Health Research Authority

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

2 June 2017

Present:

Name	Capacity	Items
Dr Murat Soncul		1a, 1b, 1c, 1d
Ms Kim Kingan		1a, 1b
Mr David Smallacombe		1a, 1b
Dr Malcolm Booth		1c, 1d
Mr Martin Andrew		1c, 1d

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0092 Evaluation of Prosthetic Joint infection (PJI) After Total Knee Replacement (TKR): Is the Assessment of Plasma Viscosity (PV) as Reliable as the Erythrocyte Sedimentation Rate (ESR)?

Purpose of application

This research application from University of Exeter Medical School set out the purpose of determining how effective the blood test called Plasma Viscosity (PV) would be in the assessment of joint infection after Total Knee Replacement (TKR) compared to the currently used blood test- the Erythrocyte Sedimentation Rate (ESR).

The research was to be carried out in response to a proposal at the hospital to replace the currently used test (ESR) with the PV test. Infection after knee replacement occurred in 1-2% of patients and was difficult to diagnose; the current ESR test combined with another blood test (the CRP) did not provide 100% accuracy in diagnosis but was a useful assessment tool.

The applicant stated that research was needed into the PV test before it could be used with confidence, as existing research had only established PV levels in non-infected joints. The applicant wished to

establish a reference range for what happened to PV after joint replacement, particularly in infected cases, to enable them to identify abnormalities in practice, and reliably identify an infection.

This would be done by retrospective review of medical notes for the 300 patients on the hospital database who had undergone re-do knee replacement. The blood tests would have been completed on these patients, pre-operatively and post-operatively and the results recorded on medical notes. The researchers (three medical students from the University of Exeter medical school) would use these existing results to try and identify how well the PV correlated with the ESR and CRP. These students would access the data onsite, and transfer it to a spreadsheet in anonymised form after which it would be forwarded to a statistician for analysis. .

A recommendation for Class 1and 6 support was requested for the purpose of extracting and anonymising the data, and to allow access to an authorised user for this purpose.

Confidential patient information requested

Access was requested to data from the database of patients, and further from the medical records in relation to patients who had undergone revision total knee replacement, had the ESR and PV blood test pre-operatively (and infected cases that had at least one post-operative assessment of these blood tests, no earlier than 6 months after surgery).

Data required in order to identify the patient:

Name

Hospital number

Data to be extracted from the medical record:

-Blood test results- to see if the patient had an infected knee replacement before surgery

-Details of other medical history that could account for abnormal blood test results as opposed to an infected knee replacement

-Details of knee replacement surgery from the hospital notes- to see if there was any evidence of infection found that has not been expected or found before

-Microbiology results to see if a micro-organism was found during the operation that supports the diagnosis of an infected knee replacement

No identifiable data would be retained – the patient would be identified by a study number.

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that there was a clear medial purpose and significant public interest in establishing a reference range for the PV blood test, and examining the effectiveness of the test before it was implemented.

Practicable alternatives

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

- Feasibility of consent

In addition to stating that obtaining consent would be resource intensive, the applicant identified further issues with accessing historical data:

Some individuals could be deceased, or have developed other serious medical complaints. In both cases, attempting to contact the individual could cause distress to relatives. Others could have moved away, resulting in a less representative sample.

Members accepted these arguments, agreeing that it was not practicable to seek consent.

- Use of anonymised/pseudonymised data

It was observed that the data would be extracted and anonymised onsite.

Justification of identifiers

It was noted that no identifiers would be removed from the site. Access to the medical record was necessary to extract and anonymise the information. Members commented that the data flow diagram was clear.

Additional points

Public engagement.

Public engagement was lacking. Members agreed that this should be implemented and reported back at annual review stage. Views should be sought from patients/the public about access to patient medical records for this study. This could be done via the patient advisory panel which the applicant described on the advice form.

Patient notification

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Although often confused with a requirement to seek consent, patient notification is not the same as seeking consent from individual patients. Patient data is still accessed without consent; however, information is made publicly available to enable patients to find out about this use of their data and to express an objection if they so wish.

