Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held via videoconference 5th August 2021

IGARD MEMBERS IN ATTENDANCE:	
Name:	**Position:**
Paul Affleck	Specialist Ethics Member
Maria Clark	Lay Member
Prof. Nicola Fear	Specialist Academic Member
Kirsty Irvine (Chair)	IGARD Chair / Lay Representative
Dr. Maurice Smith	Specialist GP Member (Items: 1 - 2.5)
IGARD MEMBERS NOT IN ATTENDANCE:	
Name:	**Position:**
Maria Clark	Lay Member
Dr. Imran Khan	Specialist GP Member
Dr. Geoff Schrecker	Specialist GP Member / IGARD Deputy Specialist GP Chair
NHS DIGITAL STAFF IN ATTENDANCE:	
Name:	**Team:**
Catherine Day	Data Access Request Service (DARS)
Louise Dunn	Data Access Request Service (DARS)
Frances Hancox	Data Access Request Service (DARS)
Dense Pine (DP)	Data Access Request Service (DARS)
Kimberley Watson	Data Access Request Service (DARS)
Vicki Williams	IGARD Secretariat
Amanda Young	Data Access Request Services (DARS) (Observer items: 2.1 to 2.3)

1	**Declaration of interests:** Nicola Fear noted she was a participant of the Scientific Pandemic Influenza Group on Behaviours (SPI-B) advising the Scientific Advisory Group for Emergencies (SAGE) on COVID-19.

	Maria Clark noted professional links to the University of Sheffield (NIC-324608-Q0G8L), but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest. Maurice Smith noted professional links to AIMES Management Service (NIC-148128-815J1) 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-148128-815J1) 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 29th 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	Department for Health & Social Care (DHSC): Cough in a Box (CIAB) Joint Bioresearch Centre (JBC) (Presenter: Kimberley Watson) NIC-460641-M8X4D **Background**: This was a new application from DHSC and JBC for COVID-19 UK Non-Hospital Antigen Testing Results (Pillar 2) data to support the 'cough in a box' (CIAB) project. The study follows a UK Government Number 10 commission to assess the potential to screen for COVID-19 vocal biomarkers. There are three different sources of participants: the first group are all those who have had a positive or negative COVID-19 test in England who will be contacted by Agile Lighthouse teams who contact patients as part of NHS Test and Trace. Patients will be asked if they wish to take part and directed to the privacy notice and website for further information, where potential participants who agree to participate, submit their voice records via the webform. The data is then linked to the patient test results in the Pillar 2 testing data previously provided by NHS Digital under NIC-406871-Q9G2Q DHSC*. The second group are participants in the REACT-1 study and have agreed to be contacted for further research and will receive an email from Ipsos MORI about the CIAB projects and directed to the privacy notice and website for further information, where the potential participant if they agree to participate, submit their voice records via the webform. This data is then linked to the patient test results in the REACT-1 study, not to NHS Digital data. The third group are participants in the Human Challenge study who, if they agree to be contacted for further research, will be directed to the privacy notice and website for further information, where the potential participant, if they agree to participate, submit their voice records via the webform. This data is then inked to the patient test results in the Human Challenge study, not to NHS digital data. The webforms had been developed by Fujitsu Services Limited and they do not access or process the NHS Digital data. The CIAB project is about developing and assessing the algorithm for the purpose of screening for COVID-19 and once a strong enough algorithm is found an 'app' will be developed, however the development of an 'app' is not within the scope of this application.

	*see COVID-19 action notes dated 27th July 2021 appended to the business as usual (BAU) minutes dated 29th July 2021, COVID-19 action notes dated 26th January 2021 appended to the BAU minutes dated 28th January 2021, and COVID-19 action notes dated 13th October 2020 appended to the BAU minutes dated 15th October 2020. **Discussion:** IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 response meeting on the 27th July 2021. IGARD also noted that aspects of NIC- 406871-Q9G2Q DHSC had been presented via a verbal update to the IGARD – NHS Digital COVID-19 response meeting on the 26th January 2021 and that they were relying in the statement in section 1 (Abstract) of this application that NIC-406871-Q9G2Q data could be used for this application, noting that they had not had sight of that application nor any supporting documentation. IGARD also noted that they were supportive of the NHS Digital DARS simple amendment precedent being utilised to amend NIC-406871-Q9G2Q, if it was not clear that data under that application could be used for the processing outlined in this application, and notwithstanding comments previously made and the significant risk area raised, save for this exception. IGARD noted that the Research Ethics Committee (REC) were told in supporting document 3.1, the Integrated Research Application System (IRAS) form, that "*Participants recruited in this way would be contacted on the basis that they had provided explicit consent to be contacted about further research as part of their routine NHS T&T engagement*". IGARD suggested that REC be advised that contrary to the documentation previously provided, which had indicated express consent to be contacted was given by all relevant subjects, that in fact a percentage (the applicant to provide an indicative percentage) of the contacts had **not** provided express consent and so The Health Service Control of Patient Information (COPI) Regulations 2002 were being relied on to contact them in this case. Any advice from REC should be followed by the applicant and a copy provided to NHS Digital, alongside any other documentation from REC, in order to be uploaded to NHS Digital's customer relationship management (CRM) system for future reference. IGARD noted that if COPI was being relied upon for any aspect, that confirmation should be provided in sections 1 and 5 (Purpose / Methods / Outputs) that the Data Processor, SITEL Limited, processing confidential patient information under Regulation 7(2) COPI, must be a health professional or person who in the circumstance owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional. IGARD also noted that should COPI be relied on, that section 3(c) (Patient Objections) should be updated to reflect that the National Data Opt-outs (NDO) were not being applied due to COPI being the legal basis for the flow of data. IGARD suggested that if COPI was **not** being relied on, that confirmation be provided in sections 1 and 5 that sufficient cohort numbers could be gathered from the reliance on express consent via a text message to be contacted and as notified to the REC. IGARD queried if the applicant was contacting all citizens, not just those that followed a link to indicate they wanted to be contacted about research. NHS Digital verbally confirmed this was the case. IGARD noted the verbal update from NHS Digital, however raised an ethical concern with regard to the approach taken by the applicant, which was to give citizens the option to expressly opt in to being contacted about further research, but then to contact them regardless of whether they choose to opt in. IGARD noted the exclusion criteria's outlined in section 5 such as groups based on age, ability to speak English and access to digital technology, and in line with NHS Digital's DARS

