Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 17 February 2022

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Dr. Robert French	Specialist Academic / Statistician Member (Observer)
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker (Chair)	Specialist GP Member / IGARD Deputy Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Paul Affleck	Specialist Ethics Member
Kirsty Irvine	IGARD Chair
Jenny Westaway	Lay Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Faris Dean	Data Access Request Service (DARS) (SAT Observer: item 3.3)
Louise Dunn	Data Access Request Service (DARS) (SAT Observer: item 3.2) (Item 5)
Mujiba Ejaz	Data Access Request Service (DARS) (Items: 3.1 - 3.3)
Danielle Gilmore	Data Access Request Service (DARS) (Observer: items 3.1 – 3.3)
Nicola Jennings	Data Access Request Service (DARS) (Observer: item 3.2)
Karen Myers	IGARD Secretariat
Dr. Jonathan Osborn	Deputy Caldicott Guardian (Observer: 3.1 – 3.3)
Joanna Warwick	Data Access Request Service (DARS) (Item 5)
Kimberley Watson	Data Access Request Service (DARS) (SAT Observer: item 3.1)
Vicki Williams	IGARD Secretariat
SAT – Senior Approval Team (DARS)	

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19. **Review of previous minutes and actions:** The minutes of the 10th February 2022 IGARD meeting were reviewed out of committee by IGARD following conclusion of the meeting, and subject to a number of minor changes were agreed as an accurate record of the meeting. **Out of committee recommendations:** An out of committee report was received (see Appendix A).
2	**Briefing Notes**
	There were no briefing papers submitted for review.
3	**Data Applications**
3.1	Saving Faces - The Facial Surgery Research Foundation: The Role of Selective Neck Dissection Used Electively in Patients (Presenter: Mujiba Ejaz) NIC-147858-KGYSS-v4.4 **Application:** This was a renewal and extension application to permit the holding and processing of identifiable Medical Research Information Service (MRIS) - Cause of Death Report, MRIS - Cohort Event Notification Report, MRIS - Flagging Current Status Report and MRIS - Members and Postings Report. It was also an amendment to **1)** add University College London as a Data Processor; and **2)** to add Civil Registration (Deaths) and Demographics data to the Data Sharing Agreement (DSA). The purpose of the application is for the 'selective neck dissection used electively' (SEND) Trial, which is a prospective randomised controlled trial that compares two standard surgical treatments for early oral cancer with no clinical evidence of lymph node metastases in the neck. The aim and purpose of the study is to find better ways of treating patients with early mouth cancer. The cohort consists of 590 patients who have consented to be randomised to resection of the tumour only or resection with neck dissection. NHS Digital noted that the Legitimate Interest Assessment (LIA) had been provided to IGARD as a supporting document, however this had not been addressed in section 5(a) (Objective for Processing) of the application as per process and advised that this would need updating accordingly. NHS Digital noted that section 3 (Datasets Held / Requested) referred to the data as being *"Identifiable"* and *"Pseudo/Anonymised"* and advised that this would be updated to correctly reflect that the data was identifiable, and all references to *"Pseudo/Anonymised"* would be removed. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD noted and commended the applicant on the excellent patient and public involvement and engagement (PPIE), as outlined within the application.

