

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 16 May 2019

In attendance (IGARD Members): Sarah Baalham, Maria Clark, Kirsty Irvine (Chair), Priscilla McGuire, Eve Sariyannidou, Maurice Smith.

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

Not in attendance (IGARD Members): Anomika Bedi, Nicola Fear, Geoffrey Schrecker.

1	<p>Declaration of interests:</p> <p>There were no declarations of interest.</p> <p>Review of previous minutes and actions:</p> <p>The minutes of the 9th May 2019 IGARD meeting were reviewed and subject to a number of minor amendments were agreed as an accurate record of the meeting.</p> <p>Out of committee recommendations:</p> <p>An out of committee report was received (see Appendix B).</p>
2	<p>Data applications</p>
2.1	<p><u>Wilmington Healthcare: Amendment and Renewal to DARS-NIC-16016-Y9H1D-v1.7</u> (Presenter: Louise Dunn) NIC-16016-Y9H1D</p> <p>Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES), Metal Health Learning Disability Data Set (MHLDDS), Diagnostic Imaging Dataset (DIDs), Mental Health Minimum Data Set (MHMDS) and Mental Health Services Data Set (MHSDS), which will be used to support the NHS either directly through the delivery of tools and bespoke analysis or indirectly through non-NHS organisations, where solutions are provided with the NHS as the end beneficiary.</p> <p>IGARD were previously unable to make a recommendation on the 26th July 2018 as there was insufficient information received on the substantive points raised previously in October and December 2017.</p> <p>NHS Digital advised that the applicant was given a three-month extension by the Director of Data Dissemination in December 2018 to enable the applicant to address the points raised at the 26th July 2018 IGARD meeting.</p> <p>Discussion: IGARD had a lengthy discussion on how the necessity test would be met and specifically on the large amount of data that was being requested, which in some instances was for ten years. IGARD queried the data minimisation efforts that had been undertaken and asked that the application was updated clarifying this, along with further details supporting the proposition that the quantum of data requested was proportionate. IGARD also queried which of the projects outlined would be undertaken over the next 12 months and asked that an indicative work plan outlining this was provided, which also clarified how the HES fields and years requested would map to the indicative work plan for the next 12 months.</p> <p>IGARD queried how the proposal outlined in the application would primarily be of benefit to health and social care and asked that in order to establish this, further details of the “Life Sciences Company” and pharmaceutical companies were provided, in particular, outlining how the work done by those entities would ultimately flow through to the NHS and how this would benefit the NHS.</p>

IGARD had a detailed discussion on the applicant's governance arrangements, in particular the set-up of the decision-making body and any lay member involvement. NHS Digital advised that there was currently a mechanism in place whereby lay members were specifically asked by the body to advise on specific matters as and when required; IGARD asked that at least one permanent lay member representative was part of the decision-making body and that a special condition was included in section 6 (Special Conditions) that the new permanent lay member representative would be in place within three months of signing the Data Sharing Agreement (DSA) and that failing to do this would be a breach of the agreement.

IGARD also asked that in addition to a permanent lay member that, to utilise the mechanism already in place, additional lay members were included to work on specialist projects of particular interest to them and that section 5 (Purpose / Methods / Outputs) was updated with additional details about the advisory board and the lay membership.

IGARD queried how the applicant would contribute to raising awareness of the particular projects being studied and how their work would bring about substantive change to how the condition(s) were treated by the NHS and how this would result in changes to the patient experience and asked for further clarification on this.

IGARD noted the information provided in section 5(d) (Benefits) and asked that that this, and the rest of the application, was updated to ensure there are no hyperbole with regard to expected benefits and that any unnecessary statements were removed to ensure that the benefits stated linked directly to the legitimate interests claimed and written for a lay audience.

IGARD queried the specific legitimate interests that were being relied on and asked that section 5(a) (Objective for Processing) was updated with a brief statement clarifying this.

IGARD queried information in section 5(b) (Processing Activities) stating that *"This information will be of value to patients, the public and to health care professionals"* and suggested that this paragraph was moved to section 5(d) together with any necessary amendments to ensure the claims made are reasonable.

