/AM07	TREE; Tumour Reactive Lymphocytes: Evaluation and			23

	Enhancement			
20/NI/0010/AM01	1. The Experience of Parenting a Child with Epilepsy and NES			13
20/NI/0025/AM02	Families' views on the involvement of children in FI version 1			9
20/NI/0026/AM01	Enhancing the patient complaints journey V1			3
20/NI/0040/AM02	ETD001 - first doses in humans			10
20/NI/0051/AM01	Brain Diabetes main study			20
20/NI/0054/AM01	Hypoglycaemia among people with diabetes and their family members			1
20/NI/0056/AM01	AFiRM Study v1.0			11
20/NI/0060/AM02	ETD002 - first doses in humans			10
20/NI/0060/AM03	ETD002 - first doses in humans			21
20/NI/0073/AM01	An observational study on the effects of repeat testing in COVID-19 [COVID-19]	Substantial Amendment 02	29/05/2020	7
20/NI/0074/AM02	Cognitive Processes in Psychosis (CPiP)			23
20/NI/0076/AM03	The CoPS study [COVID-19]			9
20/NI/0076/AM05	The CoPS study [COVID-19]			6
20/NI/0082/AM01	QT Study to Evaluate the Effect of VT-1161 in Healthy Adult Females			7
20/NI/0082/AM03	QT Study to Evaluate the Effect of VT-1161 in Healthy Adult Females			6
20/NI/0102/AM01	M19-747: ABBV-184 in Subjects with Previously Treated AML and NSCLC			21
20/NI/0103/AM01	NIS793 (+/- spartalizumab) with SOC chemotherapy in first-line mPDAC			19
20/NI/0103/AM02	NIS793 (+/- spartalizumab) with SOC chemotherapy in first-line mPDAC			18
20/NI/0104/AM02	Safety, tolerability and pharmacokinetics of inhaled GSK3923868			21
20/NI/0114/AM03	STUDY TO ASSESS THE PK OF CANNABIDIOL PRODUCTS IN HEALTHY SUBJECTS			7
20/NI/0114/AM04	STUDY TO ASSESS THE PK OF CANNABIDIOL PRODUCTS IN HEALTHY SUBJECTS	1	15/01/2021	21
20/NI/0127/AM01	Safety Tolerability & PK Study of Inhaled Murepavadin in Healthy Subj			15
20/NI/0128/AM03	WO41554 A Study of GDC 0077 in patients with HR-Positive Breast Cancer			8

20/NI/0131/AM02	WO41994-Atezo with Chemo after progression with immunotherapy in Renal			17
20/NI/0137/AM01	CONVERT			7
20/NI/0159/AM01	Bioavailability and ADME study of GDC-9545 in healthy females (204283)			14
21/NI/0013/AM01	Study of IV NPJ5008 and DANTRIUM IV [®] in Healthy Volunteers(QSC204721)			20

Favourable Opinion (continued)

Summary of substantial amendments reviewed during the reporting period – submitted via combined ways of working pathway (CTIMP studies reviewed jointly by HSC REC A & MHRA and where appropriate HRA as part of UK Pilot

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
20/NI/0032/AM04	PROPEL 2			7
20/NI/0045/AM02	ADHERE			16
20/NI/0032/AM02	PROPEL 2			28
20/NI/0053/AM01	ADHERE+			33
20/NI/0070/AM01	BRIOChe			27
20/NI/0053/AM02	ADHERE+			20
20/NI/0148/AM01	ABACUS-2			14
20/NI/0045/AM01	ADHERE			34
20/NI/0032/AM06	PROPEL 2			20
19/NI/0167/AM02	The effect of padsevonil on the blood levels of oral contraceptives			51
19/NI/0135/AM02	ADME and IVMT study of ME-401 in healthy subjects (QSC201587)			17
19/NI/0199/AM01	Safety, Tolerability and PK of SBT-272 in Healthy Subjects (QSC202648)			15

This is a pilot and the timelines represent the joint total timeline of ethics committee and MHRA & where appropriate HRA review. Timeline aim for the pilot is 35 days.