The CAG reiterated that it would be necessary to make information publicly available about the study, for example by placing notices in patient waiting rooms or on a website which patients might access. There was no requirement to contact each patient individually for consent; however it should be possible for a patient to find out about this access to medical records and to opt out.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required 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.

Request for further information

1. The applicant was asked to provide patient notifications along with a description of where they would be placed and how opt outs would be respected.

A copy of the patient notification was provided via email on 28 June 2017, which was reviewed by the Chair. A change was requested to the wording to prevent misunderstanding of the role of CAG caused by the phrase '*we have been advised by the Confidentiality Advisory Group at the Health Research Authority that it is acceptable not to seek individual consent from the 322 patients involved*..' as it gave the impression that the CAG was able to override patient consent and did not represent the considerations given.

The applicant submitted a further version dated 29 June 2017 and marked v2. This version was deemed appropriate.

Specific conditions of support

1. The applicant was asked to implement a mechanism to test the views of patients on this activity, and report back to the CAG at annual review.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 10 April 2017**
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V13 for Devon and Exeter NHS Foundation Trust confirmed published and reviewed as satisfactory.**

b) 17/CAG/0093 Hodgkin Lymphoma Survivorship Questionnaire Study

Context

This research study, to be undertaken under supervision as part of a PhD in Epidemiology in Cancer Research, set out the purpose of investigating less well-reported nonfatal but clinically significant co-morbidities which develop in female Hodgkin Lymphoma (HL) survivors treated in childhood and young adulthood.

More patients were now surviving the disease long-term, due to high dose and combination chemotherapy and radiotherapy treatments. These treatments were known to be highly toxic to patients, however, and a range of nonfatal comorbidities could develop. The applicant had identified a lack of research into these co-morbidities in young women, who were amongst the first to be treated with newer, high risk treatments. The researcher would analyse the risk of developing different late effects in relation to risk factors such as age at treatment, treatment type and lifestyle factors in this cohort. The research was expected to contribute to the development of risk profiles to help inform treatment decisions, follow up policy and lifestyle decisions in these survivors.

Participants would be consented into the study. Support was requested to allow the research team to receive the list of eligible patients in order to exclude duplicates, ensure no deceased patients were contacted and to compare the characteristics of responders and non-responders. The invitation letters would be sent by the clinician once screened in this way by the research team.

A recommendation for class 3 and 6 support was requested, to select and contact patients to seek their consent, and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to name, date of birth, NHS number, postcode, date of diagnosis and vital status.

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that the application was for a clear medical purpose with significant public interest. The study would enable more individualised risk profiles to be produced to inform treatment and follow up decisions made by future Hodgkin Lymphoma 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

It was noted that the purpose of the application was to contact patients in order to seek their consent. The data would also be used in order to characterise the differences between responders and non-responders.

- Use of anonymised/pseudonymised data

Date of birth and postcode (used to characterise differences between responders and non-responders) would be reduced to age and geographical region where retained for patients who did not consent or respond to the study invitation. Identifiable data would be retained for the length of time taken to contact patients to seek their consent, which was specified as 2 years. Members were content to recommend support on this basis.

Justification of identifiers

The data items listed were all required in order to prevent duplication, as the study took place on a national level and individual clinicians would not be aware of whether patients had accessed services at more than one site. Measures would also be taken to ensure that the families of deceased patients were not contacted – clinicians would remove the data of anyone they knew to be deceased from lists of eligible patients, and the NHS Strategic Tracing System would be checked by researchers.

Members agreed that the data items requested were the minimum necessary to achieve the purpose of the activity.

Patient notification

Questions were raised in relation to the arrangements for respecting patient opt out – where a patient opted out of the inclusion of their data for this specific activity (selecting and contacting patients to seek their consent), this data should be deleted. The patient notifications should make this clear.

Public involvement

Reference had been made in the application to previous public involvement work with other patient groups. In response to queries the applicant had suggested asking a sample of Royal Marsden Hospital Hodgkin Lymphoma patients whether they would find this recruitment method acceptable. The Sub-Committee supported this approach, and requested that the results be fed back at annual review.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required 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.

Request for further information

1. Please confirm that patient objections will be respected, and include this information explicitly on patient notifications.

