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

October 2017

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Application title:	**Impact and Evaluation of a Burns Risk Assessment of Neglect and Maltreatment in Children Tool. BuRN-Tool A multi centre study**
CAG reference:	**15/CAG/0203**
IRAS project ID:	**169420**
REC reference:	**15/WA/0259**

Context

Purpose of Application

This research application from Cardiff University set out the purpose of the application to develop and test a Clinical Prediction Tool for use in the Emergency Departments (ED)/MIU'S (Minor Injury Units) and Burns Units to help identify features that may be significant when considering if a burn or scald is due to neglect or maltreatment. A further aim was to conduct a before and after study to evaluate the acceptability, efficacy and accuracy of the BuRNtool to identify maltreatment when implemented into clinical practice in Emergency Departments, Minor injury Units and Burns Units. Finally, a further aim was to identify if a version of the tool can be developed for use by child protection professionals.

The target range for this study are those aged 16 years and under. It was stated that patterns/types of thermal injury are unique to the developing child and it is vital that any safeguarding concerns are addressed especially in the younger children who are not able to verbalise what has happened to them.

A recommendation for class 1 and 6 support was requested to achieve the activities specified within the application and to enable a specific research nurse access to identifiable information. The applicant confirmed that the selection of feasibility study in the application was done in error, the application is for all sites.

Confidential Patient Information Requested

Support was requested to allow the disclosure of confidential patient information from the BaSAT [form used to capture the related information]; on paper using the pro forma to the REDCap data base. Electronic data will be transferred from each centre, entered by the clinician onto the patient system (MEDWAY) at time of examination. The required fields are then transferred via secure download to the REDCap data base, this is overseen by NHS trust IT staff.

This would involve access to the following: Childs Medical record/Emergency department notes completed by the ED/MIU/Burn unit clinician (BaSAT); outcome of Safeguarding referrals (strategy meeting/case conference) from Children's Services. In particular, this

would involve access to the following items: Name, NHS No, postcode at sector level to enable deprivation scoring, gender, ethnicity and date of birth.

Amendment Request

The request was for a 2-year extension to the activity, due to additional funding which would enable the tool to be assessed within a wider variety of settings.

Confidentiality Advice Team Advice

The amendment requested was considered by the CAT who noted that there would be a geographical and cohort size extension in addition to the extension of time period. There would be no changes to the purpose, data sources, data items, data flows or exit strategy. The addition of any new sites would require appropriate security assurances to be provided, should any identifiable data be processed at the site outside of the direct care team.

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. (**University of Cardiff, School of Medicine, Early Years Research Programme – Confirmed published and reviewed).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. (**Not Required – non-substantial amendment).**

Reviewers:

Name	Capacity
Dr Tony Calland	Vice Chair
Dr Murat Soncul	Alternate Vice Chair
Ms Clare Sanderson	Alternate Vice Chair
Ms Rachel Heron	Confidentiality Advisor

Application title: **Epidemiology of Cancer after solid organ transplantation**

CAG reference: **16/CAG/0121**

IRAS project ID: **183974**

REC reference: **15/YH/0320**

Context

Purpose of application

This application from University Hospitals Birmingham set out the purpose of investigating mortality from cancer following organ transplantation, and comparing clinical outcomes between the transplant and the non-transplant population. There was an increasing prevalence of cancer post-transplantation; further evidence would guide and inform clinical management and counselling for patients.

Cancer data is not routinely collated by transplant centres. In order to answer the research questions, the applicant proposed to link information from various national data resources, via the HSCIC/NHS Digital. This would include the UK Transplant Registry (mandated to collect information from all UK transplant centres), HES and ONS data, the UK Renal Registry and the General Practice Extraction Service (GPES). Identifiable data with NHS number and study number would be sent by the UK Transplant Registry, UK Renal Registry and National Cancer Intelligence Network to HSCIC/NHS Digital. This would be linked with HES, ONS and GPES data and de-identified and pseudonymised data would be returned to the applicant, with a patient study number allocated for follow-up. Study data would be destroyed at the end of the study.

A recommendation for class 4 and 6 support was requested to link patient identifiable information obtained from more than one source.

Confidential patient information requested

Access was requested to date of death, gender and ethnicity.

Amendment request

The applicant had requested data from 2001 to the present day, as this was the period from which HES data was available. However they now wished to include earlier data (from 1985) found on the UK Transplant Registry and the National Cancer Registry, despite the fact that it could not be linked with HES data. This would allow more long-term survival analyses and changes in survival rates over previous decades to be analysed.

