Health Research Authority
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21 July 2021

Professor Anne Slowther
Professor of Clinical Ethics
University of Warwick
Warwick Medical School
Gibbet Hill campus
Coventry
CV4 7AL

Dear Professor Slowther,

Application title:	**Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care** **Short title: ReSPECT in primary care**
CAG reference:	**21/CAG/0089**
IRAS project ID:	**299464**
REC reference:	**21/LO/0455**

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

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 application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 08 July 2021.

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:

The application,

to allow (as part of Work package 1) the research team, who are not considered members of the direct care team, to view confidential patient information while extracting a pseudonymised set of demographic data (applicants anticipate that this will often be done by members of the direct care team, however support is sought should this not be possible),

and to allow (as part of Work package 3) the research team, who are not considered members of the direct care team, to view confidential patient information while extracting a pseudonymised dataset for analysis from the GP medical records (applicants anticipate that this will often be done by members of the direct care team, however support is sought should this not be possible),

is conditionally supported, subject to compliance with the standard and specific conditions of support.

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

The applicant has stated that the following processes are outside the scope of this application and do not require support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002:

- WP1 – Screening of eligible patients by GP practice staff, no support required
- WP1 – if data extraction undertaken by GP practice staff, no support required
- WP1 – care homes – no support required, all direct care team
- WP2 – consented focus groups and surveys with health professionals
- WP3 – Screening of eligible patients by GP practice staff, no support required
- WP3 – if data extraction undertaken by GP practice staff, no support required
- WP3 – no support required for data extraction from care homes as this is undertaken by care home staff
- WP4 – presentation of findings

Context

Purpose of application

This application from the University of Warwick sets out the purpose of medical research to evaluate the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process for adults in primary care, to determine how, when and why it is used, and what effect it has on patient treatment and care.

The ReSPECT plan is a type of emergency care treatment plan, used in hospitals and intended to help patients (or their families) and doctors or senior nurses talk about and record advice about emergency treatments that they may need or want, should they become seriously ill and unable to be involved in decisions about their care. The applicants have recently completed an evaluation of ReSPECT in NHS Acute Trusts, but the ReSPECT process may be more effective if discussed in primary care. The applicants noted the important of evaluating how this process works in primary care, and what impact it has for patients and their families. GPs were encouraged to use ReSPECT prior to COVID, and this has accelerated during the pandemic. However, rapid implementation under pressure of the pandemic risks inappropriate use, which may

have implications for future implementation. There is therefore a pressing need to explore how the ReSPECT plan currently does or does not work in primary care, the impact of the pandemic on its implementation, and implications for patients, their families and health care professionals. If the plan is effective, then patient care should be improved and NHS resources used more effectively.

The project involves a number of work packages; however, only work packages WP1 and WP3 are within the scope of support sought under s251. Support is required as members of the research team, who are not part of the direct care team, may be required to view patients medical records, as it will not always be possible for GP staff to undertake these tasks.

In Work Package 1, the applicants will undertake consented interviews with patients with a ReSPECT form, their families and GPs or senior nurses involved in the ReSPECT process, and staff in care homes. GP staff will identify eligible patients, and contact them via letter in order to consent for interview, however it may be necessary for researchers who are not part of the direct care team to view confidential patient information when extracting a pseudonymised dataset for analysis regarding all patients in participating GP practices who have had a ReSPECT form completed in the last 12 months. They will record basic demographic data, eFrailty index, and type of residence (residential care or own home). These data will not contain any items of identifiable information, but researchers may be required to access medical records to extract this dataset, which therefore requires support under 's251'. Patient contact details are required in order to invite participants for interview, however this is undertaken via the GP practice.

Work Package 3 involves a review of ReSPECT forms and patient GP records to map ReSPECT recommendations to subsequent treatment decisions. Researchers at the Univresity of Warwick will review the anonymised records of patients who have a ReSPECT form completed in the last 12 months. Support under 's251' is requested in order to allow the research team to access the patients' medical records to extract a pseudonymised dataset for analysis, and collect pseudonymised copies of the ReSPECT form, and discharge summaries or appointment letters.

A pseudonymised dataset is disclosed to the University of Warwick for analysis, however this will be effectively anonymous to researchers as the key will be retained at GP practices. 24 care homes will also be taking part in this research study, however support is not required for this element as only care home staff, who are providing direct care, will be processing confidential patient information in order to extract a pseudonymised dataset.

A recommendation for class 1, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	WP1: all adults (18 and over) in the practice with a ReSPECT form completed in the previous 6 months - will have data accessed in order to screen for eligibility. Up to 100 patient records per practice will be accessed and 48 will be invited for interview.

