Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 5th March 2020

In attendance (IGARD Members): Anomika Bedi, Maria Clark, Nicola Fear, Kirsty Irvine (Chair), Geoffrey Schrecker.

In attendance (NHS Digital): Stuart Blake, Victoria Byrne-Watts, Garry Coleman, Dave Cronin, Louise Dunn, Karen Myers, Vicki Williams.

Not in attendance (IGARD Members): Sarah Baalham, Maurice Smith.

Observers (IGARD Members): Paul Affleck, Imran Khan.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 27th February 2020 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 B).
2	**Data Applications**
2.1	University of Birmingham: National Register of RF Workers - MR1123 (Presenter: Stuart Blake) NIC-148425-R38F2 **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) data and an amendment to section 5(a) of the application outlining the purpose. The purpose is for a study to obtain new information on the topic of long-term health effects of occupational radiofrequency exposure, by examining data from the ongoing National Register of Radiofrequency Workers which was established by the Health and Safety Executive. **Discussion:** IGARD welcomed the application which came for advice on the consent and patient information materials, without prejudice to any additional issues that may arise when the application is fully reviewed. IGARD noted the information helpfully provided in supporting document 5, NHS Digital's 'Consent and Patient Information Review', and specifically in relation to the areas of concern outlined by NHS Digital. IGARD discussed and agreed with all of the concerns raised by NHS Digital, with the exception of the annual prize draw that was referred to, which in the circumstances, IGARD did not think raised any issues. IGARD noted that the application was not explicitly clear on which participants were recruited on which consent and patient information materials; and asked that the application was updated to provide further information of which forms were in place at the start of the recruitment and which forms were used in subsequent recruitments including the number of participants against each form. In addition, IGARD suggested that for those participants that have yet to be recruited to the study, that the concerns raised by NHS Digital (in supporting document 5), with the exception of the prize draw, should be addressed in the patient-facing materials, which should also include the Frequently Asked Questions (FAQs) published on the applicant's website.

	IGARD suggested that for the participants that have already been recruited to the study, the applicant may wish to apply to NHS Digital for a List Clean in order to provide an updated Privacy Notice to the participants that addressed the identified areas of concern; including (but not limited to) a more detailed description of the processing taking place, any data linkage, the involvement of NHS Digital and the ability for participants to opt-out. IGARD requested that in advance of the application returning to IGARD for a full review, that NHS Digital may wish to share a draft copy of the applicant's revised Privacy Notice. IGARD queried the information provided within section 1 (Abstract) and section 1(b) (Data Controller) that stated the University of Birmingham was the **sole** Data Controller and asked that a narrative was provided that clearly explained the reason for this. In light of the University of Birmingham being considered as the sole Data Controller, IGARD also queried the involvement of the other organisations referred to within the application, for example the Health and Safety Executive, and asked that their involvement, plus that of other relevant organisations, was also addressed, in terms of who was making strategic decisions. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. **Outcome Summary:** IGARD welcomed the application which came for advice on the consent and patient information materials and without prejudice to any additional issues that may arise when the application is fully reviewed. 1. IGARD agreed with all of the concerns raised by NHS Digital, as set out in the supporting analysis document provided. The exception to this was the prize draw which, in the circumstances, IGARD did not think raised any issues. 2. For those already recruited to the study, IGARD suggested the applicant may wish to apply for a List Clean in order to provide an updated Privacy Notice to the participants, addressing things such as (but not limited to) a more detailed description of the processing, linkage, involvement of NHS Digital and the ability to opt-out. 3. For those yet to be recruited to the study, all of NHS Digital's points of concern (with the exception of the prize draw) should be addressed in the patient-facing materials (including the website FAQs). 4. The application should be updated to clarify which participants were recruited on which consent and patient information materials. 5. To provide a narrative which clearly explains why the University of Birmingham is considered the sole Data Controller. 6. To address the involvement of HSE and other organisations listed in terms of who is making the strategic decisions, since the University of Birmingham is listed as the sole Data Controller.
2.2	<u>Imperial College London: COSMOS: Cohort Study of mobile phone use and health (MR1367) (Presenter: Stuart Blake) NIC-370843-R6V8T</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) data; Hospital Episode Statistics (HES), Mental Health Minimum Data Set (MHMDS), Mental Health Services Data Set (MHSDS), Mental Health and Learning Disabilities Data Set (MHLDDS), Civil Registrations data and a pseudonymised HES to MHMDS Bridge file. It was also an amendment to 1) add Karolinska Institutet as a data processor; and 2) add additional HES, mortality and mental health data products. The purpose is for a major international research programme (COSMOS Study) into the possible health effects of long-term use of mobile phones and wireless technologies, and other environmental exposures, in particular addressing limitations of previous studies and gaps in