	NHS Digital noted that the application had not previously been presented at an IGARD business as usual (BAU) or at a Data Access Advisory Group (DAAG) meeting (IGARD's predecessor). IGARD noted and supported the verbal update from NHS Digital in respect of the update to section 3 to correctly state that the data was *"identifiable"*, and to remove all references to *"Pseudo/Anonymised"*. IGARD noted the verbal update from NHS Digital, in respect of the LIA reference within the application; and asked that reference to the specific LIA was made at the beginning of section 5(a) (Objective for Processing), as per usual process and in line with NHS Digital's DARS Standard for Objective for Processing. 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 UK General Data Protection Regulation (UK GDPR) legal basis for dissemination and receipt of data; in accordance with the latest advice from the Privacy, Transparency and Ethics (PTE) Directorate. IGARD queried some of the expected benefits outlined in section 5(d) (Benefits) (ii) (Expected Measurable Benefits), and noted that some of the information provided were yielded benefits, and asked that section 5(d) (ii) was updated to remove any yielded benefits, which should be moved to section 5(d) (iii) (Yielded Benefits), and edit to only leave examples that reflect the expected benefits to Health and Social Care System, in line with the NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the statement in section 5(d) (iii) *"This research also looked at the social, emotional, functional outcomes and resource use of the two different treatments and found no significant difference in Quality of Life or cost between the 2 treatments."*; however, noting that this was contradictory to information provided elsewhere in the application that stated there was difference to the quality of life, asked that the statement was reviewed and updated as appropriate, or removed if incorrect. IGARD suggested that section 5(d) be updated to remove reference to "*it will*…", and instead use a form of words such as "*it is hoped*…". IGARD queried the statement in section 5(a) to there being no *"moral or ethical issues*", and noting the sensitive issues of the study, and that it was not yet known if there were any moral or ethical issues; asked that the statement was removed. IGARD noted the references in section 5(c) (Specific Outputs Expected) to the specific encryption methodology *"AES256"*; and noting the potential restriction to the data sharing agreement (DSA) in the future, in being so specific, asked that the references were removed. IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs), such as *"Patients' QoL"*, asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience. As section 5 forms NHS Digital's data uses register, IGARD asked that section 5 **and** section 1 (Abstract) were amended, to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, or example *"CMS products".*

	IGARD noted the reference in section 1 to the *"COVID-19 Inquiry"*, which prevented NHS Digital from requesting data destruction at the current time. Noting the discussion at the IGARD business as usual (BAU) meeting on the 2nd December 2021, IGARD had received a verbal update from NHS Digital to confirm that the retention of data **only** applied where the application was related to COVID-19, and that the blanket cessation had been removed. IGARD asked that section 1 was updated, to reflect the latest information, and that the application was reviewed throughout, to remove reference(s) to the *"COVID-19 Inquiry"* as it was not relevant to this application. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of section 5(d) and in line with the NHS Digital DARS Stand for Expected Measurable Benefits: a) To remove the yielded benefits from section 5(d) (ii) and move to section 5(d) (iii). b) To review the contradictory last statement in section 5(d) (iii) in respect of there being "…no significant difference in Quality of Life or cost…", and update as appropriate; or remove if incorrect. c) To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 2. To ensure the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a) (as per the verbal update from NHS Digital). 3. To remove from section 5(a) the statement that there are no *"moral or ethical issues*". 4. To amend section 3(b) to reflect that the datasets are identifiable and remove the incorrect reference to *"Pseudo/Anonymised"* (as per the verbal update from NHS Digital). 5. 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 accords with the latest advice from PTE. 6. To remove the references in section 5(c) to the specific encryption methodology (AES256). 7. As section 5 forms NHS Digital's data uses register, to amend section 5 and section 1 throughout, a. to ensure acronyms be defined upon first use, for example *"CMS products"*; and b. technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"Patients' QoL".* 8. To update section 1 and review the application throughout to remove reference(s) to the *"COVID-19 Inquiry"* as it is not relevant to this application. The following advice was given: 1. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.
3.2	Compufile Systems Limited: ESPRIT tool (Presenter: Mujiba Ejaz) NIC-01207-V9G9P-v8.4 **Application:** This was a renewal application to permit the holding and processing of pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) HES Critical Care and HES Outpatients data.

