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

January 2018

Reviewers:

Name	Capacity
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **Asbestos Workers Survey**

CAG reference: **CR4/2014**

HSCIC reference: **MR5**

Context

Purpose of Application

This application from the Health & Safety Laboratory set out the purpose of a study to monitor the long-term health of asbestos workers and help to determine whether the 1969 Asbestos Regulations were effective in reducing the risk of asbestos-related ill-health.

A recommendation for class support was requested to cover access to mortality and cancer data from the NHS Central Register, maintained by the Health and Social Care Information Centre. A cohort of approximately 100,000 patients as at 2006 had been flagged at the HSCIC. It was noted that the cohort size was projected to continue to grow by approximately 2,000 per year but that participants from 2006 onwards had provided consent and were therefore not included within the request for support.

Confidential Patient Information Requested

Access to mortality and cancer data including name, address, date of birth and NHS number was requested.

This study had previously accessed data under the NHS Central Register (ECC 2-04(c)/2010) application.

Amendment Request

The Health and Safety Laboratory (HSL) was previously an agency of the Health and Safety Executive (HSE, the legal entity and data controller for the application activity). HSL has now become an integral part of the HSE and is now referred to as HSE Buxton or HSE's laboratory. As such, the HSL can no longer be considered a separate data processor. The amendment requested a change to the data processor for the application activity to the Health and Safety Executive, with HSE Buxton as the location of the data processing.

The applicants further explained that, as part of the integration and the wider IT Infrastructure changes that are required to facilitate the above, the information which is held for this project will need to change location. It was clarified that this would affect all study data, including information received from NHS Digital.

Confidentiality Advisory Group

The amendment was considered by the Confidentiality Advice Team and clarification was sought around the data processing and storage arrangements which would be in place under the revised processing arrangements. The applicants provided the following confirmation:

- Data Controller – HSE,
- Data Processor – HSE,
- Processing Location – HSE Buxton
- Storage Locations – HSE Bootle and HSE Basingstoke [as contingency],
- The security assurance for all of the above is HSE's IG Toolkit assessment (code: 8J222) version 14. The IG Toolkit covers the HSE network, which encompasses Bootle and Basingstoke.
- The data will be accessed and processed via hardware in Buxton, connecting to the HSE network.

It was acknowledged the data had previously been stored at HSE Buxton; however, all sites are covered by the HSE network-wider IG Toolkit.

The amendment was shared with the Chair for review, as it was acknowledged that there were changes to data flows within the application activity, albeit within the wider HSE network. The Chair considered the amendment and recommended support for the revised data processing arrangements and the associated changes to data flows and storage arrangements.

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. Favourable Opinion from an NHS Research Ethics Committee. **(Confirmed as non-substantial, not required for this amendment).**
2. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Health and Safety Executive, Version 14, 2016-17, reviewed grade 66% satisfactory).**

Reviewers:

Group Members:

Name	*Notes*
Ms Sophie Brannan	Lay
Dr Tony Calland M.B.E	Chair
Professor Jennifer Kurinczuk	

Also in attendance:

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

Application title: **UK Women's Cohort Study - HES**
CAG reference: **17/CAG/0081**
IRAS project ID: **213210**
REC reference: **17/YH/0144**

Context

Purpose of Application

This application from University of Leeds set out the purpose of research through the establishment of a database. The UK Women's Cohort Study was established in 1993 on a consented basis to explore links between diet, lifestyle and chronic disease, in particular cancer. Approval was granted at this from each local REC for the study to follow participants for cases of cancer and other diseases. Individual consent forms were not required by the REC's, therefore those women who returned questionnaires with a completed back page were considered to have provided consent for participation. The back page of the questionnaire informed participants that the purpose of the study was to examine "the occurrence of certain diseases such as cancer which are registered by the National Health Service" and participants were asked to provide their NHS number and GP address in order for their medical records to be accessed. The applicants hold name, date of birth and NHS number against a participant ID number from this historic consented study.