	the scientific evidence in order to provide clarity in respect of health effects of long-term use of mobile phones. **Discussion:** IGARD welcomed the application and noted that this was an important and valuable study. IGARD also recognised the effort that had been made by the applicant in detailing the expected benefits in section 5(d) (Benefits) of the application. IGARD noted that the applicant's Data Sharing Agreement (DSA) had expired in 2016 and that the applicant had continued to hold the data and asked that, for audit purposes, further historical details were provided outlining what had happened over the last four years of the study in section 1 (Abstract). IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD noted that when this application had previously been reviewed by IGARD's predecessor the Data Access Advisory Group (DAAG) on the 13th August 2015, it was DAAG's view, that they did not think the information provided gave sufficient legal basis for the data to flow out of the UK, unless anonymous. Noting that the participants' consent was silent on international data transfer, IGARD asked that the subsequent (post 2015) patient information notices and leaflets were reviewed to assess whether they provided sufficient notification to align with the level of data flowing and the destination of such data. IGARD queried if the data flowing outside of the UK would be anonymised and asked that further information was provided of what level of data would be flowing outside of the UK. IGARD noted a number of other collaborators listed within the application and queried what the role(s) of these collaborators were and why they were not also considered joint Data Controller(s) since the protocol provided as part of the documents for review indicated collaboration across a number of organisations; and asked that section 5 (Purpose / Methods / Outputs) was updated with further clarification as to why these organisations were not considered joint Data Controllers. IGARD noted that a number of other organisations were listed within the application that were based outside of the UK and asked that confirmation was provided confirming if any of these organisations, in the countries listed, would have access to the data; and that further clarity was provided on their involvement with the study and if they were processing the data under this application. IGARD queried the reference in supporting document 2, the study protocol that stated that the cohort study would have one data analyses centre located in Denmark; and asked that confirmation was provided that the Karolinska Institutet, based in Sweden, would be the **only** processing location for the study. IGARD queried how international data transfer would be addressed post-Brexit and asked that confirmation of this was provided. IGARD also confirmed that a query had also been submitted to NHS Digital's Information Governance (IG) Helpdesk in relation to Brexit and International Transfers, and as per due process were currently awaiting a response. IGARD noted that it was not clearly outlined within the application exactly what processing the Karolinska Institutet were undertaking and asked that section 5(b) (Processing Activities) was updated with further clarity of this, for example why they are involved and what they are doing. IGARD noted the information provided in section 5(b) that stated *"Imperial College London as Data Controller will request deletion of record ID number from the dataset and therefore the data will become anonymised.";* and asked that this was expanded to provide a further explanation as to why re-identification of this data was not possible.