	Standard for Data minimisation, and noting this was a 10 Downing Street commissioned national study, asked for further clarification in section 5 as to how the exclusion of these wider societal groups would not bias the study, how any potential bias would be acknowledged and addressed, or to provide a clear explanation as to why these groups were being excluded from the study. IGARD noted the potential risk of bias in the ultimate development of an algorithm where exclusions of society applied, and as cited in the application. IGARD also noted that a significant unrepresented sample of the population may be excluded such as those with symptomatic symptoms who did not undertake a test or those who did not take part due to the financial and social impact of the current self-isolation regime. IGARD noted that patient and public involvement (PPI) did not appear to be well developed, and suggested more urgent attention was given to PPI, and the application be updated as soon as possible, and in line with the HRA guidance on Public Involvement. In line with the NHS Digital DARS Stand for Expected Measurable Benefits, IGARD suggested that the benefits outlined in section 5(d) (Benefits) were not overstated, and that the potential limitations on outputs were acknowledged such as the wider behavioural factors influencing whether members of the public undertake the test due to the financial and social impact of the current self-isolation regime. IGARD suggested that a special condition be inserted in section 6 (Special Conditions) that expressly stated that the World Health Organisation (WHO) could only receive aggregated data with small numbers suppressed. IGARD noted reference in section 5(b) (Processing Activities) to "*Test results – only negative results*". NHS Digital confirmed verbally that positive test results would be included and so IGARD suggested this was corrected. IGARD advised that NHS Digital should be assured that Amazon Web Services (AWS) do not 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. 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 novel use of the data, the complexity of the application and that NIC-406871-Q9G2Q underpinning this application has not had an independent review. **Outcome:** recommendation to approve subject to the following conditions 1. To provide confirmation in sections 1 and 5 that sufficient cohort members can be gathered from the reliance on express consent via a text message to be contacted (and as notified to REC) and that COPI is **not** being relied on; OR 2. If COPI is being relied upon for any aspect of contacting the prospective cohort: a. to provide confirmation in sections 1 and 5 that SITEL Ltd, which is processing confidential patient information, complies with the requirements of Regulation 7(2) COPI, and b. In respect of the REC approval: i. To contact the REC and advise them that contrary to the documents previously provided, which indicated that express consent to be contacted was given by all relevant subjects, to advise that a number (indicative percentage) of the contacts have **not** provided express consent and so COPI is being relied on to contact them, and

ii. To follow any advice given by the REC and upload a copy of any amendment to REC's approval or any other relevant correspondence to NHS Digital's CRM.

The following amendments were requested:

1. To insert a special condition in section 6 that WHO can only receive aggregated data with small numbers supressed.
2. In respect of the exclusion criteria cited in section 5:
   a. To provide an explanation in section 5(a) as to the exclusion of a wide societal groups based on age, ability to speak English and access to digital technology, noting this is a 10, Downing Street commissioned national study.
   b. To provide an explanation in section 5(a) how these exclusions will not bias the 10, Downing Street commissioned national study or how the potential bias will be acknowledged and addressed.
3. If condition 2 applies (above), to amend section 3(c) to reflect that NDO is not applied due to COPI being the legal basis for the flow of data.
4. To update the reference in section 5(b) "*Test results – only negative results*" to also include positive test results.
5. To ensure that the benefits in section 5(d) and in line with the NHS Digital DARS Standard for Expected Measurable Benefits, are not overstated and that the potential limitations on outputs are acknowledged such as the wider behavioural factors influencing whether members of the public undertake the test due to the financial and social impact of the current self-isolation regime.

The following advice was given:

1. Noting reference in the supporting documents to AWS EEA location, NHS Digital should be assured that AWS have no ability to process the data outside of England and Wales, as per section 2(c) Territory of Use.
2. IGARD noted that PPI did not appear to be well developed, and suggested more urgent attention was given and the application updated as soon as possible, and in line with the HRA guidance on Public Involvement.
3. IGARD noted the potential risk of bias in the ultimate development of an algorithm where exclusions of society applied, and as cited in the application. IGARD noted that a significant unrepresented sample of the population may be excluded such as those with symptomatic symptoms who did not undertake a test or those who did not take part due to the financial and social impact of the current self-isolation regime.
4. IGARD raised an ethical concern with regard to the approach taken to give citizens the option to expressly opt in to being contacted about further research, but that the applicant was contacting citizens even if they had not taken that opportunity to indicate their willingness to be contacted for research.
5. In respect of NIC-406871-Q9G2Q DHSC:
   a. IGARD noted that they were relying on the statement in section 1 of this application that NIC-406871-Q9G2Q data could be used for this application, noting that they had not had sight of that application nor any supporting documentation.
   b. IGARD noted they were supportive of the simple amendment precedent being utilised to amend NIC-406871-Q9G2Q, if it was not clear that data under that application could be used for this processing outlined in the application, notwithstanding comments previously made and the significant risk area raised, save for this exception.
6. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the novel use of data, the complexity of the

	application and that NIC-406871-Q9G2Q underpinning this application has not had an independent review. 7. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to novel use of data, the complexity of the application and that NIC-406871-Q9G2Q underpinning this application has not had an independent review. It was agreed the conditions would be approved out of committee (OOC) by IGARD members. **Significant Risk area:** IGARD members noted that NIC-406871-Q9G2Q DHSC had been a verbal update to the COVID-19 response meeting on the 26th January 2021 and that IGARD had noted a **significant area of risk**, namely "*transparency and public perception (there had been no independent review of the application or supporting documentation*)".
2.2	University of Oxford: the HOME Study (Presenter: Louise Dunn) NIC-113964-G3J0C **Background:** This was a new application for Hospital Episode Statistics (HES) to Mental Health Minimum data set (MHMDS) bridge file, Civil Registrations (Deaths) data, Emergency Care Data Sets (ECDS), HES Accident & Emergency (A&E), HES Admitted Patient Care (APC), HES Critical Care, HES Outpatient, and Mental Health Services Data Set (MHSDS) for the HOME study, which is a two arm parallel group randomised controlled trial. The trial aims to determine whether adding Proactive Liaison Psychiatry (PLP) and Proactive Psychological Medicine (PPM) to usual care, reduces the time spend by older patients in acute hospital wards in the month (30 days) after randomisation (primary outcome) when compared to care alone. A number of secondary outcomes including the patients' views of their length of time in hospital, their quality of life, their secondary healthcare use in the year post-randomisation and deaths will also be evaluated. The HOME study will also determine the cost-effectiveness of adding PLP / PPM to usual care. Participants in the HOME Study are adults aged 65 and older, who were admitted non-electively to a general hospital in Oxford, Exeter or Cambridge between May 2018 and March 2020. Recruitment to the HOME Study has closed and informed consent (or consultee agreement in accordance with the Mental Capacity Act 2005, for patients who lacked capacity to consent) was obtained for participation. **Discussion:** IGARD confirmed that they were of the view that the most recent consent materials provided the appropriate gateway and were broadly compatible with the processing outlined in the application. In respect of the privacy notice, IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement, noting that the current transparency materials do not include, for example, the UK GDPR legal basis. In addition, IGARD also suggested that the privacy notice explicitly stated how to contact the study team to withdraw from the study, since this was not clear in the privacy notice. IGARD noted that supporting document 3, the HOME patient information leaflet (PIL), did not mention that the University of Oxford would be undertaking analysis alongside research at the University of York and London School of Hygiene and Tropical Medicine (LSHTM): and suggested that any future communications with the cohort should reflect this additional