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/NI/0147/AM03	Incremental Value of Cardiac MRI in Structural Heart Disease			14
19/NI/0206/AM01	Mental Health Care: (Eastern European) Migrants' Perspectives.			15

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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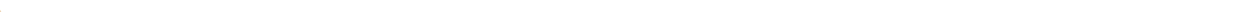
Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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HSC REC B

Annual Report

01 April 2020 - 31 March 2021



Part 1 – Committee Membership and Training

Name of REC:	HSC REC B
Type of REC:	Recognised (Type 1 and 3)
Type of Flag:	Phase 1, Research Databases, ALC (NI only), Medical Devices, Qualitative, Paediatrics
Chair:	Professor Patrick Murphy
Vice-Chair:	Dr Anne Moorhead
Alternate Vice-Chair:	Ms Sue Trouton
REC Manager:	Mrs Denise Nesbitt Mrs Melissa Stewart (PRS)
REC Assistant:	Ms Fiona McNally
Committee Address:	C/O Office for Research Ethics Committees Northern Ireland (ORECNI) Business Services Organisation Unit 4, Lissue Industrial Estate West Rathdown Walk, Moira Road Lisburn BT28 2RF
Telephone:	02895 361408
Email:	recb@hscni.net

Chair's overview of the past year:

Although it has been a difficult year in many respects because of the Covid-imposed restrictions, it was also a year in which diligence, dedication and team work combined to overcome adversity. The achievement of REC B in performing to the highest ethical and administrative standards is a credit to the professionalism and commitment of its members and staff. Together they made the difficult appear easy and I am very proud to have worked with them in what otherwise might have been challenging circumstances.

Of course, it was not all plain sailing. While the use of Zoom for virtual meetings proved to be a wonderful facility for communication, I sometimes found it difficult to encourage Committee members to engage in in-depth discussions to the same extent as would have been possible in face-to-face meetings. On the plus side, it allowed applicants from more than one centre to join the meetings from their respective homes or offices across the UK. Whereas previously, one person might have attended our Committee, Zoom allowed us to welcome two, three or more members of the application team at the same time.

The outcome was another successful year for REC B, in which we once again made a significant contribution to balancing the interests of participants and patients on one side, with facilitating research for the good of humanity on the other. This was a particularly notable achievement since the Chair and members work in a voluntary capacity which, for this level of professional expertise, is exceptionally rare.

At a time of increasing professional workloads for our members, they deserve respect, admiration and, I would suggest, remuneration for their efforts. I know of no other boards at this level which relies on volunteers. I am especially grateful to all those who have given of their time so readily on sub-committees and in Proportionate Review. It represents a significant time commitment.

Of course, our level of achievement would not have been possible without the entire OREC office staff, who continued to serve the cause of ethical research with principle and purpose. Even though they were working from home, they moved seamlessly into a new method of operation and the work of the Committee was made so much easier by their expertise, their efficiency and their endless good humour. They are a valuable asset to our public sector and I am proud to work with them.

Like most aspects of life these days, the content and culture of ethical approval is rapidly changing and the years ahead will present new and varied challenges. I think it is fair to say that REC B is prepared for those challenges because of its people, its philosophy and its continued sense of purpose.

HSC REC B Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Ronald Atkinson	Retired Consultant in Medical Oncology	Expert	01/04/2015	
Dr Aaron Courtenay	Pharmacist	Expert	22/02/2019	
Mr Martin John Fisher	Solicitor	Lay Plus	05/06/2017	
Dr Donna Kernaghan	Research & Policy Officer	Lay	01/07/2019	
Mrs Cliona McDowell	Statistician	Expert	17/02/2014	
Ms Mary McMahan	Retired	Lay	08/06/2017	
Mrs Evelyn Melanophy	Solicitor	Lay Plus	01/07/2019	
Dr Kristel Miller	Senior Lecturer Leadership Marketing and Strategy	Lay Plus	01/03/2018	22/06/2020
Mr John Edward Mone	Retired (Former Executive Director of Nursing)	Lay	17/02/2014	
Dr Anne Moorhead	Senior Lecturer in Health Communication	Lay	17/02/2014	
Ms Aine Morrison	Service Manager, Community Treatment & Support Services for Learning Disability	Expert	17/02/2014	
Professor Patrick Murphy	Advisor on Social & Economic Policy	Lay Plus	17/02/2014	
Dr Seamus O'Brien	Outcomes Manager, Primary Joint Unit	Expert	17/02/2014	
Mr Glenn Phair	Health Economist	Lay	01/07/2019	
Dr Mark Reid	Retired Consultant Paediatrician	Expert	01/04/2015	
Ms Marilyn Trimble	Lecturer in Law and Ethics and Business Law	Lay Plus	17/02/2014	
Ms Sue Trouton	Community Midwifery Sister	Expert	17/02/2014	

