NHS
Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

11th April at 10:00 at Barlow House, Manchester M1 3DZ

Present:

Name	Capacity
Dr Mark Taylor	Chair
Mr Anthony Kane	
Ms Clare Sanderson	
Dr Murat Soncul	
Dr Miranda Wolpert	
Dr Lorna Fraser	
Dr Rachel Knowles	
Mr Andrew Melville	
Ms Sophie Brennan	

Also in attendance:

Name	Position (or reason for attending)
Ms Diane Pryce	Senior Confidentiality Advisor
Mr Christopher Ward	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

No apologies were received.

The following interests were declared: Mr Anthony Kane in relation to agenda item 3e

2. Items for consideration

a. 16/CAG/0016 - The Survey of the Mental Health of Children and Young People – decision deferred at the 11th February 2016 meeting

Purpose of application

This application from NatCen Social Research set out the purpose of this study, which is the latest in a series of national social surveys focusing on the mental health of children and young people in the general

population of England and Scotland. It has been commissioned by the Health and Social Care Information Centre with funding from the Department of Health and aims to estimate the prevalence of mental health conditions in children and young people aged 2-19.

The survey involves collecting information about health and wellbeing from:

- parents/carers of children and young people aged 2-19,

- young people aged 11 and over,

- teachers of children and young people aged 5-16.

All selected participants are to be sent an advanced letter about the research. Following this letter, an interviewer will call at the address and leave a leaflet explaining more about the research. For those who consent to take part, information will be collected from parents, carers and young people in their own homes using a computer assisted personal interview (CAPI) administered by a trained social survey interviewer. Information is to be collected from teachers using an online questionnaire.

The interview with parents, carers and young people will focus on many different aspects of health - both physical and mental - as well as subjective wellbeing, use of services, risk and protective factors (such as neighbourhood context and social support, among many other things) and standard sociodemographic factors (e.g. age, sex and employment status of parents). Interviewers are trained social survey interviewers, many of whom will have previously worked on surveys involving children and or covering sensitive issues.

The survey findings will support the planning, commissioning and improvement of services across mental health, care and education from 2018 onwards. This up to date information will allow resources to be better targeted and more responsive to the mental health and well-being needs of children and young people.

A recommendation for class 3 and 6 support was requested to cover access to name, address, including postcode, age and sex.

Confidential patient information requested

Access was requested to name, address, including postcode, age and sex, to be extracted from the HSCIC MIDAS system and passed from HSCIC to NatCen and ONS.

Confidentiality Advisory Group advice

This application had previously been reviewed at a CAG meeting on 11 February 2016. At this meeting the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Members requested the following further information;

1. Patient information should be made clear that data was to be kept and may be linked in the future.
2. Patient information should be amended to remove the information about CAG giving permission for the use of patient data.
3. Revised letter with information prominently displayed about how patients can opt out prior to someone knocking on their door.
4. Favourable opinion from a Research Ethics Committee.
5. Removal of the reference to CAG approval from the participant information.

Patient notifications

Members discussed whether the timeframe between patients receipt of the letter to time of interview gave sufficient time for them to consider whether they wanted to be interviewed and then contact the researchers to decline, should they chose to do so.

Members also felt that although the patient information had been updated, the information about how to withdraw still needed to be more prominently displayed, and that it should be made clear that patients can opt out from the further use of their data at a later stage and how they could do this. They further noted that reference to other organisations involved was out of date, e.g. NHS CR, and that in general the language was a little technical.

Members were in agreement that the applicant had, in general, addressed the points they had raised but noted a number of inconsistences in the patient literature which they believed to be drafting errors.