The study had not yet commenced. The applicant would update the patient notifications accordingly.

Confidentiality Advisory Group advice

The amendment requested was forwarded to a Sub-Committee of members, who queried whether additional data sources would be used. On referring back to the original application, it was clarified that the applicant was intending to link data for a larger cohort of patients than the original request. Members agreed that there was a significant public interest in this activity and that they would be happy to recommend support subject to evidence of a satisfactory method of patient notification and opt out.

This should be complete in advance of the data being linked by NHS Digital so that patients have the opportunity to opt out in time.

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. **University Hospitals Birmingham NHS Trust – v14 confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee**. Not required for extension to timeline.**
3. Provision of patient notifications including advice to patients on how to opt out, and a description of the method for respecting opt out to be presented to the Sub-Committee.

The applicant provided the following detailed description of the plans to notify and involve the public, via email sent on 29 September:

'Our plan is to make every effort to inform the public and transplant patients of this project. This work is being carried out in partnership with the British Transplantation Society and will be actively promoted via their website and social media feeds – we will have clear details of the study published and the process for opting out if patients so wish. We also have letters of support from our multiple collaborators (e.g. Public Health England, NHS Blood and Transplant, Farr Institute) and we will simultaneously raises awareness of the study and the option to opt out if patients wish to do so. Our steering committee will also have PPI participation and we will be guided by them through the course of our study.

I am also due to present this project at the Royal Society of Medicine (December 2017) and the British Transplantation Society annual congress (March 2018) to raise awareness and we will clearly outline the process for opt-out. Finally, as part of our dissemination process, we want to involve patients groups. Some of these links are through the British Transplantation Society but also other national groups (e.g. National Kidney Foundation) and we will raise awareness through them through their websites, social media and posted leaflets.

Finally, the study will be on a public trials registry and will be openly accessible.

I hope these comments reassure the committee with regards to our active efforts and happy to discuss further. Dissemination of our project is a key aim and that involves the professional community and patient/public group – we are planning for this to be a continuous process throughout the study duration.'

The Chair reviewed the description and was content that this met the principles of the CAG in relation to patient notification and public involvement, and that on this basis support could be recommended.

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Ms Rachel Heron	Confidentiality Advisor

Application title: **Detecting and alleviating language impairments due to Traumatic Brain Injury**

CAG reference: **16/CAG/0127**

IRAS project ID: **141276**

REC reference: **14/NW/0182**

Context

This research application was submitted by the University of Manchester and detailed an activity that would be supporting PhD student research. The Academic supervisor would be acting as the Chief Investigator.

Impairments in language function, or aphasia, can have a debilitating effect on a life. Acquired impairments can arise through various conditions such as stroke, brain tumours, and traumatic brain injury (TBI). Language deficits can occur following TBI when there is obvious injury to the language centres of the brain, however, there is also some evidence to show that even when these areas remain intact, language problems can occur.

There are three arms to this project.

1. To determine how prevalent language problems are following TBI, when there is no obvious injury to the language areas, using a series of neuropsychological language tests.
2. To determine why these problems occur. Using a relatively new method of MRI scanning, called diffusion tensor imaging (DTI), which detects the diffusion of water in the brain to form maps of neural connections, the applicant aims to determine if the deficits occur due to injury to the underlying connections of the brain.
3. To test if the applicant can improve these patients' language function using a technique called transcranial direct current stimulation (tDCS). tDCS is a non-invasive neurostimulation technique which delivers a small current of electricity to the brain to increase neuronal activity. It is thought to promote regeneration and rewiring of the connections in the brain, and so it is possible it would promote regeneration of injured language neural circuits, improving language function. This will be administered during the performance of language production and comprehension tasks and will be compared to a sham condition, in which the equipment is still used but no current is applied.

A recommendation for class 3 and 6 support was requested to cover access to cover the relevant activity detailed in the application form.

<u>Confidential patient information requested</u>

The Group agreed that confidential patient information was requested only for the purposes of identifying and approaching the participant in order to seek their consent for the activity. The identifiers specified were name and date of birth in order to gauge whether the patient is

of the appropriate age, and to aid identification. Any further information held would be retained with consent.