	WP3: all adults (18 and over) in the practice with a ReSPECT form completed in the previous 12 months - will have data accessed in order to screen for eligibility and extract an anonymised dataset for analysis (not required if direct care team). 40 patient records per practice will be accessed in order to achieve the estimated sample size for analysis.
Data sources	1. 12 GP practices from across three Clinical Commissioning Groups (CCGs) 2. 24 Care homes (outside the scope of support)
Identifiers required for extracting a pseudonymised dataset	**For WP1;** Clinical patient records will be viewed in order to extract the pseudonymous dataset for analysis **For WP3**; Clinical patient records will be viewed in order to extract the pseudonymous dataset for analysis Copies of ResPECT form and entire GP record (hospital discharge letters) for 6 months following form completion. These records will be copied, but pseudonymised before being disclosed to the research team.
Identifiers required for analysis purposes	Pseudonymous participant identification number Age Sex Ethnicity eFRailty index This can be considered anonymous to researchers.
Additional information	The participant identification number will be assigned by practice staff at the original identification of patients who have had a ReSPECT form completed. Patient NHS number only will be retained with participant identification number as the key at GP practices. The pseudonymisation key will be retained until the end of data collection and analysis.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

<u>Public interest</u>

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The Members agreed that this application had a clear medical purpose and was in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicants have considered the feasibility of obtaining written informed consent and believe it would not be reasonably practical due to the costs and the risk of bias that an incomplete sample would bring to the research questions under consideration. They state the following rationale to support this assessment:

- The study requirement is for a comprehensive overview of ReSPECT decisions and therefore the design requires full and proportionate representation of all groups of patients within the eligible population.
- The most vulnerable patients (such as those with communication difficulties, learning difficulties and those that lack capacity) would be most difficult to consent and therefore most likely to be excluded due to the challenges of obtaining consent leading to a biased sample, that would differentially exclude a group of significant interest because they are particularly likely to benefit from a ReSPECT process.
- Pilot work has shown that over 50% of patients with a do not attempt resuscitation decision lack mental capacity. Moreover those with DNACPR decisions were more likely to be frail (less independent with activities of daily living) and more likely to be very unwell (McCabe scale).
- In the pilot work for the previous CAG application, of those who lacked capacity, the clinical team had been unable to inform the relatives of the presence of a DNACPR decision in one in five cases which would likely be the minimum rate of failure to obtain informed consent for research purposes. Only recruiting 20% of eligible participants in this group, would introduce bias.

Whilst the Members acknowledged that support under the Regulations cannot be used to bypass the Mental Capacity Act, it is noted that the research proposed here would not be considered intrusive, i.e. data extraction from patient records, so the activity would be suitable for a recommendation of support under the Regulations. The CAG agreed that consent would not be a practicable alternative for this application, due to the bias that would be introduced.

- Use of anonymised/pseudonymised data

Confidential patient information is required to be viewed in order to extract a pseudonymised dataset for analysis. This could not be otherwise achieved without viewing confidential patient information.

- Direct care team

The applicant originally requested additional support for members of the research team who were not part of the direct care team to undertake screening of medical notes in order to identify eligible patients, however has confirmed as part of a response to queries that the direct care team will now be able to undertake screening for eligibility. It was briefly discussed by Members that if the direct care team were now able to undertake screening, would it be a practicable alternative for the direct care team to also undertake the data extraction, and thereby removing the need for 's251' support. However the Committee accepted the justification provided as a response to queries, that this burden of work may not be possible for the direct care team to undertake, as data extraction is more time consuming that screening for eligibility. The applicant will ensure that where possible the direct care team will undertake any work involving processing confidential patient information, and where it is not possible, the research team will undertake these tasks and 's251' is in place for those occasions.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants provided a poster to be used on the GP surgery and website (ReSPECT-PC_WP3 Poster v1.0 29.06.21).

The applicants plan to send out patient invitation letters to all eligible patients in order to then take consent for interviews. This will include information on how the data will be collected and anonymised, and contact details for the study team and information on how to dissent from inclusion. At the request of CAT, the applicants provided revised materials that explained the role of the CAG and that members of the research team may access confidential patient information. The materials were also revised to make it clearer that patients information will not be processed if they opt-out.

