

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 9 September 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	Position:
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	Position:
Prof. Nicola Fear	Specialist Academic Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	Team:
Dave Cronin	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Observer: items 1-3.6)
Denise Pine	Data Access Request Service (DARS)
Charlotte Skinner	Data Access Request Service (DARS)

1	<p>Declaration of interests:</p> <p>Maria Clark noted a professional link with the British Medical Association (BMA) (NIC-344271-Q5X0S), but noted no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Paul Affleck noted professional links to the University of Leeds (NIC-318632-T0N3) but no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest.</p> <p>Review of previous minutes and actions:</p>
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	<p>The minutes of the 26th August 2021 IGARD meeting were reviewed, and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix A).</p>
2	Data Applications
2.1	<p><u>University of Oxford: How general practice team composition and climate relate to quality, effectiveness and human resource costs: a mixed methods study in England. (Presenter: Charlotte Skinner) NIC-344271-Q5X0S-v0.7</u></p> <p>Application: This application was submitted to IGARD for supplementary advice, following the IGARD review and subsequent recommendation for approval (with amendments and advice) on the 22nd April 2021.</p> <p>The workforce configurations in general practices are highly variable and there is a lack of evidence about what skill mixes and staff deployments generate the best outcomes for patients and savings for health care economies.</p> <p>The purpose is for a study, exploring how team composition and climate affect quality of care, clinical outcomes (effectiveness) and human resource costs in England, in order to inform practice management and commissioning decisions.</p> <p>The application was previously presented to IGARD on the 22nd April 2021, where IGARD had recommended for approval, for the flow of pseudonymised Hospital Episode Statistics (HES) Accident and Emergency (A&E) and HES Admitted Patient Care (APC) data; however, due to the ongoing discussions about data controllership, no data has yet flowed.</p> <p>NHS Digital advised IGARD that although this application had previously been recommended for approval at the IGARD business as usual meeting on the 22nd April 2021 (with amendments and advice); that this had been brought back for supplementary advice on a few issues raised at the meeting, and to provide an update on actions taken following the review.</p> <p>NHS Digital noted that one of the issues raised previously, was in relation to the transparency materials, and that one of the IGARD Specialist members had provided advice on another University of Oxford privacy notice out of committee. NHS Digital confirmed that the applicant had acted on the advice provided on the privacy notice, and that this was due to be published imminently.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 22nd April 2021; and acknowledged the verbal update from NHS Digital, in respect of the purpose for submitting this to IGARD.</p> <p>IGARD also noted the verbal update from NHS Digital, in respect of the applicant's privacy notice, and the imminent publication of this; however, queried the information contained within the privacy notice in respect of the data controllership and if this was a correct reflection of the arrangements for this specific application. NHS Digital advised IGARD that the applicant had a 'general' privacy notice, and a 'study specific' privacy notice, and it did not look as though they aligned. IGARD noted the verbal update and advised the applicant should ensure that both the specific and general privacy notices related to the collection and use of data and were updated appropriately with the amendments suggested in April 2021, and any other updates that may be necessary, that related to data controllership.</p>

