

*Dr Dheeraj Rai
University of Bristol
Oakfield House, Oakfield Grove
Bristol
BS8 2BN*

21st December 2021

Dear Dheeraj,

AGREEMENT BY THE UNIVERSITY OF BRISTOL TO ACT AS RESEARCH SPONSOR.

Project Title: A multicentre double-blind placebo-controlled randomised trial of SerTRaline for AnxieTy in adults with Autism (STRATA) (our ref 2019-4556)
Chief Investigator: Dr Dheeraj Rai

Date of original sponsorship	21.07.21
Anticipated end date	30.09.24
Ethics reference	21/FT/0008, 02.02.21
IRAS ID	270727
HRA and HCRW Approval	Versions of study documents as detailed on HRA and HCRW Approval letter 02.02.21 and substantial amendment 1.
EudraCT number	2019-004312-66
Insurance reference	CT2407/2020-4884
Contract reference	2019-3502
Funder	NIHR HTA
Peer review	Undertaken by funder
Confirmation of capacity and capability from participating NHS organisations	Avon and Wiltshire Mental Health Partnership NHS Trust 13.07.21 Gloucestershire Health and Care NHS Foundation Trust 09.07.21 Surrey and Borders Partnership NHS Foundation Trust 12.08.21 Hertfordshire Partnership University NHS Foundation Trust 11.05.21 Norfolk Community Health and Care NHS Trust 06.07.21 Leicestershire Partnership NHS Trust 18.10.21

	<p>Nottinghamshire Healthcare NHS Foundation Trust 13.12.21</p> <p>Coventry and Warwickshire Partnership NHS Trust 16.12.21</p> <p>PIC: Devon Partnership Trust. Subcontract signed between Devon Partnership Trust and Avon and Wiltshire Mental Health Partnership NHS Trust on 30.11.21</p> <p>PIC: Herefordshire and Worcestershire Health and Care NHS Trust. Subcontract signed between Herefordshire and Avon and Wiltshire Mental Health Partnership NHS Trust on 17.12.21</p>
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The University of Bristol hereby confirms that it agrees to act as the research sponsor for the above referenced project with you as Chief Investigator.

The investigational medicinal product can now be released for the study to commence in the **locations detailed in the table above only**. This letter supersedes that issued on 07.12.21. Please send the confirmation of capacity and capability.

We would like to remind you of your obligation to comply with all relevant regulatory guidance and legislation.

You have previously confirmed that you have read the University's Research Governance and Integrity Policy. It has been a while since study set-up and so we attach Annex 3 of the Policy here for your information.

If you intend to make any changes to the study, including an extension to the end date, you must inform us as Sponsor prior to submission to the Regulatory Authority. Annual Progress Reports are due on the anniversary of when HRA and HCRW Approval and/or NHS REC favourable opinion was granted, please send us a copy.

May we take this opportunity to wish you every success with your research.

Yours sincerely,

DocuSigned by:

December 21, 2021
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Adam Taylor
Head of Research Governance