Health Research Authority

Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 7972 2557
Email: hra.cag@nhs.net

28 November 2018

Dr Gemma Lasseter
Project Manager and Senior Research Assoicate for the Health Protection Research Unit in Evaluation of Interventions
NIHR Health Protection Research Unit (HPRU) in Evaluation of Interventions
Bristol Medical School, Population Health Sciences, University of Bristol,
(OF22) Oakfield House, Oakfield Grove, Bristol
BS8 2BN

Dear Dr Lasseter

Application title:	**Evaluation of patient access to medical test result services in general practice.**
CAG reference:	**18/CAG/0152**
IRAS project ID:	**249637**
REC reference:	**18/WA/0268**

Thank you for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held on 20 September 2018.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is approved, subject to compliance with the standard and specific conditions of approval.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

This letter should be read in conjunction with the outcome letter dated 02 October 2018.

Context

Purpose of application

This application from the University of Bristol set out the purpose of medical research which aims to gain a better understanding of the services currently offered to provide electronic medical test results of GP practice patients in England. The study involves a number of components involving patients and practice staff, on a consented basis in order to gain understanding in this area and to seek the views of patients and clinicians in relation to different text results services.

The CAG was being asked to consider one element of the overarching research programme relating to GP practice cases studies (section 3.4.3 of the research protocol). This element of the project involved the research team undertaking observations of GP practice staff. The aim was to observe how the test result services function, identify staff and staff roles, clarify electronic test result dissemination routes and collect documentation such as standard operating procedures. All GP practice staff who deal with medical test result services will be observed, which may include reception and back-office staff. There will be six GP practices involved in this element of the study, which will be observed at two time points: baseline in May 2019 and at the end of the fieldwork (January 2020). The researcher undertaking the GP practice observations is not considered part of the direct care team and may be incidentally exposed to confidential patient information during the course of the observation, though this information itself does not form the focus of the observation. It was noted that support could not be provided to healthcare professionals/staff, but that support was requested only for the incidental disclosure of relevant patient information.

A recommendation for class 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All GP staff involved in the handling of medical test results will be observed, which may include reception and back-office staff. Patients registered with six GP practices which are participating in the observational element of the study, who have undergone a medical test for which results are received during the observation period, could potentially have their confidential patient information incidentally disclosed to the researcher during the course of the observation.

The applicant is not seeking support to access any confidential patient information during the GP practice staff observations; however, it has identified that this may incidentally be disclosed. It cannot be foreseen what items of confidential patient information would be disclosed.

Confidentiality Advisory Group advice

A Sub-Committee of CAG considered the applicant's written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Further information is required to explain the public interest in the staff observation element of the research programme. This should address the value of the staff observations to the overarching project, providing assurance that that the scheduled time to undertake the observations would**

provide sufficient exposure to test result handling to provide meaningful data for analysis and confirmation that this was the only methodology which could achieve these requirements.

The applicant explained that the study was using a realist evaluation approach, which seeks to answer the question of "what works, for whom and in which circumstances?". Since so little is known about how electronic test result services are managed in general practice, observing different practices will help the applicant determine what is being done in practice.

It is possible that each participating general practice will use different systems or approaches for managing patients' electronic tests results, the applicants are interested in finding out what works well, or what does not, in each practice. The observational work will provide vital contextual information and will also help inform the quantitative and qualitative elements of the study by identifying the staff that need to be involved and the data that needs to be collected.

The applicant explained that as it was not anticipated that there would be much variation within each practice taking part in the observations, it is expected to be possible to observe the key process within the planned timeframe. Furthermore, since a maximum diversity approach is being used to select the participating practices for the observations, a good range of variation should be captured between practices. Direct observation is the best method for collecting data on non-standard processes, as interviews or surveys can result in reports of 'ideal' processes that are not actually followed in practice. For all of these aforementioned reasons, the applicant confirmed that the proposed direct observation was the only suitable methodology to achieve these requirements.

From a practical perspective, the applicant confirmed that they would liaise with each participating general practice to find out the best time to conduct the observational work. It was recognised that it was possible that some practices only manage patient test results at certain times of the day and if this was the case, it would be ensured that the researchers were present at these times in order to observe how practice staff manage patients' electronic test results.

