NHS
Health Research Authority

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

11th April 2016

Present:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a, 1b
Marc Taylor		1a, 1b
Dr Kambiz Boomla		1a, 1b

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) The Fenland Study - Phase 2 - 16/CAG/0033

Context

This application from the University of Cambridge set out the purpose to understand the causes and contributing factors to type 2 diabetes to inform effective public health policies.

Phase one of the Fenland study took a snap shot of participant's biological & physical health as well as dietary habits. Phase 2 of the Fenland study would allow the researchers to see any changes in these over time and see how lifestyle, genetic and environmental factors interact. The specific aim of this study is to recall participants of the Fenland Study for a follow-up assessment.

In order to ensure the most up to date contact information for the Fenland Study participants' information from the Personal Demographic Service, provided by the Health and Social Care Information Centre (HSCIC), will be used to validate the current contact information. This will assist in ensuring that invitations to take part in this study are sent to the correct address or that an invitation is not sent at all in the event that a participant has died since last contact. It is feasible that some of the participants may be pregnant at the time of their Fenland Study visit. Given the inclusion of a DEXA scan within the study visit the applicant will therefore ensure that any pregnant or potentially pregnant participant does not undergo a DEXA scan. Participants may either choose to defer their study visit until after pregnancy or to simply omit the DEXA scan from their study visit.

All participants from phase 1 who agreed to be re-approached for future research are eligible for phase 2. Participants will undergo a thorough health check at one of three testing facilities in Cambridgeshire. This includes collection of blood samples, an oral glucose tolerance test, height, weight, hip & waist measurements, blood pressure reading, an ECG (electrocardiogram), body fat distribution using ultrasound and Dual Energy X-ray Absorptiometry (DEXA), and a fitness test. Participants will also fill in a questionnaire assessing dietary and activity behaviours, as well as health & lifestyle elements. Following the visit participants will wear physical activity monitors to establish energy expenditure and activity in a free living environment for 7 days. The follow up phase is expected to last up to 5 years.

The applicant had put forward an application to HSCIC for mortality and address contact information which was declined because of their interpretation of the wording of the phase 1 consent form. The consent forms and patient information materials were available.

S251 support is requested to allow the disclosure of name, NHS number, GP practice code, address and postcode, date of death, to the researchers in order to contact the cohort.

A recommendation for class 2, and 6 support was requested to obtain and use information about past and present geographical location 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 death.

Confidentiality Advisory Group advice

Public interest

Members agreed this was an important medical study 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 problem the researcher faced was that although the original versions of the consent form they asked participants to sign did include agreeing to be re-contacted, it did not include consent to approach bodies such as HSCIC to update addresses, and ONS to deal with deaths. Later versions of the consent form have the appropriate modifications to allow this to occur with consent.

Members agreed that full consent was not therefore feasible, partial consent existed, and s251 was appropriate to bridge the gap.

- Use of anonymised/pseudonymised data

Only identifiers necessary for HSCIC to update contact details would be required and anonymised data would not be appropriate. A practical alternative would be an updated consent form, and this had been provided for the future.

Additional points

Retention of identifiable data was consented for the study duration.

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.
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.

b) British Association of Dermatologists Biologic Interventions Register - 16/CAG/0043

Context

This application from the University of Manchester set out the purpose of monitoring the long-term safety of biologic treatments in the U.K. and Republic of Ireland for patients with psoriasis. The study will consist of two cohorts comparing (i) patients with psoriasis newly treated with one of the biologic therapies, to (ii) patients with similar disease characteristics treated with non−biologic systemic therapies (including PUVA, methotrexate, ciclosporin and acitretin). Patients will have been exposed to a variety of conventional treatments each with its own risks before starting on the biologic therapies.

Based on recruitment rates of a similar register (the British Society for Rheumatology Biologics Register - BSRBR) it is anticipated that 2000−4000 patients for each biologic therapy will be recruited over a five year period. During the same time period, a cohort of comparison patients on standard therapy will also be recruited. Due to the NICE guidelines recommending that all patients with psoriasis should be registered with a national register, it is envisaged that patients in the biologic cohort will be recruited

from all dermatology departments in the UK. The comparison cohort will also be recruited from all contributing centres to reduce the risk of selection bias. However for the size of the comparison cohort it is estimated that a total sample of 4000 patients followed for five years is required to allow the register to detect at least a 3− to 4−fold increase in the risk of non−melanoma skin cancer, a particular concern in these patients who have been exposed to phototherapy.

BADBIR has an existing link with NHS Health and Social Care Information Centre (HSCIC) to receive Death and Malignancy information (Ref: MR1102) and are now applying for access to the Hospital Episodes Statistics data for the study participants. However, HSCIC has questioned the validity of the consent on the grounds that the consent material did not provide an adequate legal basis for the request to access HES data. HES data will allow a better understanding of the outcomes for patients receiving biologic therapy and up to 4,000 patients treated with conventional therapy to enable the short, medium, and long term safety of biologic treatment as compared to traditional therapy for psoriasis to be ascertained. The applicant has provided copies of the correspondence with the HSCIC as well as the consent forms.

S251 support is requested to allow the disclosure of name, NHS number, address and postcode, date of birth, and gender to the HSCIC for linking purposes.

A recommendation for class 4, and 6 support was requested 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, address and postcode, date of birth, and gender

Confidentiality Advisory Group advice

Public interest

Members agreed this was a study with medical purpose in the public interest.

Justification of identifiers

The application was unclear on whether the study was still recruiting or if the cohort was complete. If not complete members agreed that the patient information leaflet and consent form should be updated to seek consent from this part of the cohort that HSCIC was content with, to do so the applicant must seek advice from HSCIC.

For the cohort already recruited the applicant should ensure that they have satisfied the requirements of principle 1 of the DPA and have made a reasonable attempt to inform all subjects of linkage with HES, albeit a great deal of the spirit of that is already contained in their patient information leaflet. Members recommended that the leaflet should be updated and consulted on with HSCIC as even if section 251 support is recommended, the patent information and privacy notice will be scrutinised during the application to HSCIC (bearing in mind that section 251 support does no lift any of the

requirements of the DPA) and HSCIC will not release data unless the requirements of the DPA are satisfied.

Additional points

It was noted that the study aims to collect data from all four jurisdictions of the UK and CAG approval would extend only to data collected in England and Wales. However members noted that this application was restricted to data supplied by the Health and Social Care Information Centre (HSCIC) which is limited to English data only.

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. Support is limited to the cohort already recruited. If still recruiting new recruits must be consented in a way that satisfies the HSCIC.
2. The Patient information leaflets should be updated in line with recommendations from the HSCIC to ensure it complies with principles of the Data Protection Act (DPA).
3. Favourable opinion from a Research Ethics Committee.
4. 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.

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