Meaningful Integration of Data, Analytics and Services

Grant Agreement No. 727721

Contract Duration: 40 months (1st November 2016 – 29th February 2020)

This project is funded by The European Union

H2020-SC1-2016-CNECT
SC1-PM-18-2016 - Big Data Supporting Public Health Policies

Deliverable 2.2

Good Practice Report 2

Circulation:	Public
Nature:	Report
Version #:	1.0
Issue Date:	30/07/2019
Responsible Partner(s):	SET
Author(s):	Paul Carlin
Status:	Draft (Living Document)
Reviewed on:	31/07/2019
Reviewed by:	MIDAS Executive Board
Contractual Date of Delivery:	31/10/2018 (M24)

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Executive Board Document Sign Off

Role	Partner	Signature	Date
WP1 Lead	Ulster	Michaela Black	31/07/2019
WP2 Lead	SET	Paul Carlin	30/07/2019
WP3 Lead	VICOM	Gorka Epelde	
WP4 Lead	KU Leuven	Gorana Nikolic	30/07/2019
WP5 Lead	VTT	Juha Pajula	
WP6 Lead	DCU	Regina Connolly	
WP7 Lead	Ulster	Jonathan Wallace	31/07/2019
WP8 Lead	Ulster	Michaela Black	31/07/2019
Scientific-Technical Manager	Analytics Eng	Scott Fischaber	31/07/2019

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Abstract

This deliverable relates to the creation of the final good practice guide that was due at M24. As such this delivery is overdue and will continue to be so until project end. This is the result of a number of factors relating to resource and scope of work, but be that as it may this draft document will act as a framework for completion of the deliverable. D2.1 clearly identified the need for public engagement when considering data use, particularly when considering healthcare data. This interim document draws on this and documents a research project that will examine patient acceptability within the context of data sharing in healthcare, and offers a systematic framework, built on an Honest Brokers Model, that is currently operational in Northern Ireland as will be rolled out with the Basque region, thus offering a service design informed by direct patient involvement.

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Copyright

The MIDAS project is funded under the EC Horizon 2020 SC1- PMF-18 Big Data Supporting Public Health Policies

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Document History

Version	Issue Date	Stage	Content and Changes
1.0	30/07/2019	Draft - Living Document	First draft of living document

Statement of Originality:

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Executive Summary

Work Package:	WP 2
Work Package leader:	SET
Task:	T2.1 Create New Model
Task leader:	SET

This report will describe the current position of the Good Practice Guide deliverable that is overdue. Whilst a number of issues have resulted in the delay in this deliverable, current work is and will seek to add value to the original scoped work, by ensuring that as much time is utilised within the project context to maximise WP 2 outputs, even at this late stage. This report will highlight the work that has been done up to this point, building on D2.1, and the work going forward through the MIDAS-APP and the HBS model transfer to the Basque Region, that will tie all the work together in WP2 to give a cogent model for the use of the MIDAS platform, as well as other systems at project completion.

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1 MIDAS-APP

The Meaningful Integration of Delivery Analytics and Service Acceptability Pilot (MIDAS-APP) is a research project, that will gather information from Cardiology patients that will examine what they consider appropriate and acceptable when considering the use of personal data for Healthcare research.

2 MIDAS-APP Rationale

It has proved difficult to gather information from potential data providers (members of the public, politicians). Whilst there have been meetings with all 5 political parties in Northern Ireland, the hosting of an event that would explore political understanding and context around data use in healthcare has proved difficult to organise, particularly in the unique circumstances of Northern Ireland politics, which sees the country still without a functioning executive who have devolved responsibility for healthcare delivery, added to this has been the holding of a number of elections and ongoing talks which has exacerbated diary issues.

SET also planned to co-opt service users to articulate and develop issues and thinking around the use of data for healthcare research, but again this has proved difficult to delivery due to engagement issues. As a result, the best approach was thought to formally establish a formal ethically approved research project. To this end MIDAS-APP was created. It has undergone a number of iterations and developments over the months, as feasibility and design drove redrafting of the project over time. Initial consideration was given to a randomised control trial that would explore perception in respect of a specific use case (a research registry) and how different levels of information might either negatively or positively influence the process of consent. The complexities around information giving and management made this approach and a number of iterations around this approach difficult to deliver on, and therefore a more pragmatic, focused approach was sought, thus MIDAS-APP.

