

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

**July 2021**

1. New Applications

**a. 21/CAG/0093- Facilitating access to online NHS primary care services -  
current experience and future potential (Di-Facto)**

<b>Name</b>	<b>Capacity</b>
Dr Martin Andrew	CAG member
Dr Patrick Coyle	CAG vice-chair
Professor Lorna Fraser	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

**Context**

**Purpose of application**

This application from the university of Exeter sets out the purpose of medical research that aims to explore patient access to digital services provided by primary care.

The COVID-19 pandemic has led to an increase in digital routes of contact offered by general practices (for example online triage platforms) and therefore an increased need for patients to be capable of using digital routes to access care. During the early stages of the COVID-19 pandemic, NHS England encouraged all general practices to

move to a ‘total triage’ model which requires all patients to make an initial contact with their general practice via an online platform (those patients who cannot use online services must use the telephone) so that the information can be used to decide which type of appointment a patient requires. However, recently published data has shown that even during the pandemic, telephone was the most commonly used alternative to a face-to-face consultation, shown to comprise around 90% of all consultations, indicating that digital routes of contact are still far from routinely used by patients even though they are more available.

It is therefore important to understand how barriers to uptake might be overcome and patients best supported in the move to online services of all kinds. One way to address this is with digital facilitation; supporting NHS patients and carers in their use of online services. ‘Digital facilitation’ is defined as ‘that range of processes, procedures, and personnel which seeks to support NHS patients in their uptake and use of online services.’ There is, however, no existing evidence as to the nature and scope of applying digital facilitation. This is compounded by the fact that the nature and extent of innovative approaches offered by practices are unknown. It is important to understand the extent to which digital facilitators or other approaches to digital facilitation are being used, how they are used, how they may be impacting patient health and access to healthcare information and services, GP practices, and the wider NHS.

This study is one which primarily operates using consent as the legal basis (and therefore outside the scope of support). However, as part of the study researchers, not part of the direct care team, will be observing 8 GP practices (to be identified). These observations are interested in the interactions between patients and staff, and between staff, and are not interested in patient information. However, during the observations, confidential patient information may be incidentally disclosed (e.g. overhearing staff talk about a patient). No audio recordings are made and no notes are taken relating to confidential patient information.

A recommendation for class 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

### **Confidential patient information requested**

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

<b>Cohort</b>	Patients at 8 GP practices whose confidential patient information may be incidentally disclosed during observations
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<b>Data sources</b>	1. 8 GP practices to be identified
<b>Identifiers required for linkage purposes</b>	1. No items of confidential patient information will be collected for analysis purposes
<b>Identifiers required for analysis purposes</b>	1. No items of confidential patient information will be collected for analysis purposes

### **Confidentiality Advisory Group advice**

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

- 1. Please amend the poster to state patients can request a researcher leaves the area where a patient is present, and provide an updated version for review.**

The applicants updated the poster, and members were content with the changes made.

- 2. Please confirm that GP practice websites can also display the notification.**

It was confirmed by the applicants that practices will be asked to upload a copy to the practice website, and this will be discussed at the site initiation visit. The CAG were content with this response.

- 3. Please confirm that the researcher will wear an identity badge, and will be introduced to the patient if appropriate.**

The applicants confirmed that all researchers will wear a study identity badge, and will comply with any practice request to wear a temporary visitor pass provided by the

practice. It is expected that staff will introduce a patient if necessary, and all points will be discussed at the site initiation visit. The members were content with these responses.

**4. Please provide evidence that researchers undertaking observations have an equivalent duty of confidentiality to that of a health professional, e.g. confidentiality policy, clauses in employment contract.**

The applicants confirmed that all researchers entering the practice will have completed GCP training and will have a letter of access which reiterates the need to ensure confidentiality regarding information on patients and staff. Additionally, there will be an agreement in place between the sponsor and practice (organisation information document) which includes sections on confidentiality. Additionally, practices may also require researchers to sign confidentiality agreements and this will be discussed at the site initiation visit.

CAG were content with this explanation.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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**

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 April 2021**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed.**

Due to the number of organisations involved it is the responsibility of University of Exeter, as controller, to ensure that practices hosting researchers meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a practice.

**b. 21/CAG/0067 - Derivation and narrow validation of a clinical decision rule for paramedics to triage older adults with a traumatic brain injury. Short tile: Clinical Decision Rule for TBI in Older adults (CEREBRAL)**

<b>Name</b>	<b>Capacity</b>
Professor William Bernal	CAG alternative vice-chair
Dr Liliane Field	CAG member
Mr Andrew Melville	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor

**Context**

**Purpose of application**

This application from South East Coast Ambulance Service NHS Foundation Trust set out the purpose of medical research that aims to develop and test a clinical decision rule (CDR) that paramedics could use to aid triage of patients aged 60 years or older who could be at risk of a traumatic brain injury (TBI), to a hospital with neurosurgical services onsite.

It is now considered that older adults are a large proportion of the TBI patient population, with the majority presenting to the emergency department (ED) via emergency services. Therefore the responsibility of the initial assessment, triage, and transportation of these patients falls to the paramedic. However clinical presentation following a TBI may not correlate with the severity of injury, and as a result, the triage of older adults suffering a TBI can be inaccurate, increasing the risk of poor patient outcomes. When older adults with traumatic injuries are transported to an appropriate hospital, they are more likely to have a good outcome. Understanding which older TBI patients should be transported to a hospital with onsite neurosurgery and the variables that may predict this could help paramedics in the acute triage and management of older adults with suspected TBI.

