Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 29 April 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member / IGARD Alternate Deputy Lay Chair
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Imran Khan	Specialist GP Member
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Prof. Nicola Fear	Specialist Academic Member
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Tony Burton	Digital Services Delivery
Vicky Byrne-Watts	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Stephen Fenner	Digital Services Delivery
James Gray	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Nichola Makin	Data Access Request Service (DARS) (Observer: item 3.1)
Karen Myers	IGARD Secretariat
Stuart Richardson	Data Access Request Service (DARS)
Charlotte Skinner	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat

1	**Declaration of interests:**

	Dr. Maurice Smith noted that in his role as a GP partner at Mather Avenue Surgery, Liverpool, he had a remote professional link to the President Elect of the Association of Breast Surgery (NIC-363140-V3X2W); but no specific connections with the application or staff involved and it was agreed that this was not a conflict of interest. Maria Clark noted professional links to the Royal College of Surgeons (NIC-363140-V3X2W), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. **Review of previous minutes and actions:** The minutes of the 22nd April 2021 IGARD meeting were reviewed, and subject to a number of minor amendments 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 Papers**
2.1	<u>Un-Curated Low Latency Hospital Data Sets – Briefing Paper (Presenters: Tony Burton / Stephen Fenner / Stuart Richardson)</u> The briefing paper was to inform IGARD about the Un-Curated Low Latency Hospital Data Sets for Admitted Patient Care, Outpatient and Critical Care. The Secondary Uses Service (SUS) is the single, comprehensive repository for healthcare data in England. It is the national repository for all Commissioning Data Set (CDS) submissions. SUS data flows (SUS+) are the source of data for Hospital Episodes Statistics (HES) data sets which are existing products available for customers to request via the Data Access Request Service (DARS). NHS Digital will use the same source (SUS+) to create un-curated data sets (Un-Curated Low Latency Hospital Data Sets for Admitted Patient Care, Outpatient and Critical Care). These data sets will be offered in addition to existing HES products as they will contain data which is more current. Emergency care data will be made available as a separate product and a briefing for this will be provided to IGARD in due course. Customers will be able to access these tactical data products within the Trusted Research Environment (TRE) only. Whilst the primary purpose is to provide a solution to enable COVID-19 research (which requires data which is more current), these tactical products will continue to be available to request until HES itself becomes a more timely asset. NHS Digital advised IGARD that there was in error in the briefing paper, in respect of the legal basis, and that following discussions with Privacy, Transparency and Ethics (PTE), this would be updated to ensure the correct information was accurately reflected. IGARD welcomed the briefing paper and made no further comments, but noted that the presenter would update the briefing note, in line with advice received from PTE. IGARD looked forward to receiving the finalised briefing paper as a supporting document, alongside a first of type application.
3	**Data Applications**

3.1	University of Bristol: The Brighter study. Breast Reconstruction: Investigating long term clinical and cost-effectiveness in the National Mastectomy and Breast Reconstruction Audit cohort. (Presenter: Louise Dunn) NIC-363140-V3X2W-v0.15 **Application:** This was a new application for identifiable Demographics data, Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES Outpatients data. The purpose is for a study, aiming to address the lack of clinical and cost effectiveness evidence to guide patients and clinicians when choosing treatment options following a mastectomy for breast cancer. The study will aim to enable better informed, more evidence-based treatment decisions, to improve clinical outcomes for the 55,000+ women who are diagnosed with breast cancer in the UK each year. The study has three parts: 1) a clinical outcomes cohort study including the use of HES, 2) a patient reported outcomes cohort study, and 3) a cost effectiveness analysis. This application relates only to the clinical outcomes cohort study including the use of HES. The cohort of patients for the study, estimated to be around 16,000, will be women aged 16+, who have had a mastectomy for invasive breast cancer or preinvasive disease, or a delayed breast reconstruction following a previous breast cancer diagnosis in an NHS England setting between the 1st January 2008 and 31st March 2009; and is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital advised IGARD that the Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support does cover the use of Cancer Registration data, however noted that this version of the application did not cover this, and that further discussions were ongoing with NHS Digital in respect of the flow of this data, and that the application may return to IGARD in the future as an amendment to request this data set. **Discussion:** IGARD confirmed that they were of the view that the **most recent** consent materials and the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted the verbal update from NHS Digital in respect of the HRA CAG support for the Cancer Registration data, and that the application may return at a later date to request this data set. IGARD noted the statement in section 5(a) (Objective for Processing) *"Members of the Royal College of Surgeons are part of the study's steering committee and act in advisory capacity only. They are not involved in the processing…"*, however asked that section 5 (Purpose / Methods / Outputs) was updated to provide further confirmation as to why, the Royal College of Surgeons were **not** considered joint Data Controller and / or Data Processor, and in terms of the UK General Data Protection Regulation (GDPR) and NHS Digital's DARS Standard on Data Controllers and Data Processors, and in particular, that they do not determine the purpose and means of the processing of the data. IGARD noted that the application stated that the cohort for the study was *"women",* IGARD queried why, for example, men had not been included noting that although rare, men could also be diagnosed with breast cancer; and in addition also queried why trans women were not captured in the study. NHS Digital advised IGARD that the research would only capture cohort members whose sex is registered as female with NHS Digital. IGARD noted the verbal update from NHS Digital and asked that section 5(a) was updated to reflect that the research will **only** capture cohort members whose sex was registered as female with NHS Digital.

	IGARD noted that the last paragraph in section 5(a) that started *"Admitted Patient Care data is requested from the year before eligibility…"* was related to the processing activities, rather than 'objective for processing', and asked that this was relocated to section 5(b) (Processing Activities). IGARD queried the statement in section 5(a) that "*The dissemination of the aggregated results of this study pose no risk to the public."*, and asked that this sentence was removed as it was not necessary to include. IGARD noted that section 5(a) stated that the study was a *"…stand-alone project, separate from any other study…"*, but noting this was a gate application, asked that section 1 (Abstract) and section 5(a) were updated to clarify that the application was a gateway to the next steps of the study and **not** a standalone application. IGARD noted the inclusion of a number of technical phrases and words within section 5, such as *"Charlson Comorbidity Index"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use. IGARD queried the reference in section 5(b) to *"ISO2007"*, and noting that this appeared to be a typo, asked that this was updated to reference the correct ISO data security accreditation, for example, ISO 27001. IGARD noted the references throughout the application to *"CCG"* (Clinical Commissioning Group), and noting the ongoing changes to how CCG's will be structured in the future, asked that the references were updated, with a more general phrase, for example, *"commissioners of healthcare services"* or similar. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…" Noting that the patient and public involvement and engagement (PPIE) was running alongside this research, and would not inform its design, IGARD noted that ideally PPIE should be set up at the earliest opportunity so patients or other people with relevant experience contribute to how research is designed and conducted (see Health Research Authority advice at https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/) **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1 and section 5(a) to clarify that this application is a gateway to the next steps of the study and not a standalone application. 2. To update section 5 to confirm why the Royal College of Surgeons are **not** considered joint Data Controllers and / or Data Processors, and in terms of the UK GDPR and NHS Digital's DARS Standard on Data Controllers and Data Processors (in particular, that they do not determine the purpose and means of the processing of the data). 3. To remove the processing activities outlined in the last paragraph of section 5(a) and add to section 5(b). 4. To remove the statement in section 5(a) that *"The dissemination of the aggregated results of this study posed no risk to the public"*. 5. To update section 5(a) to note that the research will **only** capture cohort members whose sex is registered as female with NHS Digital. 6. To update section 5 to ensure that technical jargon is defined or further explained upon first use. 7. To update the ISO reference in section 5(b).

