Health Research Authority

Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

December 2017

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Amendment Request

This amendment sought clarification that two health datasets continue to be included in the ongoing scope of support which is recommended for CPRD. The datasets in question are the United Kingdom Renal Registry (UKRR) and the Public Health England Bowel Cancer Screening (PHE-BSC) programme. It was clarified that these datasets were already included within the Master Dataset List that was supported by CAG in February 2013, as part of CPRD's re-application for "s251" support in late 2012. However, the applicants identified that an ambiguity existed with the scope of these dataset approvals, due to how legacy GPRD permissions were carried over into CPRD's "s251" support from 2013 onwards.

Specifically, a pre-2013 approval was given for each dataset under the legacy Research Commissioning Programme (RCP) pilot. Notes provided to CAG in late 2012 informed that:

- For UKRR, it was "Approved for RCP Pilot in the context of a single Pilot study only"
- For PHE-BSC, it "Was a data source in the RCP Pilot for a single study".

A discussion was held between the Confidentiality Advice Team and the applicants prior to the amendment submission and it was agreed that the audit trail in relation to these two datasets was unclear. It was agreed that an amendment should be submitted for clarification purposes.

Confidentiality Advisory Group Advice

The amendment was transferred to a Vice Chair for consideration. It was commented that the request was straight-forward and clarified that support was in place for linkage to both the UK Renal Registry and Public Health England Bowel Cancer Screening programme. The Chair was content to recommend support to the amendment which clarified the position following ambiguity created from historic records.

Health Research Authority Approval Decision

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

1. The amendment is approved, subject to compliance with the standard conditions of support.

   This approval is subject to the original conditions of support provided to the overarching application.

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

This application from the University of Nottingham set out the purpose of a retrospective cohort study (over the course of 12 months) involving case note review of primary care patients to identify instances of significant harm that are judged to be avoidable. Significant harms will include any serious adverse health events occurring during the 12 month data collection period.

It will involve 16 general practices in England in the retrospective cohort study. The total population of patients covered will be around 100,000; 2,500 patients in total across all of the practices. This sample will receive detailed retrospective case note review to identify the extent to which failures in primary health care contribute to any of these significant health problems.

The findings will be published in a report to the Department of Health, and in professional academic journals. Information will also be made available to the public and organisations/charities concerned with patient safety (using presentations/focus groups, social media, and liaison with the media).

The stated aims were:

1. To estimate the incidence of avoidable significant harm in primary care in England.
2. To quantify, describe and classify the different types of avoidable significant harm, and their severity.
3. To identify factors that, if addressed, could help reduce the incidence of avoidable significant harm in primary care in England in the future.

A recommendation for class 1, 5 and 6 support was requested to achieve the above activity and aims.

<u>Confidential Patient Information Requested</u>

Access was requested to name, date of birth and NHS Number, gender, age and participating practice name.

Amendment Request

The final approval for the application, which was issued in February 2016, attached a condition to the support which stated that support to process confidential patient information was only in place until 31/12/2016, as by this time it was anticipated that pseudonymised data only will be processed. Amendments were subsequently submitted to extend the duration of support to provide cover up to 31 March 2017 and 31 December 2017 respectively, which were both supported. The current amendment requested a further extension to the duration of support to provide cover up to 31 March 2018, which is the projected study end date. It was recommended in the original outcome that should the applicants require an extension to the duration of the support, this request should be submitted four weeks in advance of the proposed end date.

The applicants explained that the amendment was required as the applicants had completed 79% of the required data collection. The extension to support under the Regulations would enable the project to be completed. The amendment was submitted in line with the previously advised timeframe ahead of the expiration of the existing support.