	<p>IGARD queried at what point the Royal College of General Practitioners (RCGP) ceded control of the data to the University of Oxford, noting that that this was not clear in the application, and asked that the RCGP needed to be clear on this point, in both the transparency materials and the other linked applications, and if there was a different point at which that happened, for example, as between different applications using the same data.</p> <p>IGARD queried the statement in section 5(a) (Objective for Processing) “<i>The RCGP, has a duty to its members, the general practitioners, who in turn have responsibility to their patients, to ensure all research using patient data is appropriate, and as thus the Royal College of General Practitioners maintains oversight of all processes and outputs involving its data and are also joint data controllers</i>”; and noting the reference to all research, asked that the statement was updated to make clear that it related to this application only; or, that if the RCGP retained oversight of the purpose and means of the use of this data under other applications, to reconsider the data controllership in those applications, and amend as may be necessary.</p> <p>IGARD noted the reference in section 5(a) to “<i>All records flagged with an opt-out code...</i>”, and noting that this data should not be flowing, asked that either further clarity was provided, or that the reference was removed.</p> <p>Outcome: IGARD gave the following supplementary points of advice:</p> <ol style="list-style-type: none"> 1. To ensure both the specific and general privacy notices, related to the collection and use of data are updated appropriately with the amendments suggested and any other that may be necessary, that relate to data controllership. 2. The RCGP needs to be clear in transparency materials and the other linked applications at which point they cede control of the data to the University of Oxford, and if there is a different point at which that happens (as between different applications using the same data). 3. In respect of the statement in section 5(a), that refers to the RCGP’s duty to ensure all research using patient data is appropriate: <ol style="list-style-type: none"> a) To update the statement to make clear it relates to this application only; or, b) If the RCGP retains oversight of the purpose and means of the use of this data under other applications, to reconsider the data controllership in those applications, and amend as may be necessary. 4. To provide further clarity on the reference in section 5(a) to data “<i>...flagged with an opt-out code...</i>”, or remove as this data should not be flowing.
2.2	<p>University of Exeter: Tracking the impact of Covid-19 on the mental health of children, young people and families; follow up of a national longitudinal probability sample: follow-on interviews (Presenter: Charlotte Skinner) NIC-402080-N3V5Z-v1.3</p> <p>Application: This was an amendment application to 1) update the purpose, to a) explore the experiences of children and young people with Special Education Needs and Disabilities (SEND) and their families during the Covid-19 pandemic (Follow-on interviews) , and b) to describe the prevalence of eating disorders, eating disordered behaviour and comorbid anxiety and depression symptoms amongst participants in Mental Health of Children and Young People in England (MHCYP) who screened positive for eating disorders in the survey, and to explore experiences of disordered eating during the pandemic and what support and coping strategies have been useful; and 2) to update the application to reflect the change of participants.</p>

	<p>The follow-up study forms part of a wider project called <i>"Tracking the impact of Covid-19 on the mental health of children, young people and families; follow up of a national longitudinal probability sample"</i>; and the follow-up interviews are referred to as the RESHAPE study (REfecting on the impactS of covid-19 on cHildren And young People in England: exploring experiences of lockdown, service access and education) as this is more accessible for participants. The amendments outlined relate to RESHAPE "Wave 2" with participants from MHCYP 2021.</p> <p>This application is limited to the parents of children / young people themselves, aged 5-23 who have previously consented to be contacted for further research in the survey and the estimated size of the cohort is approximately 600 – 1,000 patients.</p> <p>NHS Digital advised IGARD that due to the interviews for wave 1 of the study not yet being completed, that the yielded benefits had not been added to the application, and these would be added in due course.</p> <p>Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD business as usual (BAU) meeting on the 15th April 2021.</p> <p>IGARD noted and thanked NHS Digital for the verbal update in respect of the yielded benefits, and asked that a brief explanation was added to section 5(d) (Benefits) (iii) (Yielded Benefits), as per due process.</p> <p>IGARD queried how many opt-outs NatCen had received in response to the existing flyer; and were advised by NHS Digital that the applicant had confirmed there had been 25 opt-outs. IGARD noted and thanked NHS Digital for the clarification.</p> <p>IGARD noted and commended NHS Digital on quality of the information provided in section 1 (Abstract), which provided historical and additional background information which supported the review of the application by Members.</p> <p>IGARD noted the information in section 1 that Health Research Authority (HRA) Ethics support was not required due to the participant consent obtained, however IGARD queried if the reason specified was relevant; and asked that for transparency, a further detailed explanation was provided in section 1, as to why HRA Ethics support was not sought, for example, was HRA Ethics support not required due to the project being classed as non-NHS research.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To provide a detailed explanation in section 1 as to why HRA Ethics support was not sought.
2.3	<p><u>Imperial College Healthcare NHS Trust: Gender differences related to outcome after transcatheter aortic valve implantation: Insights from the NICOR UK database (Presenter: Charlotte Skinner) NIC-335169-V6F6G-v0.6</u></p> <p>Application: This was a new application for pseudonymised Civil Registration (Deaths) data, to link to National Institute for Cardiovascular Outcomes Research (NICOR) data; for the purpose of research that seeks to compare the mid-long-term survival of men versus women in patients with aortic stenosis (AS) treated with current versus older transcatheter aortic valve implantation (TAVI) technologies.</p> <p>Severe AS is the commonest form of valvular abnormality in the developed world and accounts for more than 40% of patients with native valvular disease with an approximately</p>