This application proposes the establishment of a new database, which will be generated from the existing cohort held by the applicants as part of the UK Women's Cohort Study. The new database will hold the existing dietary information collated as part of the UK Women's Cohort Study and will be linked with HES and ODR data held by NHS Digital. The applicants propose the disclosure of confidential patient identifiable data from the established cohort to the University of Leeds Integrated Research Campus (IRC). The IRC will then send this information to NHS Digital in order for the dataset to be linked with HES and ODR data for the cohort. This will be returned by NHS Digital to the IRC, whereby the research team will access the information via a Virtual Research Environment.

A recommendation for class 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

The cohort is already established and will include all participants within the existing UK Women's Cohort Study, which amounts to 35,372 women.

Confidential patient identifiable information will be transferred from the University of Leeds Nutrition Epidemiology Group UK Women's Cohort data holding to the IRC platform within the University of Leeds to enable the set-up of this new proposed database. Data will then be shared with NHS Digital for linkage and returned to the University of Leeds.

The following items of confidential patient information will be required to facilitate the data linkage to be undertaken by NHS Digital:

- NHS number,
- Date of birth,
- Participant ID.

Confidentiality Advisory Group Advice

A Sub-Committee of Members reviewed the applicant's written response to the provisionally supported outcome in correspondence.

1. **UK Women's Cohort Study – validity of consent:**
   a. **Confirm under what legal basis the UK Women's Cohort Study database continues to be retained,**

The applicants explained that at the initial inception of the Women's Cohort Study all relevant approvals had been sought for the project and participants were included in the basis of informed consent. During the course of the review, it became apparent that the patient consent which was taken at the outset of the project was no longer valid. The public interest in the ongoing retention of the rich data source which had been established across the duration of the study was acknowledged.

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

   b. **Clarify under what legal basis this database continues to receive ONS data from NHS Digital,**

The applicants provided a copy of a data sharing agreement which was in place with NHS Digital to support the ongoing linkage with ONS data.

This point was further considered by the Sub-Committee who noted that a letter from the NHS Information Centre Data Access Advisory Group had been submitted as part of the wider study correspondence. This document related to a study-specific HES linkage which had been undertaken in 2011. Within this document, it was stated that the consent taken at the outset of the study covered a 10 year study and was no longer valid. The Confidentiality Advice Team contacted NHS Digital to clarify the legal basis under which ONS data continued to be disclosed to the Women's Cohort Study, as it appeared from this correspondence that the consent was no longer valid. Response was received on 19 January 2018 which confirmed that the initial study consent no longer supported this data flow. NHS Digital stated evidence of an established legal basis would be required in order for further data to be supplied under the data sharing agreement with the applicants.

The Sub-Committee received the clarification from NHS Digital. It was noted that the linkage with ONS mortality information had not been specified in the application and therefore could not be supported at this time; however, an amendment to support this data linkage would be considered.

c. Confirm if the UK Women's Cohort Study database has been linked with any additional sources since the expiration of the original consent in 2005,

The applicants confirmed that, in addition of the ongoing linkage with ONS data, the UK Women's Cohort Study sample had only been linked with one additional source since the expiration of the consent. This linkage was with HES data in 2011, which was supported under application reference ECC 6-05(e)/2011.

The Sub-Committee received the response and no further issues were raised in this area.

d. Provide a copy of the original questionnaire supplied in 1995, which provided an overview of what the study involved for participants if they returned the document and implied consent for participation.

The applicants provided copies of the documentation as requested.

The historic documentation was considered by the Sub-Committee; however, it was commented that the detail participant information materials did not indicate the duration of the study and follow-up for which participants were providing consent.

2. Provide a clear description of what this request for support under the Regulations is required to cover.

The applicants confirmed that they were seeking support for the ongoing retention of the UK Women's Cohort Study database and for the linkage with the HES database as described in our application. Our request for support under the Regulations is intended to extend to cover the retention of all data currently held in the UK Women's Cohort Study database.

The Sub-Committee received the response and it was noted that the ongoing public interest in the retention of the UK Women's Cohort Study Database was recognised when the application was initially considered at full CAG. Members were content to provide a recommendation of support to the ongoing retention of the UK Women's Cohort Study Database.

3. Patient and Public Involvement and Engagement:

a. Provide a detailed plan for public and patient involvement and engagement activity which will be undertaken as the project progresses.