	8. To update the application throughout to replace all references to *"CCG"* with a more general phrase, for example, *"commissioners of healthcare services"* or similar. 9. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". The following advice was given: 1. IGARD noted that the PPIE is running alongside this research and will not inform its design. IGARD suggested that ideally PPIE was set up at the earliest opportunity so patients or other people with relevant experience contribute to how research is designed and conducted (see Health Research Authority advice at https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/)
3.2	University of Cambridge: NTERVAL and COMPARE trial cohorts: Long-term follow up of health outcomes and associations with genetic, biological and lifestyle traits (Presenter: Vicky Byrne-Watts) NIC-156334-711SX-v7.2 **Application:** This was a renewal and amendment application, to add identifiable COVID-19 UK Non-hospital Antibody Testing Results (Pillar 3) data, COVID-19 Vaccination Status data, COVID-19 Vaccination Adverse Reactions data, and the Sentinel Stroke National Audit Programme (SSNAP) data. The purpose is to create a multi-purpose resource, by linking detailed lifestyle and biological information collected on INTERVAL and COMPARE study participants with health-related records. This will enable detailed study of the health of blood donors and, more generally, allow studies of cardiovascular disease and other health-related outcomes. INTERVAL and COMPARE studies are multi-purpose, multi-stage research projects involving blood donors. The initial stage of these translational research studies has been related to blood donation research aiming to improve, NHS Blood and Transplants (NHSBT) core services, for example, safety and efficiency of blood donation. The INTERVAL study assessed the impact of varying the frequency of blood donation on donor health and the blood supply. Between 2012 and 2014, approximately 50,000 blood donors were enrolled in a randomised controlled trial, and then monitored for specific outcomes until June 2016. The COMPARE study evaluated the optimum method to measure hemoglobin levels, in potential whole blood donors, in advance of each donation. Between 2016 and 2017, approximately 30,000 blood donors were recruited in the study and tested using different methods to measure hemoglobin levels. This application is limited to requesting linkage on the participants who have previously consented in the INTERVAL and COMPARE studies, and the size of the cohort for data linkage is limited to 76,967 participants. NHS Digital advised IGARD that prior to the application being submitted for review, NHS England / Improvement (NHSE/I) had confirmed that this application did not need reviewing by them for the vaccine data only; however following submission of the application for IGARD's review, this position had now changed, and that NHSE/I would need to review the application (vaccine data only), and that an approval decision was expected on Friday 30th April 2021. **Discussion:** IGARD noted that this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 21st April 2020, 28th April 2020 and the 8th September 2020.

	IGARD also noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) on the 28th October 2020, and that notes from this meeting had been published in the IGARD minutes on the 5th November 2020. IGARD confirmed that they were of the view that the **most recent** consent materials provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD noted that when the application had previously been reviewed on the 5th November 2020, IGARD had advised NHS Digital, that in light of the GDPPR data requested, should the application return to IGARD in the future, that this would require PAG, or its successor's, approval before returning. IGARD therefore queried why this had not been reviewed by PAG prior to submission to IGARD, and were advised by NHS Digital that as the purpose of the application had not changed, and there was no change to how the GDPPR data was being processed, and it was NHS Digital's view that a further PAG review was currently not required. IGARD noted the verbal update from NHS Digital, however asked that for transparency, a copy of the updated application was shared with PAG for information; and that written confirmation was provided from PAG that they had noted the updates to the application; and that the written confirmation was uploaded on to NHS Digital's NHS Digital's customer relationships management (CRM) system for future reference. In addition, IGARD also asked that for audit purposes, section 1 (Abstract) was updated, to provide a brief explanatory note, as to why NHS Digital did not feel that the application required a re-review by PAG for the amendments outlined. IGARD thanked NHS Digital for the verbal update in respect of the review / approval process by NHSE/I for the vaccine data requested in the application, and that an approval decision was expected on Friday 30th April 2021. IGARD noted that they had previously been unaware of this approval process. IGARD therefore asked that written confirmation was provided of the NHSE/I approval for the use of the vaccine datasets, as per process; and that the written confirmation was uploaded on to NHS Digital's customer relationships management (CRM) system for future reference. IGARD queried the references throughout the application to the "*visiting academics"*, and noted that the supporting documents 15.1 – 15.4, the visitors Terms of Reference, agreement etc that had been provided, would **only** be signed by the user and not the employer of the individual to whom the contract relates to. IGARD asked that in line with NHS Digital's DARS standard Processing Activities, and in accordance with the special condition in the application that specifically related to the visiting academics; asked that an honorary contract was provided that complied with this policy, in particular, counter signatory by the home research institution and / or employer; and that the written confirmation was uploaded on to NHS Digital's CRM system for future reference. IGARD noted that in response to the question in section 1(a) (General Overview) 'Review requested by IGARD', the response was *"no"*, and asked that this was updated to correctly state *"yes"*. IGARD noted that where the legal basis was referenced in section 1, that this should be updated to be clear that the data was being disseminated under the Health and Social Care Act 2012. IGARD queried the reference in section 3(c) (Patient Objections) to *"reasonable expectations"* and to just refer to consent, as per usual process.

	IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…". IGARD noted the information that had been provided in section 5(d) (iii) (Yielded Benefits), however asked that this was updated, to provide further details of how the yielded benefits accrued to changes in patient care, as this was not clear and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the use of the GDPPR data; and that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the use of the GDPPR data. **Outcome:** recommendation to approve subject to the following conditions: 1. In respect of the NHS England / Improvement approval: a) To provide written confirmation of the NHS England / Improvement approval for the use of the vaccine datasets, as per process. b) To upload the written confirmation to NHS Digital's CRM system. 2. In line with NHS Digital's policy on honorary contracts and in accordance with the special condition in this application: a) To provide an honorary contract that complies with this policy, in particular, counter signatory by the home research institution and / or employer. b) To upload a copy to NHS Digital's CRM system. 3. In respect of the PAG support: a) To send a copy of the updated application to PAG for information. b) To provide written confirmation from PAG that they have noted the updates to the application. c) To upload the written confirmation to NHS Digital's CRM system. The following amendments were requested: 1. To update section 1(a) in answer to the question 'Review requested by IGARD' from *"no"* to *"yes"*. 2. To update section 1 to provide a brief explanatory note why NHS Digital did not feel that the application required a re-review by PAG for this amendment. 3. To update section 1 where referencing the legal basis, that the data is being disseminated under the Health and Social Care Act. 4. To remove the reference to *"reasonable expectations"* in section 3(c) and just refer to consent. 5. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 6. To provide further details in section 5(d) (iii) of how the yielded benefits accrued translate to changes in patient care. The following advice was given: 1. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment due to the use of the GDPPR data. 2. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent due to the use of the GDPPR data. It was agreed the conditions would be approved out of committee (OOC0 by the IGARD Chair.