Recommendations

- Members recommended to the applicant that the patient literature would benefit from proof reading, e.g. the leaflet for the 17-19 year olds refers to '…your child…' and the paragraph starting '…what's next…' would benefit from being reversed.
- The applicant should make the information about opt out and withdrawing more prominent.
- The applicant should be more accurate about the names of the organisations they are linking with and what this means (e.g events that happen rather than the organisations); naming organisations should be using their current names.
- The consent form should be specific about what and why data is being used, e.g. use of HES data in order to etc.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Change the timeframe from receipt of letter to interview to 10 days
2. Clarify the 'how to withdraw process' should patients change their minds about the use of their data at a later point.
3. Amend the reference to the Health Research Agency to the Health Research Authority.
4. Favourable opinion from a Research Ethics Committee.

3. NEW APPLICATIONS – Research

a. 16/CAG/0049 - National cohort study of late effects of Hodgkin lymphoma treatment

Purpose of application

This application from the Institute of Cancer Research set out the purpose of the proposed study was to investigate the range of long- term late-effects of treatment in young women with Hodgkin Lymphoma (HL), in order to provide better information for patients and for decisions on treatment and follow-up.

This study will collect and analyse treatment and follow-up data on women treated for HL across England and Wales at ages ≤35 years during 1956-2010.

This application was to expand an existing national cohort study, which has collected cohort data on 5,000 women with HL. The cohort would be doubled in size to include HL patients with a wider range of treatments and more-recent patients, in order to increase the power, especially for less-common and more-recent treatment types, and would extend the range of morbidity and mortality outcomes examined.

The existing cohort was the largest and most powerful worldwide on treatment-related effects in HL, and has already produced several key publications on this. By expanding the cohort the aim was to improve understanding of late-effects of different treatment alternatives, of longer follow-up periods (important because these patients are treated young, with good survival), expand greatly the range of long-term effects for which rigorous data are available, and draw implications for treatment choice and personalised follow-up and screening schedules.

The principal aim of this study was to improve understanding of the risks of the wide range of long - term fatal and nonfatal morbidities in women treated for HL at young ages in relation to their treatment, and to create a unique risk profile of incidence and severity of multiple long- term co morbidities, in order to enable clinicians and patients to understand patients' personalised risk profile when deciding on and consenting for treatment, and when managing follow-up and screening for late-effects.

A recommendation for class 2, 4, 5 and 6 support was requested to cover access to name, NHS number, date of birth, address, diagnosis, including cancer diagnosis and dates of diagnosis, treatments and dates of treatments, date and cause of death.

Confidential patient information requested

Access was requested to name, NHS number, date of birth, address, including post code at unit level, for linkage purposes and access to diagnosis, including cancer diagnosis and dates of diagnosis, treatments and dates of treatments, date and cause of death, date of birth and post code at district level for analysis purposes.

Cohort size 10,000 (5,000 from the original study and 5,000 to be added in this study)

Confidentiality Advisory Group advice

Public interest

Members were in agreement that there was a public interest in projects of this nature being conducted.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members agreed that it would be problematic to consent the cohort due to the time frame since the data was originally collected and the likelihood that the contact information would be out of date and some patients will have since passed way.

Justification of identifiers

Members agreed that identifiable data would be required in order to link data accurately and the public interest justifies the degree of disclosure, but it would encourage the applicant to seek a technical solution to enable the data to be pseudonymised.

Exit strategy

Members noted that the applicant had a long term goal to remove identifiers but this wasn't currently possible, Section 31.1. of the application form advises that the applicant will destroy identifiable data as soon as possible, but no timeframe had been provided given. Further response to the CAT advice form indicated this will take up to 3 years, but that a 'degree' of anonymisation would be applied within 1 year.

There was also reference to a move to hold non-identifiable data as soon as NHS and PHE systems would support this.

Members requested clarity about both what, the 'degree' of anonymisation meant and what was meant by as soon as NHS and PHE systems supported this. They also requested what timeframe this would be done in.

Members would encourage the applicant to adopt a technical solution when this becomes available and in the meantime if it is possible to reduce the identifiable data held this should be done immediately.

Patient notifications

Members noted that information about the study was available on the organisation website and agreed that it would be difficult to reach the study population by other means. However, they suggested that the applicant should consider how to better signpost patients to the website.