	narrative, and that the privacy notice be updated to reflect this analysis being undertaken by the University of Oxford. IGARD queried why National Data Opt-outs (NDO) would **not** be upheld for those individuals where consultee advice was being relied upon; and noting this was an open query with NHS Digital asked that written confirmation was provided from NHS Digital, that **not** upholding the NDO was in accordance with NHS Digital's NDO policy. IGARD did note the good practice statement in supporting document 4.2, the HOME study consultee verbal agreement form, "*the consultee confirmed, in their opinion, the patient would have no objection to taking part in the study and they were not aware of any advance statements that would prevent them from taking part.*" IGARD queried if there had been any public and patient involvement (PPI) on the project to date, noting that this was not clear in the application or any of the supporting documentation provided; and asked that section 5 (Purpose / Methods / Outputs) was updated with confirmation of any PPI activity the applicant had undertaken or was to undertake, such as the composition of the panel, what they had done so far and what their future intentions were and in line with the HRA guidance on Public Involvement. IGARD noted that the study protocol and patient information leaflets had been written prior to the global pandemic but wondered if the applicant had thought about the marked variations between individual facility visiting policies and how these could impact on the study, both during and post the global pandemic. IGARD suggested that section 5(c) (Specific Outputs Expected) be updated with any further narrative, noting that during the height of the pandemic no family support or care givers were allowed in to hospital with the patient and cited the article "*In this time of COVID-19 there should be more, not less caregiver partnership*". IGARD noted that in section 1(b) (Data Controllers) that the University of Oxford were listed as a "*joint*" Data Controller and suggested this was updated to correctly reflect that they were the "*sole*" Data Controller. IGARD noted that the study protocol, which had been provided as a supporting document, gave a helpful narrative to the specific psychiatric conditions targets including psychiatric illnesses such a delirium, dementia and depression, as well as psychological issues such as minor cognitive impairment or anxiety that may slow a patient's discharge from hospital and suggested that this detail be included, instead of the catch all phrase of "*psychiatric problems*", noting this was NHS Digital's public data release register. 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…"* or *"it is hoped …".* In addition, IGARD suggested removing the word "*important*" from the sentence in section 5(d) "*dissemination of **important** results*", since all results are important. **Outcome:** recommendation to approve The following amendments were requested: 1. To update section 1(b) to note that the University of Oxford is a 'sole' Data Controller, not 'joint' Data Controller. 2. NHS Digital to confirm in section 1 that the non-application of NDOs for data flow in respect of cohort members present via their consultee's advice is consistent with NHS Digital's NDO policy.

	3. To update section 5(c) with details of any PPI such as the composition of the panel, what they had done so far, and what their future intentions were, and in line with the HRA guidance on Public Involvement. 4. To update section 5(c) with how any marked variations between individual facility visiting policies could impact the study, during and post pandemic. 5. To include helpful narrative from the study protocol in section 5(a) to list the relevant specific psychiatric conditions, rather than using a catch-all phrase. 6. To remove reference to "*important*" in section 5(d) from the sentence "*dissemination of **important** results*" since all results are important. 7. To update section 5(c) and 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. In respect of the privacy notice, a. IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement, noting that the current transparency materials did not include, for example, the GDPR legal basis. b. IGARD suggested that the privacy notice explicitly state how to contact the study team to withdraw from the study. c. Noting that supporting document 3, HOME PIL, does not mention that the University of Oxford will be undertaking analysis, IGARD suggested that any future communications with the cohort should reflect this additional narrative and that the privacy notice be updated to reflect this analysis being undertaken by the University of Oxford.
2.3	University of Sheffield: Pre-hospital early warning scores for sepsis (Presenter: Louise Dunn) NIC-324608-Q0G8L **Background:** This was a new application for Civil Registration (Deaths) Data secondary care cut, Hospital Episode Statistics (HES) Civil Registrations (Deaths) Data bridge, HES Accident & Emergency (A&E), HES Admitted Patient Care (APC), and HES Critical Care. The data requested will be limited to a cohort of patients, estimated to be 92,000, conveyed by two participating Ambulance Trusts: Yorkshire and West Midlands for the period 1st January 2019 to 31st December 2019 for anyone aged 18 or over, excluding those attending A&E for trauma, pregnancy or mental health related conditions as it is felt their attendance would be for other reasons then sepsis. The School of Health & Research (ScHARR) at the University of Sheffield are running a research study to address the National Institute for Health and Care Excellence (NICE) research recommendation "can early warning scores be used to improve the detection of sepsis and facilitate prompt and appropriate clinical response in pre-hospital settings and in emergency departments?". The specific research question to be addressed is: "what are the accuracy, impact and cost-effectiveness of pre-hospital early warning scores for adults suspected of sepsis?" Sepsis is a life-threatening organ dysfunction due to dysregulated host response to infection and early recognition and treatment of sepsis is essential to reducing mortality.