The researcher will access the medical records held on the ward and in clinics and record the patients name and date of birth as well as whether they are suitable for the study. The patient will then be approached, either on the ward or in clinic that day, and asked if they would like to take part in the study. If they wish to take part they will be consented for all of the data held about them which will then be transferred to a locked cabinet at the University and if not, their data will be destroyed securely and immediately in accordance with Trust policies.

Amendment request

The amendment requested permission to access additional data items: patient's address in addition to name, date of birth and diagnosis. Support was in place to identify and seek consent from patients at the hospital site, however in order to improve recruitment this further request was to access patients' address in order to send invitation letters.

Confidentiality Advice Team advice

The amendment requested was forwarded to the Chair who expressed his understanding of the logistical difficulties involved with the proposed method of recruitment, where patients would be approached on the ward or in outpatient clinics. Although sympathetic to the request, the Chair was concerned that patients would be surprised to receive a letter from an unknown researcher, and enquired whether the letter could be sent from the treating clinician in the appropriate department

The applicant responded that they had spoken to the relevant clinician who had agreed to be the signatory on the letter.

The Chair advised that they would be content to recommend support in this case, once REC approval was in place.

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. **University of Manchester – v14 confirmed published and reviewed.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 4 October 2017.**

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title:	**Effectiveness and Cost-effectiveness of 'Usual Care' versus 'Specialist Integrated Care': A Comparative Study of Hospital Discharge Arrangements for Homeless People in England**
CAG reference:	**16/CAG/0021**
IRAS project ID:	**166237**
REC reference:	**16/EE/0018**

Context

Purpose of Application

This application from University College London set out the purpose of establishing the ways in which Specialist Integrated Homeless Health and Care (SIHHC) services are being developed and used to facilitate hospital discharge in England. The study also aims to examine the impact this is having on quality of care for homeless people admitted to hospital and whether this care can help prevent readmission to hospital shortly afterwards.

The first work package (WP1 –for which support is not requested) seeks to gain an informed understanding of the ways in which SIHHC services are being developed and implemented to facilitate hospital discharge in England and the impact this is having on quality of care and organisational outcomes such as the prevention of readmission to hospital. For this work package, local service providers will be asked to identify and nominate potential participants.

The second work package (WP2, for which support is requested for datasets 1, 3, 4, and 5) is a data linkage and health economic analysis work package that will work with twenty sites across England where homeless patients have been admitted to hospital. A cohort of homeless people who have used specialist discharge scheme will be compared to a cohort of homeless people who have not used such provision. The study will also compare patient's hospitalisation history before and after engagement with specialist services. Analysis will also be undertaken to understand whether the outcomes are a factor of homelessness specifically or are tied to deprivation.

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover the activity specified in the application for work package 2, datasets 1, 3, 4, and 5.

Confidential Patient Information Requested

Access was requested to:

- Dataset 1: Data from homeless healthcare users, as outlined in SIHHC data variables in the 'Data Flow Diagram' document, including forename, surname, aliases, date of birth, sex, address, contact number(s), hospital of admission, date of hospital admission, nationality, ethnicity, and NHS number; from study fieldwork sites: November 2013 to a maximum of November 2016
  At each site the research team will create a unique study identifier for each record for the service provider. The data requested for the study will then be securely uploaded and

processed at University College London (UCL). The data will be stored and cleaned. Identifiable information required by the Health and Social Care Information Centre (HSCIC) for the linkage to Hospital Episode Statistics/Office for National Statistics (HES/ONS) will at this point be transferred to HSCIC. When HSCIC have confirmed that the list is clean, and linkage to HES has been completed, the researchers will de-identify all data.

- Dataset 3: Data from homeless healthcare users, as outlined in SIHHC data variables in the 'Data Flow Diagram' document, including forename, surname, aliases, sex, address, and contact number(s); from Find and Treat Service: November 2008 to November 2016.
  The data requested for the study will then be securely uploaded and processed on the data safe haven at UCL. The data will be stored and cleaned. Identifiable information required by HSCIC for the linkage to HES/ONS will at this point be transferred to HSCIC. When HSCIC have confirmed that the list is clean, and linkage to HES has been completed, the researchers will de-identify all data.

- Dataset 4: Personal Demographics Service (PDS) data from homeless healthcare users, including date of hospital admission, date of hospital discharge, date of hospital appointment, and date of death: November 2008 to November 2016.
  The HSCIC will use data within PDS to provide missing NHS numbers for the two previous datasets. The research team will not at any point have access to these NHS numbers, which will be used to improve the linkage of data to HES.