The applicants provided details of a plan to reinvigorate the patient and public involvement group for the study, with the aim of expanding it to other public members who would be interested in supporting the study and its aims to enable a larger pool from which to draw expertise.

The applicants stated that the new group membership would include:

- Previous Chair and members of the group (study participants),
- Other independent lay members,
- Patient or GP practice representative.

It was confirmed that members would be recruited through targeted contacts to appropriate individuals and through web adverts on the Cohort study website. Copies of information materials were provided for consideration.

It was explained that the public and patient involvement group would be scheduled to meet annually for progress review and virtually on an ad-hoc basis after requests for access to the database had been made, in order to comment and provide feedback to the research team.

The number of these meetings will vary according to the requests for access. If requests became frequent then a more regular pattern of meetings would be instigated to assist with the workload of the group.

The public and patient involvement group activities would be independent of the research team and the Chair of the group would report directly to Professor Cade with any suggestions/comments.

The group would support the following activity regarding the UKWCS database:

- Reviewing requests for data access and analysis,
- Providing a patient and participant or carer perspective to researchers,
- Commenting on plans for dissemination of results and clarity of message,
- Supporting the research team should any media requests for comment occur.

The Sub-Committee was assured that the proposed patient and public involvement and engagement plan was appropriate to the application activity. It was acknowledged that a report would be required at the time of first annual review around the actual activity which would be undertaken in this area. It was commented that if the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

4. **Patient Notifications and Dissent:**
   a. **Provide detailed information around how and where patient notifications in relation to the project will be displayed,**
   b. **Submit copies of any notifications for consideration,**

The applicants submitted copies of updated notification materials for consideration. It was explained that the text would be displayed on the study website.

On review of the revised information, the Sub-Committee noted that the website text stated that the Women's Cohort Study would be linked with both HES data and data from the National Cancer Registration and Analysis Service (NCRAS). Members commented that the linkage via NHS Digital with the HES dataset had been outlined within the initial application and subsequent responses; however, it was not clear that the application was had also intended to support a link to NCRAS data, which was held by Public Health England.

The Sub-Committee requested further information around this point, as it was unclear whether it had been intended that the linkage with the NCRAS dataset held by Public Health England was included within this submission.

The applicants confirmed that the intention was to link the UK Women's Cohort Study with both Public Health England and NHS Digital to facilitate linkage with the NCRAS and HES datasets respectively. The applicants confirmed that there had not previously been a linkage established between the UK Women's Cohort Study and the NCRAS database held by Public Health England.

The Sub-Committee received the additional clarification; however, it was stated that the application form which had been submitted for CAG consideration did not clearly articulate the proposed linkage with the NCRAS database maintained by Public Health England. Members agreed, in light of this, that support could not be recommended to this additional data linkage. The applicants were advised that an amendment to the application for linkage to the NCRAS database would be considered.

   c. **Clarify the dissenting mechanism for the project, together with details of how any objection raised would be managed.**

The applicants explained that should a participant request an opt-out from the study, a member of the research team would make contact them by the same mode of communication to clarify if the individual was willing for their original data to be kept or if they would prefer to fully opt-out all information provided by them in the past from this project. The participant's data would be removed as per their request – either from the original database or the newly proposed database development.

The applicants confirmed that an audit database of opt-out requests would be maintained so that the research team track the numbers of opt-outs received. The audit database would only contain the participants ID number and the action taken regarding the opt-out.

The Sub-Committee received the clarification and no further issues were raised.

5. **Provide confirmation that data linkage with HES data would be undertaken by NHS Digital.**

The applicants confirmed that NHS Digital would undertake linkage with the HES dataset.

The response was received no further issues were raised in this area.