Members noted that it was intended to ask the agreement of the appropriate consultants to examine medical records for which they are responsible and asked whether it would be possible to notify patients via this route as an alternative method to reach this group.

Members also asked whether support groups had been approached about this? E.g. Bloodwise or the organisations mentioned in the application could make information available to patients.

Additional points

Members wanted to understand the purpose of examining the medical records, as mentioned in Q31.1 of the application.

Members discussed the position re the legal basis for the original database and noted the assertion made by the applicant that advice receive previously from the PIAG, the former organisation responsible for decision making related to s251 support, was that support under the regulations was not required, noting that no evidence of this decision was available. Members accepted that record keeping and advice have changed over time and requested that the applicant provide any information they hold from the original conversations with PIAG, e.g. emails, and if possible to provide the PIAG reference number.

Scope of support

Members discussed the issue of the scope of support and concluded that this was to cover the new aspects of the study as outlined in the application including the future data processing of data from

the original cohort of 5,000 along with the new cohort of 5,000. Members agreed that support could not extend to legitimise the original collection of data.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. The applicant must signpost patients to the patient information available on the website and make information available via other means e.g. via GPs or support groups. Progress should be reported at the annual review stage.
2. Scope of support covers the new aspects of the study as outlined in the application including the future data processing of data from the original cohort of 5,000 along with the new cohort of 5,000. It does not extend to the collection of the data of the original 5,000.
3. Favourable opinion from a Research Ethics Committee. **Confirmed 30/03/2016**

b) 16/CAG/0047 - Psychological Impact of Primary Screening for HPV (PIPs)

Purpose of application

This application from University College London (UCL) set out the purpose of data-linkage to allow invitations to participate in research to be sent out.

The NHS Cervical Screening Programme is piloting the use of human papillomavirus (HPV) testing as the primary test in cervical screening. Women attending for cervical screening will first have an HPV test and cytology will only be carried out on the residual samples of women who are HPV positive. This differs to current screening where cytology is carried out first, followed by HPV testing if necessary.

This means that the way in which cervical cancer risk is communicated will change. All women entering the screening pilot programme will find out whether they have certain strains of HPV which account for 70% of cervical cancer, and are sexually transmitted. It is possible that this change may have psychological implications and/or impact future engagement with the screening programme. This is particularly relevant for those women who find out they are HPV positive but do not have an abnormal cytology result; anxiety may still be present if these results are misinterpreted.

This project aims to evaluate the psychological impact of this programme & has been commissioned by Public Health England. A cross-sectional design will be adopted: questionnaires will be issued to women (N=673) who have received different standardised screening results shortly after they receive them, and at 6 months and 12 months follow-up.

Potential participants will be identified by NHS laboratories at six pilot sites across England. 3,340 women will be approached at baseline and will receive an information sheet, consent form and questionnaire pack by postal mail to their home address. For those who do not respond, a reminder pack containing the same information will be sent out 3 weeks later.

Participants who consent (as confirmed by written signature and return of questionnaire to UCL) will be sent a second questionnaire pack at 6 months and a third at 12 months. The second and third questionnaire packs will contain the same questionnaires as baseline with the exception of the

demographics which will only be issued once. For those who do not respond, a reminder pack will be sent out again 3 weeks later.

A mailing company called CPH Docmail Ltd will complete all printing and postage. CAG approval was sought for the initial transfer of address information from the NHS laboratories to CPH Docmail. Thereafter the participants will have consented to being approached for the follow-ups.

A recommendation for class 2, 3, and 6 support was requested to allow the disclosure of confidential patient information from six NHS laboratories to CFH Docmail.

Confidential patient information requested

Access was requested to data from 3,340 women undergoing cervical cancer screening; from six NHS laboratories; name, address, & postcode

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type have potential medical benefit and are in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The group was content that, given the large numbers involved, it is impracticable to seek consent for access to the data used in this study.

- Use of anonymised/pseudonymised data

Members agreed that it is not practicable to ask members of the care teams to de-identify data or to approach the participants directly.