equal prevalence in men and women. TAVI is now widely practiced with treatment of over 300,000 patients worldwide. The study team will investigate gender temporal survival trends and complications, such as stroke and heart attack, in patients with AS treated with current transcatheter valves versus older generation transcatheter valves.

The cohort to be sent to NHS Digital consists of 14,086 patients, 18 years of age and over who underwent transfemoral TAVI for the treatment of severe aortic stenosis in the UK, between 2007 and 2017; and is relying on s251 of the NHS Act 2006, for the flow of data into NHS Digital.

NHS Digital advised that supporting document (SD) 2.0, the protocol, referred to a number of organisations, and confirmed that unless specifically referred to within the application, they would not have access to, nor determine how, the data was processed.

Discussion: IGARD noted and thanked NHS Digital for the verbal update in respect of the organisations listed within the protocol, and noted that they would not have access to, nor determine how, the data was processed.

IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application.

IGARD noted within SD 4.0, the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated the 3rd December 2020, that the applicant had considered the patient and public involvement (PPI), and that they had conducted a focus group meeting with a dedicated patient focus research group used for prospective studies at Imperial College London. IGARD queried, in light of the data originating from NICOR, if their Patient Representative Group had considered or been informed of this application. IGARD noted that NICOR now had a Virtual Patient Panel, with part of their remit being to “*Advise on the appropriateness of using patient information collected for national clinical audit and research purposes*”. IGARD therefore suggested that, in line with the [HRA guidance on Public Involvement](#), that the applicant may wish to consider utilising the NICOR PPI group.

In addition, IGARD noted that the PPI would only be utilised for consultation to determine the dissemination of results, and suggested that they outline the PPI in relation to the design and conduct of the study.

IGARD noted that the name of the study referred to “*gender*” and that the HRA CAG support in SD 4.0, was for the “*gender*” data field; and queried this, noting the purpose of the study outlined within the application, was to study the difference between men and women and their survival rate. IGARD asked that, notwithstanding the conflicting information, section 5(b) (Processing Activities) was updated, to confirm that NHS Digital would be flowing “*sex*” data fields and not “*gender*”, or other suitable clarification as may be necessary, reflecting the factual scenario.

IGARD noted the inclusion of a number of technical phrases and words within section 5(a) (Objective for Processing) such as “*collaborators*”, “*introducer French size*”, and “*s251*”, and suggested that this was updated to be written in a language suitable for a lay reader and that consideration was given to the public audience and the detail necessary for NHS Digital’s Data Uses Register, and in line with [NHS Digital’s DARS Standard for Objective for Processing](#).

IGARD also noted the reference in section 5(a) to “*joint Data Processor*”, and noting that this was not a concept in the UK General Data Protection Regulation (UK GDPR), asked that this was removed.

