Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 5th December 2019

In attendance (IGARD Members): Anomika Bedi, Sarah Baalham, Kirsty Irvine (Chair), Eve Sariyiannidou, Maurice Smith.

In attendance (NHS Digital): Stuart Blake, Dave Cronin, Louise Dunn, Dickie Langley, Karen Myers, Vicki Williams.

Not in attendance (IGARD Members): Maria Clark, Nicola Fear, Geoffrey Schrecker.

1	**Declaration of interests:** There were no declarations of interest. **Review of previous minutes and actions:** The minutes of the 28th November 2019 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	<u>Clinical Registries, Databases and Audits Briefing Paper (Presenter: Dickie Langley)</u> The briefing paper was to inform IGARD about the new Clinical Registries, Databases and Audits product. In line with the Data Services for Commissioners Directions, NHS England requires defined clinical data extracts from specified Clinical Databases, Registries and Audits to be able to fulfil their statutory functions as a commissioner of NHS Services, as determined by the Health and Social Care Act 2012. The briefing was an 'overarching briefing' which intends to cover all relevant information to the inclusion of any clinical database or audit in the NHS England and NHS Digital Data Sharing Agreement (DSA) as all the material details in terms of legal basis for the purposes for and processing of the data flows is the same for all Clinical Database, Registry and Audit extracts. This briefing paper was previously presented to IGARD on the 7th November 2019, where IGARD made a number of comments and suggested amendments. IGARD welcomed the updated draft briefing paper and made the following additional comments: 1. In respect of each of the six clinical dataset appendices, to include an abstract-level statement (i.e. the level of detail provided in applications presented to IGARD) clearly setting out the verifiable legal argument that establishes **why** the parties referenced are considered Data Controller(s) and Data Processor(s). For the purposes of any applications coming to IGARD in the next six weeks, IGARD noted that an interim assurance statement from the DPO, in lieu of updated appendices, would suffice. 2. To provide a further analysis in section 3.1 of the briefing paper why NHS Digital are considered a joint Data Controller with NHS England (or a sole Data Controller or a Data Processor only), for each of the six clinical registries. 3. To amend section 2.5 of the briefing paper to make explicitly clear that *"the only purpose(s) permitted are as described and within **the scope of** the Commissioning Directions"*. 4. To clarify in section 1.7 of the briefing paper that NHS Digital are also involved with the early part of the assurance process with regard to date flowing into NHS Digital.

	5. To make it clear within the executive summary that this briefing paper is designed for commissioning and to also outline what it does **not** cover including any exclusions which may apply.
2.2	<u>Newcastle University: Examining inequalities in the provision of elective surgical and diagnostic procedures (Presenter: Stuart Blake) NIC-167794-K1P8H</u> **Application:** This was an amendment application for additional pseudonymised Hospital Episodes Statistics (HES) data to provide data on re-admissions to enable the applicant to meet the aims of the study. The purpose of the study is to examine the impact of patient choice in the NHS in both secondary care as choice of provider and in primary care as choice of GP. Following the NHS Plan in 2000, providers of health care services have expanded rapidly through the commercial contracting of NHS services. NHS Digital advised IGARD that there was a minor amendment that would need making within section 1 (Abstract) in paragraph 2 under the heading *"Background"* that would need updating to correctly state *"…**patients** included…".* **Discussion:** IGARD noted and supported the minor amendment to section 1 as outlined by NHS Digital. IGARD noted that this application had previously been reviewed and recommended for approval on the 28th February 2019. IGARD supported the additional amendment outlined to include further pseudonymised Hospital Episodes Statistics (HES) data to the Data Sharing Agreement (DSA) and confirmed they had no further comments to make in relation to this application. **Outcome Summary:** recommendation to approve
2.3	<u>Beyond Compliance: Beyond Compliance - PROMs data application (Presenter: Louise Dunn) NIC-58668-V5C0L</u> **Application:** This was a renewal application for pseudonymised Patient Reported Outcome Measures (PROMs) data for the purpose of service evaluation relating to the manufacturing of implants used in hip and knee replacements. The objective is for Northgate Public Services to provide the Beyond Compliance Advisory Committee and the implant manufacturer with the mechanism to assess the patient reported outcomes of patients receiving an implant (within the Beyond Compliance service) in comparison to the national average procedure-specific scores to monitor implant performance, and to flag any areas where patient outcomes report to be statistically significantly worse than the expected. The application was previously discussed at IGARD on the 11th July where IGARD had provided advice on the consent materials. **Discussion:** IGARD noted that there had been minimal changes to the application following the previous review / discussion points in March 2018 and the advice that was provided by IGARD on the consent materials in July 2019. IGARD noted that no additional new information had been provided either by way of the application or supporting documentation to change their previous recommendation of the 1st March 2018 or advice of 11th July 2019. IGARD and a lengthy conversation and queried the information provided in section 1 (Abstract) since it did not factually represent the historical background of the application and asked that this was revised to ensure a clear and transparent audit trail of the facts and made the following comments in relation to the application presented: IGARD noted that Section 1 should include a clear statement that in March 2018 IGARD had suggested the applicant work with NHS Digital to ensure their consent material (which at the

