Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 15 July 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark (Chair)	Lay Member
Dr. Imran Khan	Specialist GP Member
Dr. Maurice Smith	Specialist GP Member
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine	IGARD Chair / Lay Representative
Dr. Geoffrey Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Michael Ball	Data Access Request Service (DARS) (Observer: item 2.6)
Vicky Byrne-Watts	Data Access Request Service (DARS)
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Duncan Easton	Data Access Request Service (DARS)
Dan Goodwin	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Karen Myers	IGARD Secretariat
Jonathan Osborn	Deputy Caldicott Guardian (Items 2.1 – 2.4, 6)
Denise Pine	Data Access Request Service (DARS)
Pam Soorma	Data Access Request Service (DARS) (Observer: item 6)
Vicki Williams	IGARD Secretariat

GPES DATA FOR PANDEMIC PLANNING AND RESEARCH – PROFESSION ADVISORY GROUP (PAG) MEMBERS IN ATTENDANCE:	
Dr. Arjun Dhillon	PAG Chair (Item 6)
Dr. Mark Coley	PAG member (Item 6)
Dr. Amir Mehrkar	PAG member (Item 6)

1	**Declaration of interests:** Maurice Smith noted professional links to AIMES Management Service (NIC-148406-2YXPR) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. Paul Affleck noted professional links to AIMES Management Service (NIC-148406-2YXPR) but no specific connection with the application or staff involved and it was agreed that there was no conflict of interest. **Review of previous minutes and actions:** The minutes of the 8th July 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	**Data Applications**
2.1	University of Dundee: Data linkage request for Treatment in Morning versus Evening (TIME) Study (Presenter: Frances Hancox) NIC-67135-G7D9V-v3 **Application:** This was a renewal and extension application for identifiable Civil Registrations (deaths) data, Hospital Episode Statistics Admitted Patient Care (HES APC), HES:Civil Registration (Deaths) bridge and Demographics data. It was also an amendment to receive two additional fields *"Location of Hospitalisation"* within the HES APC, and *"GP Practice Code"* within the Demographics Dataset. The purpose is for a study (previously called the DIVINE or DIVINE-MOVE study), aiming to determine if morning or evening administration of blood pressure lowering medications is more effective in the prevention of heart attacks and strokes. Research has suggested that antihypertensive medications taken in the evening have a greater effect on nocturnal blood pressure (a major predictor of cardiovascular risk) than morning dosing with the same medications. If there is a significant difference in effectiveness between dosing times for these medications, this will represent an opportunity to reduce the risk of major cardiovascular events in people with high blood pressure without increased cost or exposure to additional medications. The study cohort consists of 21,114 participants, aged 18 and over, with diagnosed high blood pressure who have consented to take their usual anti-hypertensive medications in the morning or evening, according to their randomised dosing time assignment.

	Discussion: IGARD welcomed the application and noted the importance of the study. IGARD confirmed that they were of the view that the **most recent** consent materials provided an appropriate legal gateway and were broadly compatible with the processing outlined in the application. IGARD, however, suggested that the applicant review and update their transparency materials, such as the study website and any upcoming newsletters, to include, but not limited to, explicit information in respect of what data is being obtained from NHS Digital, for example retrospective data and GP details; the data controllership arrangements; the purpose; and information of how participants can withdraw their consent. IGARD noted that the privacy notice stated that *"The University of Dundee/NHS Tayside is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study."*, and cited the Health Research Authority guidance that stated that *"It is the sponsor who determines what data is collected for the research study through the protocol, case report form and/or structured data fields in a database. The sponsor therefore acts as the controller in relation to the research data".* Taking the view that a sponsor is a controller as a starting position, IGARD asked if further analysis had been undertaken to rebut this. NHS Digital advised IGARD that following discussions with the applicant, they had confirmed that NHS Tayside were not considered a joint Data Controller because they did not determine the purpose and means of the processing of the data. IGARD noted the verbal update from NHS Digital, and asked that as per NHS Digital policy that an analysis be inserted into section 1 (Abstract) and relevant standard wording be inserted in section 5(a) (Objective for Processing) to reflect that, notwithstanding published guidance regarding sponsors being Data Controllers, NHS Tayside were **not** considered joint a Data Controller based on an analysis of the facts. In addition, IGARD also suggested that the applicant updated their privacy notice to accurately reflect that the University of Dundee was the sole Data Controller, and that any suggestion that the data controllership was joint was removed. IGARD noted that the applicant had requested GP details, and queried what the researchers would obtain from GP practices, that was not already available in the HES APC and Civil Registrations (deaths) data, and asked that section 5 (Purpose / Methods / Outputs) was updated with further clarity. IGARD noted the historical reference in section 3(b) (Additional Data Access Requested) to *"Strategic Health Authority"* and noting that they no longer existed, asked that this reference was updated as appropriate. IGARD queried the references in section 3(b) to potential *"study endpoint events"*, and asked that this was amended to make clear that it was referring to topic area as opposed to an end point in time. IGARD noted a number of acronyms in section 5(b) (Processing Activities) and asked that this public facing section be updated to ensure that all acronyms upon first use were defined if the meaning was not self-evident, and explained in a manner suitable for a lay audience, for example *"e-CRF"*. IGARD noted the reference to *"database lock"* in section 5(c) (Specific Outputs Expected), and noting that it was not clear what this meant, asked that section 5(c) was updated with further clarity. IGARD noted the incorrect reference to *"Trans-Ischaemic Attack"* in section 5(a) and asked that this was updated and replaced with the correct reference *"Transient ischaemic attack (TIA)*", which was the usual accepted wording.