	The study is relying on s251 of the NHS Act 2006 for the flow of data into NHS Digital. **Discussion:** IGARD welcome the application and noted this was an important study. 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 in section 5(a) (Objective for Processing) the statement "*Ambulance services are removing patients who meet the study exclusion criteria, i.e. under 18s, patient with injury, mental health problems, cardiac arrest, and data transfers to specialist services e.g. maternity, cardiac or stroke services…*" and that the data minimisation table in section 3(b) (Additional Data Access Requested) noted that "…*[the] two ambulance trusts will exclude any patients to an emergency department due to trauma, pregnancy or mental health related conditions as it is felt these patients are highly unlikely to be suitable to creating a sepsis reference standard, as their reason for attending hospital is more likely to be due to being other reasons than sepsis…*" However, and in line with NHS Digital's DARS Standard for Data minimisation, IGARD members noted that symptoms such as delirium can present as a mental health condition when in fact they are sepsis symptoms, and that a justification should be provided in sections 3(b) and 5(a) for the exclusion of patients coded with mental health conditions. In addition, and noting that a significant number of the population under 18 were affected by sepsis, asked that a justification be provided in sections 3(b) and 5(a) for the exclusion of those aged under 18, or to confirm if this group have been covered by another study and in which case a brief outline of this study should be included in section 5(a). Finally, noting that pregnant women are usually excluded from research, IGARD asked that a justification be provided in section 3(b) and 5(a) for the exclusion of pregnant women, since this was not an invasive procedure and pregnant women were known to get more infections during pregnancy. IGARD noted that they would be supportive of the applicant receiving data for those that had been excluded due to data minimisation: data for those aged under 18 years, those that were pregnant and those with mental health conditions as an amendment via the NHS Digital Simple Amendment precedent, and without coming back to IGARD for an approval, providing the relevant justifications were included in section 5 (Purpose / Methods / Outputs), as per usual process and that this was covered by REC approval. IGARD noted the "*Think 111 first*" campaign being run by NHS England and NHS Improvement and suggested that section 5(c) (Specific Outputs Expected) be updated to give consideration of the impact of 111 call handling, plus primary care as another key pre-hospital setting where the study's outputs could be relevant and have impact. IGARD noted that supporting document 3.0, the Health Research Authority (HRA) condition of support letter dated 7 October 2019, with regard to patient and public involvement and engagement (PPIE), that the applicant was in the process of establishing a project-specific patient and public involvement group and that "…*three patients had already been identified…*" with a plan to recruit more. IGARD asked that section 5 be updated throughout to reflect the involvement of PPIE alongside any other communications which had been prepared or were being prepared for dissemination. IGARD queried the processing and storage locations noted in section 2 (Locations), noting the addresses appeared to be institutional ones as opposed to exact processing and storage locations; and asked that NHS Digital confirmed that the description of the processing locations provided sufficient granular detail for NHS Digital audit purposes.

	IGARD noted that section 3(b) (Additional Data Sets Requested) incorrectly listed Civil Registration (Deaths) data as "*pseudonymised*" and suggested that this was updated to correctly state this as being "*identifying*". IGARD noted a number of acronyms in section 5(b) (Processing Activities) and in line with the NHS Digital DARS Standard for Processing Activities asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, and technical terms were clearly defined with a supportive explanation in a language suitable for a lay audience, or removed, for example, "*ceiling of care*" and "*DNRA*". IGARD suggested that section 5(c) 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…"* or *"it is hoped …".* *I*GARD noted in section 5(d) that *"…the benefits from the study…can contribute to practice and/or debate on the pre-hospitalisation early detection of sepsis, appropriate targeting of resources for sepsis and the cost effectiveness of using early warning scores for sepsis…"*, however IGARD noted that a key benefit to the patients and public was to actually reduce mortality and morbidity in patients and that this should be expressly noted. IGARD queried reference to *"…gender…."* data being requested and asked that the datasets requested in the application aligned with the specific NHS Digital data that can flow, for example 'sex' vs 'gender'. **Outcome:** recommendation to approve subject to the following condition. 1. In respect of the data minimisation and in line with NHS Digital's DARS standard for data minimisation: a. To provide a justification in sections 3 and 5 for the exclusion of patients coded with mental health diagnoses, since symptoms such as delirium can present as mental health conditions when in fact they are sepsis symptoms; b. To provide a justification in sections 3 and 5 for the exclusion of those aged under 18 years, since they are a significant population affected by sepsis to exclude, or to confirm if they are they covered under another study, in which case to outline briefly in section 5; c. To provide a justification in sections 3 and 5 for the exclusion of pregnant women, since this is not an invasive procedure and this cohort are regularly excluded from research. d. In all cases to ensure that if any or all these three groups are to be included, that this aligns with the HRA CAG and REC approvals in place. The following amendments were requested: 1. NHS Digital to confirm that the description of the processing locations provides sufficient granular detail for NHS Digital audit purposes. 2. To update section 3(b) to be clear that Civil Registration (Deaths) data is "*identifying*" not "*pseudonymised*" 3. In respect of section 5(b) and in line with NHS Digital's DARS standard for processing activities: a. To amend section 5(b) to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example "*DNRA*" and "*ceiling of care*".

	b. To ensure that the datasets requested align with the specific NHS Digital data that can flow, for example refer to "sex" not "gender", if "sex" is what is captured in the dataset. 4. To update section 5(c) to give consideration of the impact of 111 call handling and primary care as another key pre-hospital setting where these outputs could be relevant and have impact. 5. To update section 5(c) and section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". 6. To update section 5(d) to expressly note that a benefit of the outputs is to reduce mortality and morbidity. 7. Noting the reference in the 2019 HRA CAG support, to update the application throughout to reflect the involvement of the PPI group along with any communications being prepared for dissemination. The following advice was given 1. IGARD advised that they would be supportive of the applicant receiving data for those currently excluded: data for those aged under 18, those that were pregnant and those with mental health conditions, as an amendment in the future and without coming back for IGARD approval. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
2.4	<u>University of Oxford: MR360 – Early Breast Cancer Trialists' Collaborative Group (Presenter: Denise Pine) NIC-148204-7B1XT</u> **Background:** This was an extension request to a data sharing agreement (DSA) that expired on the 1st November 2020, and an amendment to update section 5 extensively throughout to meet the current NHS Digital DARS Standards. The data access already given was for Medical Research Information Service (MRIS) – Cause of Death Report, MRIS – Cohort Event Notification Report, MRIS – Flagging Current Status Report, MRIS – Members and Posting Report and it was noted that no new data would be disseminated under this DSA. The study is for women who have been diagnosed with operable breast cancer (or breast cancer which might become operable through the use of neo-adjuvant therapy) and enrolled in one of seven randomised trials comparing treatments for breast cancer, with recurrence or death as a principal outcome. The original cohort consisted of 9,029 individuals, of which 1,385 are still alive. The Early Breast Cancer Trialists' Collaborative Group (EBCTCG) was created in 1985 and its membership share their trial data for the purpose of the meta-analysis that assesses the benefits and risks of treatments for early breast cancer. NHS Digital advised IGARD that this application and relevant supporting documentation had never had an independent review. The study is relying on s251 of the NHS Act 2006 for the flow of data into NHS Digital from 3rd December 2020 for the holding and processing of confidential patient information collected in the previous seven trials. **Discussion:** IGARD welcomed the application and noted the importance of the study. 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 Health Research Authority Confidentiality Advisory Group (HRA

