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09 June 2017

Professor Gavin Perkins
Professor in Critical Care Medicine
University of Warwick
Warwick Clinical Trials Unit
Warwick Medical School, University of Warwick
Coventry
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Dear Professor Perkins

Application title:	**Evaluation of the Recommended Summary Plan for Emergency Care and Treatment (RESPECT)**
CAG reference:	**17/CAG/0060**
IRAS project ID:	**204688**
REC reference:	**17/WM/0134**

Thank you for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable 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 27 April 2017. The response to the provisional outcome issued from this meeting was reviewed by the Confidentiality Advice Team.

Health Research Authority Approval 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 10 May 2017.

Context

Context

Purpose of Application

This application from the University of Warwick sets out the purpose of medical research into the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) Process. The ReSPECT process aims to respect patient preferences and respect clinical judgement through shared conversations between a person and their healthcare professionals. The ReSPECT process is new for the NHS and needs to be evaluated because it is designed for use with all patients in all healthcare settings. It is designed to replace the Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) system and address issues with that system by placing a decision about whether a patient should or should not be for cardiopulmonary resuscitation within an overall care and treatment plan for emergency situation. An evaluation with sites that adopt ReSPECT early will enable an assessment of whether the process is used successfully to address such concerns and to identify whether any changes to the process are needed.

One of its principal aims is to make sure people understand the care and treatment options that may be available to them and that may work in a medical emergency and allow them to make healthcare professionals aware of their preferences. Past experience (e.g. Liverpool Care Pathway) has highlighted the importance of testing any changes to the way things are done. This project plans to study how, when and why these emergency treatment plans are made and the effects they have on patient care. It will use a mixture of methods for collecting information to achieve this aim.

The project involves a number of work packages; however, only work packages WP1B and WP3 are within the CAG considerations. The research requires the research team to access the following information from the patients' clinical records:

- Information recorded on the ReSPECT form,
- Clinical justification for a ReSPECT recommendation,
- General information about the patient (e.g. demographic information, severity of illness measures, laboratory results).

This information will be linked by hospital based research staff to hospital held information on:

- NHS Safety Thermometer data for each individual patient
- Overall outcome for each individual patient (length of hospital stay, survival to discharge, discharge location type).

The data extraction will be undertaken by research nurses within the six acute NHS hospital sites for WP1 and WP3 in England. A diverse range of university affiliated and district general hospitals will be selected. The hospitals will also serve a diverse population consisting of different ethnicities in rural and urban areas.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities as defined in the application.

Confidential Patient Information Requested

Cohort

The cohorts for each work package were described as follows:

Work Package 1B – will involve the data extraction from approximately 20 patients per site involved in the project, which will be purposively sampled from the patient records used within WP3. In the first participating Trust, the applicants will initially select up to 20 records to pilot the evaluation tool in the context of the ReSPECT process. At this stage, if it is found that the tool needed to be refined, a further sample up to 20 records would be selected for analysis. Analysis of these records will inform further sampling at the next Trust with analysis and sampling continuing in an iterative process across all six participating Trusts until there are no new changes in the pattern of consistency, transparency, and ethical reasoning. It is anticipated that there will be a total sample size of approximately 140 records, including those used in the pilot, accessed within this part of the project.

Work Package 3 – will involve all adult inpatients meeting the inclusion criteria on the specified date of data collection for the NHS Safety Thermometer audit data collection. The applicants anticipate that this will be approximately 500 patients per site, totalling at least 3000 patients.

The following items of confidential patient identifiable data are requested for the following purposes:

- Name – data linkage and to facilitate opt-out,
- NHS Number – data linkage and to facilitate opt-out,
- Hospital ID – data linkage and to facilitate opt-out,
- Date of birth – data linkage and to facilitate opt-out and truncated to age for analysis,
- District-level Postcode – for deprivation scoring in analysis,
- Gender – for analysis,
- Ethnicity – for analysis,
- Wider clinical information – for analysis.

Data will be extracted from patient records by research staff that will undertake the data linkage and return a pseudonymised dataset to the research team at the University of Warwick. Research staff at the hospital will retain a pseudonymisation linkage record.

Confidentiality Advice Team Consideration

The response to further information requested as part of the provisional outcome issued on 10 May 2017 was considered by the Confidentiality Advice Team.

1. Consider whether the identifiers held within the linkage file at each research site can be reduced to specific study ID, together with one further identifier, such as the NHS Number or the Provider Identifier, to reduce the identifiability of this data set. Provide confirmation or rationale to support why this would not be possible.

The applicants confirmed the linkage file at each research site would contain the participant's specific study ID and hospital ID number to facilitate linkage with NHS safety thermometer data and opt-out requests. It was explained that data kept in the linkage file at research sites to identify participants if they wish to opt out of the study will be kept

confidential and stored in a separate file. Participant's names, Date of Birth and Postcode would not be kept in the linkage file.

The response was received and no further issues were raised.

2. Confirm the retention periods in relation to study data.

The applicants confirmed that the data sets for all three work packages would be held for 10 years in accordance with University of Warwick policy. It was further clarified that sites would destroy work package three data linkage files, the activity which required support under the Regulations, once the data set has been locked by WCTU for analysis, that is, when participants no longer have the opportunity to opt out.

The response was received and no further issues were raised.

The applicants provided confirmation of an additional research site which had been recruited to the study for information. This was the Central Manchester University Hospitals NHS Foundation Trust.

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

1. Support extends to England and Wales only.
2. Favourable opinion from a Research Ethics Committee. **(Confirmed – 01/06/2017)**
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University of Warwick – reported reviewed grade at 97% satisfactory on Version 13, 2015/16. Heart of England NHS Foundation Trust – reported reviewed grade at 71% satisfactory on Version 13, 2015/16. University Hospitals Coventry and Warwickshire – reported reviewed grade at 91% satisfactory on Version 13, 2015/16. University Hospitals Birmingham – reported reviewed grade at 72% satisfactory on Version 13, 2015/16).**

As the above conditions have been accepted, 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 **09 June 2018** 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) [Research]		21 March 2017
Covering letter on headed paper [Response to Provisional Outcome]		20 May 2017
Letter from statistician	1	28 February 2017
Other [Data Flow Diagram]	1	28 February 2017
Other [Guidance from Clive Collett]		16 March 2017
Patient Information Materials [WP3 Ward Leaflet]	1	17 February 2017
Patient Information Materials [WP3 Ward Poster]	1	17 February 2017
REC favourable opinion letter and all correspondence		01 June 2017
Research protocol or project proposal	1	21 March 2017
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation		17 March 2017

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: hra.approvals@nhs.net
NRESCommittee.WestMidlands-CoventryandWarwick@nhs.

Standard Conditions of Approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable 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.

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

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

6. Activities are consistent with the Data Protection Act 1998.

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. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.