Currently, it is difficult to accurately identify patients with a TBI until they have had a scan of the head which can only occur in a hospital. Therefore, to identify patients presenting to the ambulance service with a clinically significant TBI, the applicants plan to work backwards from the hospital records. Retrospective patient records will be identified from two different hospital sources;

1. Hospital records of patients meeting the inclusion criteria referred to neurosurgeons will be screened via the online neurosurgical referral service. These records will be screened and extracted by the applicant, who is not a member of the direct care team. The direct care team do not have capacity to undertake this screening and extraction. He has explained that the access to the online Neurosurgical referral platform will be through Kings College London NHS Foundation Trust (KCL), as they are the central Trust in SELKaM Trauma Network, who operate a hub and spoke model, and all neurosurgical referrals go through KCL, and for Sussex trauma network data will be extracted from Brighton and Sussex University Hospital. He will extract CAD incident number if available, alongside date of transport, NHS number, date of birth, date and ED admission time, Gender, ethnicity, and other clinical information. He will securely send this dataset to the Business Intelligence department at South East Coast Ambulance Service NHS Foundation Trust (SECAmb).
2. Hospital records of patients meeting the inclusion criteria who attended the ED but were not referred to neurosurgeons will be screened via the ED hospital registry. Intelligent information specialists at hospitals within East Kent Foundation Hospitals Trust for SELKaM Trauma Network, and University Hospitals Sussex NHS Foundation Trust for Sussex Trama network+ will identify and extract a dataset regarding eligible patients. Support is requested for this, as the Trusts may not consider these staff to be the direct care team. They will and extract CAD incident number if available, alongside date of transport, NHS number, date of birth, date and ED admission time, Gender, ethnicity, and other clinical information. They will securely send this dataset to the Business Intelligence department at South East Coast Ambulance Service NHS Foundation Trust (SECAmb).

The patient's hospital records regarding neurosurgical referrals and ED data will be linked together by SECAmb Business Intelligence (BI) department, and also linked to SECAmb ambulance patient record using CAD numbers, NHS numbers and dates of birth. Once linkage is complete, The BI team will assign a pseudonymous study ID, and the CAD number, NHS number and date of birth are removed and destroyed. No key between the pseudonymous ID and identifiable information is retained. The dataset is sent to the study team at University of Surrey. and it can be considered anonymous to the research team, as they will be unable to re-identify the patients. The study team will not have access to patient identifiable information.

The final dataset will also include SECAmb patients who were not transported to the hospital over the same period, however this element does not require CAG support.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

## Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

<p><b>Cohort</b></p>	<p>Older adults (60+) who have a TBI or suspected TBI or head injury, and present to South East Coast Ambulance Service (SECAMB) between the 1st of January 2020 and the 31st of December 2020 and transported to hospitals within the trauma networks of South East London, Medway, and Kent (SELKaM) Trauma Network or Sussex Trauma Network.</p> <p>Approximately 1080 patients expected.</p>
<p><b>Data sources</b></p>	<ul style="list-style-type: none"> <li>• Hospital online Neurosurgical referral platform: For SELKaM Trauma Network, accessed only at <b>King’s College Hospital</b>, and for Sussex trauma network this is accessed at <b>Brighton and Sussex University Hospital</b></li> <li>• Participating Emergency Department hospital records, in SELKaM Trauma Network;             <ol style="list-style-type: none"> <li>1. King’s College Hospital</li> <li>2. William Harvey Hospital</li> <li>3. Queen Elizabeth Queen Mary Hospital</li> <li>4. Canterbury Hospital</li> </ol> <p>and Sussex trauma network;</p> <ol style="list-style-type: none"> <li>1. Brighton and Sussex University Hospital</li> <li>2. Worthing Hospital</li> <li>3. St Richards Hospital</li> <li>4. Princess Royal Hospital</li> <li>5. Conquest Hospital</li> <li>6. Eastbourne Hospital</li> </ol> </li> </ul>

	<ul style="list-style-type: none"> <li>• SECAmb ePCR database (South East Coast Ambulance patient electronic records)</li> </ul>
<b>Identifiers required for linkage purposes</b>	<ol style="list-style-type: none"> <li>1. CAD number</li> <li>2. NHS number</li> <li>3. Date of birth</li> <li>4. Date and time of ED admission</li> <li>5. Pseudonymous ID</li> </ol>
<b>Identifiers required for analysis purposes</b>	<ol style="list-style-type: none"> <li>1. Gender</li> <li>2. Ethnicity</li> <li>3. Pseudonymous ID</li> <li>4. Age</li> </ol> <p>(Effectively anonymous for analysis)</p>

### **Confidentiality Advisory Group advice**

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

- 1. Please update the notification poster to confirm the retrospective calendar year as 2020 rather than 2019, and provide an updated document for review.**

The applicant provided an updated patient notification to CAG on 12 July 2021. This confirmed the year as 2020, and the members were content with this response.

- 2. Please update the notification poster to include a postal address for opting out, and provide an updated document for review.**

The applicant provided an updated patient notification to CAG on 12 July 2021. This included a postal address for opting out, and the members were content with this response.

- 3. Please confirm if the patient notification will be displayed in clinical areas at participating sites, on websites, or both, and confirm if the notification can additionally be displayed on the SECamb website.**

Participating sites will be asked to place the patient notification poster on their websites and notice boards. Within SECamb, the notice will be advertised on the website through the SECamb Research and Development social media page and in the SECamb member's newsletter. However, patients would be unlikely to see the poster if they were put up at ambulance stations. The applicants considered placing the posters in ambulance stations, however due to the limited space available within the ambulance to display posters, the notification will not be posted in clinical areas within SECamb. The Members were content with this response, as their query more surrounded clinical areas at participating sites, websites of participating sites, and the SECamb website, all of which the applicant has confirmed. The CAG were now content to recommend support.