	The purpose of the application is to provide the NHS and organisations providing goods and services to the NHS, with a tool set to enable them to analyse data, and in some cases consultancy to help them understand the results. The applicant processes the data for statistical purposes and generates cohorts of patients and patient episodes that are relevant to each analysis performed. CSL work with NHS organisations including Clinical Commissioning Groups, NHS England, NHS Supply Chain, Clinical Support Units and NHS Hospital Trusts. Analysis of the data will show aggregated patient pathways through the hospital system and provide an understanding of how patients are treated. The data is also used in the identification of specific high-risk patient groups and development of improved services and patient treatments. NHS Digital advised IGARD that the applicant would retain the data for a maximum of five years, which would be on a rolling basis, whereby old data was destroyed as new data was received; and that the applicant had now confirmed that the data for the period 2015/16 had been destroyed. NHS Digital noted that section 1 (Abstract) did not refer to the Legitimate Interest Assessment (LIA) and confirmed that one had been completed by the applicant, and had been provided to NHS Digital at the end of January 2022; and apologised for the oversight in not providing this as a supporting document as per process. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the Data Access Advisory Group (DAAG) (IGARD's predecessor) meeting on the 16th February 2016 and the 20th December 2016; and the IGARD business as usual (BAU) meeting on the 14th December 2017, 21st December 2017 and 3rd September 2020. IGARD noted that this application had previously been discussed as part of the 'returning applications' section of the IGARD business as usual (BAU) meeting on 28th November 2019. IGARD noted the verbal update from NHS Digital in respect of the historical data; and asked that section 1 was updated to clarify that the 2015/16 data had been destroyed by the applicant and that the applicant has provided a data destruction certificate, as per process. In addition, IGARD asked that section 1 was updated to clarify that the 2017/18 data would be destroyed upon receipt of new data. IGARD noted the verbal update from NHS Digital in respect of the LIA, and that members had not had sight of the supporting document as part of the review; and asked that reference to the specific LIA was made at the beginning of section 5(a) (Objective for Processing), as per usual process and in line with NHS Digital's DARS Standard for Objective for Processing. IGARD members noted that Section 5(d) (benefits) (iii) (Yielded Benefits) did not appear to be in line with the NHS Digital DARS Standard for Expected Measurable Benefits and asked that this section was updated. In addition, and noting the significant volume of data requested, asked that applicant provide 2 or 3 specific yielded benefits accrued to date in section 5(d) (iii) and to ensure these are clear about the benefits to both patients and the health care system more generally. IGARD noted that when the application was last reviewed on the 3rd September 2020, they had advised that the applicant may wish to develop their oversight board to include lay representation, by way of patient and public involvement; and that the oversight board may wish to publish their minutes of the meetings for the purpose of transparency. IGARD noted in section 1 that the oversight board had now been established, however queried why the minutes of the meetings had not yet been published. IGARD asked that for the purpose of