- Dataset 5: HES ONS mortality data from homeless healthcare users and a geographically comparable and representative sample of lowest quintile of deprivation population in HES (based upon the index of multiple deprivation) equal in size to the Find and Treat dataset during the hospital admission study period: November 2008 to November 2016. This data will have already been de-identified by the HSCIC.

Amendment Request

The amendment requested revisions to the variable requested from the HES dataset. The following data items would be added to the variable list for use in analysis:

1. ARRIVALDATE
2. AEATTENDCAT
3. AEATTENDDISP
4. TREAT2_N

The removal of the following data items from the HES extracted data was requested as they had been found to be unnecessary to the study:

5. CARERSI
6. CATEGORY
7. CENDUR
8. CENSAGE
9. CENSTAT
10. CENWARD
11. DET_CFL
12. DETDUR
13. DETNDATE
14. DOMPROC
15. LEGLSTATST
16. MENTCAT
17. PROVSPNO

18. VIND
19. WARDSTRT

Confidentiality Advisory Group Advice

The amendment requested was considered by the Alternate Vice-Chair, who acknowledged that the revised data items did not include any confidential patient information; however, as these formed part of the wider dataset the rationale for the amendment was sound. Support was recommended for the revisions to the dataset requested from HES.

Confidentiality Advice Team Conclusion

In line with the considerations above, the Alternate Vice-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 – UCL School of Life and Medical Sciences-Data Safe Haven reviewed satisfactory grade at 66% satisfactory on Version 14, 2016/17).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. (**Not Application – REC Favourable Opinion in place – revision to variables only requires consideration via CAG**).

Group Members:

Name	*Notes*
Dr Kambiz Boomla	CAG Member
Mr Anthony Kane	CAG Member
Dr Harvey Marcovitch	CAG Member
Dr Mark Taylor	CAG Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Testing a diagnostic aid for hip dysplasia in primary care**

CAG reference: **17/CAG/0171**

IRAS project ID: **210262**

REC reference: **17/LO/0631**

Context

Purpose of Application

This research application from Great Ormond Street Hospital for Children stated that developmental dysplasia of the hip (DDH) is a condition where the 'ball and socket' joint of the hip does not properly form in babies and young children. Dislocation occurs in 1-2/1000 infants per year but milder forms occur in 40-60/1000. Because early recognition of disease is associated with better outcomes, it is national policy to examine all infants for the presence of DDH at birth and at 6 weeks in primary care (6-week hip check). Despite a compulsory hip check at the age of 6 weeks in primary care, missed diagnoses and infants incorrectly labelled with DDH remain an important problem, potentially leading to adverse consequences for infants, their families and the NHS.

The application set out details of a pilot study that seeks to improve the diagnosis of DDH in primary care through use of a diagnostic aid. The study is intended to test an existing previously developed diagnostic aid for DDH and will develop a training video that goes along with this checklist, tailored for use in primary care. The aim is to identify whether it may reduce the number of infants diagnosed late with DDH and that it may assist in infants being wrongly labelled with DDH.

A recommendation for class 1, 5 and 6 support was requested to cover access to confidential patient information as detailed in the application.

Confidential Patient Information Requested

In this pilot, the aim is to look at the performance of a diagnostic aid when used by GPs who carry out the 6-week hip check. Data will be obtained based on the results of this hip check. In particular, this was specified to include: name (for patient identification purposes), NHS number and date of birth (to enable identification and following through to secondary care), gender, ethnicity (to analyse their influence in the primary and secondary outcomes) and follow up/ treatment details.

Three to six months following the 6-week hip check, the researcher will visit all practices again in order to discern if the infants had hospital contact for their hips. For this the research team would view any corresponding clinic letter, referral letters and any test results. Data to

be extracted from each GP database includes; if a patient was admitted for treatment of a hip, if a patient obtained treatment of a hip in outpatients and if a patient had at least one hospital appointment for the hip. A researcher will collect any follow up data only from each GP practices' database, using unique NHS patient numbers, and categorize the appropriateness of referrals by a practice.

Confidentiality Advisory Group Advice

The CAG noted that this was a resubmission of application 17CAG0064, which was considered at the CAG meeting held on 11 May 2017, at which point it was issued with a deferred outcome, pending further clarifications from the applicants. Review of the revised submission was assigned to a Sub-Committee of the original reviewers, who considered the further information provided in response to the deferred outcome in correspondence.