	Outcome: recommendation to approve The following amendments were requested: 1. To update section 5 to clarify what researchers will obtain from the GP data requested that is not available in the HES APC / Civil Registrations data. 2. To update section 1 to note that, notwithstanding published guidance regarding sponsors being Data Controllers, that NHS Tayside named in the supporting document(s) as sponsor is not taking on any Data Controller responsibilities. 3. In respect of section 3(b): a) to update the reference to *"Strategic Health Authority"*. b) to amend the reference to *"study endpoint events"* to make clear this is referring to topic area as opposed to an end point in time. 4. To amend section 5(b) to ensure that all acronyms upon first use are defined and explained if the meaning is not self-evident, for example, *"e-CRF"*. 5. To provide clarity on the reference to *"database lock"* in section 5(c). 6. To update the incorrect reference to *"Trans-Ischaemic Attack"* in section 5(a) and replace with *"Transient ischaemic attack (TIA)"*. The following advice was given: 1. IGARD suggested that the applicant review and update their transparency materials, such as the study website and any upcoming newsletters, to include (but not limited to) explicit information in respect of what data is being obtained from NHS Digital, for example retrospective data and GP data; the data controllership arrangements; the purpose; and information of how participants can withdraw their consent. 2. IGARD suggested that the applicant update their privacy notice to accurately reflect that the University of Dundee is the sole Data Controller (and remove any suggestion that the data controllership is joint).
2.2	<u>London North West University Healthcare NHS Trust: Colonoscopic Surveillance for Familial Risk of Colorectal Cancer (Presenter: Denise Pine) NIC-148406-2YXPR-v8</u> **Application:** This was an extension application for identifiable Medical Research Information Service (MRIS) data. The purpose is for a long-running surveillance programme, with the aim of seeing if surveillance is successful in preventing cases of colorectal and other cancers. It also allows an assessment of whether there are other causes of death that occur more frequently than expected in the cohort. In addition to service evaluation, associated research is being undertaken with the following aims: 1) to ensure best practice in offering appropriate surveillance to individuals at increased risk of colorectal cancer due to a strong family history of colorectal cancer; 2) to quantify the risk of colorectal cancer associated with different family histories and individual characteristics including molecular genetic testing of patients' tumours and germline DNA; 3) To understand the natural history of colorectal neoplasia and effectiveness of colonoscopy in different groups. The cohort consists of 2,110 patients; and the study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application.

	IGARD noted that the study team may be in contact with some or all of the historical cohort, and asked that, upon return, section 5(c) (Specific Outputs Expected) was updated with an explanation as to why their consent was not being sought. IGARD queried the statement in the privacy notice that referred *to "tracing patients who had been lost to follow-up"* and were advised by NHS Digital that this was incorrect and would be removed. IGARD noted the verbal update from NHS Digital and supported the removal of the incorrect statement. IGARD noted the information within supporting document 2.6, the Health Research Authority Confidentiality Advisory Group (HRA CAG) approval letter dated the 25th June 2021; specifically the condition of support that stated *"…public and patient engagement work must be carried out, ensuring that the participants are asked about the use of confidential data without consent. CAG require to see the number of patients involved, details of the meeting, the types of questions asked, and the views of the participant, within six months"*, and asked about the latest position with this. NHS Digital advised IGARD that a patient event had been arranged for October 2021, and that HRA CAG had been made aware, and had acknowledged the update in relation to the condition. IGARD noted the verbal update from NHS Digital and asked that section 5(a) (Objective for Processing) was updated to reflect the patient and public involvement and engagement (PPIE) for transparency. IGARD noted the references to "*research*" within the application and suggested that the applicant may wish to update the application, to ensure the text was consistent with the work being *"service evaluation"* and in line with the HRA CAG approval. IGARD queried whether the National Data Opt-out (NDO) would be applied, noting the conflicting information within the application. NHS Digital advised that it was NHS Digital policy to apply NDO to s251 support, regardless of the purpose. NHS Digital noted the verbal update from NHS Digital, and suggested, the applicant may wish to approach HRA CAG to seek support in setting aside the NDO in this instance. IGARD queried the statement in section 5(b) (Processing Activities) *"Access to this pseudonymised data will be restricted to one individual who is substantively employed by KCL…"*, and asked that this was reviewed and updated, for example to reflect any additional employees who may be able to access the data, in the event that the "individual" was unable to work due to sickness etc. IGARD noted a number of benefits outlined in section 5(d) (Benefits), however asked that these was updated to make clear the overall benefit of the study, for example, improving cancer survival rates. In addition, IGARD noted the yielded benefits outlined in section 5(d) (iii) (Yielded Benefits), but, asked that this was updated with examples of the yielded benefits flowing from the data used, paying particular reference to the proposed benefits set out in section 5(d) of the application and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted a number of acronyms in section 5 (Purpose / Methods / Outputs) and asked that this public facing section be updated to ensure that all acronyms upon first use were defined if the meaning was not self-evident, and explained in a manner suitable for a lay audience. IGARD also noted that some of the information in section 5 was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader and that further consideration was given to the patient audience.

