NHS
Health Research Authority

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

21st April 2016

Present:

Name	Capacity	Items
Dr Mark Taylor	Chair	1a, 1b
Mr Anthony Kane		1a, 1b
Dr Murat Soncul		1a, 1b
Dr Kambiz Boomla		1c, 1d
Dr Patrick Coyle	Chair	1c, 1d
Mr Marc Taylor		1c, 1d

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) ADDITION - 10 year follow up - 16/CAG/0024

Context

This application from the University of Cambridge set out the purpose to understand the effect of intensive treatment of multiple risk factors in the course of diabetes. People with diabetes have an increased risk of developing cardiovascular disease (heart attack or stroke). However, there can be a delay between the onset of diabetes and a person experiencing symptoms, making it difficult to detect early. If people with diabetes were found earlier in the disease trajectory and treated before symptoms developed, the risk of them suffering from an early death or cardiovascular disease would be reduced.

This study aims to collect 10 year follow up information on cardiovascular events and risk factors, treatment and mortality for the cohort of 1,212 participants of the ADDITION study who enrolled in the UK. This will allow an assessment of the long-term effects of the differences in treatment during the first five years after diagnosis. The researchers plan to contact all ADDITION participants in the UK with a self-report questionnaire to assess health behaviour and patient-reported outcomes. Prior to sending any questionnaires, the participant list will be cross-checked with available records to minimise the risk of sending questionnaires to

participants who are deceased. Each centre will also search medical records already held to collect data on intermediate biochemical and clinical measures, medication and health service use. Where an event is identified, relevant clinical information (such as death certificates, post mortem reports, medical records, hospital discharge summaries, electrocardiographs and laboratory results) will be collated. Data will be collected over a 9-12 month period. A research assistant with necessary NHS permissions will also collect primary end point data from medical records. Where possible, and with the practice's permission, this will be collected remotely through System one using the Diabetes Research Network's clinical system access. For practices not on this system, staff will travel to site to collect this data. S251 support is not requested for this element as the participants consent to access medical records had been obtained.

Section 251 support was requested to obtain up to date address details for all participants in order to inform them of the 10 year follow up (and if they wish, speak to the study team about the study), invite to fill in questionnaires and to update the study team of their current GP practice in order to complete the follow up.

Consent to participate in the study had been obtained in writing at the point of screening, including consent to collect data through medical records and consent to use information for future related projects. Participants were also consulted on the proposed 10 year follow up plans and feedback from participants who attended the 5 year follow up was overwhelmingly supportive of this. An information sheet will be included in the questionnaire confirming the nature of the 10 year follow up and reiterating the participants right to withdraw. Participants will be informed that refusal to take part in the study further will not influence their normal medical care and that their participation is completely voluntary. Participants can contact the team via email or telephone on the telephone numbers provided in the cover letter accompanying the questionnaire.

The applicant submitted two separate applications in parallel as each relate to different IRAS ID's, REC approvals and different cohorts. Please see the linked application 16/CAG/0026 - ADDITION Plus – 10 year follow up, IRAS ID 173399.

S251 support was requested to allow the disclosure of name, NHS number, GP practice code, address and postcode, date of birth and date of death, cause of death, to the researchers in order to contact the cohort. ONS and HES data will be requested from the HSCIC.

A recommendation for class 2, 4, and 6 support was requested to obtain and use information about past and present geographical location, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to name, NHS number, GP practice code, address and postcode, date of birth and date of death, cause of death

Confidentiality Advisory Group advice

Public interest

Members agreed this is a medical purpose 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

Members requested clarification on whether support was being sought to obtain further clinical data from HSCIC and ONS and if so, whether the applicant had considered seeking consent to do this through the questionnaires that would be sent to all those in the cohort who were still alive.

It was noted that the applicant would also like to obtain HES data as part of the assessment of whether or not participants had experienced a cardiovascular event as HES data would be a source of additional information for the independent scientists who are adjudicating possible endpoints.

The applicant confirmed that it was not practical to send out consent forms with the questionnaires for the following reasons;

1) Addresses were not held for a significant minority of participants so researchers were unable to correspond with them and request re-consents.
2) Excluding these participants from data collection would reduce study power and potentially introduce bias.
3) Many of the participants were now quite elderly and frail which may in part explain the 50% response rate to the questionnaire survey.
4) A 50% response rate from participants who have previously consented to allow access to their medical records would reduce study power and introduce bias to the assessment of the primary outcome.
5) A significant minority of participants were deceased and therefore unable to re-consent.
6) Excluding data on possible cardiovascular events prior to the date of death would reduce study power and potentially introduce bias in the evaluation of the primary outcome.