3 MIDAS-APP documentation

- This section will include the following:
- MIDAS-APP Protocol
- MIDAS-APP Information sheet
- MIDAS-APP Consent

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- And MIDAS-APP questionnaire

These are currently scheduled to be reviewed by the Trust Public, Patient involvement Representatives for endorsement before being ethically approved. The project is expected to report January 2020 and will be included within this deliverable as an indication of preference the appropriate and acceptability in regards to sharing healthcare information for research.

4 MIDAS-APP Protocol including appendices for information sheet and consent form

4.1 Project summary

"You can have data without information, but you cannot have information without data." – Daniel Keys Moran

The aim of this project is to examine the understanding of the acceptability of patients when consenting to share their data for research purposes in the South Eastern Health and Social Care Trust. The patient's perception and acceptability of data sharing will be explored and the outcomes of this study will help inform the deliverables of the Meaningful Integration of Data, Analytics and Service (MIDAS) project, a Horizon 2020 grant funded project examining the use of data in policy making. It will also form the basis of the model of consent/ engagement for the Good practice guide at the completion of the MIDAS project.

The creation of structured clinical data has the potential to be utilised by analytical tools and teams of researchers leading to developing an understanding of possible causation, correlation and relationships between variables in clinical datasets. These insights might be gained at a population level or organisational level but should be limited to ensure anonymity for participants, unless there is an understanding and model for an individual use case, particularly relevant in the age of genomics and proteomics.

Within any Hospital setting core data related to the individual patient, service and treatment is held in several systems, and has the potential to be structured, cleaned, accessed and analysis to bring value at a patient, organisational and population level.

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The core deliverable is to examine what information patients might find acceptable to share and under what circumstances, if any.

Project outputs will inform a usable model of consent and information giving for inclusion in the final good practice guide for the MIDAS project deliverables. Of particular interest is how use by 3rd parties, such as industry is seen as acceptable and/or appropriate by the individual, and what themes will be expressed in the sample for the study.

4.2 General information

MIDAS- Acceptability Project Pilot (MIDAS-APP)
Sponsor – South Eastern Health and Social Care Trust
Organisations:
MIDAS Consortia
Research Team
Co - Chief Investigator:
Dr Patrick Donnelly (SET) (Clinical)
Paul Carlin (SET) (Consent model)
Dale Weston (Public Health England) (Evaluation)
Researchers:
MIDAS Consortia
Primary Research Site: Ulster Hospital Dundonald

4.3 Rationale & background information

Data is a core component of a decision making process(Provost and Fawcett, 2013), whether that decision is choosing a type of car, its make, model and colour for example, to selecting something to eat. Stimuli (data) from any number of sources can be processed both consciously and subconsciously by individuals, as well as groups to generate information on which decisions are taken(Coombs, 1964).

This process happens at all levels within health care delivery systems, but can be broadly allocated within 4 key domains:

- Individual client level
- Operational level
- Organisational level

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- Population/ Policy level

(adapted from *(Building a Better Delivery System: A New Engineering/Health Care Partnership 2005))*.

Information is created by various actors, it is then processed with the data moving through these domains and being structured, analysed and interrogated within appropriate parameters/ context to bring knowledge potentially at each or multiplies of these levels.

Figure 1: Key process domains for healthcare delivery

At this moment in time, health data, as well as the functional tools for analysis, are disjointed (Cases et al., 2013) existing in heterogeneous silos, such as Electronic Care Records (ECR), Electronic Health Records (EHR) and imaging systems. Added to the challenge is that these systems can be proprietary and even if open source, require investment to link, thus limiting sharing and utility (Raghupathi and Raghupathi, 2014). This is further complicated as the intricacy of disparate types of data requiring inclusion in any viable record(Engineering a Learning Healthcare System: A Look at the Future: Workshop Summary., 2011), a lack of focus and understanding on the importance of data for transformational change/ impacting patient care, and minimal investment in infrastructure, skills and priority within healthcare delivery systems (The future of healthcare: our vision for digital, data and

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technology in health and care, 2018) lead to a devaluation of data as a healthcare resource.