	In addition, references such as "Dove-Edwin et al. (2005)", "*Robinson et al, 2014*" and "Mesher et al. (2014)" to academic papers should either contain the full searchable academic reference or include a link to the website / web page. 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 expected…"* or *"it is hoped …".* 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 queries raised on the HRA CAG approval; the service evaluation vs research question; and the possibility of consenting cohort members. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 5(a) to reflect the PPIE activity, for example, the event taking place in October 2021, as per the verbal update from NHS Digital. 2. To review the statement in section 5(b) that access to the data *"…will be restricted to one individual…"* and update as appropriate. 3. In respect of section 5(d): a) To update section 5(d) to make clear the overall benefit of the study, for example, improving cancer survival rates. b) To update section 5(d) (iii) with examples of the yielded benefits flowing from the data used, paying particular reference to the proposed benefits set out in section 5(d) of the application and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. 4. To amend section 5 to ensure that all acronyms upon first use are defined and further explained if the meaning is not self-evident. 5. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience. 6. To update the references to academic papers in section 5, to either include a fuller searchable reference or a relevant web link. 7. To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". The following advice was given: 1. IGARD suggested that the applicant ensures that the text is consistent with the work being *"service evaluation"* and in line with the HRA CAG approval. 2. IGARD noted that the study team may be in contact with some or all of the historical cohort, and asked that, upon return, section 5(c) be updated with an explanation, as to why their consent was not being sought. 3. IGARD suggested that the applicant may wish to approach HRA CAG to seek support in setting aside the NDO in this instance. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the queries raised on the HRA CAG approval; the service evaluation vs research question; and the possible consent of cohort members. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the queries raised on the HRA

	CAG approval; the service evaluation vs research question; and the possible consent of cohort members.
2.3	<u>Imperial College London: SAHSU annual renewal and amendment - HES - Adding Provisional Monthly APC, Critical Care, Emergency Care and GPES data for pandemic planning and research (COVID-19) (Presenter: Catherine Day) NIC-204903-P1J7Q-v4</u> **Application:** This was an amendment application, to 1) add NHS Number as a field to Hospital Episode Statistics (HES) Critical Care; 2) to add GPES data for Pandemic Planning and Research (GDPPR) data set to the application; for the purpose of looking at long-term exposure to air-pollution and COVID-19 mortality, and to quantify the effect of pre-existing conditions on COVID-19 mortality. This overall purpose is for a study, on the effect of long-term exposure to air pollution on COVID-19 mortality. The study will 1) identify which comorbidities increase COVID-19 mortality; 2) re-assess the effect of air-pollution after accounting for the comorbidities identified; and 3) adjust for a series of confounders, such as age, sex, ethnicity, access to health, deprivation and the spread of the disease. The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. NHS Digital advised IGARD that Registered Degree Level students would be involved with the study, and that the application would need updating to reflect this. NHS Digital also highlighted that the applicant had recently been audited by NHS Digital and stated that the main issues of concern were in respect of the contracts with the students. **Discussion:** IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 Response meetings on the 26th May 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) (see Appendix B) on the 9th June 2021. NHS Digital advised IGARD that section 1 (Abstract) would need updating to reflect the most recent PAG outcomes. IGARD noted the verbal update from NHS Digital and supported the suggested update to section 1. IGARD noted the verbal update in respect of the Registered Degree Level students being involved with the study and supported the updates to the application to reflect this information. IGARD also noted the verbal update from NHS Digital in respect of the recent audit carried out on the applicant, and the issues that been highlighted in respect of the student contracts. IGARD therefore suggested that NHS Digital satisfied itself that the appropriate contractual arrangements were in place between the students and the University, and that a redacted copy of a contract be uploaded to NHS Digital's NHS Digital's customer relationships management (CRM) system as a future supporting document. In addition, and in respect of the audit that had been carried out, IGARD requested that when the application returned to IGARD for a renewal, extension or amendment, an action plan and / or outputs from the audit were provided as a supporting document. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD queried the references in section 6 (Special Conditions) to The Health Service Control of Patient Information (COPI) Regulations 2002 being the legal basis for dissemination, and