HSC REC B: Deputy Members

Name	Profession	Status	Meeting date attended
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HSC REC B: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Lorna Lawther	Registered Midwife	Expert	11.02.2021
Mr James Cooke	Student	Lay Plus	11.02.2021

HSC REC B: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Donna Kernaghan	Donna is employed as a Research and Policy Officer for Barnardo's NI, which may potentially seek to conduct research related to health and social care. See uploaded to documents-fm	18/06/2020
Mrs Evelyn Melanophy	None, see uploads to documents.	05/06/2020
Dr Kristel Miller	Kristel works in Ulster University and is an active researcher. Kristel also chairs the filter ethics committee for the Ulster Business School and sits on the University of Ulster's central research ethics committee. See uploads to documents-18-06-2020-fm	18/06/2020
Mr John Edward Mone	Non-executive Director of the Health and Social Care Board.	05/06/2020
Dr Anne Moorhead	Any other activities or interests likely or possibly likely to be related to the conduct of research: Current relevant activities: Chair of Communication & Media Filter Committee at Ulster University (Risk and Ethics) Committee member on the research committee for the International Association for Communication in Healthcare. Regular member on Horizon2020 funding panels Section Editor for the Journal of Medical Internet Research (JMIR) Regular invited reviewer on numerous health journals and funding panels including BMJ, ESRC, NIHR Please see form in uploaded documents, signed 18-06-2020-fm	18/06/2020
Ms Aine Morrison	Lead for social work research in the Office of Social Services, Department of Health. Member of Strategic Research Advisory Group NI. Practice Assessor on Post-graduate Research course for Social Workers. Member of NI Regional Interest Group for research in mental health-fm	18/06/2020
Professor Patrick Murphy	None, see upload to documents 04-02-2020-fm	08/06/2020
Mr Glenn Phair	Employed by the Northern Ireland Clinical Trails Unit within the Belfast Health & Social Care Trust.	05/06/2020
Ms Sue Trouton	Member of CoP for R+D in SHSCT, see upload to documents.fm	08/06/2020

Meetings for Full Ethical Review 01 April 2020 - 31 March 2021:

Month	Date	Number of Members Present at Meeting
May	07/05/2020	12
June	04/06/2020	10
July	02/07/2020	9
August	06/08/2020	10
October	08/10/2020	12
November	05/11/2020	9
December	03/12/2020	9
January	14/01/2021	10
February	11/02/2021	9
March	11/03/2021	11

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2020 - 31 March 2021:

Month	Date	Number of Members Present at Meeting
May	18/05/2020	3
June	15/06/2020	3
July	27/07/2020	3
August	24/08/2020	3
October	19/10/2020	3
November	16/11/2020	3
December	14/12/2020	3
January	25/01/2021	3
February	22/02/2021	3
March	22/03/2021	3

10 proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2020 - 31 March 2021:

Month	Date	Number of Members Present at Meeting
April	03/04/2020	2
April	07/04/2020	3
April	24/04/2020	2
May	18/05/2020	2
June	08/06/2020	2
June	29/06/2020	2
July	23/07/2020	2
August	14/08/2020	2
August	24/08/2020	3
September	01/09/2020	2
September	22/09/2020	2

October	15/10/2020	2
November	09/11/2020	2
November	19/11/2020	2
November	30/11/2020	2
December	18/12/2020	2
January	07/01/2021	2
January	28/01/2021	2
February	22/02/2021	2
March	15/03/2021	2

20 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held: 01 April 2020 - 31 March 2021

Date	Reason	Action taken

Attendance of Members at full committee meetings:01 April 2020 - 31 March 2021

Name	Number of Meetings Attended
Dr Ronald Atkinson	10
Dr Aaron Courtenay	10
Mr Martin John Fisher	5
Dr Donna Kernaghan	2
Mrs Cliona McDowell	3
Ms Mary McMahan	10
Mrs Evelyn Melanophy	6
Mr John Edward Mone	9
Dr Anne Moorhead	9
Ms Aine Morrison	3
Professor Patrick Murphy	9
Dr Seamus O'Brien	1
Mr Glenn Phair	7
Dr Mark Reid	7
Ms Marilyn Trimble	5
Ms Sue Trouton	3