	<p>IGARD noted the statement in section 5(d) (Benefits) <i>“If the study team can identify novel predictors of poor outcome from this data linkage, they aim to submit their findings to a peer reviewed journal 6 months from September 2021.”</i>; and asked that in line with NHS Digital’s DARS Standard for Expected Measurable Benefits, section 5(d) was updated, to outline any proposed plans for the pathway from academic research outputs to improved patient care, as this was not clear.</p> <p>IGARD queried the statement in section 3(b) (Additional Data Access Requested) that <i>“GDPR does not apply to data solely relating to deceased individuals”</i>. Noting that the status of those patients that are still alive would be revealed, IGARD asked that this was updated to also include a UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. In respect section 5(a) and in line with NHS Digital’s DARS Standard for Objective for Processing: <ol style="list-style-type: none"> a) To update section 5(a) to ensure it is written in language suitable for a lay reader and that consideration is given to the public audience and the detail necessary for NHS Digital’s Data Uses Register, for example when referring to <i>“collaborators”</i> (i.e., to explain what those collaborators will be doing), and the technical references to, e.g., <i>“introducer French size”</i>, and <i>“s251”</i>. b) To update section 5(a) to remove the reference to <i>“joint Data Processor”</i>, as this is not a concept in the UK GDPR. 2. To update section 5(b), to clarify that notwithstanding the name of the study and the HRA CAG support for the <i>“gender”</i> data field, the purpose is to study the difference between men and women and their survival rate, and that NHS Digital will be flowing <i>“sex”</i> data fields and not <i>“gender”</i> (or other suitable clarification as may be necessary, reflecting the factual scenario). 3. In line with NHS Digital’s DARS Standard for Expected Measurable Benefits, to update section 5(d), to outline any proposed plans for the pathway from academic research outputs to improved patient care. 4. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. In respect of the PPIE and in line with the HRA guidance on Public Involvement: <ol style="list-style-type: none"> a) IGARD suggested that the applicant may wish to consider utilising the NICOR PPI group, noting the use of the NICOR data. b) IGARD noted that the PPI would only be utilised for consultation to determine the dissemination of results, and suggested that they outline the PPI in relation to the design and conduct of the study.
2.4	<p><u>Bradford Teaching Hospitals NHS Foundation Trust: Does patient ethnicity predict outcome following neck of femur fracture? (Presenter: Charlotte Skinner) NIC-318632-T0N3M-v0.9</u></p> <p>Application: This was a new application for pseudonymised Civil Registration (Deaths) data and Hospital Episode Statistics Admitted Patient Care (HES APC); for the purpose of a study,</p>

comparing the outcomes following a neck of femur (NOF) fracture across ethnic groups in the UK and explore reasons if any differences are observed.

There are large variations in the outcomes of orthopaedic surgery across ethnic groups in England and Wales, with patients from Black and Minority Ethnic (BAME) backgrounds struggling to access care and having worse outcomes. Traditionally accepted distribution for fracture types, patient demographics and patient mobility may be inconsistent across ethnic groups.

This study analysis is being completed in support of the National Hip Fracture Database (NHFD) audit activity *“to improve the quality and cost-effectiveness of hip fracture care; and to reduce the incidence of the injury by improving secondary prevention”*.

The study is relying on s251 of the NHS Act 2006, for the flow of data to NHS Digital.

Discussion: IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application.

IGARD queried the statement in section 5(a) (Objective for Processing) *“The University of Leeds have been commissioned by HQIP to undertake the study...”*, and asked if this was correct, noting that this would have implications for data controllership, and that the Healthcare Quality Improvement Partnership (HQIP) was not listed as a joint Data controller within the application. IGARD therefore asked that the statement was removed; or, if HQIP had commissioned the service evaluation, to update the application throughout to address the potential data controllership implication of the commissioning, in line with [NHS Digital’s DARS Standard for Data Controllers](#).

IGARD noted the references within the application to the purpose being for an *“audit”*, and noting that based on the facts presented, this appeared to be incorrect, asked that the references were removed. In addition, IGARD asked that the application was updated throughout, to ensure a coherent narrative that was supportive of a *“service evaluation”*.

IGARD noted the conflicting information within the application in respect of the purpose, for example, the title stated *“Does patient ethnicity predict outcome following neck of femur fracture”*, and the statements in section 5(a) *“There are large variations in the outcomes of orthopaedic surgery across ethnic groups in England and Wales, with patients from Black and Minority Ethnic (BAME) backgrounds struggling to access care and having worse outcomes.”*, and *“The primary outcome will be patient mortality...for BAME patients as compared to the White population...”*; and queried if the applicant was looking at the potentially different physiology of the groups being studied, the social determinants of health, or both; and asked that section 5(a) was updated with clarification, as this was not clear.