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. Support was extended to England and Wales only.
2. Support is extended to the ongoing retention of the original UK Women's Cohort Study database.
3. Support is only extended to the linkage of the UK Women's Cohort Study participants to the HES dataset held by NHS Digital at this stage. There is currently no support for the linkage to ONS data held by NHS Digital or NCRAS data held by Public Health England.
4. A report would be required at first annual review around the actual activity which had been undertaken to engage and involve public and the patients within the project. An updated plan of activity would also be required at this time detailing the proposed involvement and engagement activities moving forward.
5. Favourable opinion from a Research Ethics Committee. (**Confirmed – received 21/06/2017**).
6. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed - University of Leeds Integrated Research Centre shows a reported published score of 88% satisfactory on Version 14, 2016/17).**

Group Members:

Name	*Notes*
Dr Martin Andrew	
Dr Kambiz Boomla	
Dr Patrick Coyle	Vice Chair
Professor Jennifer Kurinczuk	
Ms Clare Sanderson	Alternate Vice Chair

Also in attendance:

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

Application title: **PREVALENCE AND INVESTIGATION OF LABORATORY DIAGNOSED ANAEMIA IN SECONDARY CARE**
CAG reference: **17/CAG/0167**
IRAS project ID: **233509**
REC reference: **17/SC/0524**

Context

Purpose of Application

This application from the University of Southampton sets out the purpose of medical research to evaluate current routine practice in the diagnosis and investigation of anaemia in secondary care.

The aim of the project is to use data from a large teaching hospital that will develop an understanding of how a laboratory diagnosis of anaemia, i.e. a haemoglobin concentration below the normal reference range set by the world health organisation (WHO), is investigated and the economic impact of these investigations.

Data Analysts at University Hospital Southampton will access the electronic laboratory records to acquire the dataset for the defined study period which is all cases between 01/01/2016 – 31/12/2016, which meet the inclusion criteria. The Data Analysts had legitimate access to this data as part of their standard roles and as such, did not require support under the Regulations for this task. The dataset will be matched with diagnostic codes using the digital hospital medical records. Support is requested to enable access to a sub-cohort of approximately 10% of the patient cohort records to enable the accuracy of diagnostic coding to be checked.

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

Confidential Patient Information Requested

Cohort

All patients with a confirmed laboratory diagnosis of anaemia at University Hospitals Southampton will be included. This will encompass both male and female, aged between 16 and 110 years, who were seen between 01/01/2016 and 31/12/2016 at University Hospitals

Southampton. The laboratory diagnosis is classified as a haemoglobin concentration below the normal limit set by the World Health Organisation.

Total UK sample size: 33000

The following items of confidential patient information are requested for the purposes set out below:

- Hospital Number – validation and linkage between laboratory data and patient episode information,
- Gender – for analysis.

The applicants would use the hospital number in order to access the full patient record in order to undertake an audit check of the diagnostic codes which had been applied to records.

Confidentiality Advisory Group Advice

A Sub-Committee of the CAG considered the written response provided by the applicants to the request for further information included within the provisionally supported outcome in correspondence.

1. **Confirm how the initial patient cohort of 35,000 will be reduced to the focus sample of between 2-10,000 patients. Clarify who will be involved in this process and what access to confidential patient information will be required to facilitate this.**

The applicants explained that the sample would be reduced using the exclusion criteria. The laboratory computer system had the capability to produce this dataset. It was explained that the haematology IT department routinely used this for auditing purposes. The applicants further explained that they had previously used the system as an audit tool with the preoperative anaemia service to look at the patients that had been through the service. It was confirmed that the data group in the laboratory already had access to this data as part of normal clinical care and as such, no one would be gaining new data access to complete this project.

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

2. **Further information is required around the Data Analysts who will be involved in the study to address the following points:**
    a. **Confirm who these individuals are,**
    b. **Clarify what usual right of access these individuals had to confidential patient data,**
    c. **Confirm whether these individuals would be processing confidential patient information with support under the Regulations.**

The applicant explained that the Data Analysts involved with the project would be the divisional data analysts who normally had access to all of this data. These individuals would not be gaining any new or additional access to data for this project. It was confirmed that the two individuals that were supporting the project would routinely have access to all hospital data of any patient who has had blood tests performed in the laboratory at University Hospital Southampton. The applicant confirmed that he, as the researcher, would be undertaking an audit check of patient records for a sub-sample of patients, in order to carry out an audit check of the diagnostic codes which had been applied. It was clarified that as the applicant would not ordinarily have access to these patient records, the audit-checking

process involved a breach of patient confidence for which support under the Regulations was required to provide a legal basis for this data access.