However members considered that it would be good practice were a covering letter from the treating hospital to be included in the pack sent out by CFH Docmail.

Justification of identifiers

The members concluded that the identifiers requested were necessary and appropriate to achieve the purposes.

Exit strategy

The group noted that the name and address for approach will only be kept for the minimum time necessary to recruit the numbers needed for the study, and that CPH Docmail is contractually obliged to securely destroy all identifiable information within a maximum of 4 weeks.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and there is a mechanism for registering patient objection.

The group recognised that including information on the study in the invitation letter would be misleading, as most of those screened would not be approached to take part in the study, and that this could potentially deter individuals from taking part in this important screening (especially given the sexually transmitted nature of some strains of HPV). However, after discussion, it was agreed that there was also the potential to deter people from taking part in screening if individuals discovered that their data was being accessed by a commercial company without their having been informed.

The applicant had stated that managing patient objection would place too great a burden on the clinical team, however trusts have a duty to manage data-sharing. Both general and specific objections can thus be managed by the mechanisms in place at each trust.

As such it was recommended that the applicant consider putting posters up in the screening waiting rooms stating that data may be used in research and explaining where further information may be found (for example, on a website). This further information should contain details of the trust-specific opt-out mechanisms. If the researcher does not feel this to be reasonably practicable they must provide a justification to the committee with reference to the above.

Additional points

The group noted that there was no patient and public involvement with reference to the aspects of the application for which support was requested. The applicant was advised to seek this in any future applications.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there is 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.

Clarifications required

1. Clarification is requested as to the possibility of putting posters up in the screening waiting rooms stating that data may be used in research and explaining where further information may be found (for example, on a website); this further information containing details of the trust-specific opt-out mechanisms. If the researcher does not feel this to be reasonably practicable they should provide a justification to the committee.

Once provided, the response will be reviewed by the chair and original reviewers.

Specific conditions of support

1. Receipt of the text for the patient notifications, as above.
2. Favourable opinion from a Research Ethics Committee.

c) 16/CAG/0035 - Extension of a cohort mortality study of workers with blood lead measurement to include the analysis of cancer incidence data

Purpose of application

This application from the Institute of Occupational Medicine set out the purpose of researching cancer incidence among former lead workers.

The research team has previously collected data on the relation between levels of lead in the blood & mortality (ECC 8-05(g)/2011). They now wish to extend the mortality analysis to include cancer incidence/registration data as this will provide a more informative analysis, especially for the less fatal types of cancer. This is part of an international collaboration.

The only exchange of identifiable data will be to receive cancer registration data from the National Health Service Central Registers via the HSCIC's secure data download system.

Pseudonmyised information will then be transferred to the International Agency for Research on Cancer (IARC) in Lyon, France.

A recommendation for class 4 and 6 support was requested to cover access to confidential patient information from the National Health Service Central Registers.

Confidential patient information requested

Access was requested to name, NHS number, date of birth, date of death, gender, occupation and cancer incidence data from 9,500 former lead workers; from National Health Service Central Registers to the research team

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type have potential medical benefit and are in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

The group was content that it is impracticable to seek consent from the large cohort of individuals who still survive from the original study.

Justification of identifiers, and exit strategy

Members did not think that the applicant had provided sufficient justification that all of the identifiers would be needed for the proposed linkage.

- Use of anonymised/pseudonymised data

The applicant should clarify the linkages required for the study, with full justification for each, and the steps which will be taken to reduce identifiers (through the use of flagging, for example) going forward.

Patient notification and objection

It is a general principle of activities taking place under support that there are suitable patient notification materials provided to the cohort, and that there is a mechanism for registering patient objection. Members were not reassured that this was in place as they were unable to locate any notification on the websites listed.

From the documents submitted this appears to have been previously a matter of concern in previous submissions and the applicant must inform the committee how a member of this cohort would find out that their data is being used in this way (for example, through information on the Health and Safety Executive website) and the mechanisms for opting-out should be provided.