1. **Further justification to demonstrate why the seeking of explicit consent from patients, to allow researcher access to confidential patient information, would not be feasible. This should include an indication as to patient cohort size.**

The applicants explained that in the project planning stages they met representatives from participating GP practices and with Professor Irwin Nazareth, a GP of Keats Group Practice. GPs and practice managers were informed of the proposed study and their views were sought around potential obstacles or concerns about patient flow; consenting; structure of practice and patient flow; number of eligible patients.

The applicants advised that whilst GPs emphasised they were keen to take part in the planned study, they confirmed that they would not have the time or the staff resources to consent the parents/carers of infants undergoing the 6-week hip check which was generally offered to parents as a part of routine practice. The applicants explained that the focus of the study was to introduce more structure by the use of a checklist to the GPs' 6-week routine hip examination performed on all babies. The GPs did not think it practical to seek informed consent and questioned the need for such a process as it merely offered structure to routine clinical care. Professor Nazareth was also of the view that the study would not depart from care normally provided to these infants, hence a case could be made to seek support under the Regulations to progress the study without implicit consent. If the study would run for three months as planned, the applicants clarified that approximately 291 infants would potentially undergo a 6-week hip check in the enrolled GP practices.

The Sub-Committee considered the information provided by the applicant and it was acknowledged that the additional clarifications evidenced that the GP community was in support of the project and clarified their views around the consenting requirements in relation to use of the tool. Members commented; however, that the issue which had not been explored was the practicality of seeking consent for the disclosure of confidential patient information to the research team. It was understood that parents would be passed an information sheet informing them that the research was taking place. The Group suggested that there was scope within this document to include the opportunity to seek consent for the use of the infant's data by the research team. Further correspondence with the GP practices was required to satisfy this outstanding issue as without an explanation in this area, Members were unable to assess whether the minimum thresholds required to enable a recommendation of support to be made under the Regulations had been met.

2. **Revision of the information provided to patients to ensure the mechanism of opt-out applies only to the researcher unconsented access to information.**

The applicants submitted a revised patient information leaflet (Version 3, 18/08/2017) which expressed that the 'opt-out' mechanism related only to the unconsented access to patient

information. It was clarified that for those who wished to opt-out, GPs will still use the diagnostic aid as a matter of course.

The Sub-Committee considered the content of the information leaflet and it was identified that the text still largely addressed the use of the hip check tool. Members agreed that the information leaflet required further revision to articulate that the key issues involved in the research project were around the dissemination of confidential patient information to the research team, not the use of the tool, which will be followed regardless of whether a parent expressed dissent. The document should explain what data would be collected from patient records, how this would be used and the governance arrangements around its storage. It was also commented that the reference to data not being collected should a parent opt-out was not wholly accurate and the CAG recommendation had incorrectly been referenced as approval. The revised document would need to be reviewed by the Sub-Committee for suitability prior to any recommendation of support being considered.

3. Lay person explanation of the process of transfer of information to UCL, and the key measures in place to appropriately protect the confidentiality, integrity and availability of the information.

The applicants explained that the Data Safe Haven was a service at UCL that provided a technical solution for storing, handling and analysing identifiable data. It had been certified to the ISO27001 information security standard and conformed to NHS Digital's Information Governance Toolkit.

It was explained that the researcher would take a UCL laptop to the GP sites, to enable study data to be entered directly into the Data Safe Haven. This method ensured that no person outside of the research team could access the patient data.

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

4. Explanation and justification for transfer of patient information to UCL, from the context of seeking to minimise the flows of identifiable information.

The applicants confirmed that the research team was based at UCL where all data would be analysed. It was clarified that it was not practical or time efficient to carry out data analyses in each of the participating GP practices due to the lack of staff and space resources.

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

5. Further justification for the retention period of identifiable information.

The applicants agreed to reduce the retention period for personal data from 6-12 months to 3-6 months as they were assured they would be able to carry out all analyses within this period. As for the research data storage, the applicant confirmed that it was common practice to store such data for a period of two years.

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

6. Further detail on impact of the PPI involvement undertaken.

The applicants provided an overview of the patient and public involvement activity which had been undertaken during the planning stages of the programme. Detail was provided around interaction with STEPS, a charity supporting patients affected by lower limb disorders as well as parents and carers of infants with hip dysplasia. It was identified that three carers had also showed interest in contributing to the dissemination of the research findings to the public to

ensure that future carers-to-be were well-informed about this condition, the 6-week check and its consequences.