The Sub-Committee was assured by the applicant's response that support under the Regulations did not need to be extended to the Data Analysts who would be creating the patient dataset required for the project. The Sub-Committee acknowledged that support under the Regulations was required to enable the applicant to access patient records for the sub-set of patients in order to carry out an audit of the diagnostic codes which had been applied.

3. **Clarify at what stage of the project the pseudonymisation key will be deleted and what the duration of support required under the Regulations was.**

The applicant confirmed that the audit key would be deleted as soon as the sample had been checked for accuracy. It was estimated that this process would take approximately six months from the start of the study.

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

4. **Patient and Public Involvement and Engagement – further work is required in this area to address the following issues:**
    a. **The patient survey which is referenced within the application should be undertaken in order to test the acceptability of using confidential patient information without consent for the purposes of the study,**
    b. **Feedback should be provided around the activity and its findings to support the public interest in the overall activity,**
    c. **If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.**

The applicants provided an overview of a two hour public involvement and engagement meeting that was undertaken in December at the Trust, together with the feedback provided by those present.

The Sub-Committee considered the information which had been provided and it was agreed that, whist the activity which had been undertaken was positive and evidenced support for the project, the demographics of the group was specifically focused on younger people. Members commented that the patient data which would be included in the study was more likely to be from an older demographic of patients.

The CAG agreed that further work was required in this area in order to consult with a wider cohort of individuals who were more likely to have their data included within the project. It would also be beneficial to discuss the proposal with patients who had previously been treated for anaemia. It was agreed that this additional work should be undertaken as the project progressed. A report would be required at the time of first annual review detailing the actual work which had been undertaken in this area together with any feedback provided. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

5. **Patient Notification and Dissent – further work is required to establish a system to inform patients of the activity which is being undertaken in the project and enable patient dissent to be raised. The following points should be addressed:**
    a. **Provide an overview of how a patient notification and objection mechanism will be operated for the study,**
    b. **Provide copies of any notification materials for consideration by the Group.**

The applicants created a page on the Trust website around the project which was provided for review.

The Sub-Committee considered the detail of the notification mechanism and it was agreed that this appropriate to the activity which was being carried out. It was agreed that additional opt-out contacts should be added to the notification, to enable patients to opt-out by telephone or postal address, as well as email. Members agreed that this would be added as a condition to the recommendation of support.

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. Patient Notification and Dissent – the following point should be actioned ahead of the project commencing:
    a. An additional means of contact should be added to the opt-out mechanism (postal or telephone).
2. Patient and Public Involvement and Engagement – further work should be undertaken in this area to address the following points:
    a. Additional patient and public involvement and engagement activity should be undertaken in order to seek the views of a wider patient demographic, including an appropriate patient cohort,
    b. Feedback will be required at the time of first annual review around the actual activity which has been undertaken in this area, together with feedback,
    c. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
3. Favourable opinion from a Research Ethics Committee. **(Confirmed – opinion issued 20/10/2017).**
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University Hospital Southampton Information Governance Assessment Report overall score for v14 (2016/17) – 73%, reviewed by NHS Digital as satisfactory).**

Reviewers:

Name	*Notes*
Dr Tony Calland	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from Royal Free Foundation Trust set out the purpose of building a research platform for patients with amyloidosis. Management of all UK patients with amyloidosis is via the National Amyloidosis Centre (NAC) based at the Royal Free Hospital, although other aspects of their medical care are also be provided locally to the patient in secondary care and tertiary care centres.

1. NHS Digital shares pseudonymised, non-sensitive standard monthly subscription extracts of HES Admitted Patient Care, A&E and Outpatient data with IMS Health (in line with the existing data license).
2. The NAC generates a study ID for each patient managed at the NAC. The NAC will send this and the NHS number to the HSCIC.
3. NHS Digital supplements the NAC NHS number list with pseudonymised patient IDs, which are aligned to the HES extract IMS receives in step 1. This supplemented list (comprised of pseudonymised patient IDs and study ID) is then returned to the NAC.
4. Thereafter all research activities will be conducted on de-identified data at IMS. The HES linked data will not leave IMS Health.

