Dr Gemma Lasseter
Senior Research Assoicate and Project Manager
University of Bristol
NIHR Health Protection Research Unit (HPRU) in Evaluation of Interventions
Bristol Medical School, Population Health Sciences,
University of Bristol
Oakfield House, Oakfield Grove
BS8 2BN

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

03 December 2018 RE-ISSUED

Dear Dr. Lasseter,

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

Study title:	**Evaluation of patient access to medical test result services in general practice.**
IRAS project ID:	**249637**
Protocol number:	**V1**
REC reference:	**18/WA/0268**
Sponsor	**University of Bristol**

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.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations in England and Wales that are undertaking the contrast case study site-type activities should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter. You should then work with each organisation that has confirmed capacity and capability and provide clear instructions when research activities can commence.

Participating NHS organisations in England and Wales that are only involved in the retrospective data collection and/or the questionnaire survey aspects of the trial **will not** be required to formally confirm

capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)
- 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 the site positively confirms that the research may proceed.

If not already done so, you should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. After entering your IRAS ID you will be able to access a password protected document (password: **Redhouse1**). The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

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 the devolved administrations of 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) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

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 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.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr. Birgit Whitman

Tel: 0117 331 7130

Email: Birgit.Whitman@bristol.ac.uk

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 **249637**. Please quote this on all correspondence.

Yours sincerely

Laura Greenfield

Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Birgit Whitman [Sponsor Contact on behalf of the University of Bristol]*

Ms Rachel Avery [Lead NHS R&D Office Contact on behalf of Avon Primary Care Research Collaborative, Bristol CCG]

List of Documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Appendix A - Patient Covering Letter]	2	25 September 2018
Covering letter on headed paper [Appendix D - Follow-up]	2	25 September 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Cover Letter]	V1	19 July 2018
HRA Schedule of Events [Contrasting case study]	1	29 August 2018
HRA Schedule of Events [Questionnaire]	1	29 August 2018
HRA Schedule of Events [Retrospective data collection]	1	29 August 2018
HRA Statement of Activities [Questionnaires]		
HRA Statement of Activities [Retrospective data collection]	1	29 August 2018
HRA Statement of Activities [Contrasting case study]	1	29 August 2018
Interview schedules or topic guides for participants [Primary Care Staff Topic Guide]	1	31 July 2018
Interview schedules or topic guides for participants [Appendix_F_Patient_Topic_Guide]	V1	09 July 2018
Interview schedules or topic guides for participants [Evaluation Proforma]	V1	09 July 2018
IRAS Application Form [IRAS_Form_23072018]		23 July 2018
IRAS Application Form XML file [IRAS_Form_23072018]		23 July 2018
IRAS Checklist XML [Checklist_23072018]		23 July 2018
Letter from funder [Contract Cover Letter NIHR CCF]	V1	25 April 2018
Non-validated questionnaire [Appendix_G_Patient_Demographic_Questionnaire]	V1	09 July 2018
Participant consent form [Appendix_E_Patient_Interview_Consent_Form]	V1	09 July 2018
Participant consent form [Appendix K - Staff Interview Consent Form]	2	16 October 2018
Participant consent form [Appendix C - Postal Consent Form]	3	16 October 2018
Participant information sheet (PIS) [Appendix H - Practice Staff Recruitment Information]	3	03 December 2018
Participant information sheet (PIS) [Appendix B - Patient Information Sheet]	4	29 November 2018
Research protocol or project proposal [Study Protocol]	V1	09 July 2018
Summary CV for Chief Investigator (CI) [Lasseter CV]	V1	23 July 2018

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	The patient participant information sheet and Health Care Professional participant information sheet were updated post REC favourable opinion in order to bring them in line with the HRA standards
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Applicant has identified 3 separate site-types involved within the study. A statement of activities has been submitted for each site type and the sponsor is not requesting and does not expect any other site agreement to be used. Although formal confirmation of capacity and capability is not expected of some organisations participating in this study, and such organisations would therefore be assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities

Section	Assessment Criteria	Compliant with Standards	Comments
			and information within this letter.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	In accordance with the submitted Statement of Activities, participating NHS organisations will receive funding detailed within Schedule 1.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There are 3 site-types involved within this study depending on the study arm sites are involved in. Due to the nature of the study 1 site maybe involved in multiple arms of the trial therefore this could mean that 1 site is involved in all 3 site-types. Each site-type will be conducted as per the study protocol.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).

Site-types involved in the “Contrasting case studies” arm of the trial will be expected to involve a Local Collaborator at site. The Sponsor is requesting support to identify a Local Collaborator and will include training during the site initiation visit.

All other site-types are not expected to involve a Principal Investigator or Local Collaborator.

GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

- Site-types involved within the “Contrasting case study” aspect of the trial; Should prior contractual arrangements with the host NHS sites not be in place, the researchers undertaking research activities at the NHS trusts would be expected to obtain Letters of Access on the basis of Research Passports if University employed, or NHS to NHS confirmation of pre-engagement checks letters if they are NHS employed, or have already Honorary Research Contracts. Standard DBS checks and occupational health clearance would be appropriate.
- The activities at all other site-types of participating NHS organisation will be undertaken by members of the local health care team, therefore it is expected that adequate contractual relationships are already in place; no additional arrangements (honorary research contracts or letters of access) are expected for this study.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.