The Sub-Committee received the overview of the public and patient engagement and involvement activity and it was assured that this was appropriate to the proposed activity. No Further issues were raised in this area.

7. Clarification of the upper age of the cohort.

The applicants clarified that the 6-week hip check would usually be undertaken at the six to eight week mark and 56 days would be the upper age limit.

The clarification was received and no further issues were raised.

8. Confirmation that calls made to the parent/carer would be by a member of the GP practice and not the researcher.

The applicants provided confirmation that should a call to the parents/carers of infants become necessary, this call would be conducted by a member of staff at the GP practice and not the research team.

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

Confidentiality Advisory Group advice conclusion

The CAG agreed that they were supportive in principle, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

In order to complete the processing of this application, please respond back to the following request for further information within one month:

Request for Further Information

1. Further interaction with the GP practices participating in the study is required to fully explore the potential practicable alternatives to seeking support under the Regulations for the project. The following issues need to be specifically addressed:
    a. The practicality of seeking consent from the parents for the use of their child's confidential patient information within the research project should be tested,
    b. An overview of the feedback provided should be detailed for consideration by the CAG,
    c. If it is determined that seeking consent is impracticable, justification should be provided to support this.
2. The patient information leaflet, which will serve as a patient notification mechanism, requires revision to address the following issues:
    a. The focus of the document should be around the disclosure of the infant's confidential patient information from the GP practice to the research team,
    b. An overview of the items of data which will be collected is required, the purpose of collecting the data and how this would be used, together with an explanation of the governance arrangements in relation to its storage should be included,
    c. The detail in relation to opt-out should be revised to explain that should a parent express dissent to the use of their child's data, information would still be collected as part of the direct care interaction; however, it would not be shared with the research team,

d. The CAG is an advisory body and provides a recommendation of support only – the inaccurate references to 'CAG Approval' should be corrected. If the CAG does provide a recommendation of support following resolution of the outstanding issues, approval would be granted by the Health Research Authority, as the appointed decision-maker for research proposals.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, the HRA will confirm approval.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee. **(Pending)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – UCL School of Life and Medical Sciences shows a reviewed grade of satisfactory at 66% on Version 14, 2016/17).**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Application title: **Non-Hodgkin's Lymphoma in Young Adults**

CAG reference: **ECC 7-05(c)/2011**

Context

This application from Guy's and St Thomas' NHS Trust set out details of a prospective cohort study to collect diagnosis, treatment and outcome data on every 15 to 29 year old diagnosed with non-hodgkin's lymphoma (NHL) over a 3 year period with the aim of establishing the incidence of each NHL type, document treatments and record readmission and cure rates.

A recommendation for class 4, 5 and 6 support was requested to provide a legitimate basis to access confidential patient information to collect notifications, link information from different sources and to audit, monitor and analyse current treatment.

Confidential patient information requested

The application requested access to name, NHS number, GP registration, date of birth, date of death and postcode from pathologists or clinicians making the diagnosis of the patient and from the young adult cancer registry, from Public Health England (PHE). The patient's clinical care team would be asked to provide them with patient information and the option to opt out of the study. Follow up data would then be requested from treatment centres for each case to 2 years from diagnosis and patients would be flagged for mortality on the NHS Central Register for 5 years.

Amendment request

The amendment request described several previous amendments which had been supported by the CAG in order to facilitate recruitment, including retrospective recruitment and the inclusion of deceased patients. Although study recruitment was going well, initial delays to approvals had meant that some patients were being approached for consent to the study a considerable amount of time after their treatment had taken place. In order to avoid this situation and to ensure that a full 3-year cohort could be included as per the original application, the request was to extend recruitment until December 2018.

Confidentiality Advice Team advice

The amendment requested was considered by the CAT who considered the rationale for the amendment to be sound, and noted that there would be no changes to the purpose or nature of the data flows as described in the application.

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. **Guys and St Thomas' NHS FT: v14 confirmed published and reviewed.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC approval not required for extension of time period.**

Reviewers:

Name	Capacity
Dr Martin Andrew	CAG Member
Ms Sophie Brannan	CAG Member
Dr Murat Soncul	Alternate Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

PIAG Reference Number: 1-07(e)/2004

Application title: The British Women's Heart & Health Study

Context

The British Women's Heart and Health Study was a long-running study which aimed to support the prevention and treatment of heart disease.