	CAG) were unable to give retrospective support. The s251 support only extends to 1,385 individuals from seven trials from 3rd December 2020. IGARD noted the verbal update from NHS Digital in relation to the issues uncovered in relation to the legal gateway prior to 3rd December 2020 and suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / Data Sharing Agreement (DSA) in order to maintain public trust and confidence in the sharing of health data and in light of the lack of a legal gateway for a significant number of years. IGARD noted that section 6 (Special Conditions) that "…*the data recipient must ensure that all data is securely and permanently destroyed or erased*…" and suggested that this statement should be updated to be clear that only the "*identifiers"* of the cohort who were not covered by the s251 support would need to be securely destroyed, not "*all data*" relating to all the cohort members. IGARD noted the verbal update from NHS Digital that this application had not had an independent review by IGARD nor its predecessor, the Data Access Advisory Group (DAAG), and queried why when discovered as such, it had not been brought for an independent review. IGARD suggested that section 1 (Abstract) be updated with a clear narrative, to support any future review or audit, explaining why the application had never been identified for an independent review and also suggested removing reference to "*the following simple amendments have been made*" since the application had been extensively updated over the years. IGARD noted that this study commenced in 1985 and were surprised at the lack of patient and public involvement (PPI) and engagement over the years. Given the study's importance, that it commenced in 1985, the history of the application and previous HRA CAG advice with regard to PPI, IGARD noted that on return at extension, renewal or amendment they would expect to see significant PPI engagement having taken place and plans for ongoing PPI. IGARD noted in section 3(a) (Data Access Already Given) reference to "*the original request was limited to a cohort of 9,029 individuals… s251 permissions currently allow the University of Oxford to retain data relating to the remaining 1,385 cohort members*" and suggested this section be updated and in line with NHS Digital's DARS Standard for Data Minimisation to be clear that the data will **only** be linked to the sub-cohort (1,385) for which there was continued s251 support. IGARD members suggested that references in sections 5(a) (Objective for Processing) and 5(b) (Processing Activities) to "…*retain all data received under previous iterations of this agreement… subject to their being an appropriate legal basis in place*" should be removed since this section forms NHS Digital's public data release register and they were not relevant for this DSA. In addition the paragraph in section 5(b) (Processing Activities) which starts "*The University of Oxford wish to retain all data… for these participants by the end of 2030*" should be removed, since this information has already been noted earlier in section 5 (Purpose / Methods / Outputs). IGARD noted reference in section 5(b) to "*Members of EBCTCG who are not substantive employees of the University will not have access to identifiable data unless honorary contracts are in place, or the data has been aggregated with small numbers suppressed*". IGARD members suggested a special condition be inserted in section 6 that the applicant will only enter into honorary contracts for the sharing or access of data under this DSA if that form of

	honorary contract has been approved by NHS Digital to ensure NHS Digital's contractual rights are enforceable. IGARD queried the benefits outlined in section 5(d) (Benefits), and noted that some of the information provided were outputs, and asked that section 5(d) was updated to remove any outputs and edited to only leave examples that reflect the benefits to the Health and Social Care System and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD noted the yielded benefits in section 5(d) (iii) (Yielded Benefits) and, noting these were more aligned with *"outputs"*, asked that further details were provided of the specific yielded benefits accrued to date, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally for example how this study has impacted on mortality and morbidity, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. IGARD suggested that section 5(c) (Specific Outputs Expected) and 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 previous lack of a legal gateway, the complicated history of the application and the application having never had an independent review. **Outcome:** recommendation to approve for one year only. The following amendments were requested 1. To amend section 5 and the special condition in section 6 to be clear that it is the "*identifiers*" of the cohort not covered by s251 which will be securely destroyed, not "*all data*" relating to all cohort members. 2. In respect of section 1 a. To update section 1 to remove reference to this being a "*simple amendment*" b. To include a brief narrative to support future review and audit, explaining why this application, when identified as never having an independent review, was not brought to IGARD (or its predecessor DAAG) and continued to have DSA extensions in light of the legal basis issue. 3. To update the data minimisation table in section 3 and in line with the NHS Digital DARS standard for data minimisation to be clear that the data will only be linked to the sub-cohort for which there is continued s251 support. 4. To remove reference in section 5(a) and 5(b) to "…*retain all data received under previous iterations of this agreement… subject to their being an appropriate legal basis in place*". 5. To remove the paragraph in section 5(b) which starts "*The University of Oxford wish to retain all data… for these participants by the end of 2030*" since it has already been stated elsewhere in the application. 6. To insert a special condition in section 6 that the applicant will only enter into honorary contracts for the sharing or access of data under this DSA if that form of honorary contract has been approved by NHS Digital to ensure NHS Digital's contractual rights are enforceable. 7. In respect of section 5(d) and in line with and in line with NHS Digital's DARS Standard for Expected Measurable Benefits.

	a. To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*". b. To remove any specific outputs from section 5(d) and move to section 5(c). c. To provide further details in section 5(d) of the benefits accrued to date and ensure these are clear as to the benefits to both patients and the health care system more generally, for example, how this study has impacted on mortality and morbidity. The following advice was given: 1. IGARD suggested that NHS Digital may wish to consider auditing this organisation in relation to this application / DSA in order to maintain continued public trust and confidence in sharing of health data and in light of the fact of the lack of legal gateway for a number of years. 2. Given this study commenced in 1985, the importance of the study and in light of the history of the application and previous HRA CAG advice, IGARD noted that on return they would expect to see significant PPI engagement having taken place and plans for ongoing PPI. 3. IGARD advised that they would wish to review this application when it comes up for renewal, extension or amendment, due to the previous lack of a legal gateway, the complicated history of the application, and having never had an independent review. 4. IGARD suggested that this application would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the previous lack of a legal gateway, the complicated history of the application, and having never had an independent review.
2.5	<u>University College London: MR623 – National Mother and Child Cohort (Presenter: Frances Hancox) NIC-148128-815J1</u> **Background:** This was an amendment, extension and renewal application for a Data Sharing Agreement (DSA) which expired on 3rd March 2021. The data access already given was for Medical Research Information Service (MRIS) Cause of Death Report, MRIS Flagging Current Status Report, MRIS Cohort Event Notification Report and MRIS Members and Postings Report. The amendments are **1)** Public Health England (PHE) to become the sole Data Controller, removing University College London (UCL) as a Data Controller and adding them as a Data Processors alongside AIMES Management Services, **2)** the purpose for processing the data has substantially change to that originally given, and has been expanded to involve a large cohort, new datasets and new objectives, and **3)** the addition of Cancer Registration Data and Civil Registration (Deaths) data. The National Mother and Child Cohort was established in 1995 as an extension to the National Surveillance of HIV* in Pregnancy and Childhood (NSHPC) that collects data on pregnancies in women living with HIV and their infants. Since 2018 the NSHPC has been absorbed by the Integrated Screening Outcomes Surveillance Service (ISOSS) based at UCL. Monitoring of the cohort will provide long term follow up of the cancer and death registration of children born to women living with HIV. ISOSS has collected data on approximately 25,000 pregnancies and their outcome since 1995 and aims to identify any significant health inequalities with a view of informing policies to remove barriers to this population's survival. *Human Immunodeficiency Virus NHS Digital noted that this application and relevant supporting documentation had never had an independent review.