IGARD noted the information in section 5(d) (Benefits) in respect of the Bradford resident focus group, and asked that this was correctly moved to section 5(c) (Specific Outputs Expected).

In respect of the PPIE, and in line with the [HRA guidance on Public Involvement](#), IGARD noted that the patient and public involvement (PPI) and focus groups would be consulted to determine the dissemination of outputs, and suggested that the PPI and focus groups were consulted throughout this service evaluation, including, but not limited to, the evaluation questions and the appropriate language used throughout.

In addition, IGARD suggested that the applicant should consider working with the PPI and focus groups to ensure that any narrative surrounding the description of the study, or

	<p>outcomes, was sensitive to any suggestion that the ethnicity of a person was solely responsible for their health outcomes.</p> <p>IGARD queried the storage locations in section 2(b), for example, were the locations listed all being used; and asked that these were reviewed and updated as appropriate to reflect the factual scenario.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. In respect of HQIP: <ol style="list-style-type: none"> a) To remove the reference in section 5(a) to Leeds University being “<i>commissioned</i>” by HQIP to undertake the service evaluation; or b) If HQIP have commissioned the service evaluation, to update the application throughout to address the potential data controllership implication of the commissioning, in line with NHS Digital’s DARS Standard for Data Controllers. <p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To clarify if the storage locations in section 2(b) are being used, and update as appropriate. 2. In respect of the purpose: <ol style="list-style-type: none"> a) To update the application throughout to remove references to “<i>audit</i>”. b) To update the application throughout to ensure a coherent narrative that is supportive of a “<i>service evaluation</i>”. 3. To clarify in section 5(a) if the applicant is looking at the potentially different physiology of the groups being studied, the social determinants of health, or both. 4. To move the reference to the Bradford resident focus group from section 5(d) to section 5(c). <p>The following advice was given:</p> <ol style="list-style-type: none"> 1. In respect of the PPIE and in line with the HRA guidance on Public Involvement: <ol style="list-style-type: none"> a) IGARD noted that the PPI and focus groups will be consulted to determine the dissemination of outputs, and suggested that the PPI and focus groups are consulted throughout this service evaluation, including (but not limited to) the evaluation questions and the appropriate language used throughout. b) IGARD suggested that the applicant should consider working with the PPI and focus groups to ensure that any narrative surrounding the description of the study, or outcomes, is sensitive to any suggestion that the ethnicity of a person is solely responsible for their health outcomes. <p>It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair.</p> <p>Subsequent to the meeting: IGARD noted that the applicant’s name was misleading as Bradford Teaching Hospitals NHS Foundation Trust are not involved in this application and advised that this must be changed for any summary going into NHS Digital’s Data Uses Register and should also be changed on CRM.</p>
2.5	<p><u>Imperial College London: MR1108: CT colonography, colonoscopy, or barium enema for diagnosis of colorectal cancer in older symptomatic patients: SIGGAR1 (Special Interest Group in Gastrointestinal and Abdominal radiology). Plus SOCCER (Symptoms of Colorectal Cancer Evaluation Research). (Presenter: Louise Dunn) NIC-291981-Y7J2F-v6.4</u></p> <p>Application: This was an extension application, to permit the holding and processing of identifiable Medical Research Information Service (MRIS) Cause of Death Report, MRIS</p>

Cohort Event Notification Report, MRIS Flagging Current Status Report and MRIS Members and Postings Report.

The purpose is for the SOCCER study, which follows on from an earlier study on bowel cancer symptoms (the Special Interest Group Gastrointestinal and Abdominal Radiology (SIGGAR) study), with the aim of providing evidence that is needed to show whether flexible sigmoidoscopy (a technique which examines only the last [distal] part of the colon) is an effective and safe alternative to whole colon examinations for many people; which may change how doctors diagnose bowel cancer in their patients based on their symptoms.