Amendment Request

This amendment requested support to extend the linkage of the British Women's Heart & Health Study data to the following datasets held by NHS Digital: Hospital Episode Statistics (HES) data, Mental Health Minimum Data Set (MHMDS) and the Diagnostic Imaging Dataset (HES-DID), in order to identify additional clinical outcomes of the study participants.

The applicants clarified that the following additional information would be requested from the datasets:

HES Dataset

- Information on Accident & Emergency, Critical Care, Inpatient and Outpatient admission, dates of admission and diagnosis of clinical events (expressed as an International Classification of Diseases [ICD] code). The linkage required to do this is already established at NHS Digital, where study participants are already linked on their NHS number to provide information on mortality and cancer registration. The applicants proposed to collate this information from 1999-2001, when consent was obtained until end of follow up for each participant.

Mental Health Minimum Dataset

- This will be restricted to a dementia focused dataset with medications. The focus here was dementia – Alzheimer's disease, vascular dementia and their main subtypes and symptoms.

HES-Digital Imaging Dataset

- Detailed information about diagnostic imaging tests, allowing discrimination between the different major types of dementia in particular Alzheimer's disease (AD) and vascular dementia.
- Results of cardiac imaging studies to inform us of the diagnosis of heart failure, and will allow discrimination between systolic and diastolic heart failure.
- The results of brain imaging studies, which are now extensively used in the investigation of cerebrovascular disease, allowing discrimination between different stroke subtypes.

NHS Digital already have the study participants established for linkage via NHS number, so the support request extends to the linkage to be undertaken by NHS Digital only and release of the linked information to the applicants.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Alternate Vice-Chair who advised that as the request extended to the inclusion of data from the Mental Health Minimum Dataset, the amendment review should be escalated to a Sub-Committee.

The Sub-Committee requested further clarity around how the extraction from the Mental Health Minimum Dataset would be limited the ICD10 codes which were relevant to dementia only.

The applicants provided a spreadsheet detailing an overview of the diagnostic codes which would be requested via NHS Digital.

The Sub-Committee received the response and were assured that the data requested was specifically linked to dementia.

It was further acknowledged that the patient notification system would require revision to explicitly explain this additional data linkage and enable a dissent mechanism to be operated.

The applicants provided drafted text which would be included within the newsletter circulated to all participants in the study for consideration.

Members were satisfied that the text provided appropriately described the additional data linkage activity which was proposed and described the mechanism for patients to raise an objection.

The Sub-Committee was assured that the data requested from the HES-DID imaging dataset was relevant to the overall aims of the project.

Following the additional clarifications provided by the applicants during the course of the amendment review, the Sub-Committee were content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Sub-Committee 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 – UCL, School of Life and Medical Sciences, Version 14, 2017/17 reviewed satisfactory at 66%)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – issued 24 August 2017)**.

Reviewers:

Name	Capacity
Mr Anthony Kane	CAG Member
Ms Clare Sanderson	Alternate Vice Chair
Mr Marc Taylor	CAG Member
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **Clinical Practice Research Datalink Service (CPRD)**

CAG reference: **ECC 5-05 (a)/2012**

Context

This application was originally considered in 2012 with final approval issued in February 2013 during the time of the NIGB Ethics and Confidentiality Committee. This application is a unique research application that could be considered to provide an 'honest broker' or 'safe haven' processing environment. The CPRD is a discrete function within the MHRA. Due to its national nature, the annual review is considered at full CAG meetings. The application sets out the activity to process a broad range of research and national audit datasets, and specified datasets to enable de-identified disclosure to research recipients.

At a high level, support has been provided for the following aspects:

- GP practices and specified others (according to the master dataset list) to transfer identifiable patient information to NHS Digital.
- NHS Digital to receive identifiers, undertake linkages and provide the CPRD a pseudonymised linked dataset.
- The CPRD do not receive identifiable data from the HSCIC or others under the terms of this support. The CPRD process identifiable information but not under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 e.g. through another legal basis such as consent.
- NHS Digital was operating under the control of the MHRA (via CPRD) in a data processor relationship. The applicant for the purposes of this application is the CPRD who are responsible for the actions of NHS Digital (who in turn are operating under instruction of the CPRD).