### **Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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**

The following sets out the specific conditions of support.

- 1. Favourable opinion from a Research Ethics Committee. Confirmed 10 June 2021**
- 2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**
  - South East Coast Ambulance Service NHS Foundation Trust**
  - King's College Hospital**
  - East Kent Foundation Hospitals Trust**
  - University Hospitals Sussex NHS Foundation Trust (new merged Trust, should currently be covered by the below;**

- Brighton & Sussex university Hospital NHS Trust and
- Western Sussex Hospitals NHS Trust

**c. 21/CAG/0078 - Cancer Survivorship Studies**

<b>Name</b>	<b>Capacity</b>
Dr Patrick Coyle	CAG vice-chair
Professor Barry Evans	CAG member
Dr Liliane Field	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Pauline Lyseight-jones	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Prof Sara Randall	CAG member
Mr Dan Roulstone	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager

**Context**

**Purpose of application**

This application, from University of Birmingham, sets out the purpose of medical research that aims to establish a research database by combining two research databases, The British Childhood Cancer Survivor Study and The Teenage and Young Adult Cancer Survivor Study.

By 2030 it is estimated that there will be 4 million individuals living with the long-term consequences of cancer and its treatment. Recently there have been three UK-wide research priority setting initiatives involving detailed consultations with cancer patients/survivors, their families and friends, and health care professionals who treat or follow-up individuals who are living with or beyond cancer. Half of the final top 10 research priorities ultimately identified related to an issue concerning “cancer survivorship”, that is concerns which relate to problems encountered after cancer treatment is completed and the survivor returns to ‘normal’ life. The linkage of large-scale population-based cancer survivors cohorts to electronic health care databases provides a unique opportunity to investigate the risks of a wide spectrum of long-term adverse health outcomes following treatment for cancer on a national level.

The applicants request to combine two research databases currently operating under Regulation 5 support; The British Childhood Cancer Survivor Study (BCCSS - ECC 2-02(f)/2011) and The Teenage and Young Adult Cancer Survivor Study (TYACSS - ECC 3-04(c)/2010). Confidential patient information will flow from the University of Birmingham to link to a number of datasets detailed in the data sources section. These are a combination of national datasets, those operating under consent or others operating under CAG support. Linkage will be undertaken on an annual basis. Clinical data will be flowed back to University of Birmingham to create the database.

Researchers requesting access to the database will submit a research proposal that will be reviewed by the chief investigator and Senior Researchers who may consult with patient representatives to assess whether the research is relevant and important to cancer survivors.

Following support for this application the British Childhood Cancer Survivor Study (BCCSS - ECC 2-02(f)/2011) and The Teenage and Young Adult Cancer Survivor Study (TYACSS - ECC 3-04(c)/2010) will be expired.

A recommendation for class 1, 2, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

**Confidential patient information requested**

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

<b>Cohort</b>	The British Childhood Cancer Survivor Study (BCCSS) - 35,000 individuals who were diagnosed with cancer under the age of 15 years, between 1940 and 2006, in
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	<p>England, Wales or Scotland, and who survived at least 5 years from diagnosis.</p> <p>The Teenage and Young Adult Cancer Survivor Study (TYACSS) - 200,945 individuals diagnosed with cancer when aged 15 to 39 years inclusive, between 1971 and 2006, in England or Wales and who survived at least 5 years from diagnosis.</p>
<p><b>Data sources</b></p>	<ol style="list-style-type: none"> <li>1. University of Birmingham: <ol style="list-style-type: none"> <li>a. British Childhood Cancer Survivor Study (BCCSS - ECC 2-02(f)/2011)</li> <li>b. The Teenage and Young Adult Cancer Survivor Study (TYACSS - ECC 3-04(c)/2010)</li> </ol> </li> <li>2. NHS Digital <ol style="list-style-type: none"> <li>a. National death registries (ONS Mortality datasets)</li> <li>b. National cancer registries</li> <li>c. Hospital Episode Statistics (HES)</li> <li>d. The National Mental Health Services Dataset</li> </ol> </li> <li>3. Public Health England <ol style="list-style-type: none"> <li>a. National NHS GP prescription database</li> <li>b. National Systemic Anti-Cancer Therapy Dataset</li> <li>c. National Radiotherapy Dataset</li> <li>d. National Diagnostic Imaging Dataset</li> <li>e. National Congenital Anomalies and Rare Disease Registry (CAG 10-02(d)/2015)</li> </ol> </li> <li>4. Digital Health &amp; Care Wales (DHCW) (Formerly known as NHS Wales Informatics Service, (NWIS) <ol style="list-style-type: none"> <li>a. Patient Episode Database for Wales (PEDW)</li> </ol> </li> <li>5. Barts Health NHS Trust <ol style="list-style-type: none"> <li>a. National Institute for Cardiovascular Outcomes Research (NICOR) - Various Cardiovascular outcomes datasets (17/CAG/0078)</li> </ol> </li> <li>6. Birmingham Women's and Children's NHS Foundation Trust <ol style="list-style-type: none"> <li>a. West Midlands Regional Children's Tumour Registry (17/CAG/0103)</li> </ol> </li> <li>7. British Society of Blood and Marrow Transplantation and Cellular Therapy <ol style="list-style-type: none"> <li>a. BSBMTCT Data Register (held under consent)</li> </ol> </li> </ol>