	transparency, the minutes of the oversight board were published; or, that a written narrative was provided, as to why the oversight board's minutes could not be published. In addition, IGARD noted in section 1 that 'NHS employees' had been included on the oversight board as lay representatives noting that NHS Digital do not regard NHS employees as lay representatives, and asked that this was reviewed to ensure specific lay representation was included, by way of patient and public involvement, and in line with the HRA guidelines on public involvement. IGARD asked that a special condition was inserted in section 6 (Special Conditions), that lay representation on the oversight board **must** be in place within six-months of signing the data sharing agreement (DSA). IGARD noted in section 1, that supporting document (SD) 3 had been provided, 'Type 2 customer information', which contained further information on the Type 2 customers for whom Compufile have provided aggregated data. IGARD noted that this document had not been updated since the last IGARD review on the 3rd September 2020. IGARD asked that SD3 was updated with further information on the Type 2 customers; and that the updated document was uploaded to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also noted that SD2 'Advisory Board Terms of Reference' provided had also not been updated since the last IGARD review on the 3rd September 2020. IGARD queried what safeguards were in place within the ESPRIT analysis tool, for example, in ensuring that the data was not identifiable and the data was aggregated with small numbers supressed; and asked that for transparency, section 5(b) (Processing Activities) was updated with further information of the safeguards in place in line with NHS Digital DARS Standard for processing activities. IGARD noted the information in section 5(e) (Is the Purpose of this Application in Anyway Commercial) outlining the commercial aspect of the application, however noting that section 5(a) was not clear on this, and that section 5 (Purpose / Methods / Outputs) forms NHS Digital's data uses register; asked that a brief summary was added to section 5(a) of the commercial aspect of this application, as outlined in section 5(e) and in line with NHS Digital DARS Standard for Commercial Purpose. IGARD noted the references in section 5(c) (Specific Outputs Expected) to *"severe asthmatics"* and asked that this was replaced with an alternate form of wording, for example *"people with severe asthma"*, or similar. IGARD queried the generalised statements throughout section 5, with regards to the NHS, including (but not limited to) *"The NHS is not currently a data driven organisation, and has neither the means nor capacity to conduct all of the analyses which could lead to potential improvements in care."*; and asked that these statements were reviewed and amended as appropriate, noting they could be misconstrued by many working with data within the NHS. Noting that the application had expired on the 31st December 2021, IGARD suggested that NHS Digital put in place a short-term extension until the condition and amendments had been satisfactorily addressed. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the commercial nature of the application and to review the yielded benefits accrued to date. **Outcome:** recommendation to approve subject to the following condition:

	1. In respect of the Yielded Benefits in section 5(d)(iii): a. To update the yielded benefits in line with the NHS Digital DARS Standard for Expected Measurable Benefits, and b. Given the significant volume of data, to provide 2 or 3 specific yielded benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally. The following amendments were requested: 1. In respect of the oversight board and IGARD's previous advice: a) The oversight board to publish their minutes of meetings for the purpose of transparency; or b) To provide written narrative as to why the oversight board's minutes cannot be published; and c) That the oversight board should include lay representation by way of patient and public involvement, in line with the HRA guidelines on public involvement. 2. To insert a special condition in section 6, that lay representation on the oversight board, must be in place within six-months of signing the DSA. 3. In respect of the historical data: a) To update section 1 to clarify that the 2015/16 data has been destroyed by the applicant and that the applicant has provided a data destruction certificate (as per NHS Digital's verbal update). b) To update section 1 to clarify that the 2017/18 data will be destroyed upon receipt of new data. 4. To provide more detail in section 5(b) of the safeguards in place within the ESPRIT analysis tool, for example, to ensure the data is not identifiable and the data is aggregated with small numbers supressed. 5. In respect of the language: a) To revise the references in section 5(c) to *"severe asthmatics"* and replace with an alternate form of wording, for example *"people with severe asthma"*, or similar. b) To review the generalised statements throughout section 5, with regards to the NHS, which could be misconstrued by many working with data within the NHS, and amend the language used as appropriate. 6. In line with NHS Digital DARS Standard for commercial purpose, to provide a brief summary in section 5(a) of the commercial aspect of this application, as outlined in section 5(e). 7. To ensure the specific Legitimate Interests Assessment is referenced at the beginning of section 5(a) (as per the verbal update from NHS Digital). 8. In respect of supporting document 3: a) To update SD3 with further information on the Type 2 customers. b) To upload the updated SD3 to NHS Digital's CRM system for future reference. The following advice was given: 1. Noting that the application had expired on the 31st December 2021, IGARD suggested that NHS Digital put in place a short-term extension until the conditions and amendments above had been addressed. 2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the commercial nature of the application and to review the yielded benefits accrued to date.