To some extent, this lack of operational ability in maximising the utility of data within systems, is mitigated through formal programs of research and Quality Improvement (QI).

Research/ QI methods can drive data usage by allowing the development of hypothesise/experiments/testing within the framework of a formal protocol that drives evaluation in the broadest sense of the word. A caveat to this approach is the requirement for specialist knowledge, formal systems to collate and collect data, specific methods and tools in respect of design, analysis and explicit models for dissemination. This approach has problems, it is expensive, can be seen as elitist and leads to difficulties in spreading knowledge (Gold, 2016).

This project proposes that a model that places data, its accrual, structuring, analysis and dissemination at the heart of standard clinical and operational care within a healthcare setting that ensures information is available in a timely and relevant fashion to decision makers (clients, clinicians and managers) within a research context is important, and that the individual patient should be part of the process in helping to define this model within this particular use case.

Whilst this is limited in approach, and will help inform the MIDAS Good Practice Guide (GPG), it is limited in that there is an inherent bias as all patients/ clients actively being recruited to the study are perhaps more aware of the current healthcare system and as such have a greater desire to comment than perhaps a member of the public currently healthy and well. This will be acknowledged as a study limitation, but as this is a project limited in scale, the findings whilst informing the GPG, will also be used to design a larger scale generalised project examining public sentiment in the future.

What is clear is that Government, the public, academia and industry will require innovative approaches not only in addressing the technological challenges inherent in data access, managing quality and volume, curating sources, anonymization/ pseudonymization for example, but also in gathering the support of both clients and staff in operationalising such a system that avoids the pitfalls of the past (such as in the case of DeepMind/ Royal Free Hospital,(RFA0627721 – provision of patient data to DeepMind, 2017)), thus ensuring the highest quality in meeting all statutory/ regulatory and good practice requirements, such as the General Data Protection

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Regulation (GDPR)('Guide to the General Data Protection Regulation (GDPR),' 2018).
There are difficulties in trying to understand how to deal and manage data within current practice, not least in relation to ethics, de Lecouna attests that the current development in respect of this technology will challenge current systems of ethical governance and review (de Lecuona, 2018). Currently medical apps, for example routinely share data in a less than transparent manner thus increasing risk in respect of inappropriate use, or indeed negative public perception in respect of sharing healthcare data (Grundy et al., 2019). A shared model of governance between interested parties, such as Academia, Business, Clinicians and Clients (ABCC) may bring oversight and control and thus de-escalate risk, as proposed within the HiGHmed initiative (Haarbrandt et al., 2018).

This project will use a questionnaire to examine cardiac patient understanding, that may inform the development of a model of engagement and consent within a live operational context, helping to align systems of governance and operation to manage the data within a co-created GPG.

This will require approaching clients for inclusion into a questionnaire based study. Clients will be approached by members of the clinical team for inclusion in the study and approached by the study team for consent. What is of import is to try to understand what is appropriate and acceptable for patients/ clients when data has the potential to be harvested for research purposes.

Patients will be given the information sheet (PIS) for MIDAS-APP (Appendix 1) and consented using the MIDAS-APP consent form (Appendix 2) by a member of the research team.

This information will be reviewed with the Trust, by Public, Patient Involvement (PPI)(Andrews et al., 2015) representatives for endorsement.

Each participant who consents will be asked if they wish to complete the questionnaire at the time of consent whilst they are at the clinic or they may wish to take the questionnaire home with them to complete, or indeed the consent form and return by prepaid mail as appropriate.

After 2 weeks each participant will then be contacted if they have not returned the consent and/or questionnaire. After this contact no further contact will be sought, and

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those who have not consented by writing will be assumed not to have consented and those who have consented will be deemed lost to follow up.

4.4 Study goals and objectives

The study overall goal is:
To explore the acceptability and appropriateness of data sharing using a questionnaire with a group of cardiac patients attending an Outpatients service in the Ulster Hospital, South Eastern Health and Social Care Trust.