Although there is a consent system has been in place since 2006, with a provision to ask all current patients whether they agree for their data to be used for research, there are patients who have been lost to follow up or who are deceased, where it has not been possible to ask for consent. In addition patients present in the database prior to 2006 will not have been asked this specific question. Due to the limited size of the cohorts of interest, identification of clinically meaningful and significant precursors/prognostic factors relies heavily on maximising the full historic records available.

All patients that have refused consent for their data to be used for non-clinical purposes will be excluded from the NAC dataset. Only aggregated non-patient level output will be shared. Tables of less than 5 patients will be suppressed and no data will be published that could lead to identification of a patient (even after their death).

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover the transfer of identifiable data to the HSCIC for those patients for whom there is not an alternative legal basis for this processing.

Confidential patient information requested

Access was requested to the transfer of identifiable data (NHS number) relating to those Amyloidosis patients for whom consent is not in place to cover this, from the Royal Free to the HSCIC for processing in order to provide the required output.

Amendment Request

The purpose of the amendment was to request the following two changes to the application:

1. Change in purpose – the applicants requested and extension to support in order to use the anonymised aggregated data for an additional purpose, which was to inform the design of a Phase III clinical trial.
2. Addition of Data Controller – the amendment requested inclusion of GlaxoSmithKline as a joint data controller for resulting anonymised and aggregated dataset, which would be utilised to inform the Phase III clinical trial.

Confidentiality Advisory Group Advice

Data Controllership Arrangements

The Confidentiality Advice Team requested clarification from the applicant's around the data controllership arrangements for the overall application activity as the proposed amendment appeared to contradict the understanding of the arrangements which were currently supported under the application.

The applicants confirmed in correspondence that there will now be three joint data controllers for the application activity as follows:

- IQVIA (new branding of IMS Health & Quintiles),
- Royal Free London NHS Foundation Trust,
- GSK.

Evidence was supplied from each organisation confirming that joint data controllership was in place for the application activity. The additional information was received and the Confidentiality Advice Team was satisfied that the data controllership arrangements for the activity were clear and appropriately evidenced. The Chair acknowledged the information and no further queries were raised in this area.

Change in Purpose

The amendment was shared with the Chair for consideration and it was acknowledged that the proposed change in purpose did not involve a change in the data items or data flows currently supported in the project, as the anonymised aggregated dataset was already available to GSK.

The Chair was of the opinion that the new purpose described was still a medical purpose and was assured that the strong public interest which was identified with the initial application remained in the extended purpose. The Chair noted that the patient facing literature remained fit for purpose. 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 – email received from NHS Digital 27/12/2017).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 15/11/2017).**

Reviewers:

Name	*Notes*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the University of Manchester sets out the purpose of medical research into suicide amongst prisoners. This study will conduct an independent case series examining all self-inflicted deaths in prisons in England and Wales between 2016 and 2019. The applicants will examine trends over time and explore what may have contributed to the rise in self-inflicted deaths in custody. They will also examine specific groups (such as remand, women, older prisoners) and the circumstances of suicide to make recommendations regarding the recognition, assessment and management of suicide risk and related issues of general mental health care and training needs of staff. Furthermore, although deaths by those in, or shortly after leaving police custody, and those on community supervision or licence annually account for smaller numbers than self-inflicted deaths in prison, the risk is pervasive throughout the Criminal Justice System. Therefore this study will conduct a scoping exercise to ascertain what procedures are in place, and what data are collected, when a suicide occurs in the wider Criminal Justice System. This will add to a comprehensive body of information about self-inflicted deaths across the criminal justice pathway in order to inform prevention policies going forward.

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

Confidential Patient Information Requested

Cohort

All deaths in prisons in England and Wales classified as self-inflicted from 1st January 2016 to 30th April 2019. This is estimated to be around 300 individuals.

The identification of the cohort will be undertaken by the research team at HM Prison and Probation Service and is outside of the scope of this application. The applicants will be provided with the following information:

- Identification number,
- Prisoner name,
- Establishment,
- Date of death,
- Prison number.

This information will be provided to the Healthcare Manager at the prison where the individual died in order for information to be collated from the individual's medical record (within the scope of support). The questionnaire containing information from the medical record will be returned to the applicants.