The applicants confirmed that patient objections would be respected and confirmed that this information would be explicitly included on patient notifications. The applicants provided a revised draft of the text of the patient notification which would be listed on their intranet site with a description of the study. The notification will read as follows:

"If you think that you may have been included one of these studies and want further information about it or wish to opt out of it we will fully respect your wishes, please let us know by contacting participantDPA@icr.ac.uk.

The response was received and confirmed as appropriate by the Chair.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V13 confirmed published and reviewed, for the Institute of Cancer Research.**
3. The results of public involvement work should be fed back at annual review.

c) 17/CAG/0096 A population based study of pre-disposition to breast cancer

Context

Purpose of application

This research study from the University of Cambridge set out the purpose of investigating the role of inherited genetic variation in breast cancer risk and clinical outcomes. The study began in 1996 and has 15,000 women with breast cancer and 3,400 controls as consented participants. Study participants (recruited via the Cancer Registry or local cancer networks by letter sent from the GP or network) are asked to provide a blood sample from which DNA is extracted, to complete a questionnaire on lifestyle and family history of cancer, to allow access to their medical record and for the study team to retrieve pathology material.

The application is submitted under the Precedent Set category 'Validity of consent'. The study is still ongoing and new participants are asked to give consent for access to data from NHS Digital, ONS, PHE

'and other central UK NHS bodies'. However, existing participants have only given specific consent for access to their medical record.

The study team state that since the outset they have accessed details on the patient's cancer diagnosis from data held by the local Cancer Registry concerning patients' cancer diagnosis (such as tumour size, tumour grade, node status and treatment), as well as regular updates on vital status from routine death notification data.

The applicant is now seeking to obtain cancer data from PHE, who prompted the CAG application in their letter of 17 March 2017 which asked:

'Please advise if the existing participants will be re-consented. If re-consenting is not feasible, please provide the definitive reasons and what alternative legal gateway is being sought to ensure compliance with the law'.

A recommendation for class Class 4 and 6 support was requested to link patient identifiable information from more than one source, and to allow access to an authorised user for this purpose.

Confidential patient information requested

Access was requested to enable data to be provided to PHE in order to link with data relating to patients with primary malignant breast carcinomas diagnosed between ages 18 and 70 years.

Full patient details are held under consent including names and addresses.

The applicant wished to provide PHE with the following:

Name

NHS Number

Date of birth

Cancer registry number

In order to obtain information concerning:

Tumour site

Tumour morphology, grade and receptor status

Tumour size

Number of positive nodes

Stage

Treatment data

Vital status

Cause of death

Confidentiality Advisory Group advice

Public interest

Members agreed that the application had a medical purpose and that there was a public interest in studies of this type being carried out.

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 study was a long-running study with 4,000 participants who had been consented to the study over 20 years. Members noted that the application to CAG was in relation to a query regarding the scope of the term 'medical records' in the historical consent form (which would in the future specifically request consent to obtain follow-up data from PHE).

Members accepted that it would not be feasible to re-consent the entire cohort, given the numbers of patients involved (4,000) and the long-running nature of the study (20 years). This would be likely to involve additional disclosure in order to trace individuals and ensure that relatives of deceased patients were not contacted.

- Use of anonymised/pseudonymised data

Identifiable data was held with consent from participants. The disclosure of this data to PHE in order to obtain reliable clinical data was accepted by members to be required in order to generate robust study findings.

Justification of identifiers

The data returned from PHE did include date of death. Members agreed that this identifier was one that patients would have expected researchers to access, on consenting to the study. The inclusion of date of death was deemed acceptable for the specified purpose of the study.

Additional points

Patient notification

Members sought out the patient notification mentioned within the application and commented that it was clear, easily accessible and contained a level of detail which was often not provided in patient notifications. It was agreed that the SEARCH website was the most appropriate site for these to be placed; given the dispersed nature of the cohort notices within clinics would be impracticable and ineffective.

Public engagement

The plans for public engagement work outlined by the applicant in the advice form were accepted as satisfactory by the Sub-Committee.