The study specific opt-out approach was developed with patient and public partners and implemented successfully in the previous CAG supported study evaluating ReSPECT in acute NHS Trusts. A key of the participant identification numbers will be retained at the research sites in order to enable withdrawal of participants who opt out. The key will be retained until the end of data collection and analysis. No data will be collected from medical records for four weeks after the information letters have been posted to enable time for patients to opt out. They can do this via the pseudonymous participant identification number. Additionally, as part of the screening process for eligibility carried out by practice staff, if a patient record is flagged as the patient having opted out of their data being used for purposes other than direct clinical care the patient will be excluded. A sentence has been added to the protocol describing this.

The Members were broadly content with most of the patient notification materials, and how the opt out option will work. However the Committee commented that the poster and corresponding website text for GP practices was quite short, and as such did not contain enough information. Members felt that the text should explain what ReSPECT is. They also noted that only an email address contact was offered, and that a telephone number and postal address should also be provided. The opt out offered on the poster was not immediately clear, as it refers to filling in a box on a form, which will be provided via post

at a later date to anyone who is eligible. The poster and corresponding text for the GP website should be updated according to the advice above, and provided to the Confidentiality Advice team (CAT) for review.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The application was developed with the Patient and Public Involvement group from the current ReSPECT evaluation study (17/CAG/0060). The group have agreed to continue their role for this application. The application also has a Patient and Public Involvement co-investigator, and two patient representatives are on the Study Steering Committee. The Patient and Public Involvement advisory group will be involved at all stages of the study, advising on patient and public facing documentation, contributing to analysis and interpretation of findings and active engagement in a stakeholder conference.

A Patient and Public Involvement advisory group meeting was held specifically to seek opinions on the acceptability of this use of confidential patient information without consent. The panel included patients and carers who have experience of emergency care and end of life decisions. The group were supportive of using confidential patient information without consent in this manner, and further information is in the application form.

The CAG were impressed with the Patient and Public Involvement undertaken, commenting that it was well established and included people from different faiths.

Exit strategy

The proposed exit strategy from support is the extraction of a pseudonymised dataset for analysis. Support is only required until this timepoint. Analysis of results from Work package 1 and 3 is expected to take approximately 18 months from the time of support.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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

1. The poster and corresponding website text for GP practices should be updated to explain what ReSPECT is, provide a telephone number and postal address alongside the email address, and provide a clear opt out option. Updated versions should be provided to the CAT for review, within one month from the date of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 17 June 2021.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the

‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

Due to the number of participating care providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

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

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **21 July 2022** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date ‘section 251’ annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published ‘Register of Approved Applications’. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [Sent via email]		
Covering letter on headed paper [covering letter 21.5.21]		21 May 2021
Other [17CAG0060 Final Outcome]		
Other [17CAG0060 Provisional Outcome]		
Other [Data flow map ReSPECTPC v1.0 21.5.21]	1.0	21 May 2021
Other [ReSPECT-PC Recruitment flow chart WP1&3 v1.0 21.05.21]	1.0	21 May 2021
Patient Information Materials [ReSPECT-PC Consent flow chart patient family interviews WP1 v1.0]	1.0	
Patient Information Materials [ReSPECT-PC Information about medical records review for opt out WP3 relatives patient lacks capacity_v1.1_28.6.21]	1.1	28 June 2021
Patient Information Materials [ReSPECT-PC PIL1 Invitation Letter Patient First Interview v1.1 28.6.21]	1.1	28 June 2021
Patient Information Materials [ReSPECT-PC PIS1 Information Sheet Patient First Interview v1.0 21.5.21]	1.0	21 May 2021
Patient Information Materials [ReSPECT-PC RIL3 Invitation Letter Relative First Interview (Patient lacks capacity) v1.1 28.6.21]	1.1	28 June 2021
Patient Information Materials [ReSPECT-PC RIS3 Information Sheet Relative First Interview (Patient lacks capacity) v1.0 21.5.21]	1.0	21 May 2021
Patient Information Materials [ReSPECT-PC Text for practice websites v1.0 29-6-21]	1.0	29 June 2021

Patient Information Materials [ReSPECT-PC_WP3 Poster v1.0 29.06.21]	1.0	29 June 2021
Patient Information Materials [ReSPECT-PC Easy Read Invitation Letter Patients v1.0 28.6.21]	1.0	28 June 2021
Patient Information Materials [ReSPECT-PC Summary Easy Read Information about medical records review for opt out v1.1 28.06.21_as]	1.1	28 June 2021
REC favourable opinion letter and all correspondence [Favourable_opinion_at_first_review 17.06.2021]		17 June 2021
Research protocol or project proposal [ReSPECT in Primary Care Protocol_V1.0 17.5.21]	1.0	17 May 2021
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [CAG letter of support - ReSPECT - Caldicott Guardian - 200521]		20 May 2021
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [ReSPECT-PC Information about medical notes review for opt out WP3 patients_v1.1_28.6.21]	1.1	28 June 2021