	time was pending for cohort 2) should be redrafted to meet the General Data Protection Regulation (GDPR) standard of consent **or** to choose an alternative legal basis for Data Protection purposes (with the consent to address the duty of confidentiality). IGARD also suggested in in July 2019 that since the consent had not been updated to reflect GDPR the opportunity to uplift the consent materials or choose an alternate legal basis had lapsed and that this had been clearly articulated within published minutes. In addition, section 1 should also clarify the statement in section 1 that stated *"…to allow the customer to make the required amendments to the legal basis."*. It was suggested that the reference in section 1 to *"previous applicant"* be amended to reflect that the applicant had always been Beyond Compliance (Northgate Public Services). It was also suggested that the statement in section 1 that stated *"Northgate Public Services have not stated that their legal basis to process is consent on any of their transparency information"* be clarified since IGARD provided advice on the consent materials in March 2018 and July 2019. IGARD noted that the applicant's current transparency materials including information on their website stated consent as a legal basis for data protection purposes. IGARD requested that a copy of section 1 be shared with IGARD and before any future presentation of the application to IGARD. IGARD offered NHS Digital additional support with the application out of committee and suggested that the applicant may wish to discuss with the Information Commissioners Office (ICO). **Outcome Summary:** IGARD were unable to make a recommendation because there was no additional information received to change IGARD's previous recommendations and advice on the substantive points raised when previously reviewed by IGARD on the 1st March 2018 and 11th July 2019. 1. IGARD requested that section 1 is revised to ensure the it factually represents the historical information to date to ensure a clear transparent audit trail of the facts, including but not limited to: a. To clearly state that in March 2018 IGARD suggested the applicant work with NHS Digital to ensure their consent material (which at the time was pending for cohort 2) should be redrafted to meet the GDPR standard of consent or to choose an alternative legal basis for Data Protection purposes (with the consent to address the duty of confidentiality) and that in July 2019 IGARD advised that since the consent had not been updated to reflect GDPR and the opportunity to uplift the consent materials or choose an alternate legal basis had lapsed. b. To amend the reference in section 1 to "previous applicant" since the applicant has always been Beyond Compliance (Northgate Public Services). c. To clarify the statement in section 1 that states *"Northgate Public Services have not stated that their legal basis to process is consent on any of their transparency information"* (noting that IGARD provided advice on the consent materials in March 2018 and July 2019 and their current transparency materials including the website stated consent as a legal basis for data protection purposes.) d. To clarify the statement in section 1 that states *"…to allow the customer to make the required amendments to the legal basis."*. e. To provide a copy of the updated abstract to IGARD and before any future presentation of the application to IGARD.

2.4	Royal Surrey County Hospital NHS Foundation Trust: Prostate brachytherapy survival outcomes supported by death certificate information from NHS Digital (Presenter: Louise Dunn) NIC-307462-D6B9M **Application:** This was a new application for identifiable Medical Research Information Service (MRIS) data for cause of death data for approximately 250 male patients that received Brachytherapy treatment who are known to have deceased. Brachytherapy is a form of radiotherapy, commonly used as an effective treatment for a range of tumours, in this study it was used as a treatment for prostate cancer. The purpose is to evaluate treatment quality and outcomes of cancer care, to ensure high quality evidence-based healthcare. **Discussion:** IGARD noted the information provided in supporting document 1, the final letter of support from the Health Research Authority Confidentiality Advisory Group (HRA CAG) and queried how the s251 conditions of support outlined had been met and continued to be met. IGARD asked that written evidence was provided outlining this, specifically addressing the issue of the historic dissent. IGARD also asked that a special condition was inserted in section 6 (Special Conditions) stating that the HRA CAG conditions of support had been adhered to, in terms of receiving of and processing of the data. IGARD noted the reference in section 5(a) (Objective for Processing) that stated "*RSCH is the sole data controller who also processes data"* and asked that this was amended to correctly state that the *"RSCH is the sole organisation that processes data".* **Outcome Summary:** recommendation to approve subject to the following condition: 1. To provide written evidence of how the HRA CAG s251 conditions of support have been, and continue to be, met, namely the historic dissent. The following amendments were requested: 1. To insert a special condition in section 6 stating that the HRA CAG conditions of support have been adhered to, in terms of receiving and processing the data. 2. To amend the reference in section 5(a) that states *"RSCH is the sole data controller who also processes data"* to correctly state that the *"RSCH is the sole organisation that processes data".* It was agreed the condition would be approved Out of Committee (OOC) by the IGARD Chair.
2.5	UK Biobank: MR1109 - UK Biobank – Renewal/Extension/Amendment (Presenter: Dave Cronin) NIC-08472-V9S6K **Application:** This was a renewal application for identifiable Mental Health Services Data Set (MHSDS), Medical Research Information Service (MRIS), Hospital Episodes Statistics (HES), Diagnostic Imaging Dataset (DIDs), Mental Health and Learning Disabilities Data Set (MHLDDS) and Mental Health Minimum Data Set (MHMDS). It was also an amendment to add three new datasets, identifiable Emergency Care Data Set (ECDS), National Diabetes Audit (NDA), Improving Access to Psychological Therapies Data Set (IAPT); and an extension to permit processing for a further year. The overall purpose of the research is to create a prospective epidemiological resource of 500,000 people aged 45 -69 at the time of recruitment from around the UK. The application was been previously considered on the 29th November 2018 when IGARD had been unable to recommended pending: to clearly outline the different purposes for which UK Biobank are processing data in the clinical setting and clearly identify the legal bases that relates to each separate purpose within a clinical setting; and to align the lawful basis for the