3.3	Imperial College London: A retrospective cohort study investigating reintervention rates and pregnancy rates in women undergoing myomectomy and uterine artery embolisation in 2013-2014 in England (Presenter: Charlotte Skinner) NIC-403356-Z0X1D-v0.6 **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) Admitted Patient Care (APC); for the purpose of investigating a large sample of women undergoing uterine-sparing treatment for uterine fibroids and improve understanding regarding short term readmission, and reintervention rates, pregnancies rates and leiomyosarcoma diagnosis rates over a period of 5 years. The study also aims to identify whether outcomes vary according to the surgeon, Clinical Commissioning Group (CCG) volume or caseload etc. Uterine fibroids have a high prevalence in women and cause considerable morbidity for many millions of women around the world. Women with uterine fibroids may experience problematic abnormal uterine bleeding, resulting in attendances to primary or secondary care health facilities. This study will involve a retrospective cohort study investigating reintervention rates and pregnancy rates in women undergoing myomectomy and uterine artery embolisation in 2013/2014 and 2014/2015 in England. NHS Digital advised IGARD that following submission of the application for review, NHS Digital's Security Advisor had signed off the applicants ISO data security accreditation, and that section 5(b) (Processing Activities) had been updated to reflect this. NHS Digital also noted that section 3(b) (Additional Data Access Requested) had also been updated to reflect the data minimisation efforts undertaken, in respect of the additional filters that would be applied by NHS Digital's Production Team when the cohort was created. **Discussion:** IGARD noted the verbal update from NHS Digital, and were supportive of the updates to section 5(b) to reflect the ISO data security accreditation being signed off by NHS Digitals Security Advisor; and the data minimisation that had been further outlined in section 3(b). IGARD noted and commended NHS Digital on quality of the information provided in section 1 (Abstract), which provides historical and additional background information which supported the review of the application by Members. IGARD noted that noted that section 1 and section 5(a) (Objective for Processing) stated that *"Imperial College Healthcare NHS Trust are a funding body only, who will not access, store or process any NHS Digital data."*, however asked that this was updated further to also state that Imperial College Healthcare NHS Trust, would not determine the purpose or means of the processing of the data. IGARD queried what the exact cohort age limit parameters were, since the *"premenopausal age cut off"*, as outlined with the protocol was not a term used by clinicians since f menopause typically occurs between age 45 and 55 years but maybe earlier or later than this . IGARD asked that as it was not clear within the application as to how the applicant was limiting by age that further clarity was provided in section 5(a) and the data minimisation in section 3(b); and that was in line with the information outlined in the protocol. In addition, IGARD also asked that section 5(a) was updated to provide further information, in terms of the indicative size of the cohort.

	IGARD queried the reference in section 5(a) to *"participant attrition"*, and asked that further clarity was provided, clarifying how participants would leave the cohort, for example, was this by death or other means. IGARD queried if the baby's birth weight, could be ascertained from the Mother's HES data; and were advised by NHS Digital, that this had been explored and that the Mother's HES data could include the baby's birth weight. IGARD noted the verbal updated from NHS Digital, and asked that section 1 and section 5 (Purpose / Methods / Outputs) were updated to reflect this information. IGARD noted the references within section 1 and section 5 to the *"5-year follow-up after the index treatment"* being a long-term outcome, and asked that this was updated to more accurately reflect that the 5-year follow-up was a *"medium term"* outcome. IGARD noted the potential valuable outputs coming from the work outlined in the application, and suggested that the applicant may wish to consider a longer term follow up, and advised that they would be supportive of the applicant receiving additional flows of data, to ensure they were working with as full set of relevant data as possible to look at longer term outcomes; and that an appropriate justification for this additional data should be added in section 5. In addition, IGARD also asked that the references in section 5(a) to the "*5-years of follow up after the index treatment"*, were updated to clarify what the comparator was, as this was not clear. IGARD noted in section 5(c) (Specific Outputs Expected) the output that *"Additional work investigating the variation in outcomes after UAE and myomectomy relating to ethnicity is to be submitted to the Fertility Sterility Journal in May 2022."*; and noting that section 5(a) was silent on this point, asked that this was updated to reflect the objective for processing in relation to this specific outcome. In addition, and noting the output that stated *"Additional work reporting on the variation in access to fibroid treatment according to geographical location will be submitted to the British Journal of Obstetrics and Gynaecology in January 2022."*, IGARD asked that clarification was provided, as to whether there was any further scope to develop study outputs which would look at variability of outcomes based on ethnicity as well as geographical area. IGARD noted the statement in section 5(a) and section 5(d) (Benefits) *"One other objective of the study is to identify whether outcomes vary according to…CCG volume…"*, and noting that this was absent from the protocol, asked that further clarity was provided as to whether this is actually what the applicant was planning to do. IGARD noted that a number of Myomectomies and uterine artery embolization procedures may be carried out within the private healthcare sector, consideration should be given to the number of procedures performed in the private sector and if this number would be significant; and noting that they would not be included within this study, asked that for transparency, section 5(a) was updated to acknowledge this. In respect of the patient and public involvement and engagement (PPIE), IGARD noted that the British Fibroid Trust would be involved in the dissemination of the outputs, however suggested that they could have been involved earlier, and that if there was a follow-up study, the applicant may wish to involve them in the design. IGARD also noted that the British Society of Gynaecological Endoscopy were involved, and suggested the applicant link back to the Royal College of Obstetricians and Gynaecologists; and that the applicant also considered engaging with them, in terms of disseminating the outputs of the study, as they have well established and far-reaching women's networks, and a

popular public-facing website which is where the public is likely to look for information about new research in this area.

IGARD noted the references throughout the application to *"CCG"* (Clinical Commissioning Group), and noting the ongoing changes to how CCG's will be structured in the future, asked that the references were updated, with a more general phrase, for example, *"commissioners of healthcare services"* or similar.

IGARD noted the references within section 1 and section 5 to *"delivery"* and suggested that the word "*delivery*" was replaced with the term *"birth"*.

IGARD suggested that the application be updated to remove references to "*it will*…" and instead use a form of words such as "*it is hoped*…".

IGARD noted the inclusion of a number of technical phrases and words within section 5 (Purpose / Methods / Outputs) such as *"multivariate logistic regression"* and suggested that this was updated to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use.