	noting that this was incorrect, asked that the application was updated to ensure that 251 was stated as the correct legal basis. IGARD queried the statement in section 5(b) (Processing Activities) that *"No record level will be transferred outside of the UK or EEA…"*, noting that the territory of use in section 2(c) (Territory of Use) was *"England and Wales"*; and asked that the statement in section 5(b) was reviewed and aligned with the territory of use in section 2(c). IGARD queried the references in section 5(b) to *"data extracts"*, and asked that for transparency, this was amended to clarify that this was not referring to NHS Digital data extracts. IGARD noted the statement in section 5(b) that *"Any access to sensitive or patient identifiable data…has to be strongly justified"*, and asked that this was amended, to state that it has to be *"necessary for the purpose required"*. IGARD queried the information contained within the first paragraph in section 5(d) (Benefits) and asked that this was either reviewed and updated as appropriate, or removed, noting that some of the information may be out of date and / or incorrect. IGARD also queried the paragraph that related to the *"COVID-19 pandemic"* in section 5(d) and asked that this was either reviewed and updated as appropriate, or that any irrelevant text was removed. IGARD noted that one of the benefits in section 5(d) was to help inform policy to "*reduce inequalities in health*" and asked that further clarity was provided of how this would be achieved. In addition, IGARD noted the yielded benefits outlined in section 5(d) (iii) (Yielded Benefits), however noting that this mainly consisted of publications, asked that this was updated with examples of the yielded benefits flowing from the data used, paying particular reference to the proposed benefits set out in section 5(d) of the application and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD also asked that the list of publication in section 5(d) (iii) was removed and added as an output in section 5(c) (Specific Outputs Expected). IGARD noted a number of acronyms in section 5(a) (Objective for Processing) and asked that this public facing section be updated to ensure that all acronyms upon first use were defined if the meaning was not self-evident, and explained in a manner suitable for a lay audience. IGARD also noted that some of the information in section 5 (Purpose / Methods / Outputs) was not clear and suggested that it was updated to ensure that it was written in a language suitable for a lay reader and that further consideration was given to the patient audience, for example when referring to *"Bayesian spatial hierarchical models"*. IGARD also noted the reference in section 5(c) (Specific Outputs Expected) to *"spatio-temporal"* and asked that this was replaced with a plain language alternative. IGARD noted the volume of information within section 5, and asked that this was edited, to remove excessive detail to reduce the description, which was potentially too lengthy for NHS Digital's data release register, for example, the text that related to the old method of data transfer; whilst ensuring the information still provided reassurance to the public. IGARD acknowledged and commended the applicant for taking on previous advice, but suggested that there may be a benefit in involving patients earlier in studies, and cited the HRA guidance on Public Involvement.

	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 volume and type of data requested. **Outcome:** recommendation to approve The following amendments were requested: 1. In respect of the legal basis for processing, to update the application throughout to ensure s251 is stated as the correct legal basis. 2. To review the statement in section 5(b) *"No record level will be transferred outside of the UK or EEA…"*; and ensure this aligns with the territory of use in section 2(b). 3. To amend section 5(a) to ensure that all acronyms upon first use be defined and further explained if the meaning is not self-evident. 4. To update section 5 to ensure it is written in language suitable for a lay reader and that consideration is given to the patient audience (for example when referring to *"Bayesian spatial hierarchical models"*). 5. To edit section 5 to remove excessive detail to reduce the description, which is potentially too lengthy for NHS Digital's data release register, for example, text relating to the old method of data transfer, whilst ensuring any information still provides reassurance to the public. 6. To amend the references in section 5(b) to *"data extracts"*, to clarify that this is not referring to NHS Digital data. 7. To amend the statement in section 5(b*) "Any access to sensitive or patient identifiable data…has to be strongly justified"*, to state that it has to be *"necessary for the purpose required"*. 8. To replace the reference in section 5(c) to *"spatio-temporal"* with a plain language alternative. 9. In respect of section 5(d): a) To review the first paragraph in section 5(d) which may be out of date / incorrect, and update as appropriate or remove. b) To review the paragraph relating to the *"COVID-19 pandemic"* and update as appropriate or remove any irrelevant text. c) To update section 5(d) (iii) with examples of the yielded benefits flowing from the data used, paying particular reference to the proposed benefits set out in section 5(d) of the application and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. d) To remove references to the *"papers"* that have been published from section 5(d) and add as an output in section 5(c). e) To provide further clarity of how the work will *"reduce inequalities in health"*. 10. To update section 1 to include the most recent PAG outcomes. 11. To update the application to reflect that Registered Degree Level students will be involved with the study, as per the verbal update from NHS Digital. The following advice was given: 1. IGARD suggested that NHS Digital satisfy itself that the appropriate contractual arrangements are in place between the students and the University, and that a redacted copy be uploaded to NHS Digital's CRM system as a future supporting document. 2. IGARD noted from NHS Digital, that an audit had been carried out and requested that when the application return to IGARD for a renewal, extension or amendment, an action plan / outputs from the audit are provided as a supporting document.