Following ethical and research governance approval the applicant confirmed that they were relying on previous consent to obtain data from participants' medical records. Support for this approach had been obtained from participants at the public meetings that were held and only 6

participants had withdrawn consent when questionnaires and information sheets were sent to them explaining the process.

Justification of identifiers

Members were unclear on exactly what the applicant was seeking s251 support for and whether S251 support was already in place for flagging mortality for part but not the entire cohort.

The applicant confirmed that support was being requested to obtain data from national databases/registers such as HES (Hospital Episode Statistics). S251 support was in place (ref CR38/2014) for flagging mortality of the Cambridge cohort, but not the Leicester cohort. This application would allow Leicester to flag their cohort for mortality. Furthermore, the existing section 251 permissions only referred to flagging for mortality and do not include collection of data concerning the composite cardiovascular endpoint, which is the primary outcome, nor tracing participants who have changed their home address and general practice.

Members queried whether further support was being sought for list cleaning of the demographics and vital status of the entire cohort so that they could be approached to complete a questionnaire and in addition seeking support to obtain further data direct from patients' records or whether the applicant was relying on previous consent to do this?

The applicant confirmed that there were approximately 160 participants for whom updated demographic information was required in order to firstly remind them of the study, secondly to provide them with the most recent version of the participants information sheet, thirdly to request that they complete and return study questionnaires and finally to obtain updated details of their current registered GP practice in order to request information from the medical records concerning primary and secondary trial outcomes. Vital status information would also enable the researchers to avoid sending questionnaires to deceased participants which might cause distress to their relatives.

Additional points

It was confirmed that participants for whom current address was held were given the option of opting out of the study following receipt of an information sheet. In addition, information about the linkage process was being included in the latest study newsletter and on the study website and participants were able to withdraw from the study at any time.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 9/02/2016**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 9/02/2016**

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

b) ADDITION - 10 year follow up - 16/CAG/0024

Context

This application from the University of Cambridge set out the purpose to understand the effect of intensive treatment of multiple risk factors in the course of diabetes. People with diabetes have an increased risk of developing cardiovascular disease (heart attack or stroke). However, there can be a delay between the onset of diabetes and a person experiencing symptoms, making it difficult to detect early. If people with diabetes were found earlier in the disease trajectory and treated before symptoms developed, the risk of them suffering from an early death or cardiovascular disease would be reduced.

This study aims to collect 10 year follow up information on cardiovascular events and risk factors, treatment and mortality for the cohort of 1,212 participants of the ADDITION study who enrolled in the UK. This will allow an assessment of the long-term effects of the differences in treatment during the first five years after diagnosis. The researchers plan to contact all ADDITION participants in the UK with a self-report questionnaire to assess health behaviour and patient-reported outcomes. Prior to sending any questionnaires, the participant list will be cross-checked with available records to minimise the risk of sending questionnaires to participants who are deceased. Each centre will also search medical records already held to collect data on intermediate biochemical and clinical measures, medication and health service use. Where an event is identified, relevant clinical information (such as death certificates, post mortem reports, medical records, hospital discharge summaries, electrocardiographs and laboratory results) will be collated. Data will be collected over a 9-12 month period. A research assistant with necessary NHS permissions will also collect primary end point data from medical records. Where possible, and with the practice's permission, this will be collected remotely through System one using the Diabetes Research Network's clinical system access. For practices not on this system, staff will travel to site to collect this data. S251 support is not requested for this element as the participants consent to access medical records had been obtained.

Section 251 support was requested to obtain up to date address details for all participants in order to inform them of the 10 year follow up (and if they wish, speak to the study team about the study), invite to fill in questionnaires and to update the study team of their current GP practice in order to complete the follow up.