Outcome: recommendation to approve

The following amendments were requested:

1. To update the application throughout to use a form of wording such as "*it is hoped* …", rather than "*it will…*".
2. To amend section 1 and section 5 to reflect that the *"5-year follow-up"* is a *"medium term"* (rather than long term) outcome.
3. To update the current wording to state that Imperial College Healthcare NHS Trust, will not determine the purpose or means of the processing of the data (as well as not access, store or process the data).
4. To provide further clarity in section 5(a) and the data minimisation section of 3(b) of the exact cohort parameters, for example, what is the premenopausal age cut off, and in line with the protocol.
5. To update section 5(a) with an indicative size of the cohort.
6. To update section 1 and section 5, with confirmation that the baby weight can be ascertained from the Mother's HES data.
7. To replace the reference to *"delivery"* in section 1 and section 5 with *"birth"*.
8. In respect of the ethnicity outcomes in section 5(c):
    a) To update section 5(a) to reflect the ethnicity outcomes outlined in section 5(c).
    b) To provide clarification as to whether there is any further scope to develop study outputs which will look at variability of outcomes based on ethnicity as well as geographical area.
9. To provide further clarity in section 5(a) to the reference to *"participant attrition"* and how participants will leave the cohort, for example, is this by death or other means.
10. In respect of the reference to *"CCG volume"* in section 5(a) and section 5(d):
    a) To clarify if this is what the applicant is planning to do, noting this is not referenced in the protocol.
    b) To replace all references to *"CCG"* with a more general phrase, for example, *"commissioners of healthcare services"* or similar.
11. To update section 5(b) to ensure that technical jargon is defined or further explained upon first use.
12. To update section 5(a) to acknowledge that a number of these procedures are carried out within the private healthcare sector, and this will not be captured as part of the study.

	13. To update the references in section 5(a) to *"5 years of follow up after the index treatment"*, and to clarify what is the comparator is. The following advice was given: 1. IGARD noted the potential valuable outputs coming from the work outlined in the application, and suggested that the applicant may wish to consider a longer term follow up, and advised that they would be supportive of the applicant receiving additional flows of data, to ensure they were working with as full set of relevant data as possible to look at longer term outcomes; and that an appropriate justification for this additional data should be added in section 5. 2. In respect of the PPIE: a) IGARD noted that the British Fibroid Trust will be involved in the dissemination of outputs, however suggested that they could have been involved earlier, and that if there was a follow-up study, they may wish to involve them in the design. b) IGARD noted that the British Society of Gynaecological Endoscopy are involved, and suggested the applicant link back to the Royal College of Obstetricians and Gynaecologists; and that the applicant also considered engaging with them, in terms of disseminating the outputs of the study, as they have well established and far-reaching women's networks, and a popular public-facing website which is where the public is likely to look for information about new research in this area.
3.4	University of Oxford: Improving outcomes for patients having shoulder replacements: guiding patient selection, evaluating cost-effectiveness and informing NHS provision (Presenter: Charlotte Skinner) NIC-432598-Q6S0C-v0.3 **Application:** This was a new application for a one-off drop of pseudonymised Civil Registration (Deaths) data, Hospital Episode Statistics (HES) Admitted Patient Care (APC) and HES Outpatients data; for the purpose of a longitudinal, retrospective study, to investigate temporal trends, geographic trends and variations in access for shoulder replacement surgery in the NHS. The study team will specifically address one Work Package of the larger research project, namely the current and future burden shoulder replacement surgery on the NHS, including costs of shoulder replacement surgery and an analysis of any geographical variations or inequity of access Shoulder pain is associated with increased health care utilisation and accounts for 20% of disability claims for musculoskeletal disorders. Degenerative shoulder osteoarthritis causes pain, functional limitation and disability and has an estimated prevalence between 4% and 26%. Patients with bilateral shoulder arthritis can rapidly lose function and be unable to self-care and therefore leads to significant morbidity, particularly in an ageing population. Over 45,000 shoulder replacements were undertaken in the UK between 2012 and 2020. NHS Digital advised IGARD that there was a reference within the protocol to a statistician from the University of Bristol, however advised that they had a supervisory role only and would not have access to any of the NHS Digital data. **Discussion:** IGARD had a lengthy discussion on the large volume of data that had been requested by the applicant, in particular querying what data minimisation efforts had been undertaken, for example, in respect of the minimisation of the code sets in respect of cohort members. Noting that there was some information provided that outlined some of the data minimisation efforts, IGARD asked that in addition, a written justification was also provided in section 5 (Purpose / Methods / Outputs), as to how the NHS Digital DARS Standard for Data

	Minimisation had been satisfied, particularly in respect of the minimisation of the code sets in respect of cohort members. IGARD asked that the data was either minimised further, for example to minimise the code sets further; or, If the code sets could not be minimised further, to provide an explanation of the relevance of why code sets, such as appendectomy were relevant to shoulder replacement surgery. In addition, IGARD asked that the data minimisation text in section 5(a) (Objective for Processing) was relocated to the processing activities in section 5(b) (Processing Activities). IGARD queried the content of the paragraph in section 5(b) that started *"Access to the data will be restricted to…"*, and noting that it did not fully make sense, and since this was public facing part of the application and formed NHS Digital's data release register, asked that this was reviewed and that any irrelevant text was removed as appropriate. IGARD queried the size of the cohort, and asked that section 5(a) was updated to provide further information, in terms of the indicative size of the cohort; and that this was aligned with the information outlined in the protocol. IGARD noted that section 2(b) (Storage Location(s)) only listed one storage location, and queried if this was correct, for example, was there a back-up or disaster recovery site; and asked that clarification was provided if there were any additional storage locations and to amend section 2(b) if appropriate. IGARD queried the information in section 3(c) (Patient Objections) in respect of patient objections, that stated *"Does not include the flow of confidential data"*, and asked that this was updated to accurately reflect that patient objections **will not** apply. IGARD suggested that section 5(c) (Specific Outputs Expected) and section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is expected*…". IGARD queried the paragraph in section 5(c) that referred to the study team having strong links with the National Institute for Health and Care Excellence (NICE), and asked that this was removed as it was not relevant and could be misleading. **Outcome:** recommendation to approve subject to the following condition: 1. In respect of the data minimisation: a) To provide a written justification in section 5 as to how the NHS Digital DARS Standard for Data Minimisation has been satisfied, particularly in respect of the minimisation of the code sets in respect of cohort members; and, b) To either minimise further, for example to minimise the code sets further; or c) If the code sets are not to be minimised further, to explain the relevance of why code sets, such as appendectomy are relevant to shoulder replacement surgery. The following amendments were requested 1. To update section 1 and section 5 with an indicative cohort size, and in alignment with the protocol. 2. To amend section 2(b) to add any additional storage locations, for example back-up or disaster recovery. 3. To update section 3(c) to accurately reflect that patient objections **will not** apply. 4. To move the data minimisation text from section 5(a) into section 5(b). 5. To review the paragraph in section 5(b) that starts *"Access to the data will be restricted to…"*,and remove any irrelevant text.