	3. IGARD acknowledged and commended the applicant for taking on previous advice, but suggested that there may be a benefit in involving patients earlier in studies, and cited the HRA guidance on Public Involvement. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the volume and type of data requested. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the volume and type of data requested.
2.4	University of Oxford: Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales (OPTIC-19): a comparative retrospective cohort study (Presenters: Vicky Byrne-Watts) NIC-419335-H5P8T-v0.3 **Application:** This was a new application for pseudonymised identifiable Civil Registrations (deaths) data, Emergency Care Data Set (ECDS), GPES Data for Pandemic Planning and Research (GDPPR), Hospital Episode Statistics Accident and Emergency (HES A&E), HES Admitted Patient Care (APC), HES Outpatients and Maternity Services Data Set (MSDS). The purpose is for a comparative retrospective cohort study aiming to estimate the risk of adverse outcomes (death, emergency hospital readmission, heart attacks, strokes) in patients treated on an intensive care unit (ICU) with COVID-19 in England and Wales, one year after discharge from hospital. The cohort is made up of 319,600 individuals with a COVID-19 diagnosis, aged 16 years and over admitted to an intensive care unit in England or Wales* and discharged alive from hospital, and admitted between 1st January 2016 to 1st July 2020 (*Welsh data is being sought separately). The study is relying on s251 of the NHS Act 2006, for the flow of data from NHS Digital. **Discussion:** IGARD noted that this application had also been reviewed by the GPES Data for Pandemic Planning and Research (GDPPR) – Profession Advisory Group (PAG) (see Appendix B) on the 9th June 2021. IGARD confirmed that they were of the view that the relevant s251 support provided the appropriate legal gateway and was broadly compatible with the processing outlined in the application. IGARD were unclear how many years of data the Health Research Authority Confidentiality Advisory Group (HRA CAG) support enabled linkage to, and suggested that the applicant confirmed with HRA CAG, that the support given covered the data requested under this Data Sharing Agreement (DSA), for example, 5-years of data. IGARD noted that the pseudonymised dataset would be duplicated and held by both the University of Oxford and ICNARC, and asked, that in line with NHS Digital's DARS Data Minimisation Standard, a justification was provided in section 5 (Purpose / Methods / Outputs) as to why the pseudonymised dataset would be held by both organisations, noting that remote access had been proposed in the application, so could not be based on location, and asked that section 5 was updated, with clarity as to why the data could not be held in one location, and the researchers brought to the data, noting remote access was envisaged. IGARD queried how the University of Oxford and ICNARC would handle receiving data for individuals, where they were not receiving data from NHS Digital due to the application of the National Data Opt-out (NDO) by NHS Digital; and asked that section 5 was updated with further clarity.

	IGARD noted the statement in section 5(b) that *"No data will be matched to publicly available data and there will be no requirement/attempt to re-identify individuals"*, and the statement in supporting document 5, that *"The ledger linking pseudonymous Study ID to direct identifiers will only be accessed by ICNARC for GDPR privacy enquiries and in the event of data quality concerns…"*; and asked that clarity was provided in section 5(b) **when** individuals would be reidentified. IGARD noted the reference within the application to specific anti-virus software and asked that this was removed, and the that any references to software was kept generic, since any reference may become dated over time and if the encryption changed, the applicant may be in breach of their Data Sharing Agreement (DSA). IGARD noted the language within section 5 and the special conditions in section 6 (Special Conditions) appeared to indicate that there was only one Data Controller and asked that both sections were updated to reflect there are two Data Controllers and two UK General Data Protection Regulation (UK GDPR) compliant privacy notices for each Data Controller. In addition, IGARD suggested that the Data Controllers should review their privacy notices and update where appropriate, to comply with the UK GDPR, for example, in line with Article 26(2). IGARD noted that the application talked about press releases but that this was not true public and patient involvement (PPI) and suggested that there would be a benefit in involving patients earlier in the studies, and cited the HRA guidance on Public Involvement. IGARD noted that section 5 contained historical data and references, and asked that this was reviewed, and information was removed if no longer necessary. IGARD noted the inclusion of a number of technical phrases and words within section 5(b) such as *"probabilistic matching"* 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 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 expected…"* or *"it is hoped …".* 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 query around the HRA CAG approval, the GDPPR dataset, and ICNARC having the identifiers. **Outcome:** recommendation to approve with condition 1. In line with NHS Digital's DARS Data Minimisation Standard: a) to provide a justification in section 5 as to why the pseudonymised dataset will be held by both the University of Oxford and ICNARC. b) To clarify in section 5, why the data cannot be held in one location, and bring the researchers to it, especially since remote access is envisaged. The following amendments were requested: 1. To update section 5(a) to provide clarification as to how the University and ICNARC will handle receiving data for individuals where they are not receiving data from NHS Digital, due to the application of the NDO by NHS Digital. 2. To clarify in section 5(b) when individuals would be reidentified. 3. To review section 5 to amend any historical date references or remove if no longer necessary.