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**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
   Confirmed:
   V14 published and reviewed for University of Cambridge, School of Clinical Medicine
   V13 published and reviewed for PHE

3. Progress on public engagement work should be fed back at annual review.
4. The applicant was made aware that support for this activity applied only to England and Wales. An application to the appropriate approval bodies in Scotland should be made to cover the collection or processing of any data in Scotland.

d) 17/CAG/0097 A population based study of genetic predisposition to ovarian cancer

Context

Purpose of application

This research study from the University of Cambridge set out the purpose of obtaining epidemiological information and lymphocyte DNA on a population-based series of ovarian cases, to use in genetic association studies, and to define the proportion of ovarian cancer incidence attributable to mutations in known predisposing genes such as BRCA1 and BRCA2.

Most of the ovarian cancer patients recruited since the start of the study were recruited through the local cancer registry(formerly the Eastern Cancer Registration and Information Centre - ECRIC), who would write to the patient's GP asking the GP to send out information on the study. Participants are asked to provide a blood sample from which DNA is extracted, to complete a questionnaire on lifestyle and family history of cancer, to allow access to their medical record and for the study team to retrieve pathology material.

The application is submitted under the Precedent Set category 'Validity of consent'. The study is still ongoing and new participants are asked to give consent for access to data from NHS Digital, ONS, PHE 'and other central UK NHS bodies'. However, existing participants have only given specific consent for access to their medical record.

The study team state that since the outset they have accessed details on the patient's cancer diagnosis from data held by the local Cancer Registry concerning patients' cancer diagnosis (such as tumour size, tumour grade, node status and treatment), as well as regular updates on vital status from routine death notification data.

The applicant was now seeking to obtain cancer data from PHE, who prompted the CAG application in their letter of 17 March 2017 which asked:

'Please advise if the existing participants will be re-consented. If re-consenting is not feasible, please provide the definitive reasons and what alternative legal gateway is being sought to ensure compliance with the law'.

A recommendation for class 4 and 6 support was requested to link patient identifiable information from more than one source, and to allow access to an authorised user for this purpose.

Confidential patient information requested

Access was requested to data from PHE relating to cases of primary malignant ovarian carcinomas diagnosed between ages 18 - 70 years.

The applicant wished to provide PHE with the following:

Name

NHS Number

Date of birth

Cancer registry number

In order to obtain information concerning:

Tumour site

Tumour morphology, grade and receptor status

Tumour size

Number of positive nodes

Stage

Treatment data

Vital status

Cause of death

Confidentiality Advisory Group advice

Public interest

Members agreed that the application had a medical purpose and that there was a public interest in studies of this type being carried out.

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 study was a long-running study with 4,000 participants who had been consented to the study over 20 years. Members noted that the application to CAG was in relation to a query regarding the scope of the term 'medical records' in the historical consent form (which would in the future specifically request consent to obtain follow-up data from PHE).

Members accepted that it would not be feasible to re-consent the entire cohort, given the numbers of patients involved (4,000) and the long-running nature of the study (20 years). This would be likely to involve additional disclosure in order to trace individuals and ensure that relatives of deceased patients were not contacted.

- Use of anonymised/pseudonymised data

Identifiable data was held with consent from participants. The disclosure of this data to PHE in order to obtain reliable clinical data was accepted by members to be required in order to generate robust study findings.

Justification of identifiers

The data returned from PHE did include date of death. Members agreed that this identifier was one that patients would have expected researchers to access, on consenting to the study. The inclusion of date of death was deemed acceptable for the specified purpose of the study.

Additional points

It was noted that data would be held indefinitely, which could exclude the application from review via Precedent Set pathway. Members agreed that the long-term retention of data was reasonable given that the risk of ovarian cancer increased with age. The study aimed to investigate ovarian cancer in women diagnosed up to the age of 70; some women with low grade disease could live for many years.

It was agreed that in the light of this it could be expected that researchers would continue to access data on a long-term basis, and that in this case the application could be supported via the Precedent Set pathway.

Patient notification

Members sought out the patient notification mentioned within the application and commented that it was clear, easily accessible and contained a level of detail which was often not provided in patient notifications. It was agreed that the SEARCH website was the most appropriate site for these to be placed; given the dispersed nature of the cohort notices within clinics would be impracticable and ineffective.