Primary objective:
To assess a patient's perceptions of what is appropriate when potentially sharing clinical data and an indication of the model that might be acceptable.

Secondary objectives:
None

4.5 Study Design

This is a questionnaire study. Patients will be approached using a convenience sampling methodology. Whilst this limits the range and scope of inclusion, this will be mitigated in the analysis by acknowledging this as a limitation of the study, whilst the capturing of basic demographics within the questionnaire will enable a comparison against the general population. This will help inform other potential follow up work.

Patients will have the opportunity to refuse and be assured that participation is completely voluntary. They will be offered the questionnaire to complete at the time, being assured that this is only if they will find this convenient, otherwise they can take the consent and questionnaire home and return in a prepaid envelope, or return the questionnaire in a prepaid envelope if they consent at clinic.

The questionnaire is unvalidated as this is a pilot, but they will be reviewed by the research team before use and will be reviewed by the Trust PPI representatives before use.

The research team will be introduced to prospective participants after they have been initially informed of the study by the direct care team. The research nurse will then give an overview of the study.

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All patients will consent using the standard consent form (Appendix 2).

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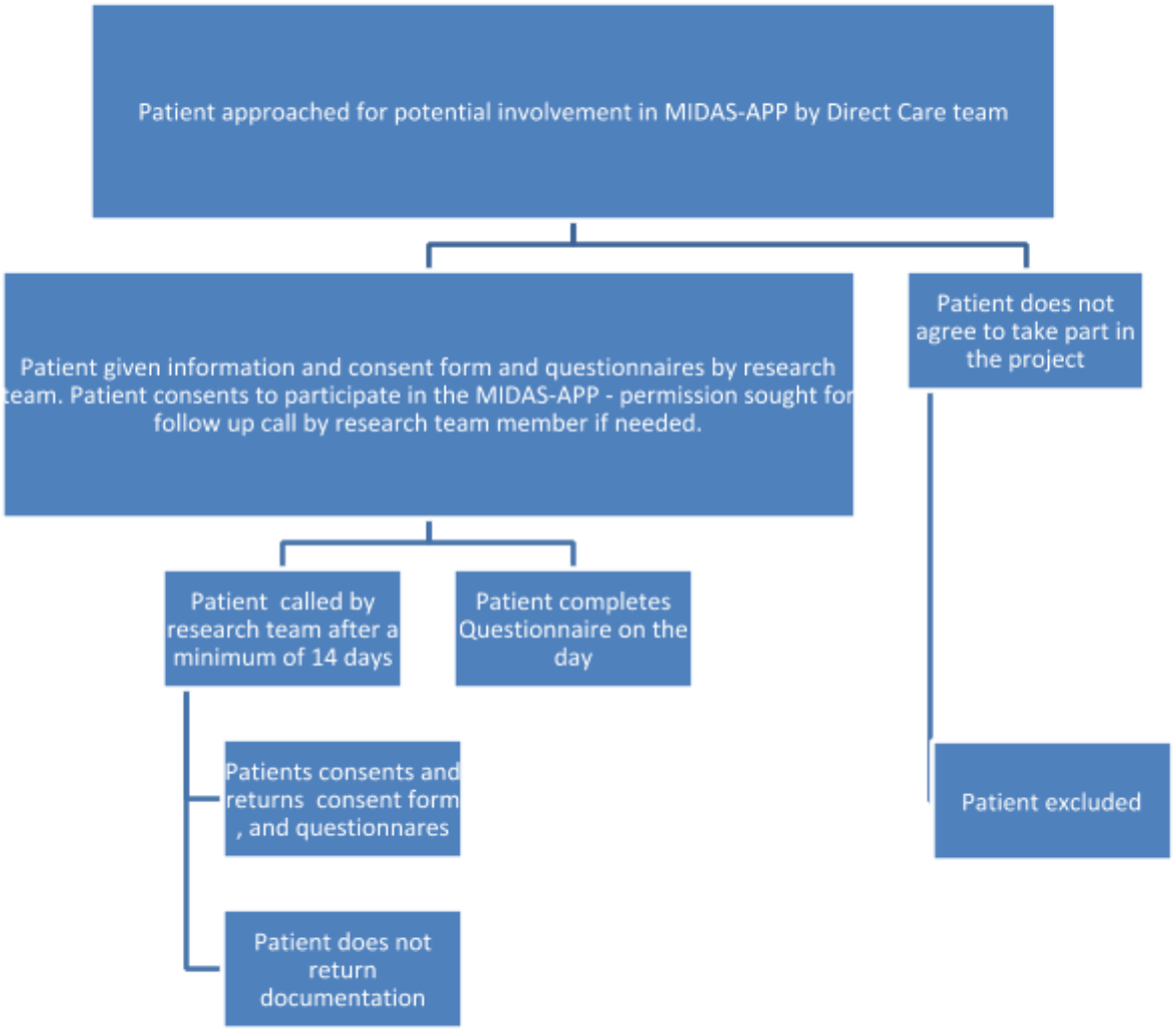