	4. To amend section 5(b) to ensure the use of technical jargon is used only where necessary such as *"probabilistic matching".* 5. To remove reference to specific anti-virus software, and to keep the terms generic, since any reference may become dated over time and if the encryption changes, the applicant may be in breach of their DSA. 6. To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 7. To update section 5 and the special conditions in section 6, to reflect there are 2 Data Controllers and 2 UK GDPR compliant privacy notices for each Data Controller. The following advice was given: 1. IGARD suggested that there may be a benefit in involving patients earlier in the studies, and cited the HRA guidance on Public Involvement. 2. IGARD suggested that the Data Controllers should review their privacy notices and update where appropriate, to comply with the UK GDPR. 3. IGARD suggested that the applicant confirm with HRA CAG, that the support given covers the data requested under this DSA, for example, 5-years of data. 4. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the query around the HRA CAG approval, the GDPPR dataset, and ICNARC having the identifiers. 5. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the query around the HRA CAG approval, the GDPPR dataset, and ICNARC having the identifiers.
2.5	MAC Clinical Research Finance Limited: Enhancing clinical research on consented patients who want to enter clinical trials - New Application - Winter 2021 (Presenters: Louise Dunn / Vicky Byrne-Watts) NIC-356980-Z5B9G-v0.6 **Application:** This was a new application for pseudonymised Hospital Episode Statistics Admitted Patient Care (HES APC) data; for the purpose of conducting clinical trials on behalf of sponsor organisations, the majority of which are pharmaceutical companies. In order to carry out the clinical trial and provide care to the clinical trial participants, medical history in respect of all clinical trial participants is requested. Currently, medical history is obtained individually from the relevant participant's own primary care practice. The relevant secondary care information from NHS Digital is requested for the following reasons: 1) to lessen the burden on individual GP practices as currently individual participant records need to be printed and mailed by the individual GP practices following a request from MAC; 2) to increase the security provided to such sensitive information as a secure digital transfer offers more protection that the manual process currently described above; 3) to ensure the quality and consistency of the data that MAC receives, which will enable them to ensure only relevant individuals are selected to participate in a clinical trial and to provide better care to those individuals for the duration of the clinical trials. **Discussion:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted that aspects of this application had been previously seen by the IGARD – NHS Digital COVID-19 Response meetings on the 3rd November 2020. Noting the complexity of the application / proposal, IGARD suggested that the language in both the consent materials and the application was reviewed to ensure it was written in a

	language suitable for a lay reader. In addition, IGARD advised that the application should be aligned with NHS Digital's DARS Standards. IGARD suggested that an example of how the data may be processed was added to the application, to provide additional support and understanding of how the data may be processed. IGARD confirmed that they were of the view that the **most recent** consent materials **did not** provide the appropriate legal gateway and were **incompatible** with the processing outlined in the application. IGARD noted that supporting document 6, the MAC consent form had been provided, and advised that this required additional updates, for example, to include, but not limited to, exactly what information MAC are planning on holding, how the elements of the data would flow to a potential trialist / investigator, and what data would flow. IGARD noted that the application stated that sub-licensing would take place outside of the EEA, and advised that this should be made clear both within the sub-licensing forms and the consent forms for transparency. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome:** IGARD welcomed the application which came for advice and without prejudice to any additional issues that may arise when the application is fully reviewed.
2.6	NHS Herts Valley CCG: DSfC - NHS Herts Valleys CCG IV & Comm (Presenter: Dan Goodwin) NIC-55752-D6X5Y-v9 **Application:** This was a renewal application for pseudonymised Secondary Uses Service (SUS+) data, Local Provider Flows, Mental Health Minimum Data Set (MHMDS), Mental Health Learning Disability Data Set (MHLDDS), Mental Health Services Data Set (MHSDS), Maternity Services Data Set (MSDS), Improving Access to Psychological Therapy (IAPT), Child and Young People Health Service (CYPHS), Community Services Data Set (CSDS), Diagnostic Imaging Data Set (DIDS), National Cancer Waiting Times Monitoring Data Set (CWT), Civil Registries Data (Births and Deaths), National Diabetes Audit (NDA), Patient Reported Outcome Measures (PROMs), e-Referral Service (eRS), Personal Demographics Service (PDS) and Summary Hospital-level Mortality Indicator (SHMI). It was also an amendment to 1) add linkage to Social Prescribing Data (collected externally) to be used for Commissioning purposes; 2) to add Medicines Dispensed in Primary Care (NHSBSA Data) as a dataset for Commissioning purposes; 3) to add Adult Social Care data (collected internally) as a dataset for Commissioning purposes. The overall purpose is for: Invoice Validation (IV) which is part of a process by which providers of care or services are paid for the work they do; and to provide intelligence to support the commissioning of health services. **Discussion:** IGARD noted the constraints placed in the Direction for the collection of NHS BSA Medicines dispensed in Primary Care data, by NHS Digital, specifically *"Providing intelligence about the safety and effectiveness of medicines…"*; and asked that In line with NHS Digital's DARS Standard for Objective for Processing, when referencing processing of Medicines Dispense in Primary Care NHS BSA data to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction.