	6. To update section 5(c) and section 5(d) to use a form of wording such as "*it is expected*…", rather than "*it will*…". 7. To amend section 5(c) to remove the reference to the study team having strong links with NICE. It was agreed the conditions would be approved out of committee (OOC) by IGARD members
3.5	<u>IQVIA Ltd: Hospital Treatment Insights (Presenter: Frances Hancox) NIC-13925-Q7R2D-v7.6</u> **Application:** This was an amendment application to 1) to remove The Bunker Secure Hosting LTD as a Data Processor, and as a storage location, 2) to change the territory of use from England and Wales to the UK. The purpose is for a longitudinal research database, the Hospital Treatment Insights (HTI), which contains unique information on diagnosis, treatment and drug usage across secondary care in England and has been linked to primary care data in the past. HTI is currently the only routinely collected population-based database available for monitoring the safety of medicines used in the secondary care setting. The data will be used to undertake a programme of research studies, in two main areas, aimed at promoting public health which will include, 1) Advanced statistical analysis, such as, Epidemiology, natural history of disease, health economics and outcomes research, drug exposures, and to estimate the number of potential patients eligible for clinical research (including clinical trials); and 2) Drug safety monitoring, such as, monitoring of adverse events for newly licenced drugs prescribed in secondary care and pharmacovigilance. NHS Digital also noted that the current end date of the data sharing agreement (DSA) was the 30th June 2021, and that on renewal of the application it would return to an IGARD BAU meeting for a recommendation. NHS Digital advised IGARD, that following submission of the application for review, the applicant had sent through further details of the yielded benefits that had accrued since the application was last reviewed by IGARD on the 8th June 2017. NHS Digital provided a verbal overview of the yielded benefits outlined by the applicant, for IGARD's information. **Discussion:** IGARD noted the verbal update from NHS Digital, in respect of the end date of the DSA being the 30th June 2021, and at which point the application would return to an IGARD BAU meeting for a recommendation. IGARD advised NHS Digital that this application had not been brought back to IGARD for any of the other numerous amendments made, following the last review by IGARD on the 8th June 2017, and that this review would be only for the specific amendments outlined in section 1 (Abstract) of the application namely to remove The Bunker Secure Hosting LTD as a Data Processor, and as a storage location; to change the territory of use from England and Wales to the UK. IGARD queried the statement in section 3(c) (Patient Objections) that patient objections would **not** be applied, and were advised by NHS Digital that this was an error, and confirmed that the previous version of the DSA had correctly stated that patient objections <u>would be applied</u>; and that as there was no new data flowing under this version of the application, it had been incorrectly stated that patient objections would not be applied. IGARD noted the verbal confirmation from NHS Digital and asked that section 3(c) was updated to accurately reflect that patient objections **will** apply. Noting that the application would return to IGARD before the 30th June 2021, IGARD would expect that the following comments / amendments should be addressed upon renewal, and

	requested that a version of the application with track changes on was provided as a supporting document, to support the review, in addition to the usual application summary. Noting the verbal update from NHS Digital in respect of the yielded benefits, IGARD asked that section 5(d) (Benefits) (iii) (Yielded Benefits) was updated with a satisfactory update to the yielded benefits section, and in compliance with NHS Digital's Expected Measurable Benefits Standard. IGARD noted that when the application was last reviewed in 2017, the applicant requested 13 years' worth of data, from 2005/2006, and that there was nothing within the DSA that clarified the data destruction of any historical data. IGARD therefore noted that data was accumulating on a rolling basis. IGARD asked that in respect of the data minimisation and in line with the NHS Digital DARS Standard for Data Minimisation, a written justification was provided in section 5 (Purpose / Methods / Outputs), for the additional years of data requested since the last IGARD review in 2017. In addition, IGARD also requested that a justification was provided, as to why there had been no rolling deletion of data, following IGARD's review in 2017. IGARD queried the statement in section 5(a) (Objective for Processing) that "*HTI is currently the only routinely collected population based database available"*, and noting that this may now be incorrect, asked that the statement was revised, and amended if appropriate. IGARD noted the references in section 5 to the data being *"non-identified"*, and asked that this was amended to align with section 3 (Datasets Held / Requested), to correctly reflect that the data was *"pseudonymised"*. IGARD queried the commercial aspect of the application, and asked that section 5(e) (Is the Purpose of this Application in Anyway Commercial) was updated to reflect any commercial aspects and in line with the NHS Digital DARS Standard for Commercial Purpose, for example (but not limited to) the reference to *"sales or marketing"* with NHS Digital data. IGARD asked that in line with NHS Digital's DARS standard Processing Activities, that a special condition was inserted in section 6 (Special Conditions) that an honorary contract would be provided, that complied with this policy, for example, counter signature by the home research institution and / or employer and that the documentation be uploaded to NHS Digital's customer relationship management (CRM) system. IGARD queried if the Independent Scientific Ethics and Advisory Group (ISEAC) minutes had been provided to NHS Digital, and were advised by NHS Digital, that it was their understanding they had not. IGARD asked that copies of the ISEAC minutes were obtained, and reviewed, for reference to the utilisation of the HTI datasets, to ensure that any useful work undertaken was captured in section 5, which formed NHS Digital's data release register. In addition, IGARD suggested that when this applicant returned to IGARD, that the ISEAC minutes from the last 12 months, should be tabled as a supporting document(s). Noting that potential users of the database may be regulatory authorities, IGARD queried if the Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (EMA) or the National Institute for Health and Care Excellence (NICE) had used the database to monitor adverse drug reactions; and asked that section 5 was updated as appropriate to clarify this. IGARD noted that section 5(a) contained duplicate paragraphs, and asked that this was reviewed and updated where necessary to remove the duplicate information.