<b>Identifiers required for linkage purposes</b>	<ol style="list-style-type: none"> <li>1. Name</li> <li>2. Gender</li> <li>3. Date of Birth</li> <li>4. NHS number</li> <li>5. Post Code</li> <li>6. (Random Key)</li> </ol>
<b>Identifiers required for analysis purposes</b>	<ol style="list-style-type: none"> <li>1. Date of birth (month and year only)</li> <li>2. Date of death (month and year only)</li> <li>3. Postcode (unit level)</li> <li>4. Gender</li> <li>5. Ethnicity</li> <li>6. Date of cancer diagnosis (month and year only)</li> </ol>

### **Confidentiality Advisory Group advice**

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

- 1. Please develop a patient notification document which is specific for this application, which describes the study purposes, processes, and describes how to opt out. Please provide this to the CAG for review.**

The applicant provided a patient notification for this application to the CAG for review. They were broadly content, however the Members requested the applicant update the notification to include correct references to the CAG functions, remove the risks section, and to change the placing of information surrounding the death registers. The applicant was to feed back to the office. The applicant provided an updated v2 of this notification, and this was reviewed by the Confidentiality Advice Team (CAT). The updated notification was satisfactory, and the CAG were content to recommend support once this had been provided.

### **Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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

The following sets out the specific conditions of support.

1. Previous applications, The British Childhood Cancer Survivor Study (BCCSS) – ECC 2-02(f)/2011 and The Teenage and Young Adult Cancer Survivor Study (TYACSS) - ECC 3-04(c)/2010, will be expired from the date of the final outcome letter, and replaced by 21/CAG/0078.
2. Support is in place for five years from the date of the final outcome letter, in line with the REC. Further support is to be sought after this time, via a duration amendment.
3. Support only extends to England and Wales.
4. Continuing patient and public involvement should be undertaken, to specifically explore the purposes and data flows involved in this specific application, and a report should be provided to the CAG within six months from the date of the final outcome letter.
5. Favourable opinion from a Research Ethics Committee. **Confirmed 23 February 2021.**
6. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for the following organisations have been assessed as 'standards met' by NHS Digital;**
  - **University of Birmingham**
  - **Public Health England**
  - **NHS Digital**
  - **Birmingham Women's and Children's NHS Foundation Trust (WM cancer registry)**
  - **British Society of Blood and Marrow Transplantation and Cellular Therapy**
  - **Barts Health NHS Trust**
  
  - **A CPiP assessment is in place for NWIS.**

**d. 21/CAG/0076 - Configuration and utilisation of clinical pathways by patients who attend A&E in suicidal crisis. Short title: Clinical pathways for patients attending A&E in suicidal crisis**

<b>Name</b>	<b>Capacity</b>
Dr Patrick Coyle	CAG vice-chair
Professor Barry Evans	CAG member
Dr Liliane Field	CAG member
Dr Rachel Knowles	CAG member
Professor Jennifer Kurinczuk	CAG member
Dr Pauline Lyseight-jones	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Professor Sara Randall	CAG member
Mr Dan Roulstone	CAG member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service

**Context**

**Purpose of application**

This application from Liverpool John Moores University sets out the purpose of medical research that aims to gain an understanding of how visits to A&E for self-harm, suicidal ideation and crisis are coded, and whether the pathways of care are consistent at each A&E site. This study will explore suicidal crisis data at A&E level and will test feasibility across two trusts with the aim of developing a national data collection tool for A&E departments to record people who attend in suicidal crisis. This study requires CAG support for phase one only, phase two is out of scope for CAG support.

Suicide is a major public health issue. Although national data is available for individuals who attend A&E for self-harm and suicidal injury, there is no national data for those individuals who attend A&E in suicidal crisis. The clinical pathways available for service users after presentation in suicidal crisis are complex and have not been

examined systematically. Gaining a greater insight into the configuration and utilisation of clinical pathways for service users in suicidal crisis will better inform modelling of service provision for these patients.

The initial identification of potential participants medical notes, using the electronic databases at each of nine A&E sites, will be undertaken by the direct care team who will inform the researcher. The named researcher, who is not a member of the direct care team, will have on-site access to patient medical records, which include confidential patient information. Retrieving information will be a time-consuming activity, and the direct care team have indicated that they do not have the time and resources to complete this work. Therefore CAG support is required. Potential participants will be screened by the named researcher, and if eligible, pseudonymised data will be recorded. Although a key is retained between the NHS number and the unique anonymised study ID, this is retained by the direct care team only. Therefore support is not required for this retention, and the collected dataset can be considered anonymous to the named researcher. No confidential patient information will be recorded or retained by the researcher. Data will subsequently be analysed at Liverpool John Moores University.

A recommendation for class 1 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

### Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

<p><b>Cohort</b></p>	<p>Individuals aged 16 and over who have attended A&amp;E in suicidal crisis between January 2019- December 2020.</p> <p>(people who may have presented in suicidal crisis, for self-harm or following suicide attempts)</p> <p>sample size of 1200 (approximately 133 per site)</p>
<p><b>Data sources</b></p>	<ul style="list-style-type: none"> <li>• Electronic databases at 9 A&amp;E departments, and associated Trust medical records</li> </ul> <p>Cheshire and Wirral A&amp;E sites are:</p>