Public engagement

The plans for public engagement work outlined by the applicant in the advice form were accepted as satisfactory by the Sub-Committee.

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**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
   Confirmed:
   V14 published and reviewed for University of Cambridge, School of Clinical Medicine

   V13 published and reviewed for PHE

1. Progress on public engagement work should be fed back at annual review.
2. The applicant was made aware that support for this activity applied only to England and Wales. An application to the appropriate approval bodies in Scotland should be made to cover the collection or processing of data in Scotland.

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

16 June 2017

Present:

Name	Capacity	Items
Dr Kambiz Boomla		1a
Dr Tony Calland	Chair	1a
Mrs Diana Robbins		1a

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

2. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0098 Population based study of genetic predisposition to endometrial cancer

Context

Purpose of application

This research study from the University of Cambridge set out the purpose of investigating the role of inherited genetic variation in endometrial cancer and clinical outcomes. The study began in 1996 as one of several projects investigating genetic predisposition to a variety of cancers. This study recruited 4,000 patients with endometrial cancer and 3,400 controls.

Study participants (recruited via the Cancer Registry or local cancer networks by letter sent from the GP or network) were asked to provide a blood sample from which DNA was extracted, to complete a questionnaire on lifestyle and family history of cancer, to allow access to their medical record and for the study team to retrieve pathology material.

The application was submitted under the Precedent Set category 'Validity of consent'. The study was still ongoing and new participants were asked to give consent for access to data from NHS Digital, ONS, PHE 'and other central UK NHS bodies'. However, existing participants had only given specific consent for access to their medical record.

The study team stated that since the outset they had accessed details on the patient's cancer diagnosis from data held by the local Cancer Registry concerning patients' cancer diagnosis (such as tumour size, tumour grade, node status and treatment), as well as regular updates on vital status from routine death notification data.

The applicant was now seeking to obtain cancer data from PHE, who prompted the CAG application in their letter of 17 March 2017 which asked:

'Please advise if the existing participants will be re-consented. If re-consenting is not feasible, please provide the definitive reasons and what alternative legal gateway is being sought to ensure compliance with the law'.

A recommendation for class 4 and 6 support was requested to link patient identifiable information from more than one source, and to allow access to an authorised user for this purpose.

Confidential patient information requested

Access was requested to linked data from Public Health England (PHE) concerning patients with cases of primary malignant endometrial carcinomas diagnosed between ages 18 - 70 years.

Full patient details are held under consent including names and addresses.

The applicant would provide PHE with the following:

Name

NHS Number

Date of birth

Cancer registry number

In order to obtain information concerning:

Tumour site

Tumour morphology, grade and receptor status

Tumour size

Number of positive nodes

Stage

Treatment data

Vital status

Confidentiality Advisory Group advice

Public interest

The Sub-Committee agreed that the study had a medical purpose and that there was a public interest in the investigation of genetic predisposition to cancers.

The request to access cancer data via PHE was agreed to be in the public interest, in line with the overall aims of the study.

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 noted that participants had consented to the study, including access to their medical record. The point in question was whether this consent was adequate to provide a legal basis for the research team to access clinical data relating to the cancer diagnosis from PHE.

The consent form was updated for new participants in order to cover access to data from other central UK NHS bodies; however there were 4,000 patients and 3,400 controls already in the study. Members accepted that it would not be practicable to contact and reconsent all of these patients; in order to this the researchers would need to check vital status (to avoid contacting relatives of deceased patients) and obtain up to date addresses, which would necessitate additional disclosure of data.

Therefore consent would not be practicable.

- Use of anonymised/pseudonymised data

It was accepted that identifiers (held with consent) were required by PHE in order to carry out data linkage, therefore pseudonymised data could not be used in this case.

Justification of identifiers

The Sub-Committee was satisfied that the identifiers provided to PHE for linkage were the minimum required. The data returned to the research team consisted of clinical data only.

Additional points

Patient notification and opt out mechanism

The patient notification and opt out mechanism publicised on the study website were deemed appropriate.

Public engagement

The plans for public engagement work outlined by the applicant in the advice form were accepted as satisfactory by the Sub-Committee.