Attendance of Members at proportionate review sub-committee meetings: 01 April 2020 - 31 March 2021

Name	Number of Meetings Attended
Dr Aaron Courtenay	5
Ms Mary McMahan	7
Mrs Evelyn Melanophy	1
Mr John Edward Mone	4
Dr Anne Moorhead	7
Dr Seamus O'Brien	4
Ms Sue Trouton	2

Attendance of Members at sub-committee meetings: 01 April 2020 - 31 March 2021

Name	Number of Meetings Attended
Dr Ronald Atkinson	1
Dr Aaron Courtenay	3
Ms Mary McMahan	5
Mrs Evelyn Melanophy	3
Mr John Edward Mone	7
Dr Anne Moorhead	11
Professor Patrick Murphy	5
Dr Seamus O'Brien	4

Training 01 April 2020 - 31 March 2021

Name of Member	Date	Event(s) attended
Dr Ronald Atkinson	22/06/2020	BSO Equality and Diversity Training
Dr Ronald Atkinson	08/07/2020	HRA-Podcast on CID Trials
Dr Aaron Courtenay	02/04/2020	Research on Pandemics
Dr Aaron Courtenay	06/07/2020	Podcast 1 What is a complex innovative design and why do them
Dr Aaron Courtenay	06/07/2020	Podcast 2 What is the role of the Data Monitoring Committee in CID trials
Dr Aaron Courtenay	06/07/2020	Podcast 3 Transparency and publication of finished arm data
Dr Aaron Courtenay	06/07/2020	Complex innovative design trials
Dr Aaron Courtenay	08/07/2020	Podcast 4 What information is important to Patients and their families?
Dr Aaron Courtenay	08/07/2020	Podcast 5 What do REC members need to know about CID trials?
Dr Aaron Courtenay	08/07/2020	Podcast 7 Complex innovative design trails and HRA approval.
Dr Aaron Courtenay	08/07/2020	Podcast 6 How to write patient facing documents that make sense
Dr Aaron Courtenay	06/08/2020	Webinar – Introduction to phase
Dr Aaron Courtenay	01/10/2020	COVID challenge studies workshop 1
Dr Aaron Courtenay	06/11/2020	COVID challenge studies workshop 2
Mrs Cliona McDowell	07/07/2020	HRA REC Training Day -Epac
Mrs Evelyn Melanophy	06/08/2020	introduction to phase one training
Mrs Evelyn Melanophy	01/10/2020	adults lacking capacity in an emergency
Mrs Evelyn Melanophy	23/10/2020	Focused discussions of applications – Children, CTIMP, Medical Devices
Mrs Evelyn Melanophy	05/02/2021	Adults Lacking Capacity
Mr John Edward Mone	02/07/2020	BSO Equality & Diversity Training
Mr John Edward Mone	04/03/2021	Focused discussion of Application-Prison Research
Dr Anne Moorhead	02/07/2020	BSO Equality and Diversity Training
Dr Anne Moorhead	06/08/2020	Complex Innovative Design (CID) trial Podcast
Dr Anne Moorhead	06/08/2020	We should do research involving children - Dr Bod Phillips explains why! Podcast

Dr Anne Moorhead	06/08/2020	Couldn't make the webinar on How to chair remotely? Recording now available Podcast
Dr Anne Moorhead	06/08/2020	Information on Remote Chairing of REC Meetings Podcast
Dr Anne Moorhead	06/08/2020	Have you seen our Research on Pandemics area within the Library? Podcast
Dr Anne Moorhead	05/02/2021	GPIP Podcast CID Trials and study delivery during COVID Pandemic
Ms Aine Morrison	26/06/2020	BSO Equality and Diversity Training
Ms Aine Morrison	03/07/2020	HSC REC Training Day -epac
Professor Patrick Murphy	19/06/2020	BSO Equality and Diversity Training
Dr Seamus O'Brien	05/02/2021	Research Involving Adults Lacking Capacity
Mr Glenn Phair	25/02/2021	Innovation in Trial Design and Study Delivery during the COVID pandemic Podcast Series II
Dr Mark Reid	05/02/2021	GPIP Podcast CID Trails and study delivery during COVID Pandemic
Ms Marilyn Trimble	19/06/2020	Equality & Diversity Training