	<p>8. Arrowe Park,  9. Countess of Chester Hospital,  10. Macclesfield District General Hospital,  11. Leighton Hospital.</p> <p>Mersey Care A&amp;E sites are:</p> <p>12. Royal Liverpool University Hospital,  13. Aintree University Hospital,  14. Southport and Formby District Hospital,  15. Whiston Hospital,  16. Warrington Hospital</p>
<b>Identifiers required for data extraction purposes</b>	<p>7. Researcher will view medical notes to extract a pseudonymised dataset  8. Hospital ID  9. NHS number  10. Unique anonymised study number</p>
<b>Identifiers required for analysis purposes</b>	<ol style="list-style-type: none"> <li>1. Age</li> <li>2. Gender</li> <li>3. Ethnicity</li> <li>4. Education</li> <li>5. Employment status</li> <li>6. Has the patient had COVID-19</li> <li>7. Unique anonymised study number</li> </ol> <p>It is not possible for the researcher to re-identify a patient from this data extract.</p>
<b>Additional information</b>	<p>A key that will be held within each Trust linking NHS number to a unique anonymised study number. If researcher MM needs to go back to a patient file this key will allow re-identification, however only the Trust would hold this information. No identifiable data will be held by the researcher.</p>

### Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

**1. Please provide a definition of suicidal crisis, and explain how this relates to the other described clinical contexts surrounding A & E attendances relating to suicide.**

The applicant explained that suicidal crisis involves the experience of overwhelming distress combined with suicidal thoughts and/or a suicide attempt. This temporary state can be characterised by severe and intense emotional pain in which death by suicide seems to be the only option. Self-harm risk during this time is often heightened. If risk is deemed “high” by clinical staff, the crisis becomes an emergency situation which demands immediate intervention to minimise suicide risk. A&E departments are often the first point of contact for individuals in suicidal crisis. Although national data is available for individuals who attend A&E for self-harm or following a suicide attempt, current systems to monitor and record suicidal crisis are lacking. The CAG were content with the definition provided.

**2. Please clarify what information is being recorded in the proforma as part of the mental state examination and physical examination sections, and provide assurance to the CAG that this will not be identifiable data.**

The applicant confirmed that no identifiable data will be recorded on the proforma. Mental state examination refers to notes made on whether the individuals has presented in a calm, distressed, agitated or aggressive manner when attending A&E. Physical examination will include notes made on whether the individual appears appropriately dressed or whether self-neglect is evident. Physical examination also refers to the individual’s behaviour – e.g., overactive, fidgety, tearful or not engaging. The Members were content with this response.

**3. Please confirm that Trust IT departments extracting an anonymised dataset for the researcher is not a practicable alternative, and provide justification to CAG.**

The applicant provided confirmation that it is not practicable for the Trust IT department to extract an anonymised dataset. To get the level of data needed to conduct this research, the data required is not coded data. Thus, a member of the direct care team would be required to go into each individual patient record and extract the information needed from the case notes, as it would not be possible for the IT department to extract. Further justification is provided as part of the responses, and the Members were content with the response provided.

4. **Please provide an updated patient notification which is written in less complex language.**

The applicant provided an updated version (v3) of the patient notification materials. The CAG were content with the new content.

5. **Please confirm that the national data opt out would be applied via MESH by the local Trusts.**

The applicant has confirmed this is the case, and the CAG accepted this response.

6. **Please provide evidence of NHS Digital review of the DSPT for Cheshire & Wirral Partnership NHS Trust (standard condition of support, see below).**

This was provided by email to the CAG inbox on 29 July 2021.

### **Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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**

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 27 May 2021**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

The NHS Digital **19/20** DSPT review for **Mersey Care NHS Foundation Trust** was confirmed as '**Standards Met**' on the NHS Digital DSPT Tracker (checked 16 June 2021)

The NHS Digital **20/21** DSPT review for **Cheshire & Wirral Partnership NHS Trust** was confirmed as '**Standards Met**' (by email to the CAG inbox 29 July 2021).

#### e. 21/CAG/0049 - The FIREFLI study v1.0

<b>Name</b>	<b>Capacity</b>
Dr Murat Soncul	CAG Alternate Vice Chair
Ms Sophie Brannan	CAG Member
Dr Rachel Knowles	CAG Member
Dr Simon Kolstoe	CAG Member
Professor Jenny Kurinczuk	CAG Member

### **Context**

#### **Purpose of application**

This application from the University of York set out the purpose of medical research that seeks to determine whether the Safe and Well Visits delivered by the Fire and Rescue Service reduce the number of falls and improve the quality of life of people over 70 years of age.

The Fire and Rescue Service (FRS) routinely carry out approximately 670,000 Safe and Well Visits (SWV) each year. These visits take place in people's home and are aimed to reduce the risk of fire, as well as addressing wider issues related to health and wellbeing. This includes falls prevention, smoking cessation, winter warmth advice and social isolation. Falls can be a serious issue for older people. Around 1 in 10 people who have a fall suffer a serious injury as a result, costing the NHS £2.3 billion per year to treat. Some evidence exists that interventions to improve home safety are effective at reducing falls, however it is not known whether SWV delivered by the FRS reduce falls, improve quality of life or are good value for money.

The applicants will recruit 1156 people aged 70 years and over from lists held on FRS databases. All participants will receive a falls prevention leaflet from Age UK and usual care from their GP and/or other healthcare professionals. Participants will be randomised into two groups. Half will receive a SWV at the start of the study and half will receive a SWV after 12 months. All participants will complete a falls calendar and four postal questionnaires sent out over the 12-month period of the study. The applicants will also conduct interviews participants and members of the FRS to find out if the visits were acceptable to older people and the FRS.