IGARD noted that the applicant's fair processing notice did not meet NHS Digital's fair processing criteria for privacy notices and suggested that section 4 (Privacy Notice) be updated to clearly state that the application privacy notice 'does not' meet the criteria.

IGARD queried the statement in section 1 (Abstract) and section 5(a) that *"...that they would reasonably expect the processing and it would not cause unjustified harm."* and asked that this was removed.

IGARD noted and endorsed NHS Digital's request for an audit of the organisation in relation to this application / data sharing agreement.

IGARD noted the applicant's website contained a lot of interesting informatics, but suggested that the applicant may wish to revise their website communications to consider the patient experience and to consider making the website more patient friendly in terms of how the burden of the disease is presented.

IGARD advised when the application returns to IGARD for renewal, IGARD would expect to see very specific details of the proposed benefits that have been realised.

Outcome Summary: recommendation to approve subject to the following conditions:

1. In order to meet the necessity test, the applicant should:
 - a. Provide further details of the data minimisations efforts undertaken and update the application to provide further detail supporting the proposition that the quantum of data requested is proportionate.

- b. To provide an indicative work plan for the projects to be undertaken for the next 12 months.
 - c. To clarify how the HES fields and years requested will map to the indicative work plan for the next 12 months.
- 2. In order to establish that the proposal is primarily for the benefit of health and social care, to provide details of the Life Sciences Company / pharmaceutical companies and, in particular, how that work will ultimately flow through to the NHS and how this will benefit the NHS.
- 3. In respect of the governance arrangements:
 - a. To include at least one permanent lay member as part of the decision-making body (such condition to be satisfied within three months of the signing of the agreement – see amendment one below),
 - b. To continue, in addition, to utilise the mechanism in place to include additional lay members to work on specialist projects of particular interest to them,
 - c. To update section 5 with additional details about the advisory board and the lay membership.

The following amendments were requested:

- 1. To include a special condition in section 6 that the new permanent lay member representative that forms part of the decision-making body will be in place within three months of signing of the agreement and that failing to do this would be a breach of the agreement.
- 2. To provide clarification how the applicant will contribute to raising awareness of the particular projects being studied and how their work will bring about substantive change to how the condition(s) is treated by the NHS and will result in changes to the patient experience.
- 3. To update section 5(d) and throughout the application to ensure there are no hyperbole with regard to benefits and to remove any unnecessary statements to ensure that the benefits stated link directly to the legitimate interests claimed.
- 4. To move the paragraph in section 5(b) that starts *“This information will be of value to patients, the public and to health care professionals”* and include in section 5(d), together with any necessary amendments to ensure the claims made are reasonable.
- 5. To update section 5(a) to include a brief statement on the specific legitimate interests relied on.
- 6. To update section 4 to clearly state the applicant’s fair processing notice ‘does not’ meet the NHS Digital’s fair processing criteria for privacy notices.
- 7. To update section 1 and section 5(a) to remove the statement *“...that they would reasonably expect the processing and it would not cause unjustified harm.”*

The following advice was given:

- 1. IGARD advised when the application returns to IGARD for renewal, IGARD would expect to see very specific details of the proposed benefits that have been realised.
- 2. IGARD noted and endorsed NHS Digital’s request for an audit of the organisation in relation to this application / data sharing agreement.
- 3. IGARD suggested that the applicant may wish to revise their website communications to consider the patient experience and to consider making the website more patient friendly in terms of how the burden of the disease is presented.

It was agreed the conditions be approved Out of Committee (OOC) by IGARD Members.

University of Hull: Examining the characteristics and predictors of alcohol withdrawal readmissions and emergency department attendances (Presenters: Louise Dunn) NIC-226185-B6C2J

Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data for a study aiming to examine routine hospital data to look at characteristics and predictors of alcohol withdrawal in relation to admissions and Accident and Emergency attendances in England. Patients experiencing wholly attributable alcohol diagnosis often present with acute clinical presentations related to alcohol use or secondary clinical conditions. With over 1 million alcohol-related hospital admissions the burden and unmet needs of excessive alcohol consumption and related conditions remain a priority under the NHS 10-year plan and for Public Health England.