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	1	2.33
Phase 1	9	20.93
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	6	13.95
Others	27	62.79
Applications via Combined Ways of Working – Clinical Trial of investigational Medicinal Product / Phase 1	5	
Total Applications Reviewed	48	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	5
Number of student applications reviewed	11
Number of paediatric applications reviewed	10
Number of device applications reviewed	6
Number of prisoner applications reviewed	2
Number of applications involving adults unable consent reviewed	2
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	7

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	6	13.95
Favourable Opinion with Additional Conditions	7	16.28
Unfavourable Opinion	0	0.00
Provisional Opinion	30	69.77
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	43	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	30	69.77
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	13.95
Favourable Opinion with Additional Conditions	7	16.28
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	43	100

Table 5: Applications assigned to a proportionate review sub-committee within the reporting period

Total Applications Reviewed	21
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	7
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	3	14.29
Favourable Opinion with Additional Conditions	2	9.52
No Opinion transfer to full committee for review	1	4.76
Provisional Opinion	15	71.43
Unfavourable Opinion	0	0.00
Total	21	100

Table 8: Other Management Information based on the number of completed applications for

Average number of applications reviewed per full meeting	4.30
Number of completed applications for full ethical review	43
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	2.33%
Number of days taken to final decision – average (mean)	24
Number of completed proportionate review applications for ethical review	20
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	0
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	76
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.32%
Number of CWOW amendments reviewed	12
Total of substantial amendments reviewed.	88
Number of modified amendments reviewed	1
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	34
Number of substantial amendments received for information	1

Number of substantial amendments received for new sites/PIs	2
Number of annual progress reports received	70
Number of safety reports received	50
Number of Serious Adverse Events received	0
Number of final reports received	29

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
20/NI/0062	Office Lighting for Correction of Vitamin D Deficiency in Winter	58
20/NI/0063	PK Study of MR Amifampridine Formulations (QSC202075)	27
20/NI/0064	Covid-19 Myocardial Injury Study v1.0 [COVID-19]	9
20/NI/0067	A PK Dose Proportionality Study of OPL-002 in Healthy Volunteers	22
20/NI/0075	Objective measures of lung function in children	25
20/NI/0080	Sexting, Consent and Young People: Regulatory Challenges	22
20/NI/0083	GSK3882347 First time in human study	25
20/NI/0093	Monitored Dosage Systems and potential patient harm	22
20/NI/0096	HipHOP	22
20/NI/0098	Study to Evaluate the PK of BMS-986165 Tablets (QSC203891)	22
20/NI/0099	An evaluation of the IFA's 'Stay Onside' programme.	28
20/NI/0120	Multicenter ascending study of nebulized CSL787 in healthy&NCFB subj	23
20/NI/0122	Northern Ireland Motor Neurone Disease Register 2020	25
20/NI/0129	Co-produced physical activity programme for empowerment and well-being	23
20/NI/0132	Northern Ireland Cancer Registry Research Databases - Renewal	40
20/NI/0140	A prospective evaluation of the i-gel Plus supraglottic airway device	23
20/NI/0146	Safety, tolerability and PK of NIO752 in Patients With PSP	31
20/NI/0149	Taste and Mouthfeel Evaluation of an Oral Suspension (QSC204795)	22
20/NI/0150	The Genomic Basis of Inflammatory Skin Disease	23
20/NI/0151	Data sharing: pilot study	26
20/NI/0171	Remote paediatric ECG monitoring with the AliveCor KardiaMobile 6L	23
20/NI/0172	CLEAR	22
21/NI/0003	Strategies to improve iodine status in early pregnancy. Version 1	21
21/NI/0008	COVID-19: Attitudes towards drinking in LD patients during lockdown	26
21/NI/0009	ECG and POC Ultrasound guided central line insertion in neonates	23
21/NI/0020	Experiences of parents living with mental distress	24
21/NI/0029	Experience of donating breastmilk within the process of grief	23
21/NI/0050	Comparing ultrasound and plain X-Rays for erosions in Lupus	24
21/NI/0051	Psychosexual Identity Development After Testicular cancer Recovery	21
21/NI/0053	COVALENT	21