The Humberside Fire and Rescue Service will submit an application to the NHS Primary Care Registration Management (PCRM) at NHS Digital to request a new ‘cleansed’ set of Exeter data, which is held by NHS England and Improvement, specifically for the study. The PCRM will then disclose a list of people aged 70 years and over, living in the catchment areas for Humberside FRS, to the Humberside FRS. The Fire Service will use this information to create a list of eligible patients. Confidential patient information from the Exeter dataset is routinely shared with Fire and Rescue Services in England to allow the Services to prioritise which households to target with their SWV, however the current data sharing agreement does not allow use of this data for research purposes; therefore the applicants are seeking support to use data from Exeter to identify and invite eligible people to take part in the study. FRS staff will then remove those who have already received an SWV and send potential trial participants an invitation pack in the post, asking if they would like to take part in the study. The invitation pack will contain an invitation letter from Humberside Fire and Rescue Service (FRS), addressed to a named individual in the household. Participants who wish to take part in the study, will complete the consent and screening forms and return them to the York Trials Unit. Their participation will then be on a consented basis. The applicants advised that members of the research team based at the University of York, York Trials Unit (YTU) will not know which households have been mailed out to until the study documentation is returned to the University. However, the FRS may require help from the research team when undertaking the mailout of invitation packs and the researchers may be exposed to confidential patient information when assisting.

A recommendation for class 2, 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

### Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

<b>Cohort</b>	Those aged 70 years and over, living in the catchment areas for Humberside Fire and Rescue Service who have not previous received an SWV. 1156 patients will be included.
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<b>Data sources</b>	1. Exeter database at NHS England and Improvement 2. Primary Care Registration Management at NHS Digital
<b>Identifiers required for linkage purposes</b>	1. Name 2. Date of birth 3. Postcode – unit level 4. Gender
<b>Identifiers required for analysis purposes</b>	Analysis will be undertaken after participants have consented to the research.

### **Confidentiality Advisory Group advice**

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

- 1. Clarify whether support is needed to amend the data sharing agreement between the FRS and the NHS to permit access to the Exeter database for research purposes.**

The applicants explained that support was required in order to amend the Data Sharing agreement. The current DSA does not refer to sharing of data for research purposes. The CAG noted this and raised no further queries.

- 2. Further clarification is needed on the identifiers that will be disclosed between the FRS and NHS Digital PCRM:**
  - a. Clarification needs to be provided on why the PCRM would return the addresses, date of birth and gender to the FRS, as the FRS already held these details.**

The applicants explained that the FRS already hold the addresses and year of birth. The data that the FRS receive from NHS PCRM includes those who have opted-out, via the National Data Opt-out, of the sharing of their data for research purposes. The applicants also noted that the routine data currently held by the FRS to arrange Safe and Well visits was provided to them by the applicants in summer 2020. Therefore, the

applicants are requesting the data again as the information will be more up to date. The CAG noted this and raised no further queries.

- b. If the above details are not required, then the identifiers need to be revised to remove these data items.**

The applicants agreed that full date of birth will no longer be needed and that year of birth can be used instead to verify whether patients meet the age criteria. Gender was also not required to undertake the mail out and will no longer be used. The CAG noted this and raised no further queries.

- 3. The CAG suggest that the data flow is revised as below. If this cannot be implemented, please provide justification as to why not:**

- a. FRS search the data they already hold to identify the eligible group.**
- b. FRS send the unique property reference of eligible people to NHS Digital (support under Regulation 5 is not needed for this step as this identifier is not confidential patient information).**
- c. The PCRM at NHS Digital use the property reference to identify the correct addresses and send names only to FRS - minus the opted-out people (support under Regulation 5 is needed for this stage)**

The applicants advised that they had discussed this with the FRS and the change was feasible, however NHS England and Improvement would need to confirm whether the DSA needs to be amended, as the current DSA does not allow the use of data for research purposes. The CAG noted this. Members agreed that confirmation needed to be provided within three months of the issuing of the outcome letter that the new data flow would be implemented. If the data flow had not been implemented within this timeframe or NHS England and Improvement did not agree to the change, then reasons for this needed to be provided to the CAG.

- 4. Clarify whether the list that the FRS receive from the NHS PCRM will contain the same information as the information already held by the FRS to determine eligibility and whether the NHS PCRM will send two lists to the FRS.**

The applicants explained that, under the original data flow, the FRS would receive two lists from NHS PCRM. The list that the FRS request from the NHS specifically for the

trial will differ from the data they routinely receive. The trial data will not include those who have opted-out of being contacted for research via the National Data Opt-out. The trial data will also include the names of residents. The routine data currently held by the FRS was sent to them in summer 2020, therefore the new dataset will be more up to date.

The routine dataset is disclosed to the FRS each year, however the disclosure is often delayed. Providing an up-to-date dataset specifically for the trial will minimise the risk that an invitation pack to those who have moved or passed away. The CAG noted this and raised no further queries.

**5. Clarify whether the list sent by the PCRM will list those who have received a Safe and Well visit in the previous 3 years.**

The list sent by the PCRM will not include whether a patient has received a Safe and Well Visit in the previous 3 years, as the NHS do not hold this information. The FRS will remove patients who have already received a visit. The FRS will also remove those at the highest risk of fire. These households will not be eligible to take part in the trial, as they may be randomised to the control group, meaning that they may wait more than 2 months for the visit. It would not be ethical to keep a high-risk household waiting for this amount of time. The CAG noted this and raised no further queries.

**6. Provide the number of staff who will be involved in this process and their job titles.**

The applicants explained that no members of staff at the University of York Trials Unit will be involved in searching the FRS records. This task would be undertaken by FRS staff. One member of staff at the York Trials Unit will assist in mailing out the recruitment packs only. The CAG noted this and raised no further queries.