Consent to participate in the study had been obtained in writing at the point of screening, including consent to collect data through medical records and consent to use information for future related projects. Participants were also consulted on the proposed 10 year follow up plans and feedback from participants who attended the 5 year follow up was overwhelmingly supportive of this. An information sheet will be included in the questionnaire confirming the nature of the 10 year follow up and reiterating the participants right to withdraw. Participants will be informed that refusal to take part in the study further will not influence their normal medical care and that their participation is completely voluntary. Participants can contact the team via

email or telephone on the telephone numbers provided in the cover letter accompanying the questionnaire.

The applicant submitted two separate applications in parallel as each relate to different IRAS ID's, REC approvals and different cohorts. Please see the linked application 16/CAG/0024 - ADDITION – 10 year follow up, IRAS ID 160001.

S251 support was requested to allow the disclosure of name, NHS number, GP practice code, address and postcode, date of birth and date of death, cause of death, to the researchers in order to contact the cohort. ONS and HES data will be requested from the HSCIC.

A recommendation for class 2, 4, and 6 support was requested to obtain and use information about past and present geographical location, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to name, NHS number, GP practice code, address and postcode, date of birth and date of death, cause of death

Confidentiality Advisory Group advice

Public interest

Members agreed this is a medical purpose 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

Members requested clarification on whether support was being sought to obtain further clinical data from HSCIC and ONS and if so, whether the applicant had considered seeking consent to do this through the questionnaires that would be sent to all those in the cohort who were still alive.

It was noted that the applicant would also like to obtain HES data as part of the assessment of whether or not participants had experienced a cardiovascular event as HES data would be a source of additional information for the independent scientists who are adjudicating possible endpoints.

The applicant confirmed that it was not practical to send out consent forms with the questionnaires for the following reasons;

1) Addresses were not held for a significant minority of participants so researchers were unable to correspond with them and request re-consents.
2) Excluding these participants from data collection would reduce study power and potentially introduce bias.
3) Many of the participants were now quite elderly and frail which may in part explain the 50% response rate to the questionnaire survey.
4) A 50% response rate from participants who have previously consented to allow access to their medical records would reduce study power and introduce bias to the assessment of the primary outcome.
5) A significant minority of participants were deceased and therefore unable to re-consent.
6) Excluding data on possible cardiovascular events prior to the date of death would reduce study power and potentially introduce bias in the evaluation of the primary outcome.

Following ethical and research governance approval the applicant confirmed that they were relying on previous consent to obtain data from participants' medical records. Support for this approach had been obtained from participants at the public meetings that were held and only 6 participants had withdrawn consent when questionnaires and information sheets were sent to them explaining the process.

Justification of identifiers

Members were unclear on exactly what the applicant was seeking s251 support for and whether S251 support was already in place for flagging mortality for part but not the entire cohort.

The applicant confirmed that support was being requested to obtain data from national databases/registers such as HES (Hospital Episode Statistics). S251 support was in place (ref CR38/2014) for flagging mortality of the Cambridge cohort, but not the Leicester cohort. This application would allow Leicester to flag their cohort for mortality. Furthermore, the existing section 251 permissions only referred to flagging for mortality and do not include collection of data concerning the composite cardiovascular endpoint, which is the primary outcome, nor tracing participants who have changed their home address and general practice.

Members queried whether further support was being sought for list cleaning of the demographics and vital status of the entire cohort so that they could be approached to complete a questionnaire and in addition seeking support to obtain further data direct from patients' records or whether the applicant was relying on previous consent to do this?

The applicant confirmed that there were approximately 160 participants for whom updated demographic information was required in order to firstly remind them of the study, secondly to provide them with the most recent version of the participants information sheet, thirdly to request that they complete and return study questionnaires and finally to obtain updated details of their current registered GP practice in order to request information from the medical records concerning primary and secondary trial outcomes. Vital status information would also enable the researchers to avoid sending questionnaires to deceased participants which might cause distress to their relatives.

Additional points

It was confirmed that participants for whom current address was held were given the option of opting out of the study following receipt of an information sheet. In addition, information about the linkage process was being included in the latest study newsletter and on the study website and participants were able to withdraw from the study at any time.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 1/02/2016**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 9/02/2016**

c) 2016 Adult Inpatient Survey - 16/CAG/0041

.

Context

This application from Care Quality Commission set out the purpose of the 2016 Inpatient Survey. The inpatient survey would include all eligible trusts who would be asked to conduct the survey with preparations expected to begin in August 2016. All trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey. Administration of the Inpatient survey requires NHS trusts to share two distinct sets of information with their approved contractor; a mailing fila and a sample data file.

