Re-issued to remove Capacity and Capability paragraph

Health Research Authority

Yorkshire & The Humber - South Yorkshire Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 104 8079

02 March 2021 – Re-issued
15 December 2020

Dr Orla Gray
Consultant Neurologist
South Eastern Health and Social Care Trust
Ulster Hospital
Dundondald
BT161RH

Dear Dr Gray

Study title:	**MSBase Registry Global Cohort Study of Multiple Sclerosis (MS) and other Neuroimmunological Diseases (NIDs)**
REC reference:	**20/YH/0344**
Protocol number:	**N/A**
IRAS project ID:	**286711**

The Proportionate Review Sub-committee of the Yorkshire & The Humber - South Yorkshire Research Ethics Committee reviewed the above application via correspondence.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

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Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

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The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Contract/Study Agreement template [MSBase Registry Site Participation Agreement]	2.1	02 September 2020
Covering letter on headed paper [MSBase Registry_REC Chair Cover Letter]	1.0	15 November 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [MSBase Foundation Association Indemnity]		10 June 2020
IRAS Application Form [IRAS_Form_23112020]		23 November 2020
Letters of invitation to participant [MSBase Registry Participant Invitation Letter]	1.0	15 November 2020
Other [MSBase Registry_Site PI roles and responsibilities (Registry Participation Agreement Schedule 3)]	2.0	09 June 2020
Other [MSBase Registry_Privacy Notice]	1.0	10 August 2020
Other [MSBase Registry_Organisational Structure]	-	10 February 2014
Other [MSBase Registry_Correspondence with HRA regarding type of review]	-	27 August 2020
Other [MSBase Registry_Data Processing Agreement (Registry Participation Agreement Schedule 1)]	2.0	09 June 2020
Other [MSBase Registry_HRA Assessor/Devolved Nation Reviewer Cover]	1.0	15 November 2020
Other [MSBase Registry_R&D Offices Cover Letter]	1.0	15 November 2020
Participant consent form [MSBase Registry_UK_ICF]	UK 1.0	15 November 2020
Participant information sheet (PIS) [MSBase Registry_UK_PIS]	UK 1.0	15 November 2020
Research protocol or project proposal [MSBase Registry_Protocol (Registry Participation Agreement Schedule 2)]	2.0	09 June 2020
Summary CV for Chief Investigator (CI) [MSBase Registry_CI_Dr Orla Gray_CV]	-	19 November 2020

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

With the Committee's best wishes for the success of this project.

IRAS project ID: 286711	**Please quote this number on all correspondence**

Yours sincerely
Pp

Dr David Broomhead
Chair

Email: southyorks.rec@hra.nhs.uk

Enclosures:	List of names and professions of members who took part in the review
	"After ethical review – guidance for researchers" [SL-AR2]
Copy to:	Research Governance Administrator
	Lead Nation Northern Ireland: research.gateway@hscni.net

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Yorkshire & The Humber - South Yorkshire Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting via correspondence

Committee Members:

Name	*Profession*	*Present*
Dr Geraldine Boyle	Senior Lecturer	Yes
Dr David Broomhead (Chair)	Therapy Consultant	Yes
Dr Alison Patrick	Lecturer in Law and Ethics	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Miss Donna Bennett	Approvals Administrator