	The study is relying on Regulation 3 of the Health Services (Control of Patient Information) Regulations 2002 (COPI). **Discussion:** IGARD noted that the application was relying on Regulation 3(1)(b) and 3(1)(c) of The Health Service Control of Patient Information (COPI) Regulations 2002 and that supporting document 1.2, PHE approval letter for Regulation 3, had been provided but that it did not specifically note the sub-sections of Regulation 3 in the "*legal basis for processing*", but noted the specific text of the relevant sub sections of Regulation 3 in the section "*classification of Regulation 3 support*", namely Regulation 3(1)(b) "*recognising trends in such diseases and risks*" and Regulation 3(1)(c) "*controlling and preventing the spread of such diseases and risks*". IGARD draws to the applicant's attention the narrow scope of Regulation 3(1)(b) and 3(1)(c) COPI and that it did not provide a legal basis for any activity beyond surveillance of communicable disease and other risks to public health. For example, IGARD referred to the stated aim of: "*identifying health inequalities [that] will allow targeted interventions to be developed*". In addition, IGARD noted that if COPI was being relied upon for any aspect, that confirmation should be provided in sections 1 (Abstract) and 5 (Purpose / Methods / Outputs) that the Data Processor, processing confidential patient information under Regulation 7(2) COPI, must be a health professional or person who in the circumstance owes a duty of confidentiality which is equivalent to that which would arise if that person were health professional. IGARD noted the verbal update from NHS Digital that this application had not had an independent review by IGARD nor its predecessor the Data Access Advisory Group (DAAG) and queried why when discovered as such, it had never been brought for an independent review. IGARD suggested that section 1 be updated with a clear narrative to support a future review and audit explaining why the application had never been identified for an independent review and continued to have Data Sharing Agreement (DSA) extensions. In respect of the privacy notice, IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK General Data Protection Regulation (UK GDPR) compliant, publicly accessible transparency notice was maintained throughout the life of the agreement, noting that the current transparency materials, if they existed, were not easily accessible. IGARD noted that this study commenced in 1995 and were surprised at the lack of patient and public involvement and engagement (PPIE) over the years but that should some PPIE have taken place, that section 5 should be updated with the detail of the engagement undertaken over the last 30 years and any future engagement plans. Given the study's importance, that it commenced in 1995, the history of the application, IGARD noted that on return at extension, renewal or amendment and given the breadth and long running nature of this study (since 1995) that the applicant should give consideration to setting up a patient advisory panel. In addition, section 5 should be updated to be clear that the PPI stakeholders would be involved in all aspects of the study, not just some parts, and in line with the HRA guidance on Public Involvement. IGARD also noted reference to "*activists*" in supporting document 2.1 (protocol) and suggested section 5 was updated to clarify the type of activist, such as "*HIV activist*" or similar who had been involved in any PPI. IGARD noted reference in section 3(b) (Additional Data Access Requested) to the cohort being 25,00 and asked this was updated to correctly reference the cohort size of 25,000.

	IGARD also noted the cohort indicated in section 3(b) and section 5, and queried if the cohort number indicated, referred to just the mothers, the mothers and their children, or just the children, and in all cases the numbers attributable to each group should be updated to sections 3(b) and 5. IGARD also noted reference in section 5(a) (Objective for Processing) to "*primary ethical consideration*" and asked that the applicant expressly acknowledged the ethical consideration given to following individuals for an extended period of time (up to 30 years and continuing) without their knowledge and as outlined in the application and supporting documentation provided. It should also be clear throughout section 5 that the application is focused on the surveillance of children of the mothers or the surveillance of the mothers and their children, since they are distinctly different, and currently the application is not clear. IGARD noted a number of acronyms in section 5(b) (Processing Activities) and in line with the NHS Digital DARS Standard for Processing Activities asked that this public facing section be updated to ensure that all acronyms upon first use were expanded, and technical terms were clearly defined with a supportive explanation in a language suitable for a lay audience, or removed, for example, "*long latency periods*". IGARD noted reference in section 5(c) (Specific Outputs Expected) to "*see protocol section 4.2*" but since this is not publicly available via NHS Digital's public data release register that further detail of this reference be provided as a short overarching paragraph. IGARD noted the yielded benefits in section 5(d) (Benefits) (iii) (Yielded Benefits) and, asked that further details were provided of the specific yielded benefits accrued to date, noting the study had been in place for over 30 years, and asked that it was clear as to the benefits to both the patients and the health and social care system more generally, and in line with NHS Digital's DARS Standard for Expected Measurable Benefits. In addition, IGARD noted that the benefits to patients should be prioritised and that the list of benefits should be re-ordered accordingly. IGARD suggested that section 5(c) (Specific Outputs Expected) and 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, or any subsidiary or related applications, when it comes up for renewal, extension or amendment and that this application, or any subsidiary or related applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of the data, the sensitive data flowing, the complicated history of the application, the application having never had an independent review and the extensive extensions undertaken and the lack of PPI involvement. On renewal, in particular, IGARD would expect to see much more developed transparency, PPI, and an update on consideration given to setting up a participant panel. **Outcome:** recommendation to approve subject to the following conditions 1. In respect of the reliance on Regulation 3(1)(b) and 3(1)(c) COPI: a. To review the proposed processing outlined in section 5 of this application to ensure that it is within the narrow scope of Regulation 3(1)(b) and 3(1)(c), and in line with the PHE Caldicott Advisory Panel support. b. To insert a special condition that all processing undertaken in this application must be within the scope of Regulation 3(1)(b) and 3(1)(c).