	In addition, IGARD remained concerned that there may be widespread use of the NHS BSA dataset despite the narrow scope of the relevant Direction. IGARD noted the statement in section 5(b) (Processing Activities) that the application would permit *"reidentification for direct care"* and asked that this either deemed not relevant and removed; or, that a justification was added to section 5(b), of how this was necessary if there were incidental findings from carrying out commissioning. IGARD queried the minimal yielded benefits outlined in section 5(d) (Benefits) (iii) (Yielded Benefits), and asked that a satisfactory update was provided of the yielded benefits to date, and to ensure they complied with the NHS Digital's DARS Standard for Expected Measurable Benefits; or that section 5(d) (iii) was updated with a clear explanation as to why there are currently no yielded benefits. IGARD noted the reference in section 5(d) to *"Using value as the redesign principle"* when referring to the commissioning benefits and asked that this was removed as it was unclear. IGARD noted the amendment to add linkage to Social Prescribing Data to be used for Commissioning purposes, and queried how this data would be handled, including the free text; and asked for transparency, that section 5(a) (Objective for Processing) was updated with written confirmation. IGARD noted that with reference to "*reidentification for direct care"* in section 5(b), that they understood this would be exceptionally rare. If it is not rare thought needs to be given as to whether it should be a specific purpose in section 5 (Purpose / Methods / Outputs). IGARD advised that NHS Digital should be assured that Amazon Web Services (AWS) have no ability, to process the data, outside of England and Wales, as per section 2(c) (Territory of Use); or that the territory of use would need to be updated to reflect the factual scenario. **Outcome:** recommendation to approve subject to the following conditions: 1. To update section 5(c) to remove references to the application permitting *"reidentification for direct care"* as not relevant OR add justification of how this is necessary if there are incidental findings from carrying out commissioning. 2. In respect of the yielded benefits: a) To provide a satisfactory update to the yielded benefits in section 5(d) (iii) to ensure they comply with NHS Digital's DARS Standard for Expected Measurable Benefits; or, b) To update section 5(d) (iii) with a clear explanation as to why there are currently no yielded benefits. 3. To provide written confirmation within section 5(a) as to how the Social Prescribing Data will be handled, including the free text field. The following amendments were requested: 1. In line with NHS Digital's DARS Standard for Objective for Processing when referencing processing of Medicines Dispense in Primary Care NHS BSA data to ensure a clear narrative is provided linking the purposes and processing to the relevant Direction. 2. To amend section 5(d) to remove reference to *"Using value as the redesign principle"*. The following advice was given: 1. IGARD noted that with reference to "*reidentification for direct care"*, that they understood this would be exceptionally rare. If it is not rare thought needs to be given as to whether it should be a specific purpose in section 5.

	2. NHS Digital should be assured that AWS have no ability, to process the data, outside of England and Wales, as per section 2(c) or the territory of use needs to be updated. **Significant Risk Area:** 1. IGARD remained concerned that there may be widespread use of the NHS BSA dataset that goes beyond the narrow scope of the relevant Direction. It was agreed the condition would be approved out of committee (OOC) by IGARD members
3	<u>Returning Applications</u> 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 GP data for planning & research discussion and IGARD / GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) Workshop at today's meeting, IGARD were unable to review any applications as part of their oversight and assurance role.
4	<u>COVID-19 update</u> 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. IGARD noted that due to IGARD member availability, and as agreed between IGARD and NHS Digital, the COVID-19 response meeting on Tuesday 12th July 2021 was cancelled.
5 **5.1**	<u>AOB:</u> <u>NIC-454217-D9J5X Lincolnshire CCG & County Council (Presenter: Dan Goodwin)</u> IGARD noted that this application was recommended for approval on the 24th June with amendments. NHS Digital advised that two of the amendments could not be met by the applicant, which are as follows: 1. To amend the application throughout to ensure that the date range for the datasets requested is **only** from 2016 onwards at the earliest. 2. To update section 5(c) to remove references to the application permitting *"reidentification for direct care"*. NHS Digital attended the meeting, to discuss proposed statements to include within the application, in respect of the two outstanding points. IGARD noted the information provided in advance of the meeting to support this item, however advised that a more detailed discussion would be required at a future IGARD meeting, not just in respect of this application, but as a wider CCG issue. NHS Digital noted the feedback from IGARD and agreed to provide additional information to support a future discussion.