The size of the cohort is 7,472 patients; and the study is relying on consent and s251 of the NHS Act 2006, for the flow of data into NHS Digital.

NHS Digital advised IGARD that that the applicant's Data Sharing Agreement with NHS Digital had expired.

Discussion: IGARD welcomed the application and noted the importance of the study.

IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) on the 10th November 2015, where DAAG had been unable to recommended for approval; and the IGARD business as usual (BAU) meetings for advice on the 31st January 2019 and the 20th August 2020.

IGARD also noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on the 4th February 2021.

IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application.

IGARD noted the statement in supporting document (SD) 15.5, the e-mail correspondence from the Health Research Authority (HRA) "*...you do not retain any items of confidential patient information, and the dataset retained regarding the randomised consented cohort was pseudonymised*", however, advised that it was not clear if the consented cohort was truly pseudonymised. In addition, section 5(b) (Processing Activities) stated "*For the SOCCER study, all data is stored in a separate database to the SIGGAR trial data. All data on the SOCCER database is pseudonymised and is only accessible to a limited number of individuals (data analyst/developer and approved study researchers)*". In addition, section 5(b) stated that "*pseudonymised cancers and mortality data were not uploaded to the SIGGAR database*", however, if the applicant holds the identity of the pseudonyms, they could identify the SOCCER subjects via their study number and going back to the SIGGAR database, and were therefore holding identifiable information. IGARD asked that written confirmation was provided as to whether or not the SIGGAR database currently contained any confidential patient information about the SOCCER cohort who have consented, noting that the consent was **not** compatible with the proposed processing outlined in the application.

IGARD queried the statement in section 5(a) (Objective for Processing) "*The CSPRG at Imperial College London would like to continue to keep the SIGGAR cohort flagged*", and were advised by NHS Digital that this statement was no longer relevant and would be removed. IGARD noted the verbal update from NHS Digital and supported the update to the application to remove the statement.

IGARD queried the statement in section 3(b) (Additional Data Access Requested) that "*GDPR does not apply to data solely relating to deceased individuals*", however, noting that the status of those patients that are still alive would be revealed, asked that this was updated to include a

	<p>UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data. IGARD noted that a query had been raised on this particular point with the Privacy, Transparency and Ethics (PTE) Directorate and welcomed an update from DARS in due course.</p> <p>IGARD noted and thanked the applicant for the information provided, in respect of the yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits).</p> <p>IGARD noted the verbal update from NHS Digital in respect of the applicant's Data Sharing Agreement with NHS Digital having now expired; in light of this, it was suggested that NHS Digital might wish to consider a short-term extension, with Imperial College London as the sole Data Controller, to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.</p> <p>Outcome: unable to make a recommendation as not all the necessary information about the SIGGAR database was available to enable IGARD to make a full assessment of the CAG correspondence.</p> <ol style="list-style-type: none"> 1. To provide written confirmation as to whether or not the SIGGAR database currently contains any confidential patient information about the SOCCER cohort. 2. To update section 3 to include a UK GDPR legal basis for those datasets that give information about cohort members who are still living, if this approach is supported by advice on this point from PTE. 3. To update section 5(a) to remove the statement <i>"The CSPRG at Imperial College London would like to continue to keep the SIGGAR cohort flagged"</i>. <p>The following advice was given:</p> <ol style="list-style-type: none"> 4. IGARD noted that the applicant's Data Sharing Agreement with NHS Digital had expired; in light of this, it was suggested that NHS Digital might wish to consider a short-term extension, with Imperial College London as the sole Data Controller, to permit the applicant to hold but not in any other way process the data while work was undertaken to address the queries raised by IGARD.
2.6	<p><u>University of Aberdeen: MR756: Knee Arthroplasty Trial (KAT) (Presenter: Denise Pine) NIC-322051-S8N9N-v3.3</u></p> <p>Application: This was an amendment application to add two additional storage locations which were identified during an audit by NHS Digital on the 18th June 2021.</p> <p>The purpose is for a long-running trial, which started in 1998 to examine the clinical effectiveness and cost-effectiveness of four aspects of knee replacement surgery.</p> <p>In total, 116 surgeons in 32 UK centres participated in the trial. Between July 1999 and January 2003, 4070 potentially eligible participants were identified and 2352 gave consent and were randomised.</p> <p>NHS Digital advised IGARD that the references in section 1 (Abstract) to the Data Sharing Framework Contracts (DSFC) end date being the 31st July 2021, was now out of date and would be removed, noting that the correct and most up to date information had been provided elsewhere in the application.</p> <p>NHS Digital noted that at the last IGARD review, IGARD had asked that a suitable communication plan was produced, with specific timeframes for communication with the participants of the cohort; and that this had now been produced and a copy had been shared with NHS Digital.</p>