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**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.
   Confirmed:
   V14 published and reviewed for University of Cambridge, School of Clinical Medicine

   V13 published and reviewed for PHE

3. Progress on public engagement work should be fed back at annual review.
4. The applicant was made aware that support for this activity applied only to England and Wales. An application to the appropriate approval bodies in Scotland should be made to cover any collection or processing of data in Scotland.

b) 17/CAG/0106 NICE Fit

Context

Purpose of application

This application from Croydon University Hospital set out the purpose of determining whether the Faecal Immunochemical Test (FIT) could be used as an effective triaging tool to identify patients at risk of bowel cancer, avoiding the need for unnecessary endoscopic examination. This would ultimately reduce cost to the NHS and avoid risk and discomfort for patients.

There is currently no way to predict if a patient's symptoms are due to bowel cancer, which means that patients presenting to their GP with bowel symptoms that warrant investigation are automatically referred for colonoscopy, which must be carried out within 2 weeks. Only 10-15% of these turn out to have underlying bowel cancer or significant pathology such as precancerous polyps. NICE guidelines stipulate a two week referral time for investigation of symptoms associated with a high probability of bowel cancer, and to improve pick up rates for bowel cancer widened the criteria for investigation in 2015 – resulting in a large number of unnecessary examinations. The FIT test is a one-off stool test that can be done by patients at home and has shown promise in predicting cancer in both the screening and symptomatic patient settings. It has been identified as a priority by NHS England as a technology that can improve early cancer diagnosis and save costs.

The FIT team would work with the cancer services team at Croydon Health Services NHS Trust to extract information on patients first referred by their GP, then triaged to undergo colonoscopy within 2 weeks. The team would obtain a list of eligible patients including addresses and basic demographics, send them the study information and testing kit by post and follow up with one phone call to discuss the study.

A recommendation for class 3 and 6 support was requested in order to select and contact patients to seek their consent, and to allow access to an authorised user for this purpose.

Confidential patient information requested

Access was requested to data from the Patient Tracking List (usually held by individual Trust cancer service offices) in relation to patients referred with suspected bowel cancer under the 2 week rule, who are triaged to undergo colonoscopy

Name

Hospital ID Number

Postcode

Telephone number

Date of colonoscopy

Confidentiality Advisory Group advice

Public interest

Members were of the opinion that there was significant public interest in the activity, both in terms of economics (reducing the costs of treatment) and ethics (reducing unnecessary investigations and associated risk to patients). The medical purpose was clear.

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 accepted the arguments given in relation to the impracticability of seeking consent, including variations in the referral systems at local sites which made it difficult for clinicians to identify patients and lack of time to recruit the necessary 5000 patients. There was evidence that where postal recruitment methods were used as opposed to face to face recruitment by clinicians, the response rate improved dramatically. There was also some evidence that patients preferred to receive the information by post.

- Use of anonymised/pseudonymised data

This would not be possible where full names and addresses were required to mail out study invitations.

Justification of identifiers

Members accepted that the requested identifiers were necessary in order to complete the mail-out.

Additional points

Patient notification

Members observed that it might be surprising for patients to discover that researchers had accessed their contact details in order to send the study invitation.

It is a general principle of the CAG, when recommending support under Regulation 5, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the Data Protection Act 1998.

Although often confused with a requirement to seek consent, patient notification is not the same as seeking consent from individual patients. Patient data is still accessed without consent, however information about the activity is publicly available, giving patients the option to find out about this use of their data and to express an objection if they so wish.

Members agreed that this principle had not been observed.

Members advised that it should be possible to notify patients despite the short recruitment timescale – for example, posters could be placed around the hospital and where the Trust had a two week wait

website, the information could be made available on the website. An email to GPs informing of the study and enabling them to advise any patients who might be included would also be useful.

This information should explain how patients could opt out of the use of their data. Any dissent should be managed prior to researcher access to the data.

Public engagement

It was noted that some public engagement work had been done, although this was not extensive.

Members recommended that further work was carried out, and reported back at annual review stage.