Additional points

Members noted that the applicant had mentioned a contract with IARC and requested to see a copy of the terms and conditions of the contract, so that the group can reassure themselves that this is suitable.

Clarification was requested as to whether there are any implications with regards to the data previously collected under the previous approval (ECC 8-05(g)/2011). They asked if an implication of this project was that this data will now be stored for longer than it otherwise would have been?

Members noted that Scottish data would be collected as part of this project. The applicant should be aware that support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent covers only England and Wales. Separate approvals will be required for the Scottish data.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there is 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.

Clarifications required

1. Clarification is required as to whether there are any implications with regards to the data previously collected (under ECC 8-05(g)/2011). Is one of the implications of this project that this data will now be stored for longer than it otherwise would have been?
2. The applicant must inform the committee how a member of this cohort would find out that their data is being used in this way (for example, through information on the Health and Safety Executive website) and the mechanisms for opting-out provided.
3. The applicant should confirm the linkages required for the study, with full justification for each, and the steps which would be taken to reduce identifiers (through the use of flagging, for example) going forward.

Once provided, the response will be reviewed by the chair and original reviewers.

Specific conditions of support

1. Receipt of the text for the patient notifications.
2. Receipt of the terms and conditions of the contract with IARC.
3. Favourable opinion from a Research Ethics Committee.

d) 16/CAG/0039 Niemann-Pick Type C (NP-C) Patient Finder Initiative

Purpose of application

This application set out the purpose to evaluate if using combinations of England, Hospital Episode Statistics (HES) ICD-10 codes linked to specific symptoms seen in Niemann-Pick C (NP-C), can identify patients who may have this disease. Having identified a patient who could potentially have NP-C, the

treating physician is to be contacted with a letter from the Principal Investigator. This will inform the physician about the study, tell them that the study has identified a patient who might have NP-C, provide the HES patient identifier and suggest how they might confirm the diagnosis if they wish to do so.

England, Hospital Episode Statistics (HES) data applies an ICD-10 code to each clinical symptom and procedure a patient experiences while attending a hospital, as either an inpatient or outpatient.

A recommendation for class 6 support was requested to cover access to all HES data; HES; ICD-10 codes, LOPATID, the hospital ID where the patient was seen, the consultant code of the treating physician and the patients' HES identifier.

It is also noted that the consultant code will enable the identification of the treating physician in order for the PI to make contact with them.

Confidential patient information requested

Access was requested to (HES LOPATID).

Confidentiality Advisory Group advice

Public interest

Members discussed this issue at length but felt strongly that the current design does not demonstrate sufficient public benefit, and could in fact lead to significant anxiety for the patients identified for screening.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members were disappointed that the feasibility of consent did not appear to have been considered, and a clear justification for why consent was not practicable had not been put forward.

Patient notifications

It is a principle of support that patients are fully informed about the use of their information and they are given the opportunity to opt out of the further use of their information. Members noted that patients were not provided with information about this project therefore would not have an opportunity to object to the further use of their information.

User involvement

Members noted that there had been no user involvement in the design or planning of this research project.

Justification of identifiers

Members did not believe that the application demonstrated that the proposal would yield the benefit which would justify the disclosure of the identifiable information requested.

Security

Members noted that it is intended to store data on a laptop but it is not clear if this laptop was subject

to the security review carried out under the Information Governance Toolkit.

Study design

Members noted that the applicant states that this study is using a validated scoring system. This scoring system has been developed and internally validated using information directly from patient notes. However this current study involves HES data which was ICD10 coded. One of the key criteria in the initial scoring system is family history of NP-C. This information is not available in HES therefore the scoring system would not appear to be complete. The applicant has not highlighted this or shown how he will therefore interpret the scoring system. In order to adequately assess whether this scoring system using HES data was useful members were of the view that either this explanation would need to be provided or a different study design to the one outlined would be required.

Members were of the opinion that there was not a clear indication whether the algorithm proposed was valid.