The end product from this survey will be a set of aggregate statistical data that does not contain patient identifiable information. This statistical dataset is used for a wide variety of purposes to support ongoing improvement in overall patient experience: The survey data is used extensively by NHS trusts and Clinical Commissioning Groups (CCG's) in local improvement.

Approximately 1,250 patients would be included at each trust. These are inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in July 2016 (and earlier for smaller trusts), having had one overnight stay in hospital.

A recommendation for class 5 and 6 support was requested to cover access to information from relevant trusts to allow surveys to be administered.

<u>Confidential patient information requested</u>

Access was requested to; name address and postcode, ethnicity, year of birth, date and time of attendance, CCG code, ICD10 code, NHS site code on admission or discharge, main specialty on discharge, whether admission from Treatment Centre, route of admission.

Confidentiality Advisory Group advice

Justification of identifiers

Members queried whether there was an alternative legal basis as CQC has extensive powers to use CPI in the exercise of its functions. CQC responded that although they use the survey data in in their regulation, the survey was not part of the regulation of individual services and that it was not a periodic or special review either. On that basis, their powers were not engaged.

The applicant confirmed that the survey programme didn't currently come under CQC's statutory powers and there was no alternative legal basis for this request within CQC's own powers. This would be kept under review for future surveys and If CQC start to take regulatory action on the basis of survey results, which was being considered, then this approach would be re-assessed.

Additional points

Members noted that the process did not substantially differ from last year.

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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Recommendation from the Caldicott Guardian (or equivalent).
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries.

d) Young ER follow up - 16/CAG/0042

Context

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

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

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

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

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

Confidential patient information requested

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

Confidentiality Advisory Group advice

Public interest

Members were in agreement that this was an important research topic with a medical purpose 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

It was noted that the answer to Q29.3 had been filled in as N/A. It was presumed that the applicant had assumed that they had consent already and had not realised they may need to consider the practicable alternative of re-consent for linkage. Members wanted to clarify if participants would be re-consented to include linkage with HSCIC and ONS. If the applicant will not re-consent participants but rely on section 251 support, Members queried whether they will they fulfil principle 1 of the DPA by doing their best to inform subjects via privacy notices that linkage will occur and inform them of how they may 'opt out'?

- Use of anonymised/pseudonymised data

Members queried the use of the word pseudonymise and whether that meant there would be no data released to researchers other than those working in the applicants department? Similarly confirmation was requested on which fields would be stripped out and whether they would be allocating a project number to identify individual cases and allow linkage? The applicant was reminded that if another researcher were to ask for identifiers it would be necessary for them to seek their own section 251 support.

Justification of identifiers

It was noted that at Q12.1 and Q12.2 the applicant had indicated that they would not be separating identifiers and clinical data into separate databases. Members reminded the applicant that to do so was best practice and asked if they would consider separating the data in this way.

Additional points

The applicant was asked to clarify what was meant at Q21 by the statement that 'there are no plans to share data with outside researchers?' Will they release only aggregated data to researchers or will they release patient level data?

In terms of an exit strategy had this been considered and if so when would they be able to remove identifiers from the database?

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. Would participants be re-consented to include linkage with HSCIC and ONS?
2. If the applicant will not re-consent participants but rely on section 251 support, will principle 1 of the DPA be fulfilled by the applicant doing their best to inform subjects via privacy notices that linkage will occur and inform them of how they may 'opt out'?
3. Does the use of the word pseudonymise mean there would be no data released to researchers other than those working in the applicants department?
4. Which fields would be stripped out and would the applicant be allocating a project number to identify individual cases and allow linkage?
5. Will only aggregated data be released to researchers or will patient level data also be released?
6. Would the applicant consider separating the identifiers and clinical data into separate databases?
7. Has an exit strategy been considered and if so when could identifiers be removed?
8. Letter of recommendation from the Caldicott Guardian or equivalent of the applicant's organisation.
9. Favourable opinion from a Research Ethics Committee.
10. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-

advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries. **Confirmed 14/03/2016**

Please provide confirmation that the above conditions have been accepted and/or met. Once provided, the response will be reviewed and if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

Signed – Officers of CAG	Date

Signed – Confidentiality Advice Team	Date