Further Information Favourable Opinion (continued)

Summary of applications reviewed during the reporting period – submitted via combined ways of working pathway (CTIMP studies reviewed jointly by HSC REC A & MHRA and where appropriate HRA as part of UK Pilot

REC Reference	Title	Number of Days on Clock
21/NI/0001	Substudy 03A: Phase 1b/2 Umbrella Study of Combination Therapies in RCCHRA ApprovalCWoW Pilot	58
21/NI/0002	Substudy 03B: Phase 1b/2 Umbrella Study of Combination Therapies in RCC	58
20/NI/0058	Relative Bioavailability and Food Effect Study of Nilotinib NFECWoW Pilot	55
20/NI/0091	BP40087 Evaluating RO7122290 in combination with atezolizumab (P1a/b)	55
20/NI/0119	UCB7853- first doses in humansCWoW Pilot	50

This is a pilot and the timelines represent the joint total timeline of ethics committee and MHRA & where appropriate HRA review. Timeline aim for the pilot is 60 days.

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0069	Northern Ireland Vascular Access Research Database	22
20/NI/0092	NCRS_Linkage_to_OX_CRIS	19
20/NI/0170	Compliance with COVID-19 restrictions & ways to help improve adherence	19
21/NI/0018	Evaluation of PLN-74809 on Biomarkersfrom Bronchoalveolar Lavage Fluid	19
21/NI/0028	STABILISE HF	27
21/NI/0044	ATTITUDE Study v1	19

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0059	ADME and PK Study of AZD4831 in Healthy Males (QSC202884)	23
20/NI/0066	A first in man study to treat acute cough on coronavirus [COVID-19]	19
20/NI/0094	Crossover Study to Evaluate the ECG Effects of Telaglenastat in Adults	21

20/NI/0095	Co-morbidity and Refractory Asthma - UK Severe Asthma Registry	21
20/NI/0169	Mothering without a Mother	19
20/NI/0173	Advance care planning for nursing homes in a COVID-19 outbreak	18
21/NI/0025	Creative Feasibility Study with Hospice Day Therapy Patients	30

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
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Further information response not complete

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0072	MR-BIO	6
20/NI/0088	Lung nodule Imaging Biobank for Radiomics and AI research (LIBRA)	7
20/NI/0089	REMOTE AF	6
20/NI/0105	Monitoring skin health of clinical staff wearing PPE during COVID-19	10
20/NI/0117	PRINTO Revision of the ILAR Classification Criteria for JIA	7
20/NI/0161	Elderly Patients' perspectives on deprescribing. Version 1	8

20/NI/0166	Autoflow	10
20/NI/0175	Reliability and Validity of the CORE-10 in a Stroke Population	16
21/NI/0021	Perception and management of diabetes in Somali children and COVID-19	16
21/NI/0048	Lifestyle discussions in UK primary care: an analysis of consultations	11
21/NI/0064	COVID-19: Risk of infection, outcomes and impact for IBD patients	13

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0106	Study into Crohn's Disease Treatment Efficacy	7
20/NI/0144	REDUCE BME URDU sub-study	12
21/NI/0045	Imaging Technology to Assess the Effect of COVID-19 on Retinal Tissues	12
21/NI/0066	Remote consultations in primary care during COVID-19	17

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0177	Delivery of Supported Self-Management in Asthma Reviews	6
20/NI/0179	DRIVEN v0.6	7
21/NI/0026	Amyloid Proteins in Medullary Thyroid Cancer and Laryngeal Amyloidosis	6

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
20/NI/0107	Community Seroprevalence of SARS-CoV-2 in NW London (COM-SARS-2) [COVID-19]	6
20/NI/0143	MRI and psychometric investigation of BMS pain mechanism. (Version 1)	7