Members noted that this research was a form of screening but were of the view the methodology would not allow the applicant to make a statistical assessment of the scoring system as was undertaken in the original study. Given that there are currently 85 patients diagnosed with any type of NP disease in the UK and the applicant has identified 3500 individuals within the HES data, even allowing for a degree of under diagnosis it would appear that the false positive rate may be very high. The implications of false positives for an assessment of overall public benefit did not appear to have been addressed within the application.

Members noted that there are clear guidelines on when screening was appropriate (see PHE guidance https://www.gov.uk/government/publications/evidence-review-criteria-national-screening-programmes) one of which is that there is an effective treatment. The licensed drug has been shown to slow the progress of the disease in some patients but not all patients with NP-C. Members requested that the applicant provides further information about the criteria for prescribing this drug.

Fair processing

Members discussed the Fair processing information provided by the applicant and were of the opinion that this was a broad statement and did not inform patients about the use of their information for this research.

Members were unable to make a recommendation but welcome a re-submission of the application if the applicant were to submit evidence of independent peer review of the design of the study, and how that design met best practice on the practice of screening and study design on the implementation of screening programmes.

Additional points

Members were of the opinion that as each individual identified in the HES data was likely to have more than one episode and may well have more than one consultant code, therefore it may not be possible to identify the treating clinician; the applicant has not addressed how he will deal with this. Members further noted that it was intended to write to the treating clinician. They also commented that it would be useful to see a draft of the letter which would be sent to clinicians.

Members were of the opinion that some of the associated codes could be indicative of something else and not related to this condition.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the

applicant in order for a recommendation under the Regulations to be provided.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

e) Evidence of independent peer review of the design of the study and following this advice to provide details of any change in methodology and explanation of how any unavailability of family history of NPC would be addressed.
f) Provide further information about the criteria for prescribing this drug.
g) Develop patient information materials and submit along with a re-submitted application, also providing details of how patients will be able to access this information and it is clear how they can opt out of the further use of their information should the wish to do so.
h) Advise what considerations have been given to obtaining consent or provide justification as to why consent is not practicable
i) Provide a plan of how patients would be engaged in the design and development of this study in the future.
j) Provide further information on the benefit of the study which justify the release of identifiable data
k) Update the Fair processing information on the organisation's web site.
l) Confirm the process to identify the clinicians and provide a draft of the letter intended to go to clinicians
m) Provide a data flow diagram
n) Favourable opinion from a Research Ethics Committee

e) 16/CAG/0032 - The Christie Skin Cancer Surgery Research Database (CoNCuR database)

Purpose of application

This application from The Christie NHS Foundation Trust set out the purpose to establish a database of patients who have undergone surgery for various types of skin cancer at The Christie NHS Foundation Trust (The Christie) from 2002 to March 2016. This includes primary melanomas, basal cell carcinomas (BCCs), squamous cell carcinomas (SCCs) and Merkel cell carcinomas.

This database will build on current databases at The Christie to be used for research. There is currently a Melanoma Database for Medical and Clinical Oncology at The Christie, this does not include surgical-related clinical fields. Therefore, the proposed database would focus on collecting data from surgical patients only, from 2002 to 2016. The aim is to incorporate the 'CoNCuR database with the current melanoma database from 2016 onwards. This joint melanoma database will encompass medical and clinical oncology, translational medicine and surgical data for The Christie.

The proposed database will provide follow-up data and more complete data that will positively complement the existing database. It was anticipated that this would also support future research and data collection more efficiently and successfully for future patient benefit.

Support was requested for the retrospective data collection only and a recommendation for class 1, 2, 4, 5 and 6 support was requested to allow the disclosure of confidential patient information from;

1. The assigned data manager, or scientific officer, to extract patient identifiable data from the electronic hospital systems, medical case notes and GP letters into the Christie Skin Cancer Surgery Research (CoNCuR) database.

2. The assigned data manager, or scientific officer, to then separate the patient identifiable data within the database into separate tables which will be connected by a Unique Code.