Membership of the Committee

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

No conflicts of interest were declared.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

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

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Copy to: londonsoutheast.rec@hra.nhs.uk

Confidentiality Advisory Group meeting attendance
08 July 2021

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Professor Barry Evans	CAG member
Dr Rachel Knowles	CAG member
Dr Simon Kolstoe	CAG member
Professor Jennifer Kurinczuk	CAG member
Mr Andrew Melville	CAG member
Professor Sara Randall	CAG member
Mr Marc Taylor	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Standard conditions of support

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

The applicant and those processing the information under the terms of the support 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 ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and relevant 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.

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02 March 2023

Professor Anne Slowther
Professor of Clinical Ethics
University of Warwick
Warwick Medical School
Gibbet Hill campus
Coventry
CV4 7AL

Dear Professor Slowther,

Application title:	**Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care** **Short title: ReSPECT in primary care**
CAG reference:	**21/CAG/0089**
IRAS project ID:	**299464**
REC reference:	**21/LO/0455**

Thank you for your amendment request to the above research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported 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 supported, and if so, any relevant conditions.

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 amendment, to extend 's251' support to include 3 care homes as additional data processors, to allow members of the research team to view confidential patient information whilst accessing care home residents' ReSPECT forms and care records, and for the research team to use care home records (rather than GP records) to identify acute clinical events for the care homes recruited to the feasibility study, is supported, subject to compliance with the standard conditions of support.

Amendment request

This application aims to evaluate the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) process for adults in primary care, to determine how, when and why it is used, and what effect it has on patient treatment and care. The application has 's251' support to allow (as part of Work packages 1 & 3) the research team, who are not considered members of the direct care team, to view confidential patient information while extracting a pseudonymised set of demographic data from GP records. The applicants anticipated that this will often be done by members of the direct care team, however support is in place should this not be possible.

No 's251' support is currently in place for data extraction from care homes as this was planned to be undertaken by care home staff.

The purpose of collecting these data from GP practices was to assess congruence between clinical recommendations on the patient ReSPECT form with decisions made during any acute clinical episode in the following six months. Initial data collection has found that much lower numbers of ReSPECT forms and associated acute clinical episodes were identified than expected, using GP practice records.

This amendment sought support to extend the 's251' support from GP practices to 3 care homes as a feasibility exercise. Applicants will explore whether accessing residents' ReSPECT forms and their care home record to identify acute medical events, would enable them to answer the research question on congruence. Access would be required to care home residents' ReSPECT forms and care records. Care homes are involved in the main project but were not included within the scope of the original CAG application, as the expectation was that all research activities undertaken within care homes would be conducted by the direct care team. However, the study teams' recent experience of recruiting care homes to the main project is that these organisations are unlikely to have the capacity and capability to complete the necessary work, so the investigators propose for a member of the study team (who is not part of the direct care team) to undertake these tasks.

Applicants have provided patient notification designed for care homes, which are based on their originally supported documents.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to support this amendment request, noting it appeared reasonable to extend the 's251' support to care homes.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

Due to the number of participating care providers involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a care provider. These will not be individually checked by the CAT team due to the number of organisations involved.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 16 February 2023

Reviewed documents

Document	*Version*	*Date*
Amendment request form		25 January 2023
IRAS Project ID 299464 - Favourable_opinion_of_a_substantial_amendment		16 February 2023
CAG letter of support - ReSPECT - Caldicott Guardian - 25.01.2023		25 January 2023
ReSPECT in Primary Care Protocol v1.9_19.01.23_clean	1.9	19 January 2023
Feasibility Study_Email text for CH managers_v1.0_05.01.22	1.0	05 January 2022
Feasibility Study_Information for Care Home_v1.0_31.12.2022	1.0	31 December 2022
Feasibility Study_Information for relatives (resident lacks capacity)_v1.0_06.12.2022	1.0	06 December 2022
Feasibility Study_Information for resident (Easy Read)_v1.0_09.12.2022	1.0	09 December 2022
Feasibility Study_Information for resident_v1.0_06.12.2022	1.0	06 December 2022
Feasibility Study_Poster for Care Home_v1.0_06.12.2022	1.0	06 December 2022

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: Standard conditions of Support

cc. londonsoutheast.rec@hra.nhs.uk

Health Research Authority

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 ongoing 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 supported 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.