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4.6 Methodology

This is a single site study within the South Eastern H&SC Trust the following departments will be involved:

- Medicine: Cardiovascular
- Information Technology
- Innovation Research and Development
- Clinical Coding

4.6.1 External

The MIDAS consortium
The protocol is the principal descriptor for the project.

4.6.2 MIDAS-APP

This is the underpinning structure for the overall project. By creating a model through client/ healthcare provider interaction, the project team will develop a practical process to ensure informed consent for appropriate data use and thus help inform the GPG for the MIDAS Project.

Specific questionnaires will be used to assess both willingness and understanding of the issues at hand.

Qualitative operational data will also be assessed:

- Number of participants
- Number of rejections
- Number of withdrawals
- Number of requests for further information from prospective contributors
- Number of complaints
- Percentage of completed questionnaires
- Percentage of participants postal return versus face to face

4.7 Safety Considerations

All participants will have opportunities to formally consent and reaffirm consent when contacted. All participants will be identifiable to the research team for the duration of the study, although all data will be stored using a unique identifier that will be used for analysis.

All participants have the right to withdraw from the study at any time

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4.8 Follow-Up

Each participant will be offered the draft final report for review and an opportunity to feedback to the research team on the outputs, before final publication, any feedback will be incorporated into the report (appendix 3, draft cover letter for sending report and receiving feedback).

4.9 Data Management and Statistical Analysis

Data collected to specifically drive outputs in the consent study will be treated confidentially, personal data will be recorded by the researchers and collated and stored using unique identifiers for full comparative analysis. Whilst this is a pilot study, and as such will not be powered for effect, a total of 100 patients will be recruited. Descriptive statistics will be used, and for analysis a Mann-Whitney U test and Chi square test will be performed between groups if themes are developed and sub groups identified.

4.10 Quality Assurance

The study will be monitored and audited by the South Eastern H&SC Trust Innovation, Research and Development Office.

4.11 Expected Outcomes of the Study

The outcome of the study is to gain an understanding of patient/ client acceptability and appropriateness when considering the sharing of data.

4.12 Dissemination of Results and Publication Policy

Dissemination will take place through standard gateways:

- Conference presentation
- Project website
- Policy briefings
- Publication in peer review journals
- MIDAS Deliverable - Report generation

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4.13 Duration of the Project

The project will run for a total of 4 months, 2 months for data collection and 2 months for analysis and reporting.

4.14 Problems Anticipated

The project is simple in design with a limited reach as previously stated in regards to sampling, although this is mitigated as it is a pilot. Questionnaire return may prove challenging, and thus limit the potential for analysis.

4.15 Project Management

The project is seen as a core corporate priority over the next year, with management and support through the Innovation Research and Development (IRD) team and the Informatics team within the Trust. This is reflected within the project team who have the support of the Hospital Services directorate and Executive Management Team within the Trust.

This project will form the basis for a deliverable within Work Package 2 MIDAS.

4.16 Ethics

Ethics will be sought through ORECNI. The Trust will act as sponsor, and governance will also be sought.
Budget

This will be funded through the MIDAS budget and contributed to by all those responsible for deliverable 2.2

5 References

Andrews, L., Allen, H., Sheppard, Z., Baylis, G., & Wainright, T. (2015). More than just ticking a box…how patient and public involvement improved the research design and funding application for a project to evaluate a cycling intervention for hip osteoarthritis. Research Involvement and Engagement, 1(13).