Amendment Request

The amendment was submitted to the CAG for information purposes due to a change in the overall methodology for the study. These changes were outside of scope of the element of the application which was supported under the Regulations; however, it was acknowledged

that the change in protocol had led to revisions in the data questionnaires which were previously considered by the CAG.

The applicants clarified that additional information would be received directly from HMPPS. Rather than sending an email detailing name, prison number, prison and date of death, the Death in Custody team at HMPPS had agreed to send the research team a Death in Custody (DIC) questionnaire that would provide additional information. The DIC questionnaire is currently in use and completed by prison staff following a death in custody. By receiving this, the applicants clarified that this would prevent duplication through staff being required to complete the project specific questionnaire.

It was explained that the DIC questionnaire included additional demographic information (e.g. nationality, ethnic origin, age, religion); details relating to offence and sentencing (e.g. status of prisoner, type of recall if applicable, offence, sentence length); details of death (e.g. date of death, ligature and ligature point if applicable); prisoner location (e.g. location of cell, shared cell, type of cell); ACCT information (e.g. history of self-harm/suicide attempt, on an open ACCT, previous on an ACCT); healthcare (e.g. history of drug/alcohol abuse, detoxification). It was recognised that this information was not disclosed with support under the Regulations.

The applicants had revised the content of the study-specific Governor questionnaire in line with the additional information which would be provided direct from HMPSS. Further revisions were made to the healthcare questionnaires following feedback from a member of the Independent Steering Committee.

Confidentiality Advice Team Advice

The amendment requested was considered by the Confidentiality Advice Team and it was acknowledged that the proposed amendments did not impact on the elements of the application activity which had received support under the Regulations. It was recognised that the change in protocol had resulted in revisions being made to the questionnaire documents which had previously been reviewed by the Confidentiality Advisory Group, notably the healthcare questionnaire, which was being completed and returned to the researchers with support under the Regulations. It was agreed that support should be recommended to the revised documentation.

Confidentiality Advice 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 Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – University of Manchester – Offender Health Research Network shows a reviewed grade of 83% satisfactory on Version 14, 2016/17).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 19/12/2017).**

Reviewers:

Name	*Notes*
Dr Tony Calland	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from the Health and Safety Laboratory (HSL) detailed a large cohort study of pesticide users comprising of more than 60,000 individuals with the aim to determine whether exposure to pesticides can be associated with an increased risk of neurological disease.

Confidential Patient Information Requested

Access was requested to patient level HES data in relation to inpatient episodes from NHS Digital, this would then be linked to study data retained by the HSL using a unique reference number. In addition, support was requested to access mortality and cancer registration data in relation to the cohort from the NHS Digital. This data had previously been accessed under the NHS Central Register (ECC 2-04(c)/2010) application.

Amendment Request

The Health and Safety Laboratory (HSL) was previously an agency of the Health and Safety Executive (HSE, the legal entity and data controller for the application activity). HSL has now become an integral part of the HSE and is now referred to as HSE Buxton or HSE's laboratory. As such, the HSL can no longer be considered a separate data processor. The amendment requested a change to the data processor for the application activity to the Health and Safety Executive, with HSE Buxton as the location of the data processing.

The applicants further explained that, as part of the integration and the wider IT Infrastructure changes that are required to facilitate the above, the information which is held for this project will need to change location. It was clarified that this would affect all study data, including information received from NHS Digital.

Confidentiality Advisory Group

The amendment was considered by the Confidentiality Advice Team and clarification was sought around the data processing and storage arrangements which would be in place under the revised processing arrangements. The applicants provided the following confirmation:

- Data Controller – HSE,
- Data Processor – HSE,
- Processing Location – HSE Buxton
- Storage Locations – HSE Bootle and HSE Basingstoke [as contingency],
- The security assurance for all of the above is HSE's IG Toolkit assessment (code: 8J222) version 14. The IG Toolkit covers the HSE network, which encompasses Bootle and Basingstoke.
- The data will be accessed and processed via hardware in Buxton, connecting to the HSE network.

It was acknowledged the data had previously been stored at HSE Buxton; however, all sites are covered by the HSE network-wider IG Toolkit.