	3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the commercial nature of the application and to review the yielded benefits accrued to date. It was agreed the conditions would be approved out of committee (OOC) by IGARD members.
3.3	London School of Hygiene and Tropical Medicine: Prioritising patients for Emergency Surgery Or Not: the impact of COVID-19 (ESORT-C19) (Presenter: Mujiba Ejaz) NIC-583534-X7S2N-v0.12 **Application:** This was a new application for pseudonymised Civil Registration (Deaths) - Secondary Care Cut, Hospital Episode Statistics Admitted Patient Care (HES APC), HES Critical Care, and HES:Civil Registration (Deaths) bridge. The purpose of the application is for a study, which aims to provide a rigorous evaluation of the relative effectiveness and costs of emergency surgery versus non-operative care for common acute conditions during different time periods before and during the COVID pandemic and inform change to emergency general surgery provision across the NHS. The specific objectives are **1)** to estimate the effects of the 'peak' and 'recovery' periods versus 'pre' COVID-19 period, on access to ES according to patient- level characteristics, for common acute conditions presenting as emergency admissions; **2)** to estimate the effectiveness and cost-effectiveness of emergency surgery (ES) versus non-emergency surgery (NES) for common acute conditions presenting as emergency admissions during the 'peak' and 'recovery' versus 'pre' periods, according to patient-level characteristics; 3) to recommend which patients to prioritise for ES for common acute conditions presenting as emergency admissions during the COVID-19 recovery period. The cohort of patients is defined as all adult patients with an emergency admission which includes a diagnosis (via ICD-10 code) of one of 5 acute conditions (appendicitis, gallstones, diverticulitis, hernia, intestinal obstruction) in any diagnosis field of any episode of the admission, with an admission date between 1st April 2013 and the latest available. This application closely relates to data sharing agreement (DSA) NIC-185179-V0B0T, the ESORT Study, which was reviewed by IGARD on the 12th November 2020; however, no data will be linked between the two DSAs. **Discussion:** IGARD welcomed the application and noted the importance of the study. IGARD commended the applicant on their study website, which was easily accessible and transparent, and contained a published privacy notice and minutes; and that this was an exemplar to other applicants. Noting the helpful and transparent information on the study website in relation to the patient and public involvement and engagement (PPIE), and that section 5 forms NHS Digital's data uses register, IGARD asked that section 5(a) was updated to reflect further information on the PPIE. IGARD noted that NIC-185179-V0B0T related to this application and queried why there were two separate DSAs. NHS Digital advised that the DSAs had been separated due to a number of reasons, including (but not limited to) having different funders and different DSA end dates. IGARD asked that for transparency, section 1 (Abstract) and section 5(a) (Objective for Processing) were updated with further clarity, as to why the study required a separate DSA and could not be covered under NIC-185179-V0B0T.

	IGARD also queried what the benefits were from the work being undertaken under NIC-185179-V0B0T and asked that narrative was added to section 5(a); and that a clear justification was provided on the duplication of data flowing under this DSA and NIC-185179-V0B0T. IGARD queried how the data flowing under this DSA and NIC-185179-V0B0T would be kept separate, and asked that confirmation was provided, noting this was currently unclear. IGARD noted the exclusion criteria in section 5(a) that would be applied for defining the index admission, and queried the reasons for the exclusions, for example those aged less than 18, a previous emergency admission for the condition within the year prior to the index admission, and referrals from tertiary referral centres, IGARD asked that for transparency, section 3(b) (Additional Data Access Requested) and section 5 (Purpose / Methods / Outputs) were updated with a justification of the various exclusion criteria. In addition, IGARD queried what procedure(s) were in place to address how the excluded groups would be included in the research in the future. IGARD also suggested that as part of the research development the applicant should complete an Equality and Health Inequalities Impact Assessment (EHIA), if not already done so; and if one had been completed, that section 5(a) was updated with any outputs of the EHIA. IGARD noted that there were a number of co-applicants and research partners referenced on the study website, and noting that this information was not contained within the application; asked that section 5(a) was updated with information on the co-applicants and research partners, including (but not limited to) their role, and why they were not considered joint Data Controller(s) / Data Processor(s), in line with NHS Digital DARS Standard for Data Controllers and NHS Digital DARS Standard for Data Processors. IGARD queried the information provided in section 5(a), in respect of the objective for processing, and noting that this information was more clearly defined within the study protocol; asked that section 5(a) was updated with further clarity of the purpose of the application, for example, by replicating the process and purpose section from the study protocol into section 5(a). IGARD queried the reference to the COVID-19 *"recovery period"* in section 5(a) and asked that further clarity was provided and what this covered, noting it was currently unclear. IGARD queried the projected dates stated in section 5(c) (Specific Outputs Expected), for example *"The aim is to complete the study by September 2022 with all the below outputs scheduled between approximately March 2022 and April 2023."*; and asked that the dates were reviewed and amended as appropriate to ensure they are achievable and realistic, and aligned with the end date of the DSA which was 2025. IGARD queried the statement in section 7 (Ethics Approval) *"Ethics approval is not required because this request does not include the flow of confidential data"*; and asked that this was updated to correctly reflect that there was local institutional ethics approval for the study; and that this information was also reflected in the public facing section 5 for transparency. IGARD noted the inclusion of a number of technical phrases and words within section 5, such as *"instrumental variable"* and *"immortality bias"*, and asked that this public facing section, that forms NHS Digital's data uses register, was amended throughout, to ensure acronyms be defined upon first use, and technical terms are explained in a manner suitable for a lay audience.