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

5. Patient notification approach to be identified and progress to be reported back at annual review.
6. Further public engagement work to be carried out and reported back at annual review.
7. Favourable opinion from a Research Ethics Committee. **Confirmed 8 June 2017.**
8. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **v14 confirmed published and reviewed**

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

30 June 2017

Present:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a
Professor Barry Evans		1a
Dr Sophie Brannan		1a

Also in attendance:

Name	Position (or reason for attending)
Rachel Heron	Confidentiality Advisor, HRA

3. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 17/CAG/0116 The incidence, presentation, treatment, and motor outcomes of essential infantile esotropia in the UK

Purpose of application

This application from Cardiff and Vale University Health Board set out the purpose of investigating essential infantile esotropia or congenital esotropia, a large angle accommodative squint which develops within first six months of life. Reported incidence from population studies in the USA did not correspond with clinical experience in ophthalmology departments in the UK, where the condition appeared to be rare and declining in incidence.

The study aimed to determine the number of incident cases of the condition, the presentation, treatment choice and early motor outcomes of cases in the UK. This would provide better understanding of the epidemiology of the disease and guide future surgical decisions.

The BOSU reporting card system, a methodology approved in principle by the CAG, would be used: this is a compulsory reporting system for ophthalmologists who are obliged to report an incidence of any of the rare conditions currently under surveillance. In this case when a case of congenital esotropia was encountered, the clinician would record this on a monthly reporting card which would be returned to BOSU. BOSU would then notify the research team, who would send a questionnaire to every clinician for each reported case of this condition. Clinical data in relation to the patient would be entered on the questionnaire and returned to the research team by the treating clinician. A follow-up questionnaire is sent after a year.

A recommendation for class 1 and 6 support was requested for the purpose of extracting and anonymising the information and to allow access to an authorised user for the above purpose.

Confidential patient information requested

Access was requested to data from treating ophthalmologists in relation to patients with non-accommodative, stable angle of esotropia, greater than 20 prism dioptres with an onset before 6 months of age in a neurologically normal child:

Hospital number, date of birth, ethnicity, gender and postcode.

Confidentiality Advisory Group advice

Public interest

Members agreed that the activity had a clear medical purpose.

There was little or no existing data in the UK on the current practice for timing of surgery and surgical outcomes, therefore this research would bring benefits to the patient group through improved clinical decision making and management of the condition in the future. It was agreed that the public interest was clear.

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 there would only be a maximum of 300 cases of this rare condition over the duration of the study (15-25 per hospital per year). It was accepted that complete ascertainment was needed to avoid bias to the results; therefore members agreed that it would not be feasible to seek consent.

- Use of anonymised/pseudonymised data

It was observed that postcode would be converted to deprivation index, although the applicant had not specified at which point this would happen. Date of birth would be retained for analysis. Members requested further information regarding the point at which these data items would be anonymised.

Justification of identifiers

The use of hospital number and date of birth in order to identify and remove any duplicate reports was agreed to be justified, as was the use of postcode to calculate deprivation indices. However, the Sub-Committee requested further justification for the retention of date of birth for analysis.

Additional points

Patient notification and opt out

Although the applicant had stated that similar patient notifications as those for BPSU would be used, along with the BPSU method of opt-out, no specific information for this study had been provided.

Members requested the wording of the patient notification to be used for this study along with a description of the method for respecting patient dissent.

Public involvement

Public involvement work to date had consisted of seeking the views of one lay reviewer. Members requested evidence of further work to gauge the opinions of patients and the public in relation to this access to patient data. It was agreed that this would not prevent the study from commencing, but progress should be reported back to the CAG within 6 months.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required 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.

Request for further information

1. Please provide justification for retaining full date of birth, or further information as to how and when the date of birth will be deleted.
2. Please provide the wording of the patient notification to be placed on the BOSU website, ensuring that the method a patient should follow in order to opt out is clearly described.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed.**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Please contact Darren Lloyd,** Darren.lloyd@wales.uk **at NWIS (NHS Wales Informatics Service) to arrange for NWIS to provide confirmation of suitable security assurances in the absence of the IG Toolkit.**

Please note that the CAG recommendation applies to England and Wales only. Applications would need to be made to the appropriate bodies