**7. Changes are to be made to the patient notification and dissent mechanism as follows:**

- a. Consider whether other methods of patient notification could be undertaken, in addition to the website notification, and provide information on the further notification.**

The applicants agreed that the pre-notification approach could be broadened. Notices would be placed on electronic platforms, including the University of York twitter account and Trials Unit website, and the FRS's Instagram, Twitter and Facebook accounts. The applicants have liaised with the FRS and will include information about the study on the "My community alerts" and "Next Door" as well as engaging with the Police and Crime Commissioners Engagement Network, Age UK, Ward Newsletters, Parish council and Fire Authority. The CAG noted this and raised no further queries.

**b. The website text needs to explain that the FRS already receive data from the NHS in order to offer the Safe and Well Visits.**

The applicants advised that text had been added to the information to be included on the FRS website and other locations, to explain that the FRS routinely receive information from the NHS in order to offer the Safe and Well Visits. The CAG noted this and raised no further queries.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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. Confirmation on whether the new data flow, suggested by the CAG, will be implemented needs to be provided within three months of the issuing of the outcome letter. If the data flow had not been implemented within this timeframe or NHS England and Improvement did not agree to the change, then reasons for this need to be provided to the CAG.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 27 April 2021**
3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

**Confirmed:** The NHS Digital **2019/20** DSPT review for **the University of York** and **the Humberside Fire and Rescue Service** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (26 July 2021)

## 2. New Amendments

### 17/CAG/0130 – Colonoscopic surveillance for familial risk of colorectal cancer

<b>Name</b>	<b>Capacity</b>
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Dr Tony Calland MBE	CAG Chair

#### **Context**

##### **Amendment request**

This non-research application from London North West Healthcare NHS Trust aims to audit and monitor care provided to individuals at increased familial risk of colorectal cancer and develop evidence-based guidelines on the management of familial risk for the NHS. The applicant has support to obtain outcome and mortality data from NHS Digital regarding over 3000 retrospective patients (prior to support provided 8 September 2017) who are undergoing colonoscopic surveillance for an increased familial risk of colorectal cancer at The Family Cancer Clinic at St Mark's Hospital. Pseudonymised data was then disclosed to Queen Mary College, University of London (QMUL) in order for the statistician to undertake analysis.

This amendment seeks support for a change in data processor from Queen Mary University of London (QMUL) to Kings College London (KCL), as the statistician has moved institutions. Although the applicant has previously described this data flow as pseudonymous, it has been clarified that this data flow contains date of birth and date of death. Therefore Kings College London do receive identifiable information, and support is in place for this data flow.

## Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries with this amendment request.

### Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

### Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

The NHS Digital **2019/20** DSPT review for **King's College London - Cancer Epidemiology and Population Health** and the equivalent for **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 08 January 2021)

The NHS Digital **2019/20** DSPT review for **London North West Healthcare NHS Trust** was confirmed as 'Standards Met' by email to the CAG inbox on 24 June 2021.

### 19/CAG/0132 – Frequency of observations (FOBS)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

## Context

### Amendment request

This research from the University of Portsmouth sets out the purpose of medical research which aims to investigate how often a patient's vital signs need to be monitored to track progress to recovery or to highlight a deterioration in condition.

This amendment sought support to extend the duration of support from 31 March 2021 until 30 September 2021, due to delays caused by the Covid-19 pandemic.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who considered the duration amendment justified.

### Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

### Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

The NHS Digital **19/20** DSPT review for **Oxford University Hospitals NHS Foundation Trust and Portsmouth Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 March 2021),

The NHS Digital **19/20** DSPT review for **University of Oxford - Nuffield Department of Clinical Neurosciences - Critical Care Research Group (EE133863-NDCN-CCRG)** was confirmed as 'Standards Met' by email to the CAG inbox on 17 June 2021,

The NHS Digital 20/21 DSPT review for **University of Portsmouth - Centre for Healthcare Modelling and Informatics (CHMI) (EE133867-CHMI)** was confirmed as 'Standards Met' by email to the CAG inbox on 09 July 2021.

2. Confirmation of a favourable opinion from a Research Ethics Committee.  
**REC confirmed non substantial 1 March 2021**

**20/CAG/0136– A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach: NightLife**

<b>Name</b>	<b>Capacity</b>
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Kathleen Cassidy	HRA Confidentiality Advisor

## **Context**

### **Amendment request**

The applicants have existing support to allow potential incidental disclosure of confidential patient information when researchers from the University of Leicester, who are not members of the direct care team, carry out consented interviews with haemodialysis unit staff, consented interviews with patients, and observations on haemodialysis units at nine named NHS trusts. Two of the Trusts named in the original application were Northamptonshire Healthcare NHS Foundation Trust and Peterborough NHS Foundation Trust. This was an error. Northampton Dialysis Unit and Peterborough Dialysis Unit are included in the study, however these units are part of the University Hospitals of Leicester NHS Trust. The applicants are therefore seeking to remove the Northamptonshire Healthcare NHS Foundation Trust and Cambridge and Peterborough NHS Foundation Trust as data processors. The University Hospitals of Leicester NHS Trust is already included in the scope of support.

## Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who determined that the applicants were correcting an error made in the original application. This correction did not affect the data flows or the scope of support.

## Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

## Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed non-substantial 7 July 2021**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information: **Security assurances are required for the sites where the observations take place. Support will be based on confirmation that the DSPT at the site will be complied with and that no identifiable information will be kept onsite or removed from the site. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.**

## 20/CAG/0067 - Learning Disability Mortality Review (LeDeR) programme

Name	Capacity
Dr Paul Mills	Confidentiality Advice Service Manager

## **Context**

### **Amendment request**

The Learning Disabilities Mortality Review (LeDeR) programme reviews the deaths of all people with learning disabilities (aged 4 years and over) in England. The activity was previously given support under reference 16/CAG/0056. A new application was given support in May 2020 as the controller for the application had changed from HQIP to NHS England.

