Health Research Authority
London - Bromley Research Ethics Committee
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 104 8057

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

07 September 2018 revised 12/10/18

Dr Matthew Sargeant
Consultant Psychiatrist
Hywel Dda University Health board
CORPORATE OFFICES, YSTWYTH BUILDING
HAFAN DERWEN
ST DAVIDS PARK, JOBSWELL ROAD CARMARTHEN DYFED
SA31 3BB

Dear Dr Sargeant

Study title:	**An observational, real world evidence study to describe clinical experience with lurasidone in the treatment of adult patients with schizophrenia in routine clinical practice in Europe.**
REC reference:	**18/LO/1591**
Protocol number:	**NA**
IRAS project ID:	**250852**

The Proportionate Review Sub-committee of the London - Bromley Research Ethics Committee reviewed the above application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited

circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Add as an inclusion criterion that the participant should be stable/in remission in order to give consent to take part.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

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").

Extract of the meeting minutes

The Sub Committee raised concerns that patients with schizophrenia may not always have capacity to consent, and the clinical in charge should verify this. It stated that it should be in the inclusion criteria that they should be stable/in remission in order to give consent to take part.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		23 August 2018
IRAS Application Form [IRAS_Form_23082018]		23 August 2018
Letter from sponsor [Sponsor's letter]		19 July 2018
Letter from statistician [Stat letter]		20 July 2018
Letters of invitation to participant [Invitation letter]	v0 2	13 July 2018
Other [Thankyou letter]	v1 0	24 July 2018
Participant information sheet (PIS) [PIS]	v0 2	13 July 2018
Research protocol or project proposal [Protocol]	v2 0	07 June 2018
Summary CV for Chief Investigator (CI) [CI CV]	v1 0	02 August 2018

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.

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

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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 Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

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

18/LO/1591	**Please quote this number on all correspondence**

Yours sincerely

Pp Dr Jacqueline Tavabie
Alternate Vice-Chair

Email: nrescommittee.london-bromley@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Mrs Marlena Radzikowska*
Ms Lisa Seale, Hywel Dda Health Board
Lead Nation
Wales: research-permissions@wales.nhs.uk

London - Bromley Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Abdulzahra Hussain	Upper GI Consultant Surgeon	Yes	
Canon Tim Mercer	Hospital Chaplain	Yes	
Dr Jacqueline Tavabie (Alternate Vice-Chair and Meeting Chair)	General Practitioner	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Sadie McKeown-Keegan	REC Manager
Mrs Frances Riggs	Retired Deputy Head Teacher