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/NIR03/113/AM25	The TUDA Study	Substantial Amendment 19	28/01/2020	3
08/NIR03/113/AM26	The TUDA Study	SA20	29/05/2020	27
14/NI/0068/AM10	Cardiovascular Event (CVE) Risk Study			11
14/NI/1037/AM29	Treatment of lymphoma by Betalutin targeted internal radiation therapy			10
14/NI/1038/AM16	The Paediatric EVICELÂ® Neuro Study			21
15/NI/0137/AM19	Phase 1 Study of BLU-554 in Patients with Hepatocellular Carcinoma			27
16/NI/0029/AM08	OptiPREG			16
17/NI/0002/AM01	Vision related quality of life measured using Virtual Reality.			14
17/NI/0113/AM11	GS-US-419-4016 Filgotinib in treatment of Perianal Fistulizing Crohns			21
17/NI/0113/AM12	GS-US-419-4016 Filgotinib in treatment of Perianal Fistulizing Crohns			18
17/NI/0113/AM13	GS-US-419-4016 Filgotinib in treatment of Perianal Fistulizing Crohns			14
17/NI/0113/AM14	GS-US-419-4016 Filgotinib in treatment of Perianal Fistulizing Crohns			18
17/NI/0141/AM11	SPECTA: Screening Cancer Patients for Efficient Clinical Trial Access			17
17/NI/0215/AM04	HV Study to Evaluate the PK, Safety & Tolerability of MEDI7219 117903			21
17/NI/0227/AM04	Infant feeding, non-nutritive sucking and speech development			23
18/NI/0007/AM01	The Northern Ireland Human Movement Analysis Database-V2	Substantial Amendment 1	01/05/2020	5
18/NI/0101/AM02	Post-radiation dental disease			12
18/NI/0127/AM08	Spotlight			4
18/NI/0127/AM10	Spotlight			22
18/NI/0133/AM02	SS-INQ Information Needs Questionnaire in Sjögren's Syndrome			14

18/NI/0136/AM01	Healthcare, Through The Eyes Of Our Children	18/NI/0136 Substantial Amendme	18/03/2020	16
18/NI/0145/AM09	Safety, Tolerability, PK and PD Study of Inhaled ION-827359 - HV&CF			14
18/NI/0164/AM06	Low-dose atropine eye drops for children with myopia in the UK			12
18/NI/0164/AM08	Low-dose atropine eye drops for children with myopia in the UK			15
18/NI/0176/AM04	Vestibular Stimulation to Trigger Apidose Loss (VeSTAL) Clinical Trial	AM07	31/03/2020	4
18/NI/0180/AM01	The Northern Ireland Cerebral Palsy Register (NICPR) 2018	Substantial Amendment #1	05/05/2020	12
18/NI/0199/AM04	AIMM: Acipimox in Mitochondrial Myopathy			21
18/NI/0199/AM06	AIMM: Acipimox in Mitochondrial Myopathy			25
18/NI/0203/AM04	KX-ORAX-012 Oraxol food effect study			15
18/NI/0212/AM03	Walking fOR Health: The WORTH trial			16
18/NI/0212/AM04	Walking fOR Health: The WORTH trial			21
18/NI/0212/AM05	Walking fOR Health: The WORTH trial			8
18/NI/0212/AM06	Walking fOR Health: The WORTH trial			19
18/NI/0224/AM04	Double-Blind, Efficacy and Safety of Durvalumab plus Olaparib			24
18/NI/0224/AM05	Double-Blind, Efficacy and Safety of Durvalumab plus Olaparib			20
18/NI/0224/AM06	Double-Blind, Efficacy and Safety of Durvalumab plus Olaparib			22
19/NI/0005/AM04	MOSAIC PSA014			11
19/NI/0005/AM05	MOSAIC PSA014			19
19/NI/0005/AM07	MOSAIC PSA014			18
19/NI/0016/AM01	DECADE			27
19/NI/0024/AM03	Efficacy and Safety Study of PRN1008 in Patients with Pemphigus			3
19/NI/0024/AM04	Efficacy and Safety Study of PRN1008 in Patients with Pemphigus			29
19/NI/0024/AM05	Efficacy and Safety Study of PRN1008 in Patients with Pemphigus			6
19/NI/0024/AM07	Efficacy and Safety Study of PRN1008 in Patients with Pemphigus			23
19/NI/0024/AM08	Efficacy and Safety Study of PRN1008 in Patients with			16