	As section 5 forms NHS Digital's data uses register, to amend section 5, to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident, or example *"HES APC"*. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of NIC-185179-V0B0T: a) To update section 1 and section 5(a) with clarity as to why the study requires a separate DSA and cannot be covered under NIC-185179-V0B0T. b) To add narrative to section 5(a) outlining the benefits from NIC-185179-V0B0T. c) To provide a justification in section 5 on the duplication of data flowing under this DSA and NIC-185179-V0B0T. d) To provide confirmation as to how the data flowing under this DSA and NIC-185179-V0B0T will be kept separate. 2. In respect of data minimisation: a) To provide a justification in section 3(b) and section 5 as to why significant exclusions in the data fields have been made, for example, under 18s. b) To update section 5(a) with the output of any Equality and Health Inequalities Impact Assessment completed. 3. To update section 5(a) with information on the co-applicants and research partners, as outlined on the study website, including (but not limited to) their role, and why they are not considered joint Data Controller(s) / Data Processor(s). 4. To update section 5(a) with further clarity of the purpose of the application, for example, by replicating the process and purpose section from the study protocol. 5. To update section 5(a) with further information of the PPIE, as outlined on the study website. 6. To provide further clarity in section 5(a) on the reference to the COVID-19 *"recovery period"* and what this covers. 7. As section 5 forms NHS Digital's data uses register, to amend section 5 throughout, a. to ensure acronyms be defined upon first use; and b. technical terms are used only where necessary and explained in a manner suitable for a lay audience, for example *"instrumental variable"* and *"immortality bias"* etc. 8. To review the projected dates in section 5(c) and amend as appropriate to ensure they are achievable and realistic, and align with the end date of the DSA. 9. To update section 5(a) and section 7 to reflect that there is local institutional ethics approval for the study. The following advice was given: 1. IGARD noted that there were a number of excluded groups in the study, however queried what procedure were in place to address how the excluded groups will be included in the research in the future. IGARD also suggested that as part of the research development the applicant should complete an Equality and Health Inequalities Impact Assessment, if not already done so. 2. IGARD suggested that this application would be suitable for NHS Digital's Precedent route, including the SIRO Precedent.