Confidentiality Advisory Group Advice

A sub-committee of the main CAG considered the response provided by the applicants to queries raised from the CAG meeting held on 09 February 2017 and a subsequent response provided following a request for further clarification which was issued on 02 June 2017.

<u>Conflict of Interest</u>

During the course of the review of applicant responses in relation to the annual review, a potential conflict of interest was noted in discussion amongst the Sub-Committee. Mr M Taylor had identified that he had been involved in wider communications with the applicants in relation to other business on behalf of the Health Research Authority. The Chair queried whether this presented a conflict of interest to the ongoing involvement in the consideration of the annual review. Response was considered by the Sub-Committee and it was agreed that this wider contact did not relate to the review in hand and no further action was required.

Communication to General Practices

The applicants provided confirmation that they had undertaken a review and revisions of the communications with GPs. Details were provided of a new patient poster for participating practices, together with an easy-to-reach webpage. A copy of the poster was provided for information purposes together with links to the webpage.

The applicants further advised that a letter for GPs newly contributing to the CPRD had been devised, which explained the requirement to display the poster within the practice. This document was also supplied for information purposes. A new webpage specifically for GPs had been made available, for which a link was provided for information purposes.

It was confirmed that the applicants sought specific consent from GPs to permit the flow of data from practices to NHS Digital to facilitate linkage. Where consent is not granted, CPRD does not link primary care practice data with other datasets.

Additional data was provided around future linkages with data obtained from practices using the EMIS IT system provider.

With regard to consistency of communications with NHS Digital and on communication of opt-outs available, the applicants explained that NHS Digital were currently working with the Understanding Patient Data initiative on producing an agreed position for the general public, following the Government response to the public consultation on the National Data Guardian's Review. It was confirmed that CPRD would align with this agreed position when it has been finalised.

Members were assured by the response provided in this area with the exception to the response provided around working with NHS Digital to cross reference communications around CPRD and clearly explaining the opt-out methods available. It had been proposed as part of the original outcome that work was undertaken to ensure clear information was also available via NHS Digital's website around CPRD and this detail was cross-referenced between the two for consistency. It had been recommended that work was undertaken through engagement with patients in drafting these new communications. The Sub-Committee agreed that an update against this requirement would be required at the time of next annual review.

High-Risk Protocols

The applicants provided an overview of the assessment process which applications undergo to determine whether there is potential high-risk of disclosure. It was confirmed that should a potential risk of identification be recognised, CPRD would inform the applicant that their request raised a confidentiality risk and would work them to mitigate this. An overview was provided around how this confidentiality risk could be mitigated.

It was explained that the applicants had not referred any cases to the CAG within the preceding 12 months as, when risks were identified, they had worked with the applicants to mitigate this risk by 'anonymising' the data before it was released.

The Sub-Committee received the response – no further clarifications were requested in this area.

Free Text

The applicants acknowledged that confirmation of the completion of Free Text disposal must be reported within the 2017 annual review period, by February 2018. A high-level summary

of the disposal plan was shared for information and the applicants confirmed that the CGA would be informed once this had been fully implemented.

The Sub-Committee received the response – no further clarifications were requested in this area.

Retention of Date of Death

The applicants confirmed that they can only release ONS death registration data to researchers where this was considered anonymised and in accordance with the ICO Code. This is a specific condition for the release of Office for National Statistics (ONS) data to CPRD, captured in CPRD's Data Sharing Agreement with NHS Digital. The applicants advised that they had confirmed with ONS that they are content that date of death data can be considered anonymised, due to restrictions on other fields associated with this field, and that this data can be shared worldwide. This was confirmed by the ONS Head of Life Events via email on 31 May 2017.

The applicants reiterated that the CPRD Policy for Managing Anonymisation and the Risk of Identification in Observational Research lays out how CPRD complies with the ICO Code and the high-level management controls used. An overview of these controls was provided for information, together with an updated version of the policy for information.

The Sub-Committee received the response – no further clarifications were requested in this area.

Confidentiality Advisory Group Advice Conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter, to the date specified above.

Further Information Required

The following points were identified as requiring feedback to be provided as part of the 2018 annual review submission.

1. Provide an overview of how communication improvements are planned more broadly, particularly in relation to providing a unified message between CPRD and NHS Digital.
2. Confirm that destruction of free text information had been undertaken as per the previously provided destruction plan.