The amendment also advised of physical relocation of servers at Cardiff University for information purposes.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Chair who considered the rationale provided by the applicants and recommended support to the duration extension included within the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair 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 of suitable security arrangements via IG Toolkit submission. (**Confirmed – Cardiff University Primary Care Patient Safety Research Group, reviewed grade was confirmed satisfactory at 91% on Version 14, 2016/17).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. (**Confirmed – Non-substantial amendment has been submitted which will not require a formal outcome to be issued).**

Reviewers:

Name	Capacity
Dr Tony Calland	Vice Chair
Ms Rachel Heron	Confidentiality Advisor

Context

The MRC National Survey of Health and Development is a national birth cohort study, comprising a sample of all the babies born in England, Scotland and Wales in one week in March 1946.

The MRC Unit for Lifelong Health and Ageing at UCL (LHA) is responsible for this study. The study has been continually funded by the MRC since 1962 – data has been collected data throughout the life of the study members and the intention is to continue to collect data for the remainder of their lives. Biennial postal questionnaires are sent to the surviving members of the cohort, and follow-up home visits have been completed on 24 occasions, with the last one occurring in 2015.

In addition to this, NHS Digital provides information on the cohort under the legal basis of consent and under Section 251, as follows:

1. Linkage with cancer registry and mortality data under s251 for those who have not consented (either deceased or lost to follow-up)
2. 2. Linkage with cancer registry, mortality and HES data and the provision of address details for participants who have consented.

Amendment Request

In order to obtain equivalent information for medical research on the remainder of the cohort (for those who have not consented), the purpose of this amendment was to seek section 251 approval for:

1. A new data flow for the provision of address details in order to re-contact study members who have been lost to follow up and had not originally consented to linkage with cancer registry and mortality data.

This was requested in order to avoid bias to the results, due to loss of participants to follow-up. Obtaining address details will enable the applicant, where possible, to re-contact the study members who had not previously refused and who had been lost to follow-up, to invite them to continue participating in the study, as well as inviting them to consent to future participation.

2) NHS Digital to link identifiable information provided from the NSHD research team to HES data, for participants who could not be contacted.

In a similar vein, NSHD has collected much of its data from birth through to early childhood and early adulthood before participants were lost to follow-up. For study members who remain lost to follow up and have not been contacted section 251 support is sought as linkage to

additional routine data items such as HES, will allow us to make full use of data that had previously been collected.

Confidentiality Advisory Group Advice

The amendment requested was considered by the Chair who took into consideration the fact that the cohort for this long-running study had consented to inclusion in the study and had been contacted biannually with updates throughout the study. The cohort would be well aware of the study.

The Chair was of the opinion that it was reasonable to attempt to trace those lost to follow-up, and to link with HES data to ascertain mortality status and cause of death if applicable.

On the understanding that any dissent would be respected, and that no further contact beyond that described in the current amendment would be made without further application to the CAG, the Chair was content to recommend support for the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair 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 of suitable security arrangements via IG Toolkit submission. **Confirmed**.
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed**

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the NCEPOD set out the purpose of reviewing clinical practice and identifying potentially remediable factors in the practice of medical and surgical care. NCEPOD examines the quality of the delivery of care, not specifically cause of death; this is done by reviewing the provision of care and treatment and the management of health services. The commentary and recommendations made in each report are based on peer review of the data submitted to them. A recommendation for class 1, 4, 5 and 6 support was requested to achieve the purposes set out in the application.

Confidential Patient Information Requested

Information would be obtained from case notes. This included: NHS Number, hospital number, date of birth, gender, date of admission, source of admission, name of admitting clinician/operating clinician, date of discharge/death (if appropriate), date of procedure, type of procedure (OPCS code), diagnosis (ICD10 code (if relevant)). In addition, name and postcode where required (for ONS/HES outcome linkage only).

Amendment Request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes this year. This amendment covered the first which involved review of pulmonary embolism. The methodology follows the standard retrospective case identification case note review as previous reviews, but the topic is new.

Confidentiality Advisory Team Advice

The amendment request was reviewed by the Confidentiality Advice Team who noted that the request was for an extension to apply the same methodology that had been previously used and for which the applicant already has support.

Confidentiality Advisory Team Conclusion

In line with the considerations above, the Confidentiality Advice Team 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.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2016-17, reviewed grade of satisfactory).**