Dr Philip Scott
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Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

14 September 2021

Dear Dr Scott

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**MicroGuide-2: A randomized controlled trial of the impact of MicroGuideâ„¢ computerized decision support modules on antimicrobial prescribing behaviours and clinical outcomes.**
IRAS project ID:	**295323**
Protocol number:	**8543**
REC reference:	**21/EM/0183**
Sponsor	**MERCK SHARP & DOHME (UK) LIMITED**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **295323**. Please quote this on all correspondence.

Yours sincerely,
Kelly Rowe

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Dr Philip Scott*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Research Collaboration Agreement]		11 June 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [MSD liability policy]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		30 September 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University Portsmouth Professional Indemnity]		11 August 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Southampton Insurance]		28 July 2020
Interview schedules or topic guides for participants [Interview guide]	2	19 November 2020
IRAS Application Form [IRAS_Form_02072021]		02 July 2021
Letter from sponsor [MSD sponsor letter]		12 April 2021
Letter from statistician [Letter from statistician]		12 April 2021
Organisation Information Document [NHS Trust info sheet v4.1]	4.1	11 August 2021
Other [Horizon-PHU data sharing agreement]		17 March 2021
Other [NHS Trust consent form]	3	24 June 2021
Other [NHS Trust information sheet (tracked changes)]	4.1	11 August 2021
Other [Interview participant information sheet (tracked changes)]	3.1	11 August 2021
Participant consent form [Interview consent form]	3	12 April 2021
Participant information sheet (PIS) [Interview PIS v3.1]	3.1	11 August 2021
Research protocol or project proposal [Study protocol]	2.5	21 June 2021
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		21 June 2021

IRAS project ID	295323

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
The lead site will undertake all protocol activities. (Site Type 1) Participating NHS organisations will be randomised to one arm of the study, Health care professionals in the NHS organisation will be approached to take part in an interview. (Site Type 2)	Site Type 1 - Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study. Site Type 2 - Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met. • You have contacted participating NHS organisations (see below for details)	The sponsor intends to use their own Research Collaboration Agreement to form an agreement with the lead site. The sponsor does not intend to form an agreement with any other participating NHS organisations, the signed consent form (NHS Trusts) will be the agreement to take part.	No interactive Costing Tool (iCT) has been provided. This is due to the temporary suspension of the expectation that iCT is in place prior to IRAS submission, in place whilst NIHR prioritises its resources in line with its response to COVID-19	A local collaborator is expected at participating NHS organisations.	It is anticipated that all study activities at site will be conducted by local staff with an existing contractual relationship. No further HR Good Practice arrangements expected.

	• HRA and HCRW Approval has been issued • The NHS organisation has not provided a reason as to why they cannot participate • The NHS organisation has not requested additional time to confirm. You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. You may now provide the local information pack for your study to your participating NHS organisations in England and/or Wales. If you have not already started to provide the local information packs to participating NHS organisations in Northern Ireland and/or Scotland please do so when you are ready. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. The				

	password to access the R&D contact list is Redhouse1				

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.