	IGARD noted the references within the application to *"pooled"* data and asked that further information was provided confirming what the pooled data comprises, for example the level of identifiability. IGARD queried the 'ODS Code' referenced in section 1(b) (Data Controller(s)) and 1(c) (Data Processor(s)) for Imperial College London and asked that this was clarified and updated as necessary. IGARD queried the Imperial College London storage locations in section 2(b) (Storage Location(s)) and noted that this differed from information provided in another Imperial College London application; and asked this was clarified and updated as necessary. IGARD queried the inconsistent participation numbers stated in section 1 (Abstract) of the application and supporting document 1, the Policy Research Programme Central Commissioning Facility letter; and asked that these figures were reviewed and amended where necessary. **Outcome Summary:** Recommendation to defer, pending: 1. To provide further details of what has happened during the last four years of the study, noting the applicant's DSA expired in 2016 and the applicant has continued to hold the data. 2. To update section 5 to clarify why the other collaborators listed within the application are not also considered Data Controllers; and to provide further clarification of the roles of the other collaborators. 3. To clarify that the Karolinska Institutet, based in Sweden, will be the only processing location (noting the reference within the protocol to a processing location being in Denmark). 4. To confirm if any of the organisations in the countries listed will have access to the data; and to clarify their involvement. 5. To update section 5(b) to confirm exactly what processing the Karolinska Institutet are undertaking. 6. Noting participants' consent is silent on international data transfer, and the previous DAAG review did not think the information provided gave sufficient legal basis for the data to flow out of the UK, unless anonymous, to review the subsequent (post 2015) patient information notices and leaflets to assess whether they provided sufficient notification to align with the level of data flowing and the destination of such data. 7. To provide confirmation of how international data transfer will be addressed post-Brexit. 8. To provide confirmation of what level of data is flowing outside of the UK. 9. To expand on the statement in section 5(b) that states the research data is "anonymised" and provide an explanation why re-identification of this data is not possible. 10. To advise what the "pooled" data comprises (i.e. level of identifiability). 11. To update sections 1(b) and 1(c) to confirm the ODS code for ICL. 12. To clarify in section 2(b) the storage locations for ICL. 13. To review the inconsistent participation numbers stated in section 1 and SD1; and amend where necessary.
2.3	<u>Imperial College London**:** North West London collaboration: Imperial College Health Partners (Presenter: Stuart Blake) NIC-274351-Y9N6J</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES), Patient Reported Outcome Measures (PROMs), Mental Health Services Data Set (MHSDS), Mental Health Minimum Data Set MHMDS), Civil Registrations, Emergency Care

	Data Set (ECDS), Diagnostic Imaging Dataset (DIDs) and Mental Health and Learning Disabilities Data Set (MHLDDS). This request is to transfer work previously done under a previous Data Sharing Agreement (DSA) (NIC-05934-M7V9K) to this DSA to be done in partnership with The Big Data & Analytical Unit (BDAU) at Imperial College London. This application will be used to support current projects and new projects which cover the following themes: uptake of innovation and national policy guidelines, patient pathway analysis, benchmarking, disease burden analytics, business cases, epidemiological research, health economic research and quality and outcome analysis. **Discussion:** IGARD noted the content of the application and advised NHS Digital that the application would need to be updated to reflect an Academic Health Science Network (AHSN) type application, which should also include AHSN-style supporting documents, including, for example, revised Terms of Reference (ToR). In addition, IGARD also advised that the application should also be updated in line with NHS Digital's published Data Minimisation Standard 3. IGARD queried the various 'Imperial College London' parties referred to within the application, for example 'Imperial College Health Partners'; and asked that the application was updated to clearly delineate the difference parties referenced and to clarify what their roles are. IGARD also asked that consideration was given to any of these parties who are not currently listed as Data Controllers and whether they should be considered as joint Data Controllers. IGARD noted the information provided in section 5(a) (Objective for Processing) that outlined a wide range of research projects that the applicant may be involved with and asked that this was updated to provide details of more specific goals; as well as further information outlining which projects they are wanting to be involved with. In addition, IGARD also asked that further information was provided in section (5a) of how they are evaluating and deciding which research projects will be pursued. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD suggested that application NIC-05934-M7V9K (the current Data Sharing Agreement for this application) was reviewed to ensure it reflected the revised change in purpose. IGARD suggested that in light of the research activities outlined, the applicant may wish to consider seeking ethics approval for the database. IGARD suggested that the applicant may wish to consider if the *"Advisory Group"* referred to may wish to recruit public or patient representatives to form part of this group. **Outcome Summary:** Recommendation to defer, pending: 1. The application should be updated to reflect an AHSN-style of application, including AHSN-style supporting documents, e.g. terms of reference following other AHSN applications. 2. To update the application in line with NHS Digital's published Data Minimisation Standard. 3. To clearly delineate the different 'Imperial College London' parties referred to within the application and what their roles are; and to consider if any of these parties who are not currently listed, should be considered joint Data Controllers. 4. To update section 5(a) to provide details of the specific goals, and further information outlining which projects they are wanting to be involved with, and how they are evaluating and deciding which research projects will be pursued. The following advice was given:

	1. IGARD suggested that application NIC-05934-M7V9K (the current Data Sharing Agreement) was reviewed to ensure it reflects the revised change in purpose. 2. IGARD suggested that in light of the research activities outlined, the applicant may wish to consider seeking ethics approval for the database. 3. IGARD suggested that the "Advisory Group" referred to may wish to recruit public or patient representatives to form part of this.
2.4	<u>Manchester University NHS Foundation Trust: The UHSM Cardiovascular Magnetic Resonance Study (Presenter: Louise Dunn) NIC-324040-N7L9R</u> **Application:** This was a new application for identifiable Hospital Episode Statistics (HES) and Civil Registrations data, for the purpose of a follow-up to a study investigating the diagnostic and prognostic utility of Cardiac Magnetic Resonance (CMR) scanning in a large cohort of unselected patients who are already undergoing CMR scanning for clinical indications. This study is assessing how well CMR is in not only being able to identify heart conditions (diagnosis), but also how specific heart findings impact on people's life expectancy and quality of life. The study requires follow-up information on the health status of the study cohort. **Discussion:** IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD noted the information provided in the study protocol that stated funding would be provided by the Cardiac Magnetic Resonance (CMR) fund; and that this conflicted with the information provided in the application that stated the study was funded by the National Institute for Health Research (NIHR). IGARD asked that confirmation was provided that the funding for the study was provided exclusively by the NIHR, as the application and other supporting documents seemed contradictory. Assuming that this was an NIHR funded study, IGARD queried what the scope of any patient involvement was with the study and asked that further clarity of this was provided in section 5(c) (Specific Outputs Expected). IGARD queried the name of the project stated in supporting document 5, the NIHR funding letter, and noted that this was different from the name of the project outlined within the application; and asked for confirmation that the name of the project within the supporting documents aligned with the project outlined in the application. IGARD noted the outputs outlined in section 5(c), but asked that this was further updated to clearly articulate the outputs that would flow from the establishment of the database. IGARD noted that the table in section 3(b) (Additional Data Access Requested) did not contain the standard text usually provided to reflect that the data would be limited to the cohort size; and asked that the text was updated accordingly. IGARD noted the reference in section 5(b) (Processing Activities) to *"pseudoanonymised"* and asked that this was amended to correctly reference *"pseudonymised"*. IGARD queried the references in section 1 (Abstract) and section 5(a) (Objective for Processing) to the study impacting on people's *"quality of life"* and asked that these references were reviewed. IGARD noted the reference in section 1 that the *"…application is not compatible with the consent"* and asked that this was updated to correctly state that the consent materials **are** compatible. IGARD advised that they would wish to review this application again when it comes up for renewal. **Outcome Summary:** recommendation to approve subject to the following condition:

	1. To provide confirmation that the funding for the study is provided exclusively by the NIHR. The following amendments were requested: 1. Since this is an NIHR funded study, to provide further clarity in section 5(c) of the full scope of any patient involvement. 2. To update section 5(c) to clearly articulate the outputs that will flow from the database that will be established. 3. To provide confirmation that the name of the project within the supporting documents aligns with the project outlined in the application. 4. To update section 3(b) to reflect that the data will be limited to the cohort size. 5. To update section 5(b) to replace the reference to *"*pseudoanonymised*"* with *"pseudonymised"*. 6. To review the reference in section 1 and section 5(a) to *"quality of life"*. 7. To update section 1 to correctly state that the consent materials **are** compatible. The following advice was given: 1. IGARD advised that they would wish to review this application again when it comes up for renewal. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.5	<u>London School of Hygiene and Tropical Medicine: (MR1355) The MANCHESTER and (MR1016) ARTISTIC COHORTS (HPV and Cervical Cancer) (Presenter: Victoria Byrne-Watts) NIC-58603-S6Z1B</u> **Application:** This was a renewal application for identifiable Medical Research Information Service (MRIS) and an amendment to join two cohort studies (The Manchester Cohort Study NIC-58603-S6Z1B and The ARTISTIC Trial Cohort Study NIC-226323-X4L5B) and merge into one Data Sharing Agreement (DSA) in order to streamline processing activities and analysis. The objective for the two cohorts is to study the long-term risk of cervical cancer and cervical pre-cancer following Human Papilloma Virus (HPV) infection. The Manchester Cohort Study participants were recruited between 1987-1993 and The ARTISTIC Trial Cohort Study participants were recruited between 2001-2004. Both studies targeted the same Greater Manchester area with the aims for both to study the same subject: HPV. The questions this research aims to influence are: Is it safe to leave a longer interval between screening tests when a woman has a negative HPV test?; What follow-up tests should be done in women who test positive for HPV? The study can evaluate cytology, genotyping (identifying the strain of HPV) or new testing methods; what age is it safe to stop screening? The application was been previously considered on the 31st October 2019 when IGARD had deferred pending: to insert in section 5(a) a paragraph clearly explaining: a) why a reduction in smear test screening frequency is in the public interest despite the publicity surrounding the perceived benefit in increased smear test screening; b) how a reduction in smear test screening frequency may be of particular benefit to some women who avoid such invasive testing; c) the background to the introduction of HPV screening which was an outcome of earlier studies; d) the further detail contained in the protocol relating to the benefits of the study to secondary outcomes e.g. other gynaecological cancers. To clearly explain why the University of Manchester is not considered a joint Data Controller since a key member of the research team is outlined in The ARTISTIC Trial Cohort Study protocol as being based at that University. In respect of Ethics: a) to either provide updated ethical support for the combined studies due to substantial amendments made, or to otherwise provide written confirmation that the combination of the two studies does not constitute a "substantial amendment" requiring

	updated support; b) in addition, if the ethical support does not need to be refreshed on the basis of "substantial amendment", to provide written confirmation that the ethics support does not need to be refreshed due to the time elapsed since the original REC reviews; c) with regard to either new REC support or if using the "old REC support", that in either case, to confirm that the condition of ethics support has been met with regard to approval for the research to be carried out on NHS sites. In respect of HRA CAG support for The Manchester Cohort Study: a) to provide a copy of the HRA CAG register (via a screen shot) and to upload an updated copy to the CRM holder; b) to provide written clarification when the 20-year period of flagging, referred to in the HRA CAG letter of support, started for The Manchester Cohort Study (such as from the point of recruitment to the study or from the date of HRA CAG support); c) REC support should be in place and unconditional for the HRA CAG support to be valid. In respect of the HRA CAG support for The ARTISTIC Trial Cohort Study: a) to provide a copy of the HRA CAG register (via a screen shot) and to upload an updated copy to the CRM holder; b) REC support should be in place and unconditional for the HRA CAG support to be valid. In respect of Fair Processing: a) the website could be updated with current approach to language such as changing reference from "*management of women with…*" to "*managing conditions*"; b) In respect of The Manchester Cohort Study in particular, the women in that cohort should be given the opportunity to opt out (which is a standard condition of HRA CAG support) and consideration given how to publicise the ongoing study to give effect to this; such communications may be via publicity in GP practices, or women's health clinics in the local hospital in the geographical area the women were recruited. Section 5(c) to be updated, if possible, to reference a more concrete plan for the involvement of the Jo's Cervical Trust and / or the Eve Appeal (both cervical cancer charities) with steps for engagement with the cohort and the wider public (particularly important with regard to the large cohort and the fact that the researchers are relying on s251 support). To update the projected dates of publication and conference presentations within section 5(c) with a more realistic timeframe. To reorder the bullets in section 5(d) under "*The expected impact of the research on the NHS and public include…*", so that the benefits to women come before the projected cost savings. To provide documentary evidence of the approval route through NHS Digital for The ARTISTIC Trial Cohort Study limb (NIC-226323) and any issues that application may have brought up, including Data Controllership. **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made. IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices. IGARD discussed the points previously raised on the applicant's transparency arrangements and it was IGARD's opinion that this issue had not been sufficiently addressed and in line with the Health Research Authority Confidentiality Advisory Group (HRA CAG) conditions of support. IGARD therefore asked that a written transparency plan was provided, that provided details of how the applicant would meet the relevant transparency requirements, in order to fulfil s251 support, the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. This should also include (but not limited to) updating their Privacy Notice; and in light of the fact that the applicant is not in contact with the cohort, engaging with relevant local women's health charities who may be representative of the cohort. The detailed plan should also include a timeframe for engaging with such charities and providing updated transparency information materials and incorporate the view of the women's health charity/ies of how to communicate with the cohort.

