



# Health Research Authority

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26 November 2019

Dr Matthew Snowsill  
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Dear Dr Snowsill

<b>Application title:</b>	<b>Pre-Hospital Emergency Medicine (PHEM) Feedback</b>
<b>CAG reference:</b>	<b>18/CAG/0018</b>
<b>REC Reference:</b>	<b>Not applicable – non-research</b>
<b>IRAS ID:</b>	<b>Not applicable – non-research</b>

Thank you for your amendment request to the above service evaluation application, submitted for approval 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 Secretary of State for Health and Social Care on whether an application should be supported, and if so, any relevant conditions.

## **Secretary of State for Health and Social Care support decision**

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment to extend the scope of the application activity to ten additional NHS sites within the scope of the programme, extend feedback to additional members of the clinical team and to include additional identifiers within the dataset is conditionally supported subject to compliance with the standard and specific conditions of support.

## **Amendment request**

The amendment request set out changes to the following areas:

### **1. Inclusion of additional sites**

This amendment requested an extension to the scope of support in place for the application activity to enable the roll out of the service evaluation activity across seven additional hospital Trusts and the three ambulance service Trusts which served them. These additional sites are as follows:

1. Barts Health NHS Trust,
2. East Suffolk and North Essex Foundation Trust,
3. Mid Essex Hospital Services NHS Trust,
4. Southend University Hospital NHS Foundation Trust,
5. Basildon And Thurrock University Hospitals NHS Foundation Trust,
6. The Princess Alexandra Hospital NHS Trust,
7. West Hertfordshire Hospitals NHS Trust,
8. East Anglian Air Ambulance,
9. Essex Air Ambulance,
10. East of England Ambulance Service NHS Trust.

The amendment also sought to extend the scope of the feedback to include the Essex County Fire and Rescue Service which, as a non-NHS organisation, would be handled separately within the scope of the amendment.

### **2. Inclusion of additional items of confidential patient information**

Currently, the proposal operated linkage on the Emergency Department number, assigned by ambulance Trusts, alone. The amendment sought support to include both Hospital number and NHS Number within the scope of the support to facilitate sample validation and linkage and to ensure any dissenting patients can be respected across all sites participating within the scope of the application activity. The applicants also sought to record the date of the clinician-patient interaction in those instances where NHS number is unknown at initial presentation.

### **3. Inclusion of clinicians not accompanying patients to hospital within the scope of support**

The current scope of support enabled ambulance trust staff to request feedback around patient care and outcomes. The amendment sought to extend this scope of support to wider pre-hospital staff who have provided care to the patient but may not have accompanied the individual to hospital. This will extend to clinicians who may have been first on-scene such as lone responders on motorcycles, bicycles and fast-response vehicles.

## **Confidentiality Advisory Group advice**

The amendment requested was considered by the Chair's Action. The additional items of confidential patient information which had been requested would enable identification of patients across sites. Currently, the programme operated using emergency

department number only. However, as this was a single-use ID assigned by the ambulance service, this would not enable identification of patients within wider hospital systems to facilitate linkage and to enable any known dissents to be applied.

The request to extend the availability of the feedback service to all pre-hospital clinicians who have provided care to the patients would enable the maximum potential of the feedback programme operated under the application to be achieved. This would enable those wider clinicians who potentially had the most impact on the patients care, by being first on scene as example, to follow-up on patient outcomes and gain feedback on the incident for future learning. The CAG recognised that first responders and pre-hospital clinicians were an essential part of the medical team which required access to the same learning support as clinicians attending in a more structured environment and agreed that there was a high public interest in extending the scope.

With respect of the inclusion of additional NHS sites within the scope of the application support, the applicant had sought prior guidance from the Confidentiality Advice Team around the most appropriate mechanism for including these sites. It was confirmed that the additional sites should be requested as an amendment to the existing scope of support, rather than via individual applications. The applicant had provided copies of information sharing agreements between the listed sites to support the feedback programme.

When including numerous sites within the scope of an application for support under the Regulations, it is standard process that security assurance requirements would not be checked by the Confidentiality Advice Team for each site. Support is recommended on the basis that the applicant takes responsibility for ensuring the appropriate standard has been met, prior to undertaking any processing of confidential patient information within the scope of support. The standards for security assurance standard for sites processing in England with section 251 support had been determined by a Department of Health and Social Care policy position, which was set out below for the applicant's information. Support would be recommended on a conditional basis that these standards were achieved prior to the roll out of the evaluation service within the newly named research sites.

The amendment had sought to include the Essex County Fire and Rescue Service as an organisation within the scope of support which could request feedback within the evaluation system. It was recognised that, as a non-NHS site, this organisation did not appear to have submitted a Data Security and Protection Toolkit which was the security assurance standard against which organisation seeking to process confidential patient information with section 251 support were assessed. On this basis, support could not be extended to the Essex County Fire and Rescue Service at this time. The applicant was advised to contact the IG Delivery Team within NHS Digital to explore options to seek bespoke security assurance for this organisation. Once confirmed, a future amendment could be submitted to include this entity within the scope of the application activity.

### **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 Secretary of State for Health and Social Care.

## Specific conditions of support

1. Support does not extend to the Essex County Fire and Rescue Service at this time. The applicant is advised to contact the IG Delivery Team at NHS Digital to discuss seeking bespoke security assurance for this organisation, to enable this organisation to be included within the scope of support.
2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.
  - a. **Not checked due to the number of additional research sites to be included within the scope of support.**
  - b. **Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations – see section below titled 'security assurance requirements' for further information.**
  - c. **Where NHS Digital confirms confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training: the applicant must ensure that all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.**

## Security assurance requirements

It is the policy position of the Department of Health and Social Care (DHSC) in England that all approved applications seeking 'section 251 support' to process confidential patient information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the relevant Data Security and Protection Toolkit (DSPT). All organisations that are processing confidential patient information under this support must have completed a DSPT submission, and NHS Digital must have reviewed the self-assessment.

There is an agreed bespoke process in place, specifically for applicants seeking 'section 251 support', where the IG Delivery Team at NHS Digital will review the relevant DSPT submission and confirm to CAG that the submission meets the 'Standards Met' threshold. An organisational self-assessment does not provide sufficient evidence; the submission must be independently reviewed by NHS Digital.

To enable NHS Digital to confirm to CAG that the relevant DSPT submission has achieved 'Standards Met', applicants must ensure that the relevant organisations have completed a DSPT submission and submitted their self-assessment(s) through the usual process. At this stage, the applicant must email the Exeter Helpdesk via [exeter.helpdesk@nhs.net](mailto:exeter.helpdesk@nhs.net) and provide this CAG reference number, the organisational names and references that require review, and ask NHS Digital to review the DSPT submissions due to a CAG application. Once reviewed, NHS Digital will confirm to CAG by email that the submission has met the required level.

## Reviewed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
Amendment request		21 June 2019
Information sharing agreements (20 agreements provided)		Various dates
PHEM Feedback Terms of Service	2.3	27 February 2019
PHEM Feedback Report Writing Guidance		
PHEM Feedback User Survey – 6 month report		
Patient Panel – Letter of support (Princess Alexandra Hospital)		26 March 2019
Barts Health Trust NHS Trust – Letter of support, Chair Patient Panel		22 December 2018
PHEM Feedback Patient Engagement Day		02 July 2019

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

Miss Kathryn Murray  
Senior Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: [HRA.CAG@nhs.net](mailto:HRA.CAG@nhs.net)

Enclosures: Standard conditions of support

### **Standard conditions of support**

Support to process confidential patient information without consent, given by the Secretary of State for Health and Social Care, 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 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.