2. As COPI is being relied upon, to provide confirmation in sections 1 and 5 that all Data Processors, processing confidential patient information, comply with Regulation 7(2) COPI.

The following amendments were requested:

1. To include a brief narrative in section 1 explaining why this application, when identified as never having an independent review, was not brought to IGARD (or its predecessor DAAG) and continued to have DSA extensions.
2. In respect of the cohort:
   a. To update the cohort size reference in section 3(b) from 25,00 to 25,000.
   b. To clarify in sections 3 and 5 if the cohort indicated refers to just mothers, mothers and their children, or just children and the numbers attributable to each group.
3. To amend section 5 to ensure statistical terms of art and technical terms are either removed or explained in a manner suitable for a lay audience, for example "*long latency periods*".
4. To update section 5a when referencing "*primary ethical consideration*" to expressly acknowledge the ethical consideration given to following individuals for an extended period of time (up to 30 years and continuing) without their knowledge.
5. To remove reference in section 5(c) to "*see protocol section 4.2*" since this is not publicly available via NHS Digital's public data release register and instead provide detail of this reference.
6. To be clear throughout section 5 if the application is focused on the surveillance of children of the mothers or the surveillance of the mothers and their children, since they are distinctly different.
7. In respect of PPI and in line with the HRA guidance on Public Involvement.
   a. To update section 5 to be clear that PPI stakeholders will be involved in all aspects of the study.
   b. That further detail be included in section 5 of the engagement which has been undertaken over the last 30 years, and the future planned engagement.
   c. To clarify what is meant by the term "*activist*" and what cause they are representing, for example are they a "*HIV activist*" or similar.
8. In respect of section 5(d) and in line with and in line with NHS Digital's DARS Standard for Expected Measurable Benefits
   a. To update section 5(d) to use a form of wording such as "*it is expected…"* or *"it is hoped …"*, rather than "*it will…*".
   b. To reorder the list to ensure that benefits to the patients are prioritised.
   c. To provide further details in section 5(d) of the benefits accrued over the past 30 years for example have any decisions been made to stop, continue or change treatment regimens, based on the data processed under this application.

The following advice was given:

1. IGARD wished to draw to the applicant's attention the very narrow scope of Regulation 3(1)(b) and 3(1)(c) COPI and that it did not provide a legal basis for any activity beyond surveillance. For example IGARD referred to the stated aim of: "*identifying health inequalities [that] will allow targeted interventions to be developed*".
2. In respect of the privacy notice and in line with NHS Digital's DARS Standard for Transparency (fair processing), IGARD wished to draw to the applicant's attention, the statement in section 4, that a UK GDPR compliant, publicly accessible transparency notice is maintained throughout the life of the agreement, noting that current transparency materials, if they existed, were not easily accessible.

	3. IGARD suggested that PPI stakeholders should be involved in "all" aspects of the study and in line with the HRA guidance on Public Involvement. 4. Given the breadth of and long running nature of the study, the applicant should give consideration to setting up a patient advisory panel. 5. On renewal, IGARD would expect to see much more developed transparency, PPI, and an update on consideration given to setting up a participant panel. 6. IGARD advised that they would wish to review this application, or any subsidiary or related applications, when it comes up for renewal, extension or amendment, due to the novel use of data, sensitive data flowing, complicated history of the application having never had a previous independent review and the extensive extensions and lack of participant involvement. 7. IGARD suggested that this application, or any subsidiary or related applications, would not be suitable for NHS Digital's Precedent route, including the SIRO Precedent, due to the novel use of data, sensitive data flowing, complicated history of the application having never had a previous independent review and the extensive extensions and lack of participant involvement. **Significant Risk area:** 1. There is a reputation risk to NHS Digital that the applicant maybe processing data that is not within scope of the PHE's Caldicott Guardian support for Regulation 3(1)(b) and 3(1)(c) COPI because the processing does not relate to "*recognising trends in such diseases and risks*" and "*controlling and preventing the spread of such diseases and risks*" of a communicable disease (HIV/AIDS) and instead extends to a longitudinal study of the children exposed to the antiretroviral drug(s). Subsequent to the meeting, the presenter provided the historic CAG record which expressly noted that Regulation 3 COPI could be relied on for **surveillance only** and that any research aspects would need CAG support. It was agreed the condition would be approved out of committee (OOC) by IGARD members.
2.6	Royal Devon & Exeter NHS Foundation Trust: CLARITY IBD – understanding the impact of biological and immunomodulatory therapy on SARS-CoV-" infection and immunity in patients with inflammatory bowel disease (Presenter: Cath Day) NIC-435152-C0H4N **Background:** This was an amendment application to **1)** include COVID-19 vaccination status data and **2)** remove of Public Health England (PHE) as a Data Processor. The aim of the study is to understand the impact of biological and immunomodulatory therapy on SAR-CoV-2 (COVID-19) infection and immunity in patients with inflammatory bowel disease (IBD). The Impact of Biologic Therapy on SARS-CoV-2 Infection and Immunity Study (CLARITY) is to investigate the impact of specialist immunomodulatory drugs and shielding on COVID-19 infection and subsequent immunity following infection or vaccination and the results of the study will inform health policy decisions for patients with IBD, alongside other patients treated on immunosuppressant drugs. The request for the COVID-19 vaccination status data for 7,229 patients who are part of CLARITY IBD and have given informed consent will include the date, first or second dose, and type received and this data will enable a more detailed analysis to be undertaken on SARS-CoV-2 antibody (nucleocapsid and spike) responses and provide a clearer picture of impact of COVID-19 infection and vaccination of patients with IBD on immunosuppressant therapies.