	IGARD also suggested that, in addition to any engagement suggested by the relevant local women's health charities, the applicant may also want to re-consider using the information screens within local GP surgeries and women's health clinics in local hospitals. IGARD asked that a special condition was inserted to section 6 (Special Conditions) of the application stating that engagement and communication with the cohort would commence within three months of the Data Sharing Agreement (DSA) being signed. IGARD advised that they would wish to review this application again when it comes up for renewal; and at that time would expect to see an analysis of the transparency plan and what had been done to achieve said transparency plan. **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide a written transparency plan, detailing how the applicant will meet the relevant transparency requirements (in order to fulfil s251 support, GDPR and the DPA 2018), including (but not limited to) updating the Privacy Notice and engaging with relevant local women's health charities who may be representative of the cohort (in light of the fact that the applicant is not in contact with the cohort). The detailed plan will also include a timeframe for engaging with such charities and providing updated transparency information materials and incorporate the view of the women's health charity/ies of how to communicate with the cohort. The following amendment was requested: 1. To insert a special condition in section 6 stating that engagement and communication with the cohort will commence within three months of the DSA being signed. The following advice was given: 1. IGARD suggested that, in addition to any engagement suggested by the relevant local women's health charities, the applicant may also want to re-consider using the information screens within local GP surgeries and women's health clinics in local hospitals. 2. IGARD advised that they would wish to review this application again when it comes up for renewal; and at that time would expect to see an analysis of the transparency plan and what has been done to achieve said transparency plan. It was agreed the condition would be approved Out of Committee (OOC) by IGARD members.
2.6	<u>Bangor University: HES data request for SANAD-II trial (Presenter: Dave Cronin) NIC-75079-V7Y7L</u> **Application:** This was a new application for pseudonymised Hospital Episode Statistics (HES) data for the purpose of the Standard And New Antiepileptic Drug (SANADII) trial. The trial is aiming to assess the clinical and cost effectiveness of standard and new antiepileptic drugs to identify which drugs are the most effective and which ones make the best use of NHS resources. SANAD II has two arms, Arm A comparing lamotrigine, levetiracetam and zonisamide in patients with focal onset seizures, and Arm B comparing levetiracetam and valproate in patients with generalised onset seizures or seizures which are difficult to classify. This application previously came to IGARD on the 2nd May 2019 for advice on the consent related materials, where IGARD made a number of observations and suggestions for further consideration. **Discussion:** IGARD noted and endorsed NHS Digital's review that the applicant did **not** meet NHS Digital's Standard for privacy notices.