	Pemphigus			
19/NI/0075/AM01	Arm cycling improves trunk function			14
19/NI/0108/AM08	First Contact Physiotherapy in Primary Care (FRONTIER)	SA01	22/04/2020	25
19/NI/0108/AM11	First Contact Physiotherapy in Primary Care (FRONTIER)			18
19/NI/0110/AM02	EluNIR HBR study			16
19/NI/0161/AM03	Portico NG Approval Study			15
19/NI/0173/AM03	IBD Prepare for care			10
19/NI/0176/AM01	The HELP intervention for carers of patients with heart failure			19
19/NI/0176/AM04	The HELP intervention for carers of patients with heart failure			18
19/NI/0216/AM03	CC-5013-MM-034_A non-interventional study of lenalidomide			6
19/NI/0216/AM04	CC-5013-MM-034_A non-interventional study of lenalidomide			25
19/NI/0218/AM05	MOSAICC Study (Version 1.1)			22
19/NI/0220/AM01	IMPASS			24
20/NI/0002/AM02	ASTX727			21
20/NI/0004/AM02	HL-2018-01-TS Feasibility: EU/AU (v3.0)			25
20/NI/0018/AM01	A Study of subcutaneous KY1005 in Healthy Volunteers (19-018)			10
20/NI/0044/AM01	Heart rhythm interpretation ECG using Artificial Intelligence			17
20/NI/0062/AM01	Office Lighting for Correction of Vitamin D Deficiency in Winter			9
20/NI/0066/AM03	A first in man study to treat acute cough on coronavirus [COVID-19]			7
20/NI/0067/AM02	A PK Dose Proportionality Study of OPL-002 in Healthy Volunteers			6
20/NI/0067/AM03	A PK Dose Proportionality Study of OPL-002 in Healthy Volunteers			6
20/NI/0067/AM05	A PK Dose Proportionality Study of OPL-002 in Healthy Volunteers			25
20/NI/0067/AM07	A PK Dose Proportionality Study of OPL-002 in Healthy Volunteers			8
20/NI/0083/AM01	GSK3882347 First time in human study			24
20/NI/0083/AM02	GSK3882347 First time in human study			19
20/NI/0094/AM02	Crossover Study to Evaluate the ECG Effects of Telaglenastat in Adults			12
20/NI/0094/AM03	Crossover Study to Evaluate the ECG Effects of Telaglenastat in Adults			3
20/NI/0096/AM01	HipHOP			21

20/NI/0106/AM03	Study into Crohn's Disease Treatment Efficacy			8
20/NI/0120/AM01	Multicenter ascending study of nebulized CSL787 in healthy&NCFB subj			11
21/NI/0018/AM01	Evaluation of PLN-74809 on Biomarkersfrom Bronchoalveolar Lavage Fluid			18

Favourable Opinion (continued)

Summary of substantial amendments reviewed during the reporting period – submitted via combined ways of working pathway (CTIMP studies reviewed jointly by HSC REC A & MHRA and where appropriate HRA as part of UK Pilot

Amendment REC Reference	Title	Number of Days on Clock
19/NI/0171/AM02	Phase 2a RSV Human Challenge Study of MK-1654 in Healthy Participants	29
20/NI/0006/AM04	ASCEND-WAIHA	34
20/NI/0006/AM01	ASCEND-WAIHA	21
19/NI/0098/AM05	The effect of SEP-363856 on brain dopamine synthesis capacity	35
19/NI/0171/AM01	Phase 2a RSV Human Challenge Study of MK-1654 in Healthy Participants	22
20/NI/0006/AM02	ASCEND-WAIHA	25
19/NI/0098/AM03	The effect of SEP-363856 on brain dopamine synthesis capacity	35
19/NI/0098/AM04	The effect of SEP-363856 on brain dopamine synthesis capacity	36
19/NI/0141/AM04	AUT00201 - first doses in humans	20
19/NI/0141/AM02	AUT00201 - first doses in humans	17
20/NI/0091/AM01	BP40087 Evaluating RO7122290 in combination with atezolizumab (P1a/b)	40
20/NI/0091/AM02	BP40087 Evaluating RO7122290 in combination with atezolizumab (P1a/b)	38

This is a pilot and the timelines represent the joint total timeline of ethics committee and MHRA & where appropriate HRA review. Timeline aim for the pilot is 60 days.

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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20/NI/0170/AM01	Compliance with COVID-19 restrictions & ways to help improve adherence			17
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Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
20/NI/0170/AM01/1	Compliance with COVID-19 restrictions & ways to help improve adherence		18/01/2021	10

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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