NHS Digital advised that the statement in section 5(b) (Processing Activities) *“This data will be securely stored but not otherwise processed”*, was no longer relevant and would be removed.

Discussion: IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD’s predecessor) on the 5th July 2016; and the IGARD business as usual (BAU) meetings on the 26th September 2019 and the 30th April 2020.

IGARD noted the verbal updates from NHS Digital, and supported the updates, to remove the historical DSFC information from section 1, and to remove the incorrect statement outlined from section 5(b) that was no longer relevant. IGARD noted that the communication plan had now been produced and that a copy had been shared with NHS Digital, and asked that a copy was uploaded to NHS Digital’s customer relationship management (CRM) system for future reference.

IGARD noted that the last newsletter shared with them was from 2016, and suggested that the applicant published the updated and historical newsletters on the public facing website for transparency to the public.

IGARD noted and supported the advice within supporting document 6.0, NHS Digital’s audit report, that the Data Controllers should either complete a Data Protection Impact Assessment (DPIA) or document the rationale for not completing a DPIA. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that the applicant complete a DPIA within three months of signing the Data Sharing Agreement (DSA), and that the applicant will furnish a copy to NHS Digital for future reference.

IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, for example, summarising the excellent yielded benefits published on the Nuffield Department of Population Health website, and in line with [NHS Digital’s DARS Standard for Expected Measurable Benefits](#).

Outcome: recommendation to approve.

The following amendments were requested:

1. In respect of the verbal amendments outlined by from NHS Digital:
 - a) To remove the references in section 1 to the DSFC end data being the 31st July 2021.
 - b) To amend the application to reflect that communication plan has now been received by NHS Digital, and ensure a copy is uploaded to NHS Digital CRM system for future reference.
 - c) To remove the statement in section 5(b) that *“This data will be securely stored but not otherwise processed.”*, as this is no longer relevant.
2. To insert a special condition in section 6, that the applicant complete a DPIA within three months of signing the DSA, and that the applicant will furnish a copy to NHS Digital for future reference.
3. To provide further details in section 5(d) of the yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally, for example, summarising the excellent yielded benefits published on the Nuffield Department of Population Health website; and in line [NHS Digital’s DARS Standard for Expected Measurable Benefits](#).

The following advice was given:

	1. IGARD suggested that the applicant published the updated and historical newsletters on the public facing website for transparency to the public.
3	<p><u>Returning Applications</u></p> <p>IGARD noted that they do not scrutinise every application for data, however they are charged with providing oversight and assurance of certain data releases which have been reviewed and approved solely by NHS Digital.</p> <p>Due to the volume and complexity of applications at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.</p>
4	<p><u>Expired / Expiring Data Sharing Agreements (Presenter: Dave Cronin)</u></p> <p>IGARD noted that NHS Digital attended the IGARD business as usual meeting on the 19th August 2021 to discuss the 'Class Action Approval to Extend Data Sharing Agreements (DSAs) Prior to Expiry and to Issue DSAs in Place of Expired DSAs – DRAFT Briefing Paper'. It was agreed at this meeting that NHS Digital would provide a further update before the end of September 2021.</p> <p>NHS Digital presented a number of live examples of expired DSAs for information, and an overview of emerging issues.</p> <p>IGARD noted the verbal update from NHS Digital and looked forward to future updates.</p>
5	<p><u>COVID-19 update</u></p> <p>To support NHS Digital's response to COVID-19, from Tuesday 21st April 2020, IGARD will hold a separate weekly meeting, to discuss COVID-19 and The Health Service Control of Patient Information (COPI) Regulations 2002 urgent applications that have been submitted to NHS Digital. Although this is separate to the Thursday IGARD meetings, to ensure transparency of process, a meeting summary of the Tuesday meeting will be captured as part of IGARD's minutes each Thursday and published via the NHS Digital website as per usual process.</p> <p>IGARD noted that due to the Bank Holiday, and as agreed between IGARD and NHS Digital, the COVID-19 response meeting on Tuesday 7th September 2021 was cancelled.</p>
6	<u>AOB:</u>
6.1	<p><u>COPI Notice Extension</u></p> <p>IGARD noted that NHS Digital had received confirmation from the Secretary of State for Health and Social Care, that The Health Service Control of Patient Information (COPI) Regulations 2002 Notice had been extended until the 31st March 2022.</p>
6.2	<p><u>IGARD Meeting Quoracy</u></p> <p>In light of the ongoing situation with COVID-19, and following consideration by IGARD members, it has been agreed with NHS Digital that from the 26th March 2020 meeting, the in-meeting quoracy may be temporarily reduced to three members (from four members), which must include a Chair and at least two specialist members. This is to ensure business continuity in the event that COVID-19 impacts on members ability to dial-in to meetings (due to COVID-19 illness or caring for a household member with COVID-19) and to support those IGARD members who have other roles linked to the COVID-19 response. This will be reviewed as and</p>

	<p>when required, but no less than monthly, and in response to new guidance that is released. This relates to COVID-19 only and the next formal update in IGARD minutes will be at the end of December 2021.</p>
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	<p>There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.</p>
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Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 03/0921

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-226261-M2T0Q-v3.6	The Nuffield Trust For Research And Policy Studies In Health Services	29/07/2021	<ol style="list-style-type: none"> 1. To provide clarification with regards to the arrangements of the corporate events outlined in section 5(c), and if there is a commercial element, to outline this in section 5(a) and section 5(e); in line with NHS Digital DARS Standard for Commercial Purpose. 2. In respect of the data controllership and in line with NHS Digital's DARS Standard for Data Controllers: <ol style="list-style-type: none"> a) To clarify which other organisations involved in the projects should be considered a joint Data Controller, as borne out of the facts presented with particular reference to <i>"DH Policy Innovation Research Unit"</i>. b) To update the application and any relevant supporting documents with a clear justification. 3. To clarify in section 5, who is undertaking the <i>"risk assessment"</i> in relation to the linkage with the national datasets and how, to ensure this does not lead to the additional risk of reidentification of individuals. 	IGARD members	Quorum of IGARD members	<p>IGARD Comments:</p> <p>"The statement in section 5a <i>"The LSHTM does not have access to the data"</i> is clarified to state that not only does the LSHTM not have access to the data but <u>that it neither determines the purposes or means of processing data under this agreement.</u>"</p>

In addition, a number of applications were processed by NHS Digital following the Precedents approval route. IGARD carries out oversight of such approvals and further details of this process can be found in the Oversight and Assurance Report.

In addition, a number of applications were approved under class action addition of:

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-422195-G1Y7D-v1.3 - DSfC - NHS Frimley CCG - Comm, RS & IV
- NIC-422218-V6L8T-v1.2 - DSfC NHS Coventry and Warwickshire CCG - IV, RS & Comm

Graphnet Class Actions:

- NIC-362236-D7W4M-v3.2 - DSfC - NHS Surrey Heartlands CCG - RS, IV, Commissioning