3.4	University College London (UCL): Educational outcomes in children born after assisted reproductive technology; a population-based linkage study (No Presenter) NIC-258079-G7W1Y-v0.12 **Application:** This was a new application for pseudonymised Birth Notification Data and Civil Registration (Births); and identifiable Demographics data. The purpose is for a population-based cohort study, to, **1)** compare educational outcomes among children born following assisted reproductive technology (ART) with children born following natural conception (siblings); **2)** to compare the frequency of special educational needs (SEN) and school exclusion among children born following ART with children born following natural conception; **3)** To compare outcomes for specific types of ART and specific causes of infertility. The cohort of ART conceived children and their naturally conceived siblings will be linked with the National Pupil Database (NPD), in order to explore their educational outcomes. The NPD contains detailed information about the educational attainment of all pupils in state sector schools and sixth-form colleges in England; and is now being made available for research purposes through the Office for National Statistics Secure Research Service (ONS-SRS). The NPD will also be used to identify a second control group of unrelated (non-sibling) school-matched controls for the ART Cohort. The Department for Education (DfE) will flow the identifiers of the unrelated school-matched controls to the ONS, for the ONS to retrieve their key confounding variables for deposition in the ONS-SRS. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted that the application and relevant supporting documents had previously been presented at the IGARD BAU meeting on the 7th October 2021; where the application had been recommended for approval with conditions, amendments and advice. IGARD noted that as outlined in the Out of Committee (OOC) Standard Operating Procedure, any applications returned to the IGARD Secretariat for review OOC by the IGARD Chair or quorum of IGARD Members which were over three months old, would be automatically placed on the next available BAU meeting agenda for review by IGARD Members as per the current standard processes. Members would only review if the conditions have been met or not, and would not re-review the application, unless significant legislative or policy changes had occurred since last reviewed by a full meeting of IGARD or the application had been significantly updated, in which case the conditions may be updated to reflect such changes which will be noted for transparency in the published minutes and a full review of the application undertaken. The condition from the 7th October 2021 BAU meeting was as follows: 1. In respect of the security arrangements: a. To provide written confirmation (such as an e-mail) that NHS Digital's Security Advisor has expressed satisfaction that the appropriate security is in place. b. To upload the written confirmation from NHS Digital's Security Advisor to NHS Digital's CRM system for future reference. A quorum of IGARD members were content that the condition had been met. IGARD noted that when the application was review on the 7th October 2021, they had suggested the applicant carried out a DPIA, due to the possible contentious nature of the processing, and the sensitivities around the data. As part of this review, IGARD suggested that

	NHS Digital request a copy of the DPIA once completed and upload it to NHS Digital's customer relationships management (CRM) system for future reference. IGARD also reiterated advice in respect of the PPIE undertaken to date within the application, and strongly suggested that the applicant undertakes PPIE, in some form and throughout the lifetime of the DSA, given the significant amount of data flowing, public interests and wide scope of the application, and in line with the HRA guidance on Public Involvement.
4 **4.1**	Applications progressed via NHS Digital's Precedent route, including the SIRO Precedent Applications that have been progressed via NHS Digital's Precedent route, including the SIRO Precedent, and NHS Digital have notified IGARD in writing (via the Secretariat). NIC-28591-H5Q3X University College London (No Presenter) The purpose of this application was to inform and develop a larger programme of research on the prevention of cardiovascular disease (CVD), heart failure and CVD related ageing conditions including dementia, frailty and physical disability. IGARD noted that this application was last reviewed at the IGARD business as usual meeting on the 28th June 2018. IGARD noted that on the 8th February 2022, NHS Digital had advised in writing (via the IGARD Secretariat) that the SIRO had agreed to authorise a one-year extension to the Data Sharing Agreement (DSA), to align with the end date of the linked DSA NIC-148411-Q64H8. IGARD noted that the SIRO had authorised a four-month extension to the DSA, to allow the applicant to retain the data while NHS Digital investigated a possible DSA breach, and that the applicant has confirmed that no breach had occurred. IGARD suggested that section 1 was updated with clarification that NHS Digital had also found that no breach had occurred following the investigation. IGARD queried the statement in section 1, that Newcastle University would need adding to the DSA as a joint Data Controller, however advised that the application did not appear to reflect this addition. In addition, IGARD noted that if Newcastle University were added to the DSA as a joint Data Controller, would Health Research Authority Confidentiality Advisory Group (HRA CAG) need to be informed of this update? IGARD noted and thanked NHS Digital for the written update and asked that the next iteration should be brought to a future IGARD BAU meeting.
5	Oversight & Assurance 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. • **NIC-334952-R5M7K University College London** (extension & renewal precedent) IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the fact that this application had not had an independent review since 2016, that the study appeared to have changed since HRA CAG provided support and that the Yielded Benefits were not in line with the NHS Digital DARS Standard for Expected Measurable Benefits. • **NIC-63347-R8J2M Royal College of Anaesthetists** (extension & renewal precedent)