	IGARD queried the reference in section 5(b) (Processing Activities) to the *"data aggregated in line with the HES analysis guide",* and asked that this was updated to reflect that was aggregated with small numbers suppressed. IGARD advised that given the amount of time that had passed since the last full IGARD review, and the volume of data, diverse use, significant commercial element, and the noted queries over years of data retained and data deletion, 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. **Outcome:** recommendation to approve the two amendments outlined in the application only until the 30th June 2021. The following amendment was requested: 1. To update section 3(c) to accurately reflect that patient objections **will** apply. When the application returns to IGARD, the following amendments should have been undertaken: 1. In respect of the data minimisation and in line with the NHS Digital DARS Standard for Data Minimisation, to provide a written justification in section 5, for the additional years of data requested since the last IGARD review in 2017. 2. To provide a justification as to why there has been no rolling deletion of data, since when reviewed in 2017, the applicant stated they only required 13-years of data. 3. To revise the statement in section 5(a) that "*HTI is currently the only routinely collected population based database available"*, and amend if appropriate. 4. To amend the references throughout section 5 from *"non-identified"* data to correctly refer to *"pseudonymised"*. 5. To update section 5(a) to remove any duplicate paragraphs. 6. To update the reference in section 5(b) *"data aggregated in line with the HES analysis guide"* to reflect that this is aggregated with small numbers suppressed. 7. To update section 5(e) to reflect any commercial aspects and in line with the NHS Digital DARS Standard for Commercial Purpose, for example (but not limited to) the reference to *"sales or marketing"* with NHS Digital data. 8. To insert a special condition in section 6, that the applicant, in line with NHS Digital's policy on honorary contracts, provide an honorary contract, that complies with this policy, for example, counter signature by the home research institution and / or employer. 9. To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's Expected Measurable Benefits Standard, and as per the verbal update provided by NHS Digital. 10. To review the ISEAC minutes for reference to the utilisation of the HTI datasets, to ensure that any useful work undertaken is captured in section 5 (which forms NHS Digital's data release register). 11. To update section 5 to reflect any use by the MHRA, EMA or NICE, of the HTI to monitor adverse drug reactions. The following advice was given: 1. IGARD suggested that when this applicant returns to IGARD, that the ISEAC minutes from the last 12 months, should be tabled as a supporting document(s).

	2. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to volume of data, diverse uses and significant commercial element. 3. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to volume of data, diverse uses and significant commercial element.
3.6	<u>University of Oxford: ATEMPT: Antihypertensive Treatment in Elderly Multimorbid Patients (Pilot Study) (Presenter: James Gray) NIC-311182-F5W4X-v0.5</u> **Application:** This was a new application for identifiable Demographics data; for the purpose of a pilot study, aiming to improve the understanding of blood pressure (BP) management in older, multimorbid people, by comparing the effectiveness and safety of changing the number of prescribed antihypertensive drugs in two similar groups of such individuals. The study will assess the acceptability and tolerability of the and to rule out any major excess harms. If the Pilot shows that an intervention can lead to important changes in BP, this information will help to assess whether a larger trial is worthwhile to investigate the effect of the intervention on clinical outcomes. In addition, the study aims to test the feasibility of the main components of the trial, namely participant recruitment, randomisation, delivery of treatment, and remote assessment of trial outcomes and to obtain information about resource requirements for the main trial. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital, and is hoping to recruit approximately 200 cohort members. NHS Digital advised IGARD that the study team were planning to issue 20,000 invitation letters to potential participants, to recruit 200 participants for this pilot study. **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 noted the verbal update from NHS Digital in respect of the anticipated distribution of the 20,000 invitation letters to prospective participants, and suggested that this was carefully designed, and that the applicant may wish to consider sending the letters in staggered smaller batches. IGARD advised that if the acceptance rate was higher than anticipated then not all 20,000 letters may need to be sent out, and that it would be less intrusive to citizens. In addition, IGARD asked that further clarify was provided as to the logistics and / or process of the mailout of the 20,000 letters, as this was not outlined in the application. IGARD noted the description of NHS Digital's activities, in supporting document 3.3, the invitation letter, and suggested that NHS Digital checked with their internal communication team to ensure it aligned with NHS Digital's agreed corporate description. If appropriate, NHS Digital may then wish to request an update to their description in the invitation letter. IGARD also asked that supporting document 3.3, was updated to include an additional header *"How can I avoid being contacted like this in the future?",* or similar; and that a clear explanation was included, under this new header, as to how the recipients of the invitation letter can exercise their National Data Opt-out. IGARD advised that the addition of this important information, would help to maintain public trust in the pilot study, maximising transparency, provide additional protection to the University of Oxford, for example, in terms of

	any complaints and fulfil NHS Digital's duty to make participants aware of their right to exercise the National Data Opt-out. IGARD queried the statement in section 5(a) (Objective for Processing) *"…this information will help to assess whether a larger trial is worthwhile…"*, and asked that this was amended and replaced with a more sensitive term to those involved in the pilot study, for example, *"feasible and beneficial"*. IGARD noted the statement in section 5(b) (Processing Activities) that *"…staff are currently working from home and accessing their infrastructure via a secure VPN…"*, and asked that section 1 (Abstract) and section 5 (Purpose / Methods / Outputs) was updated, to confirm that NHS Digital Security Advisor had reviewed the data processor's VPN and were content. IGARD suggested that section 5(d) (Benefits) be updated to remove reference to "*it will*…" and instead use a form of words such as "*it is hoped*…". Noting that this was a pilot study and that a future application would be submitted to a future IGARD business as usual (BAU) for a recommendation, IGARD suggested that NHS Digital may wish to utilise an IGARD BAU agenda slot to review relevant draft consent materials, for all three cohorts: mail, website and online pharmacy portal, and prior to any application being submitted for review. **Outcome:** recommendation to approve The following amendments were requested: 1. To amend the reference in section 5(a) to a larger trial being *"worthwhile"*, and replace with a more sensitive term, for example *"feasible and beneficial"*. 2. To clarify the logistics / process of the mailout of the 20,000 letters. 3. To provide confirmation in section 1 and section 5 that NHS Digital Security Advisor have reviewed the data processor's VPN and are content. 4. To update section 5(d) to use a form of wording such as "*it is hoped* …", rather than "*it will…*". 5. In respect of SD3.3, the invitation letter: a) To include an additional header *"How can I avoid being contacted like this in the future?"* (or similar). b) To include a clear explanation under this new header as to how the recipients of the invitation letter can exercise the National Data Opt-out. The following advice was given: 1. IGARD suggested that the 20,000 letter mailout to prospective participants was carefully designed; the applicant may wish to consider sending the letters in staggered smaller batches. If the acceptance rate was higher than anticipated then not all 20,000 letters may be required (which would be less intrusive to citizens). 2. NHS Digital to check with their internal communication team, with regards to the description of NHS Digital's activities within SD 3.3, the invitation letter, to ensure it aligns with NHS Digital's agreed corporate description. NHS Digital may then request an update to their description in the letter, as may be appropriate. 3. IGARD suggested that NHS Digital may wish to utilise an IGARD BAU agenda slot to review relevant draft consent materials (for all three cohorts: mail, website and online pharmacy portal), and prior to any application being submitted for review.