The response was received by the Sub-Committee and no issues were raised.

2. Clarify what safeguards would be put in place during the staff observations to ensure that the risk of exposure to confidential patient information is minimised.

The applicant reiterated that researchers would not be collecting confidential patient information during the observational work, but appreciated that they may be accidentally exposed to such data during their observational work. The applicant explained that as it was envisaged that electronic test services would be provided differently in each practice, it was difficult to provide a definitive list of safeguards that would be put in place to minimise the risk of exposure in every situation. The applicant explained that the safeguards could include, but were not limited to the following:

- asking practice staff at the start of observations to limit their discussions to non-confidential information (whenever possible);
- ensuring that the researchers were not able to view any computer screens with confidential patient information on (for example, by positioning the researcher or re-positioning/covering computer screens as appropriate);
- ensuring that paper patient records were not visible to researchers;

- when looking at screens to observe the upload of patient test results, the part of the screen that shows confidential patient information may be covered with a post-it or similar device.

The applicant also confirmed that advice would be sought from practice staff about the best safeguards to use in their practice, as they were keen to ensure that the methods used still allow researchers to capture a true representation of the processes used in general practice to manage patients' electronic test result services.

In addition to these physical suggestions, the applicant confirmed that they had already taken proactive steps to ensure that all the researchers working on this project were aware of their responsibilities for safeguarding confidential patient information throughout the proposed study, by checking contracts of employment and ensuring GCP training was up to date. All researchers would have a current research passport and also be required to sign confidentiality agreements. The applicant also advised that observations of the wider practice would be kept at a minimum, to ensure observations were restricted to electronic test results services.

The Sub-Committee received the assurance and raised no queries in this area.

3. Confirm how researcher Dictaphone recordings would be managed to ensure there was no inadvertent recording of confidential patient information.

The applicant explained that, due to concerns raised around the use of digital audio recording devices during the observational work, it had been decided to limit the recording of observational work to written notes only.

The response was received by the Sub-Committee and no further issues were raised.

4. Revise the GP practice poster to provide clear explanation that researchers would be present within the practice undertaking observations of the practice staff.

The applicant provided a revised copy of the GP practice poster which addressed the point raised.

Members received the revised document and raised no queries.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 03 August 2018**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Six Participating GP practices which have not yet been identified. Not requested for each site; support is based on the assumption that the applicant will ensure that satisfactory security assurances are in place for each site**).

As the above conditions have been met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Annual review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than **28 November 2019** and preferably 4 weeks before this date. If at any stage you no longer require support under the Regulations as you will cease processing confidential patient information without consent you should inform the Confidentiality Advice Team of this in writing as soon as possible.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_Form]		24 August 2018
CAG application from (signed/authorised) [CAG_Response_to_Further_Information_Request]		13 November 2018
Covering letter on headed paper [CAG_Covering_Letter]		24 August 2018
Data Protection Registration [UoB Registration Certificate]		17 April 2002
Other [CAT Advice Form Repsonse]		10 September 2018
Patient Information Materials [UoB_Access_study_poster]	1	07 September 2018
Patient Information Materials [UoB_Access_Study_Poster]	2	18 October 2018
REC favourable opinion letter and all correspondence [REC Favourable Opinion]		03 August 2018
REC favourable opinion letter and all correspondence [REC_18WA0268_Response_Letter]		09 August 2018
REC favourable opinion letter and all correspondence [REC_18WA0268 Acknowledgement of additional conditions met]		14 August 2018
Research protocol or project proposal [Study_Protocol_Access_to_Results]	1	09 July 2018
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [UoB Information Governance Letter]		24 August 2018

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

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/

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Enclosures:	*List of members who considered application* *Standard conditions of approval*
Copy to:	penny.beresford@wales.nhs.uk hra.approval@nhs.net

Confidentiality Advisory Group Sub-Committee Meeting in Correspondence

Group Members:

Name	*Present*	*Notes*
Mr. David Evans	Yes	
Professor Barry Evans	Yes	
Dr. Liliane Field	Yes	
Ms Clare Sanderson	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Standard conditions of support

Support to process confidential patient information without consent, given by the Health Research Authority, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate on going training to ensure they are aware of their responsibilities.

6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.