3. To permit the disclosure of data to the HSCIC for the purpose of linking with the HES database.

Confidential patient information requested

Access was requested to NHS No, date of birth, date of death, post code, hospital ID and GP for the purpose of linking.

NHS No, date of birth, date of death, post code, gender, occupation ethnicity, marital status, next of kin, skin colour for the purpose of analysis.

Confidentiality Advisory Group advice

Public interest

Members were in agreement that this project was in the public interest with clear benefits to patients.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members were supportive of the approach the applicant was taking in order to consent as many of the retrospective cohort group as possible and accepted that it was not practicable to consent those who were lost to follow up or had passed away. They did however point out that anyone who was approached for consent but was undecided would not come within the scope of support. The applicant should refer to the ICO guidance on non-respondents to consent for further information.

Justification of identifiers

Members were in agreement that identifiable information was needed for linkage purposes.

They did however question whether there was justification to hold NHS number, full date of birth and date of death for analysis purposes.

User involvement

Members were of the opinion that there had been minimal patient and public engagement in the development of this research database. Members requested to see plans about how the applicant would engage more widely with patients and the public.

Patient notifications

Members discussed the content of the patient information and consent materials and were of the view that these materials did not make clear to patients that their data was being collected to establish a research database. They also were of the view that the focus of the material was toward the prospective cohort but noted that the same information was to be used for both the prospective and retrospective cohort groups.

It should be clear in all the literature that the information was to be held in perpetuity.

They were also of the opinion that the language could be clearer and would benefit if written in plain English, e.g. the use of the term pseudonymised could be explained more clearly.

Exit strategy

Members were of the view that no clear exit strategy had been put forward and would remind the applicant that it was a principle of support that a clear exit strategy to move away from the use of confidential patient information without informed consent should be developed. Although members did note the applicant stated that identifiable information would be separated from other data, it did not however clarify what would happen to the identifiable information.

Additional points

Members were of the opinion that GPs would require evidence of the legal basis before they would be willing to agree to the release of this information, and discussed the benefit of writing to GPs to inform them.

Members noted that the applicant had confirmed that the inclusion of HES data in the application form was done in error and this was not requested as part of this application, HES data was therefore not included in the scope of this 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

4. Confirm that use of NHS number, date of birth and date of death are not required to be kept for analysis purposes or whether these fields could be reduced to month and year or provide justification why these fields are needed.
5. Update the patient literature and consent materials to make it clear to the retrospective members of the cohort that this was a research database, that it was intended to hold the data in perpetuity and that other researchers will be allowed access to it.
6. Clarify what will happen to the identifiably data when it is separated from other data and provide a clear exit strategy and time frame for this.
7. Favourable opinion from a Research Ethics Committee.

The following was shared with the CAG for information.

Secretary of State approval decisions

The DH senior civil servant on behalf of the Secretary of State for Health (SofS) agreed with the advice provided by the CAG in relation to the 17th March 2016 and 11th April 2016 meeting applications.

HRA approval decisions

The HRA agreed with the advice provided by the CAG in relation to the 17th March 2016 and 11th April 2016 meeting applications.

4. MINUTES OF THE MEETING HELD ON 25th February 2016

The minutes were agreed as an accurate record.

5. ANY OTHER BUSINESS

The Chait tabled a letter to all RECs from Janet Wisely and provided a verbal summary as follows

- HRA approval will bring together all the approval processes into one, and has now been rolled out, although there will continue to be changes where issue are identified in use.
- If overlaps are identified in implementation, these will be addressed to ensure that there are no unnecessary duplications.
- REC responsibilities will remain unchanged.
- Information Governance (IG) aspects of the HRA approval process may have some significance issues for CAG. The IG work stream within HRA approval is not yet live. Questions are being developed now and will be tested before these are integrated into IRAS.
- The CAG Chair is leading this workstream and will be coming to CAG formally in due course, to ensure that everything is covered, e.g. DPA questions asked are these the right questions etc?

Signed – Chair	Date
Signed – Confidential Advice Team	Date