4	Returning Applications 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. 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.
5	COVID-19 update 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. The ratified action notes from **Tuesday 27th April 2021** can be found attached to these minutes as Appendix B.
6	AOB: 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.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 23/04/21

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

Appendix B

Independent Group Advising on the Release of Data (IGARD)

Action Notes from the IGARD – NHS Digital COVID-19 Response Meeting

held via videoconference, Tuesday, 27th April 2021

In attendance (IGARD Members):	Paul Affleck (IGARD Specialist Ethics Member)
	Kirsty Irvine (IGARD Chair / Lay Representative)
	Dr. Imran Khan (IGARD Specialist GP Member)
In attendance (NHS Digital):	Louise Dunn (DARS)
	James Gray (DARS)
	Karen Myers (IGARD Secretariat)
	Andy Rees (DARS)
	Vicki Williams (IGARD Secretariat)

3	**Welcome** The IGARD Chair noted that this was a weekly meeting convened to support NHS Digital's response to the COVID-19 situation and was separate from the IGARD business as usual (BAU) meetings. IGARD members present would only be making comments and observations on items that were presented, and were not making formal recommendations to NHS Digital. Should an application require a full review and recommendation, then it should go through the usual Data Access Request Service (DARS) process and be presented at a Thursday IGARD meeting. The action notes from the Tuesday meeting will be received out of committee and then published alongside the minutes of the next Thursday BAU meeting as an appendix. **Declaration of interests:** One member noted they are a participant in one of the research cohorts intended for inclusion in the UK Longitudinal Linkage Collaboration. However, this was not judged to be a conflict of interest.
2.1	NIC-437579-V8J59-v0.4 University of Nottingham **Background:** this was a new national core studies (NCS) application that had not been prioritised as an application to review at an IGARD business as usual (BAU) meeting for a recommendation and full review, and would therefore be progressed via NHS Digital's SIRO precedent. The aim of the trial is to set in place a research and governance infrastructure for the efficient delivery of a suite of randomised comparisons to prevent COVID-19 infections and reduce severity / transmissions and death in residents in care homes. The trial has been commissioned by the National Institute of Health Research (NIHR) and badged as NCS Urgent Public Health initiative trial under the Data and Connectivity banner. Data will be collected from care homes in England, Wales, Scotland and Northern Ireland before similar

	data is requested from NHS Digital, and devolved nation equivalents of NHS Digital, and processed in a Trusted Research Environment (TRE) at the University of Dundee. The following observations were based on the *SD3.3 Participant ICG V1.0_25Mar2021; SD3.4 Participant IS V1.0_07Apr2021; SD3.5 Legal Rep ICG V1.0_08Apr2021; SD3.6 Legal Rep IS V1.0_0.7Apr2021* provided as supporting documentation. The application v0.4 and other supporting documentation provided for information had not been reviewed. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided. Should a full review of the application and documentation be required including the consent materials and patient information leaflets, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted this was potentially valuable and useful work. IGARD members noted that they were supportive of the National Core Studies. NHS Digital noted that they had undertaken an initial assessment of the participant informed consent form and patient information sheet (PIS) and legal representative informed consent form and legal representative information sheet and concluded that the documentation required further information and clarification. IGARD members noted that the application was to be presented to a future IGARD BAU Meeting. IGARD members noted that the discussion today was not to pre-empt discussions that would take place at the BAU meeting and gave the following high-level comments on the four documents provided for review: *Informed consent form SD3.3* • The informed consent materials (consent form and PIS) should not only satisfy the common law duty of confidentiality, but also satisfy the transparency requirements of Article 13/14 of UK General Data Protection Regulation (UK GDPR). • Noting the applicant was not seeking any historical data, and this was a prospective study, that the language throughout the documentation should be clear as to what is meant by "*historical*". The applicant may wish to give careful consideration of whether historical data was in fact required since past medical conditions and medications may impact on the outcomes being studied under this application. • Reference to "*health status*" should be updated since this could be construed as a fixed point in time. IGARD suggested using more expansive language, for instance referring to ongoing health information or other such terminology which encompassed the wide range of ongoing health data being requested, followed and linked and also, ultimately, cause of death details. • Noting the PIS states that the data will be held for 7 years and then disposed of, but the protocol states the data will be held indefinitely or at least 25 years, to ensure the date references corelate across all documentation or to remove reference to specific dates if not strictly necessary. • Noting reference to "*central UK NHS bodies*", IGARD members suggested removing "*UK*" since this study was England / Wales. Conversely, IGARD noted if this material

	was being used in Scotland and Northern Ireland, the relevant health bodies in those nations should be expressly referred to. • Noting reference to "*anonymised*" in the informed patient consent forms, IGARD suggested ensuring that this term is accurately described in any supporting documentation, such as the PIS. • Noting this is a vulnerable group and sector, IGARD members would usually expect to see studies of this nature having a positive ethical opinion for oversight. • Again, noting the likely profile of the cohort, IGARD strongly suggested that a large print version or other aids for the visually impaired were readily available. *Participant information sheet SD3.4* • NHS Digital noted the lack of detailed information with regard to how a participant could withdraw from the study. IGARD Members agreed and further suggested that reference to "*PALS*"* should be removed and that more information should be included as a clear heading to "*how to withdraw from the study*" including the telephone number, postal address and email address for the trial team since this related to a Clinical Trial of an Investigational Medicinal Product (CTIMP) in a care home (rather than a hospital site). *Patient Advice & Liaison Service (PALS) • NHS Digital suggested that more information should be included about the data being shared and the relevant organisations that data was being shared with and that they should be name checked and IGARD agreed. • NHS Digital noted that any reference to "*medical information*" should be updated to include "***relevant** medical information*". • IGARD members noted reference to "*UK*" care homes and if this was just England and Wales, then to remove reference to "*UK*", noting that if care homes in Scotland and Northern Ireland were to be included then the relevant NHS bodies and legal parameters would need to be clearly set out. • IGARD members noted the possibly optimistic commentary with regard to side effects and suggested the wording be updated to be more realistic, noting from a risk perspective these were elderly and potentially vulnerable adults taking part in a trial. • IGARD noted that the documentation stated that that should a resident wish to take part that the Care Home may appoint a legal representative. IGARD cautioned that it is not the role of the care home to appoint a legal representative and may be in contradiction to a resident's own personal circumstances, for example a relative may already hold an appropriate power of attorney. • IGARD noted reference to linkage to research records and suggested for transparency that in addition to the date of birth, that this be expanded to include another couple of examples to give a sense of the full detail and personal nature of the information being shared and linked. • To ensure that where appropriate the term *"gender"* is replaced with the term *"sex"* to reflect the available field in the data sets requested from NHS Digital. • Noting that the PIS references storage of data by the University of Nottingham, not as outlined in the application of the TRE at the University of Dundee, that the PIS be updated to reference that the data will be held securely in a research environment. • IGARD suggested that when referencing "*anonymised*" that the phrasing be updated to include "*will not **directly** identify you*" or other such form of words, since it may still be possible to identify a participant from an anonymised dataset.