	IGARD noted that the application had been updated to reflect the advice previously given and that in their view, on balance, the proposed processing was consistent with the consent materials provided for review as part of this application. IGARD noted that the Data Protection Act (DPA) Registration expiry dates noted in section 1(b) (Data Controller(s)) and section 1(c) (Data Processor(s)) expired in January 2020 and asked that these were updated to ensure they reflected the correct dates. IGARD queried the reference in section 5(d)(ii) (Benefits) to *"sciatica"* and asked that further information was provided on this and how it related to the trial, or asked that it was removed if not relevant. **Outcome Summary:** recommendation to approve The following amendments were requested: 1. To update section 1(b) and 1(c) to ensure this reflects the correct DPA Registration expiry dates. 2. To provide further information on the reference to "sciatica" in section 5(d) (ii) and how this relates to the trial; or to remove if not relevant.
2.7	<u>NHS West Cheshire CCG: DSfC - NHS West Cheshire CCG, RS (Presenter: Dave Cronin) NIC-47238-Y6L3M</u> **Application:** This was a renewal application for identifiable Secondary Uses Service (SUS+) data and an amendment for to the process of Risk Stratification (RS) which is a tool for identifying and predicting which patients are at high risk or likely to be at high risk and prioritising the management of their care. The application was previously considered on the 16th January 2020 when IGARD had been unable to recommend pending: IGARD endorsed NHS Digital's assessment that the Fair Processing Notice did not meet GDPR requirements and in addition to the points raised by the case officer, made the following suggestions that it be updated: a) To be written in Plain English and in language suitable for a lay reader; b) To describe in detail the profiling and any automated decision making that will take place; c) To ensure the different processing activities and the controllers and processors involved for each activity are clearly outlined. The DPIA should be updated to: a) Reference the GDPR legal basis (not just s251); b) To address the potential different controllership models depending on the processing being undertaken. To update the application throughout to clarify at what stages there is profiling, solely automated decision making; and automated decision making with human interaction and to describe how these types of processing comply with the requirements of the GDPR. To replicate in section 5 of the application the statement from the DPIA into section 5(a) that states *"Under no circumstances do GP practices have access to data for patients outside of their practice population…".* To ensure the application reflects that there may be different Data Controllers depending on the processing that is taking place. In light of the further detail provided in the DPIA, to update the application to ensure it accurately reflects the correct Data Controllers. To update section 5(b) to provide a further definition of *"DSCRO".* **Discussion:** IGARD noted that the application had been updated to reflect most of the comments previously made, however advised that there were still outstanding queries in relation to automated decision making and data controllership. IGARD discussed and agreed that a wider system discussion needed to take place in relation to automated decision making and Risk Stratification; however confirmed that the outstanding issues for this application in relating to the automated decision making, and particularly, in respect of those patients who were not called for review or assessment had still not been

	addressed. IGARD were of the opinion that those patients not selected are not being reviewed by a GP, since the GP cannot review every patient, that by excluding patients from the active review by GPs on the basis of score were part of automated decision making. IGARD noted that the issues around data controllership continue to be open and that the application should be updated to ensure, for example, it accurately reflects the correct Data Controllers as outlined in the Data Protection Impact Assessment (DPIA) provided to be clear who is the Data Controller at each stage of the processing. **Outcome Summary:** Unable to recommend for approval 1. Outstanding issues relating to the automated decision making in respect of those patients who were not called for review or assessment have not been addressed. 2. Outstanding queries relating to data controllership are still open.
3 **3.1** **3.2**	AOB: Associate Director, Data Access The Associate Director, Data Access attended (part of) the meeting as part of his regular catch-up with IGARD. Education Item – Research Ethics As part of IGARD's continuous learning and development, IGARD Lay member, Maria Clark, presented an overview of Research Ethics. IGARD welcomed the presentation and thanked Maria for the time and effort taken in providing this learning item. 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.

Independent Group Advising on Releases of Data (IGARD): Out of committee report 28/02/20

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-325899-B0C9B	Group Application 4 CCG's	13/02/2020	1. To provide an explanation to the references within the application to *"consented data"*; or if this is not relevant to remove this reference from the application.	IGARD Chair	OOC by IGARD Chair	N/A

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 notified to IGARD