	applicant with the permissions listed under the Access Procedures supporting document (which appears to presume consent is the legal basis for processing). **Discussion:** IGARD had a lengthy discussion on the legal basis for processing data under this Data Sharing Agreement (DSA), noting that there was conflicting information in the application, the consent materials and the applicant's website that referenced the legal basis as 'consent' and / or 'legitimate interests'. IGARD asked that, taken as a whole, what was the correct legal basis under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 that the applicant has been relying on since the end of the transitional period (25 May 2018) and if the applicant was relying on more than one legal basis for each type of processing, to clarify which processing activities had been carried out under which legal basis. IGARD noted that although the applicant had advised that they had obtained additional Legal Counsel, the application remained substantively unchanged following the last IGARD review in November 2018. IGARD asked that the **full** formal official legal analysis document was provided, (not an extract) that outlined the legal advice received by the applicant's Legal Counsel to allow IGARD to assess what had changed since IGARD's last review in 2018, since IGARD were fixed with only the consent materials and transparency material provided with the application as part of their review IGARD noted a previous point discussed at the review in November 2018 had still not been addressed; which related to the information outlined in supporting document 6.2, Biobank UK Access Procedures that appeared to presume that the legal basis for processing was consent, and asked that the lawful basis for the applicant was aligned with the permissions listed within this document. IGARD queried information provided in section 1 (Abstract) that appeared to indicate that 'consent' under the GDPR was going to be phased out by stating "…*the GDPR makes consent a much more problematic lawful basis to rely upon and over time I think it is likely that legitimate interests will be the main lawful basis that we use, but there are certain areas where retaining consent may still be helpful (for example in relation to the national data opt out)*" and asked that further clarification was provided, noting that historical information in relation to this application clearly indicates that 'consent' was the legal basis being relied upon and that Article 29 Working Party Guidelines on Consent under Regulation 2016/679 had been adopted. IGARD noted that section 5 (Purpose / Methods / Outputs) made no reference to the additional new datasets that are to be disseminated under this application and asked that the section was updated to reflect the datasets. IGARD also asked that section 5 was amended to ensure that it aligned with the NHS Digital Standards that were relevant to this application, such as Standard 5d, Expected Measurable Benefits IGARD queried the reference in the 'data minimisation' column in section 3(a) (Data Access Already Given) and section 3(b) (Additional Data Access Requested) to **"466,953"** and asked that this figure was clarified. IGARD suggested that the sentence in section 5(a) (Objective for Processing) that stated: "…*there are no moral or ethical issues raised*..**"** was removed since it was not necessary to include in the application. IGARD noted that they last considered the application at the meeting on 29 November 2018 and raised a number of specific points. These points remain, and whilst the applicant has advised that they have obtained additional legal advice, the application itself remains substantively unchanged in regard to addressing them. As the material therefore

	presented is essentially the same, IGARD would reach the same recommendation. If the applicant were willing to share the full formal official legal analysis document (not an extract) outlining the legal advice received by the applicant from their Legal Counsel, then this may enable a different position to be taken. **Outcome Summary:** As it stands, IGARD is unable to recommend for approval and had the following recommendations for change: **1.** Noting the conflicting information in the application, the consent materials and the applicant's website, taken as a whole, to confirm the correct legal basis under GDPR and the Data Protection Act 2018 that the applicant has been relying on since the end of the Transitional Period. If more than one basis has been relied on, to clarify which processing activities have been carried out under which basis. **2.** To align the lawful basis for the applicant with the permissions listed under the Access Procedures supporting document (which appears to presume consent is the legal basis for processing). **3.** Section 5 to be amended to align with the relevant NHS Digital Standards. **4.** To provide further clarification in section 1 that appears to indicate that GDPR 'consent' is going to be phased out. **5.** To update section 5 to include reference to the new datasets disseminated under this application **6.** To clarify the reference in the data minimisation column in section 3(a) and 3(b) to "466,953". **7.** To remove from section 5(a) reference to 'there are no moral or ethical issues".
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. • NIC-302994-C2Q2Y (academic) • NIC-148465-PJQ4L (agenda / public body) • NIC-33318-X4Q1B (academic) • NIC-90989-D6T1T (commercial) IGARD welcomed the four applications as part of their oversight and assurance role and noted a number of comments to NHS Digital and suggested that further information and comments be provided in an IGARD Oversight and Assurance Report which would be published separately to the minutes of the meetings, for transparency of process, and on a quarterly basis.
4	<u>AOB:</u> 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 29/11/19

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC Reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
None						

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