The amendment was shared with the Chair for review, as it was acknowledged that there were changes to data flows within the application activity, albeit within the wider HSE network. The Chair considered the amendment and recommended support for the revised data processing arrangements and the associated changes to data flows and storage arrangements.

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 – Health and Safety Executive, Version 14, 2016-17, reviewed grade 66% satisfactory).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Noted this change does not constitute a substantial amendment for REC purposes, which would not be acknowledged).**

Reviewers:

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

Context

The ARTISTIC trial compared cytology with and without HPV testing among 24,510 women attending for routine cervical screening in 2001-04. This project is an epidemiological follow-up based on their history of HPV infection and cytological abnormality, irrespective of their initial random allocation. Women were followed to 2009 through the two local participating cytology laboratories for cytology and histology. Additional linkages to Open Exeter and pathology reports were now required in order to obtain complete cytological follow-up by linkage to NHS cervical screening call-recall records.

A recommendation for class 1, 4, 5 and 6 support was requested to link cytology records, to confirm coded diagnoses and to identify women who have had a hysterectomy performed. Support was also requested to allow continued access to cancer and mortality data from the NHS Central Register, maintained by the Data Linkage Service (DLS) at the Health and Social Care Information Centre. Linkages would be undertaken using NHS number and date of birth.

Amendment Request

Support is in place for the applicants to flag for current patient status on cancer registrations and death data via NHS Digital and ONS and linkage vis NHS Digital to Open Exeter records to obtain full cervical screening history. This amendment requests an extension to flag patients with locally collected cervical screening records from histology, virology and cytology laboratories and data from colposcopy clinics.

Confidentiality Advisory Group Advice

The amendment request was forwarded to the Chair who recognised that the inclusion of additional data sources locally in Manchester would increase the clinical detail available from colposcopy, improve knowledge of HPV subtypes and improve the timeliness of the data. The additional linkage did not propose any increased risk around confidentiality or security, but would notably enhance the study. The Chair was content to recommended support to 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 – Version 14 published as satisfactory).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – 19 July 2017).**

Reviewers:

Name	*Notes*
Miss Kathryn Murray	Senior Confidentiality Advisor

Context

Purpose of Application

This application from St Georges, University of London set out the purpose to identify individuals who have died and the causes of death from a database of approximately 4500 individuals who underwent voluntary cardiac screening with a medical questionnaire and ECG through a program organised by the charity Cardiac Risk in the Young (CRY).

The purpose of the database is to look for an association between sudden death and particular feature's on an individual's ECG. These features are known as the early repolarisation pattern (ERP). ERP has been shown to be more common in people who have suffered a cardiac arrest and has been associated with an increased risk of sudden death in large populations of middle-aged individuals. However, it is seen commonly in young healthy people and its significance in this group is unknown. An application to the Health and Social Care Information Centre (HSCIC) for ONS data has been submitted by the applicant to identify those individuals who have died and date and cause of death.

All individuals whose data is included have signed a consent form stating "I do agree that data from these tests [ECG] will be held on a database ... and can be used anonymously for research purposes." The consent form is accompanied by a comprehensive information sheet that explains the potential role for such research. This is further supported by regular paper-based literature and on-line publicity and information from CRY supplied to all participants and the charity's supporters.

A recommendation for class 1 and 6 support was requested to cover access to name, GP registration, Postcode, date of birth, date of death and cause of death.

The applicant has provided details of their correspondence with HSCIC and copies of the consent and participant information details.

Confidential Patient Information Requested

Access was requested to name, GP registration, Postcode, date of birth, date of death and cause of death.

Amendment Request

The amendment requested an extension to the duration of support through to January 2020. It was clarified that extension was required due to an unexpected delay in receiving the required data from NHS Digital, as the initial data access request had not yet been completed.

Confidentiality Advice Team Advice

The amendment requested was considered by the Confidentiality Advice Team who noted that there would be no changes to any aspect of the application other than the timescale, and that there would not be an increase in the time taken for data processing overall. It was acknowledged that, should it be identified that a further extension to the duration of the application is required, submission of a further amendment would be required at that time.

Confidentiality Advice Team 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. **(Extension amendment not required for REC).**