NHS Digital advised that the table in section 3(b) (Additional Data Access Requested) had been updated to reflect that the data requested was pseudonymised.

Discussion: IGARD welcomed the application and noted the importance of the valuable study.

IGARD noted and supported the amendment outlined by NHS Digital in relation to section 3(b) being updated to reflect that the data requested was pseudonymised. IGARD also queried the information provided in the 'data minimisation' column in section 3(b) and asked that further narrative was provided to support the percentage of HES fields requested, for example selected by age, condition etc.

IGARD noted the reference to 'common law' (duty of confidentiality) in section 3 (Datasets Held / Requested) and asked that this was updated to remove this reference.

IGARD noted that a copy of the study protocol was not included with the application and asked that the study protocol was provided to support IGARD with their evaluation of the application (particularly, how the study was articulated in section 5).

IGARD noted the reference in section 5(a) (Objective for Processing) that states "*This application will build on previous research undertaken at King's College London*" and queried the involvement of other parties outlined both now, and in the future, and asked for a further explanation of this. IGARD also queried if the PhD project outlined in the application was part of a wider project and asked for further details of this, including clarification if it was part of a wider project and how it links to the earlier research undertaken at King's College London.

IGARD queried the funding arrangements outlined in the application and asked if the funding was ongoing, and if funding was in place requested written evidence of this.

IGARD noted that the legal basis under the public task section of the General Data Protection Regulation (GDPR) in section 1 (Abstract) was incomplete and asked that this was updated further to expand on the information provided.

IGARD noted that NHS Digital's assessment of the privacy notice against the Information Commissioners Office (ICO's) checklist in section 1 was inconsistent and asked that this was amended to correctly state which of the criteria was not met.

IGARD queried the reference in section 5(a) (Objective for Processing) stating that "*previous data*" had been received by the researcher and asked for a further explanation clarifying where the previous data came from and what has now happened to this data.

Outcome Summary: Recommendation to defer, pending:

1. To provide a copy of the protocol.

	<ol style="list-style-type: none"> 2. To provide written evidence of the funding outlined in the application. 3. To update section 1 to further expand on the public task section under GDPR. 4. To amend section 1 review of the privacy notice checklist to correctly state which criteria were not met. 5. To explain where the “previous data” came from and what has happened to this data. 6. To update section 3(b) to include a narrative to support the percentage of HES fields requested (example: selected by age / condition). 7. To update section 5 to provide a further explanation of the involvement of other parties outlined now, and in the future, and to provide further detail on the PhD project, if is this is part of a wider project and how it is linked to the earlier research undertaken at Kings College London. 8. To update section 3 text to remove reference to ‘common law’.
2.3	<p><u>Cancer Waiting Time Precedent (Presenter: Dickie Langley)</u></p> <p>NHS Digital provided an overview of the Cancer Waiting Time Precedent and associated template to IGARD. IGARD welcomed the review of the template and made the following comments:</p> <ol style="list-style-type: none"> 1. In light of information provided in section 7, to consider if Article 9(2)(h) would be more appropriate legal basis under GDPR. 2. To amend any typos within the templated wording.
3	<p>AOB</p> <p>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.</p> <p>As part of their oversight role, IGARD discussed the following matters:</p> <ul style="list-style-type: none"> • Use My Data Conference • Overview Framework including a review of NHS Digital’s Dashboard • Precedent and Standards Review

Independent Group Advising on Releases of Data (IGARD): Out of committee report 10/05/19

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)
NIC-230360-H3Y3C	Erasmus University Rotterdam	25/04/2019	<ol style="list-style-type: none"> 1. To provide confirmation that the direct identifiers are kept separate from the data returned and that there will be no attempt to re-identify individuals. 2. NHS Digital to review and provide written confirmation that the s251 support extends to both the randomised and registry patients. 3. To update the abstract to explicitly set out the official authority for Erasmus under Article 6(1)(e). 	OOO by IGARD Members.	OOO by quorum of IGARD members.	

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None