	Discussion: IGARD welcomed the application which had come for advice on the legal basis and consent, and without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted this was an important study IGARD noted that aspects of this application had been previously seen at the IGARD – NHS Digital COVID-19 response meeting on the 23rd February 2021 and that all comments previously raised remained live, including the significant risk area. IGARD suggested that a step plan be put in place and provided some high-level suggestions which are included in the outcome below. Separate to this application, IGARD would welcome an information sharing session with the Royal Devon & Exeter NHS Foundation Trust. **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. IGARD provided some high-level suggestions including, but not limited to: 1. updating the application throughout to reflect all previous comments made by IGARD, 2. assessing whether the consent extends to the data, given the added layer of complexity because the cohort members were given the opportunity to volunteer their information and "opt in", but that the applicant was getting the information regardless of this point. 3. ascertaining who consented on which version of the consent materials and then for each version to ensure there is a legal gateway to undertake the processing. 4. considering if there is any ambiguity in the consent materials. If so, the applicant may wish to confirm with the study participants (more than 3 but less than 7) as to whether they feel their consent encompasses the fact that the researchers would be getting vaccine status from UK Government agencies, and that they would not be surprised by this fact. 5. to clarify the involvement of ICL, as borne out of the facts, who are named in the study protocol and PIS, but not mentioned in the application. **Significant Risk Area (previously noted):** Transparency regarding the pharmaceutical funders of this study (in both the NHS Digital Release Register (the published section 5 of the application) and GDPR-compliant transparency materials. Separate to this application, IGARD would welcome an information sharing session with the Royal Devon & Exeter NHS Foundation Trust.
2.7	University of Bath: the impact of urban development on health and wellbeing (Presenter: Cath Day) NIC-435236-H4X4N **Background:** This was a new application for Civil Registration (Deaths) data – secondary care cut, Emergency Care Data Set (ECDS), Hospital Episode Statistics (HES) Civil Registration (Deaths) bridge, HES Accident and Emergency (A&E), and HES Admitted Patient Care (APC) in order to analysis the impact of urban development on on-communicable diseases (NCDs) and generate evidence on the economic valuation of health impacts. This study will contribute to a larger project by implementing the evaluation of urban planning in Bristol and Manchester as well as across the country and will focus on particular risk factors such as pollutions, transport and green spaces and examine their impact on health and wellbeing. The study will also contribute to the economic valuation by determining the benefits

	and the costs of these urban planning interventions taking a wider social perspective and understanding health inequalities. NHS Digital noted in section 3(b) (Additional Data Access Requested)) that the HES Civil Registration (Deaths) bridge did not include the relevant UK General Data Protection Regulation (UK GDPR) legal bases and that this would be updated within the application. **Discussion:** IGARD noted the verbal update from NHS Digital with regard to the inclusion of the UK GDPR legal basis for the HES Civil Registration (Deaths) bridge. IGARD noted that the postcodes which related to the geographical areas where clean air zones had been introduced (not record level data) had been obtained via Freedom of Information Act 2000 (FOI) requests to Bath and North East Somerset Council, Birmingham City Council and Transport for London with an estimated number of postcodes circa 330,500. In respect of the data obtained under the FOI Act from those bodies, IGARD queried if there were any restrictions on the use of the data obtained under the FOI Act and if not, to confirm in section 5 (Purpose / Methods / Outputs). However, if there were restrictions on the use of data, the applicant should ensure that all necessary permissions have been obtained for each FOI request and section 5 updated appropriately. IGARD noted the inclusion of a number of technical phrases and words within section 5(a) (Objective for Processing), for example, *"key leverage points"*; and suggested that this section was updated in line with NHS Digital's DARS Standard for Objective for Processing to be written in a language suitable for a lay reader and technical terms used only where necessary, or further explained upon first use, and for inclusion in NHS Digital's public data release register. IGARD also noted reference in section 5 to "…*disentangle the impact of urban development from other confounders on physical health and wellbeing…*" but noted that not all the necessary data would be available and it seemed to be beyond its current scope and the data being processed, and asked that this sentence be revised appropriately. In respect of the privacy notice, IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement, noting that the current transparency materials did not appear to include the use of NHS Digital data, and suggested that the privacy notice be updated appropriately. IGARD queried how the data would be minimised for particular projects and NHS Digital confirmed that the applicant would look at the impact of the environment on NCDs and have different questions as to which environmental factors affect different dimensions of health, so only the minimum number of variables required would be used. IGARD noted the verbal update from NHS Digital and in line with the NHS Digital DARS Data Minimisation standard, asked that section 3 (Datasets Held / Requested) and 5 were clear that data minimisation also encompassed geographical restrictions, as well as data field restrictions. IGARD queried if work package two had any public and patient involvement (PPI) to date and were advised by NHS Digital that none had taken placed due to the global pandemic and its limitations with respect to PPI. IGARD noted the verbal response and in line with the HRA guidance on Public Involvement, suggested that the public was involved at the earliest opportunity. **Outcome:** recommendation to approve subject to the following condition 1. In respect of the data obtained under the FOI Act from various bodies:

	a. To confirm in section 5 that there is no restriction on use of data obtained under the FOI Act, OR b. That all necessary permissions, as may be required to use the data, have been obtained under each FOI request. The following amendments were requested: 1. In line with the NHS Digital DARS Data Minimisation standard, to be clear that data minimisation also encompasses geographical restrictions, as well as data field restrictions. 2. As section 5 forms NHS Digital's public data release register, to amend section 5(a) in line with NHS Digital's DARS standard for Objective for Processing in a language suitable for a lay reader to clarify what is meant by the term "*key leverage points*". 3. Noting that not all necessary data will be available to "*disentangle the impact of urban development from other confounders on physical health and wellbeing*" to amend the application appropriately, since it seems beyond its current scope and data being processed. 4. To update section 3(b) to include the UK GDPR legal basis for the HES Civil Registration (Deaths) bridge. The following advice was given: 1. IGARD wished to draw the applicant's attention to the statement in section 4 (Privacy Notice) of the application and in line with NHS Digital's DARS Standard for Transparency (fair processing), that a UK GDPR compliant, publicly accessible transparency notice was maintained throughout the life of the agreement, noting that the current transparency materials did not appear to include the use of NHS Digital data and suggested that the privacy notice be updated appropriately. 2. IGARD suggested that the public was involved at the earliest opportunity and in line with the HRA guidance on Public Involvement. It was agreed the condition would be approved out of committee (OOC) by the IGARD Chair
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 volume and complexity of applications 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 at the request of DARS, and as agreed between IGARD and NHS Digital, the COVID-19 response meeting on Tuesday, 3rd August 2021 was cancelled.

5	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 30/07/21

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-456778-J0G3H-v0.2 -	GRAIL Bio UK Ltd	24/06/2021	To provide a satisfactory explanation of the involvement of the University of Leeds and UCL and why they are not noted as Data Controllers or Data Processors.	IGARD members	Quorum of IGARD members	IGARD comment: "*It is very encouraging to know that Grail and KCL are carrying out a DPIA given the importance of this work and scope of the processing activities*."

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-422207-N1D1V-v1.2 NHS Shropshire, Telford and Wrekin CCG - Comm, IV, RS

Graphnet Class Actions:

- None