	• IGARD members noted reference in the PIS that participants could not access the data being held on them, however this statement seems incorrect since under the Data Protection Act (DPA) 2018 Act the care home resident could submit a subject access request. It is also not clear why a participant's autonomy would be restricted in this way. • IGARD members noted that the study did not have a specific study Privacy Notice and that it was imperative that one was drafted, if not done so already, and shared as appropriate (or that the PIS was fully revised to cover off all UK GDPR transparency requirements). • Noting the likely profile of the cohort, IGARD strongly suggested that a large print version for the visually impaired was readily available. IGARD Members commended the applicant on how the PIS was set out with clear headers and numbering of paragraphs and suggested this was an exemplar of good practice. *Legal representation forms SD3.5 and SD3.6* • IGARD members noted that individual care home residents may have their own power of attorneys in place and that it was the applicant's responsibility to ensure that the clinical trial was assured that any appointment of a legal representative was legally effective. The documents provided for review would not in of themselves suffice to create a "*legal representative*" relationship between the care home resident and their friend or relative. The applicant should have an assurance process in place to check that each participant had either a named legal representative or plans to appoint one, and only that duly appointed person was consulted regarding this trial. • Noting reference in the documentation to "*friend / relative*"; if this term is retained it should be clearly defined as referring to a friend or relative who has been duly appointed as a legal representative. • IGARD members queried if patient objections would be applied, since the care home resident when competent may have applied a national data opt-out (NDO) and it would not be for the power of attorney or legal representative to override the NDO, and that advice should be sought from NHS Digital's Privacy, Transparency and Ethics directorate with regard to respecting the NDO. IGARD suggested that flows of data in to NHS Digital should distinguish between where consent has been obtained direct from the resident and where consent has been gained via a legal representative (the latter being a bar to data flowing back where an NDO is in place). IGARD members noted that the application was still in draft and that the full suite of documentation was still to be presented to a Research Ethics Committee (REC) and that when presented to IGARD at a future BAU Meeting, the REC favourable opinion should be included as a supporting document. IGARD members noted that from an NHS Digital perspective, they need to be satisfied that right processes are in place to be reassured when the data flows.
2.2	<u>NIC-420168-K4N1F-v0.11 University of Bristol</u> **Background:** this was a national core study (NCS) application that had not been prioritised as an application to review at an IGARD business as usual (BAU) meeting for a recommendation and full review, and would therefore be progressed via NHS Digital's SIRO precedent.

	Previous versions of the application for the consented cohort and relevant supporting documents had previously been discussed at the COVID-19 response meetings on the 30th March, 16th March, 2nd February, 26th January, 12th January 2021, 15th December and 8th December 2020, and at the IGARD business as usual (BAU) meeting on the 4th March and 4th February 2021. The UK Chief Scientific Advisor established (October 2020) a programme of NCS for SARS-CoV-2 (COVID-19) research as a coordinated, long-term, national research initiative. This will consider COVID-19 in terms of a viral pandemic (including issues of cases, transmission, symptoms and outcomes) and in terms of the health and social impacts of behavioural restrictions designed to mitigate the harms of the pandemic. The NCS has six different sub-programmes which are addressing major COVID-19 research areas; one of these is the Longitudinal Health and Well-being (LH&W) NCS which is designed to use data from longitudinal studies to address the impact of Covid-19 and of associated viral suppression measures on health and well-being. The UK Longitudinal Linkage Collaboration (UK LLC) is the central hub component of the Longitudinal Health and Wellbeing NCS. The UK LLC has been designed to underpin the LH&W NCS, although not exclusively as the NCS are designed to support each other, where for example: the LLC could form the infrastructure for the long-term patient follow-up of consenting trial participants or, where UK longitudinal population studies (LPS) are being used to collect specific new study data which is not available through routine records. For this reason, users of the LLC may come from across the full range of NCS studies and the resource will be accessible to other legitimate UK-based researchers investigating COVID-19 through a sub-licence framework. The NCS is planned to be a two/three-year research programme commencing October 2020. The following observations were made on the basis of the three of the supporting documents namely: *SD18 IG advice on COPI; SD19 PAG feedback DARS-NIC-420168-K4N1F-v0.9 University of Bristol 10.03.21*; and *SD20 Cohorts to include in the DSA updated* namely: the National Study of Health & Development (NSHD); The Southall and Brent Revisited (SABRE); Avon Longitudinal Study of Parents and Children (ALSPAC); TwinsUK; Twins early development study (TEDS); Genetic Links to Anxiety & Depression Study (GLAD); English Longitudinal study of ageing (ELSA); 1958 National Child Development Study (NCDS); 1970 British cohort study (BCS70); New Steps; The Millennium cohort study (MCS); Generation Scotland; INTERVAL; STRIDES BioResearch; Track-COVID; National Institute for Health Research (NIHR) BioResource; Extended cohort for e-health, environment and DNA (EXCEED); the Northern Ireland cohort for the longitudinal study of ageing (NICOLA); Understanding society; and Born in Bradford. The application v0.11 had not been reviewed and other supporting document available on the customer relationship management system (CRM) had not been provided. **IGARD Observations:** IGARD members noted that due to the nature of the meeting and when papers were disseminated, they had not conducted a full review of the application and supporting documents provided, noting that not all the supporting documents available had been provided for consideration. Should a full review of the application and documentation be required, the full suite of documentation should be presented to a IGARD business as usual (BAU) meeting for a recommendation. IGARD members noted this was potentially valuable and useful work.

	IGARD members noted that they were supportive of the National Core Studies. IGARD noted the verbal update from NHS Digital that the Privacy, Transparency and Ethics Directorate had reviewed the flow of data into the Trusted Research Environment (TRE) under the National Health Service (Control of Patient Information Regulations) 2002 (COPI) and that that since confidential data was flowing into NHS Digital for this study, the use of COPI was appropriate. IGARD members noted that COPI did not provide a legal gateway outside of England and Wales to flow data into the TRE, and queried the use of Northern Irish and Scottish datasets and that the relevant legal bases to support these cohorts being included should be clearly cited in the application. Notwithstanding the reliance on COPI, IGARD suggested that steps should be undertaken to inform the cohort members prior to the flow of data into the TRE including the processing that was being undertaken in order to satisfy the UK General Data Protection Regulation (UK GDPR) transparency requirements and digital ethics (for example, maintaining good faith with cohort members since their involvement flows from the consent they originally gave to particular research). The work undertaken now would pave the way and be a good investment in order to augment the consent materials across the different cohorts or provide further evidence if the applicant was to seek Health Research Authority Confidentiality Advisory Group (HRA CAG) s251 support. NHS Digital verbally noted that the applicant had sought independent legal advice and that assurance of this fact would be uploaded to the NHS Digital customer relationship management (CRM) system as a future supporting document. For the avoidance of any doubt, IGARD reminded the applicant that reliance on COPI should be within the parameters of responding to a pandemic and the data cannot be used for general research, no matter how valuable or interesting the data may be. IGARD members noted that the application would proceed down the SIRO precedent and noted that for such a potentially repercussive application that NHS Digital may also wish for the assurance of an independent review via a Thursday BAU IGARD meeting, notwithstanding the apparent urgency and that NHS Digital were hoping to flow the data by mid-May 2021.
3	<u>AOB</u> There was no further business raised, the IGARD Chair thanked members and NHS Digital colleagues for their time and closed the meeting.