5.2	Primary Care Network access to data for their patients (Presenter: Duncan Easton) Following discussions with NHS Digital's Privacy, Transparency and Ethics (PTE), the Data Access Request Service discussed with IGARD, as to whether access to data for patients in the Primary Care Network, can be achieved via sub-licencing. IGARD noted the verbal update from DARS, but suggested that this complex discussion item be brought back to a future IGARD as an agenda item alongside any supporting documentation, such as a briefing note and PTE's advice.
5.3	NIC-480562-G9R5X-v0.2 University of Oxford / AstraZeneca UK Ltd The purpose of the application is to permit the University of Oxford and AstraZeneca to access data which is held by University of Oxford under a different active Data Sharing Agreement (DSA), for a different purpose, to allow them to use the data to start preparation ahead of the data production delivery of the Vaccination data. This is to support work on vaccine efficacy and side effects. IGARD noted that on the 9th July 2021, NHS Digital had advised in writing (via the IGARD Secretariat) that the above DSA, had been progressed for a sort-term (3-month) agreement, via the SIRO Precedent, due to the urgency of the date requested and internal pressures within NHS Digital. IGARD noted and thanked NHS Digital for the written update. 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.
6	IGARD / GPES Data for Pandemic Planning and Research – Profession Advisory Group (PAG) Workshop Following conclusion of the IGARD meeting, IGARD and PAG held a workshop, following on from the last one held on the 17th June 2021, to discuss the draft PAG Standard. The PAG Chair and IGARD Chair thanked members for their time.

Appendix A

Independent Group Advising on Releases of Data (IGARD): Out of committee report 02/07/21

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)
NIC-448252-L2R6Q-v1.2	NHS England (Quarry House)	24/06/21	1. To provide an appropriately detailed justification in section 5 for the use of the GDPPR data requested that aligns with both the service evaluation scope of the application and the narrowly permitted use of the GDPPR data collection .	IGARD members	Quorum of IGARD members	*N/A*
NIC-338864-B3Z3J-v0.12	Barts & the London School of Medicine & Dentistry		1. NHS Digital to provide written confirmation that the use of the NHS Digital datasets that have geographical restrictions (as per the NHS Digital public-facing UK GDPR information on its website) are compatible with worldwide use as permitted by the application.	IGARD members	Quorum of IGARD members	*IGARD advised that all relevant transparency notices should be updated promptly.* *IGARD suggested updating the special conditions (section 6) to make it clear that the territory of use relates to UK and EEA.*

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

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

Liaison Financial Service and Cloud storage:

- None

Optum Health Solutions UK Limited Class Actions:

- NIC-398666-H2S4K-v1.2 – Leicester City CCG, West Leicestershire CCG, East Leicestershire & Rutland CCG, Leicestershire City Council, Rutland County Council

Graphnet Class Actions:

- None

Appendix B

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 9th June 2021

Application & application version number: **DARS-NIC-204903-P1J7Q-v4.3** **Organisation name: Imperial College London** **Profession Advisory Group Agenda item: 3**
PAG are content that the applicant has reviewed the application and has significantly reduced the extent of the GP Data it requires from population level (60 million) to approximately 300,000 patients. The profession would like the applicant to reflect on the importance of maintaining public trust with the use of such sensitive and disclosive data; the Caldicott principles; and the GDPR principles. PAG require the protocols and analysis code and code lists used to be published in the public domain; and the applicant to declare on their website the study and purpose no later than three months from application approval. The applicant has not clearly defined whether they intend to use a USB stick to transfer the GP Data to their secure environment. Under no circumstances can a USB stick be used for the GP Data. PAG require the applicant to explicitly confirm that they will not use a USB stick or other removable devices. PAG require the applicant to explicitly explain how this will be done in section 5 of the application. PAG support the application subject to NHS Digital being satisfied that the data transfer is compliant with security standards.

Attendees	**Role**	**Organisation**
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Peter Short	Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Catherine Day	Senior Case Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital

GPES Data for Pandemic Planning and Research - Profession Advisory Group

Record of feedback: Wednesday, 9th June 2021

Application & application version number: **DARS-NIC-419335-H5P8T-v0.3** **Organisation name: University of Oxford** **Profession Advisory Group Agenda item: 2**
PAG support this application subject to the following conditions: PAG require clarification on why this cannot be done within the NHS Digital TRE. This detail must be included in the application. PAG require the protocols and analysis code and code lists used to be published in the public domain; and the applicant to declare on their website the study and purpose no later than three months from application approval. PAG request the applicant to clarify that the aggregated results will be independently reviewed by at least two output checkers to ensure effective disclosure controls have been applied to the results. If this is currently not in place PAG request a special condition to be added that the applicant move towards this. PAG requires a special condition to be added to the application which states that the GP data will be handled in compliance with the end of COPI policy arrangements. The current requirement is to delete the data.

Attendees	Role	Organisation
Arjun Dhillon	Chair, Caldicott Guardian	NHS Digital
Peter Short	Clinical Lead	NHS Digital
Amir Mehrkar	GP, Clinical Researcher	RCGP
Mark Coley	Deputy IT Policy Lead	BMA
Liz Gaffney	Head of Data Access	NHS Digital
Victoria Byrne-Watts	Senior Case Officer	NHS Digital
Pam Soorma	Secretariat	NHS Digital