	• **NIC-79526-V8F2X University of East Anglia** (extension & renewal precedent) • **NIC-351761-F8Z6V NEC Software Solutions UK Ltd** (SIRO precedent) IGARD noted that the current DSA ran until the 28th February 2022 and that DARS had identified this application as "*high risk*" and suggested that a clear narrative be included in section 1 (Abstract). • **NIC-393510-D6H1D University College London** (simple amendment precedent) IGARD noted that when they had seen the application in March 2021 it had been recommended for approval for 1 year, however when the application had progressed via the precedent route (noting that IGARD had specifically requested to see it again at renewal, extension and amendment) the DSA had been extended by a further 6 months. NHS Digital where unclear why the DSA end date had been amended and IGARD requested that a clear narrative was included in section 1 (Abstract). IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and that the focused areas would be to review the yielded benefits, what has been done with the data, and how it has impacted on the patient experience due to the quantum of data provided. • **NIC-147750-8GS7S University of Cambridge** (class action precedent) IGARD noted that whilst they were briefed on a proposed 'class action' approach, there is no agreed "class action precedent". IGARD were unable to say if the application had proceeded under the correct precedent route. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, and that the focused area would be the legal basis concerns (no annual reports submitted to CAG and no ethics reports submitted since 2018). • **NIC-148425-R38F2 University of Birmingham** (class action precedent) IGARD noted that whilst they were briefed on a proposed 'class action' approach, there is no agreed "class action precedent". IGARD were unable to say if the application had proceeded under the correct precedent route. IGARD noted that they had previously provided advice on this application on the 5th March 2020 on the consent and patient information materials and without prejudice to any additional issues that may arise when the application was fully reviewed and noting the application had progressed under precedent noted that they would have expected the application to return to IGARD for a recommendation. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent since the application had not had an independent review. • **NIC-40493-G5Y6K University of Leeds** (class action precedent) IGARD noted that whilst they were briefed on a proposed 'class action' approach, there is no agreed "class action precedent". IGARD were unable to say if the application had proceeded under the correct precedent route. IGARD noted that they moved to their new ways of working on the 1st May 2019, and advised that they would wish to review this application when it comes up for renewal, extension or amendment and that this application would not be suitable for NHS

	Digital's Precedent route, including the SIRO Precedent and that the focus would be the consent review undertaken by NHS Digital and if ethics support IGARD Members noted that they had not yet been updated on the issues raised at the 27th May 2021 IGARD business as usual (BAU) meeting with regard to previous comments made on the IG COVID-19 release registers March 2020 to May 2021. IGARD noted that in addition, they had not been updated on the issues raised on the IG COVID-19 release registers June to October 2021. IGARD Members noted that the last IG COVID-19 release register that they had reviewed and provided comments on was October 2021
6	<u>COVID-19 update</u> *No items discussed.*
7 **7.1**	<u>AOB:</u> <u>COPI Notice Extension</u> 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 30th June 2022. There was no further business raised, the Deputy IGARD Chair thanked members and NHS Digital colleagues for their time and closed the application section of the meeting.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 11/02/22

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)
None						

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:

- None

Graphnet Class Actions:

- None