This amendment request removes the University of Bristol as a data processor for web notifications, a web based platform and a linked database, coding completed review forms and redacting reviews. These functions will now be undertaken by NHS South Central and West Commissioning Support Unit who are part of the Data Controller - NHS England and NHS Improvement.

### **Confidentiality Advice Team advice**

The amendment requested was considered by the Confidentiality Advice Team who raised no concerns about the request.

### **Confidentiality Advice Team conclusion**

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

### **Specific conditions of support**

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:

The NHS Digital 19/20 DSPT review for NHS South Central and West Commissioning Support Unit was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 06 July 2021)

## PIAG 4-08(b)/2003 - National Confidentiality Enquiry into Patient Outcome and Death

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

### Context

#### Amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the second of the reviews due to take place in 2020, which will investigate Epilepsy.

The review has been commissioned as there is believed to be room for improvement in the quality of acute and long-term care provided to patients who have an epileptic seizure.

The applicants aim to publish the results of the review in Summer 2022.

#### Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. The Chair agreed that the amendment request was in the public interest and in line with the support in place for NCEPOD.

#### Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

#### Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:

Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold (**Confirmed – The NHS Digital 2019/20 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by check of the NHS Digital DSPT Tracker on 06 April 2021).**

### 18/CAG/0131 - Inflammatory Bowel Disease Registry

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

#### Context

#### Amendment request

This amendment seeks to extend the duration of support until 14 September 2023 to allow the applicant to continue and complete work on a new consent model, launch and rollout that is properly required for the function of the IBD Registry. This amendment is requested due to the impact on the planned consent rollout during 2020, primarily due to the impact of Covid-19. The applicants were given support in July 2020 to extend the duration of support until September 2021, however the rollout is still being impacted by the Covid-19 pandemic and a further extension is sought.

#### Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team...

#### Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

## Specific conditions of support

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold:
  - **Confirmed for IBD Registry Ltd by NHS Digital email 23 June 2021.**
  - **Confirmed for: Chamaeleon Information Management Services (CIMS), University of Liverpool, NHS Digital and AIMES Management Services have confirmed 'Standards Met' on DSPT 2019/20 (by check of DSPT Tracker 04 March 2021).**
  - **Confirmed for NWIS 2020/21 (by CPIP letter).**

### 3. Annual Review Approvals

20/CAG/0001	Optimum Patient Care Research Database (OPCRD)
18/CAG/0072	Getting it Right First Time Program - Litigation Claims for NHS Improvement
CR2/2014	Whitehall II Study (Stress and Health Study)
15/CAG/0207	NHS Cancer Screening Programmes
17/CAG/0126	Surveillance of Severe Microcephaly in the UK and Ireland (SSM-UKI)
19/CAG/0131	Systems research into child-centred medical education v1.0
19/CAG/0040	Translational Research in Pulmonary Hypertension at Imperial College (TRIPHIC)
16/CAG/0013	Risk stratification in suspected acute coronary syndrome
19/CAG/0207	Survival of people with screen-detected HF (ECHOES-Survive)
19/CAG/0055	Triage Heart Failure
16/CAG/0006	UK National Flap Registry (UKNFR)
16/CAG/0053	Prolonged Effects of ART: a Record Linkage study (PEARL)
18/CAG/0131	IBD Registry (CAG 6-07(d)/2013)

ECC 5-05(j)/2012	Long term risk of cervical cancer following a HPV infection
18/CAG/0040	The eLIXIR project/ eLIXIR: Early Lifecourse data Cross-Linkage in Research: a Multidisciplinary partnership - linked data for research into maternal and child health
17/CAG/0180	MR865 (Whitehall Study)
20/CAG/0015	Clinical outcome modelling of rapid dynamics in acute stroke
17/CAG/0124	Clinical outcome modelling of rapid dynamics in acute stroke
19/CAG/0190	A prospective study of conservative care in childhood ESKD
16/CAG/0066	HAVEN
16/CAG/0048	LATTE: Long-term Anastrozole vs Tamoxifen Treatment Effects
20/CAG/0055	Can Innovative Methods Improve Risk Modelling in Emergency Laparotomy
18/CAG/0205	Long-term survival after surgery. Version 1.4 (10 May 2018)
15/CAG/0005	Dr Foster
20/CAG/0054	SHINE
20/CAG/0027	CHAMPION
20/CAG/0031	EDGE2
16/CAG/0071	Benchmarking clinical quality healthcare measures
20/CAG/0034	Detecting clinical deterioration using machine learning
20/CAG/0039	Pheno-typing patients with pulmonary arterial pressure
ECC 3-04(f)/2011	SLAM IG Clinical Dataset Linking Service
ECC 2-06(n)/2009	National Cardiac Arrest Audit
PIAG 2-10(g)/2005	National Gestational Age Statistics.
19/CAG/0182	National Joint Registry
PIAG 1-05(g)/2007	HES and STATS19 one to one matching project
16/CAG/0124	A Study to Investigate The Association Between Selective Uptake Of Cervical Cancer Screening
17/CAG/0103	West Midland's Regional Children's Tumour Registry

18/CAG/0066	United Kingdom Childhood Cancer Study v2
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Signed – Chair

Date

Minutes signed off as accurate via correspondence  
by Dr Tony Calland, MBE, CAG Chair

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21/10/2021

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Signed – Confidentiality Advice Team

Date

Katy Cassidy

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21/10/2021

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