Cases, M., Furlong, L. I., Albanell, R., Bellazzi, R., & Boyer, S. (2013). Improving data and knowledge management to better integrate health care and research. Journal of Internal Medicine, 321-328.

Committee on Engineering and the HealthCare System, National Academy of Engineering, Institute of Medicine. (2005). Building a Better Delivery System: A New Engineering/Health Care Partnership . (P. Reid, W. Compton, J. Grossman, & G. Fanjiang, Eds.) Washington: National Academies Press.

Coombs, C. (1964). A theory of data. Oxford: Wiley.

Department of Health and Social Care. (2018). The future of healthcare: our vision for digital, data and technology in health and care. London: Department of Health and Social Care.

Gold, M. R. (2016). Critical Challenges in Making Health Services Research Relevant to Decision Makers. Health services research, 51(1), 9-15.

Information Commisioners Office (ICO). (2017, July 3). RFA0627721 – provision of patient data to DeepMind. undertaking cover letter to Royal Free Hospital. London, UK: ICO.

Information Commisioners Office (ICO). (2018, December 15). Guide to the General Data Protection Regulation (GDPR). Retrieved from ICO. Information Commissioner's Office: https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/

Institute of Medicine (US) and National Academy of Engineering (US) Roundtable on Value & Science-Driven Health Care. (2011). Engineering a Learning Healthcare System: A Look at the Future: Workshop Summary. Washington (DC): National Academies Press (US).

Provost, F., & Fawcett, T. (2013). Data Science and its Relationship to Big Data and Data-Driven Decision Making. Big Data, 1(1), 51-59.

Raghupathi, W., & Raghupathi, V. (2014). Big data analytics in healthcare: promise and potential. Health information science and systems, 2(3), 2047-2051.

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6 Appendix 1 and Appendix 2

Meaningful Integration of data analytics and service (MIDAS)
Acceptability Pilot (MIDAS-APP)

Participant Information Sheet and Consent form V1 27/7/2019

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Informed Consent Form for MIDAS Acceptability pilot

This consent form and information sheet is only to be used for the MIDAS Acceptability pilot research project, by the MIDAS research team based in the South Eastern Health and Social Care Trust. This Consent form and Information sheet will be used by the patients approached for inclusion in the study.

You may provide the following information either as a running paragraph or under headings as shown below.

Principal Investigator - Paul Carlin
South Eastern Health and Social Care Trust
Sponsor - South Eastern Health and Social Care Trust on behalf of the MIDAS consortia
MIDAS Acceptability Pilot - MIDAS APP

This Informed Consent Form has two parts:
• Information Sheet (to share information about the study with you)
• Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction
My name is Paul Carlin and I am currently working with a team of researchers across Europe and the United States on the Meaningful Integration of Data, Analytics and Service (MIDAS) project funded through the European Horizon 2020 programme. As part of this project we are examining how ethical/ practical it might be to access personal healthcare data from individuals, such as yourselves.

Any data that is collected for this MIDAS-APP project will be anonymised, and will never be identifiable.

We want to understand how much information you may think it is appropriate for researchers from a variety of organisations to be able to access and how this might be achieved.

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You can discuss the project and your involvement in it at any time with any member of the research team, either face to face or through the phone numbers and email addresses given below. If you do not understand any of the wording or terminology when reading this document or being talked to by any member of the research team, please ask for clarification/ further information, the research will be more than happy to explain and answer any questions.

You do not have to participate in this MIDAS-APP project, and you can withdraw at any time.

Purpose of the research

The use of data from individuals is becoming more and more important in the modern world, and the potential within healthcare will be significant. Currently there is real debate on how we could and should access this data and many people feel differently on how this should be achieved.

Some feel that allowing anybody to use the data for any purpose should be allowed, others that people should be paid for their data when it is used and yet others that would completely restrict the data use to those working in the NHS/ healthcare provider. This becomes more and more complicated when you then start to understand that some private companies for example provide healthcare systems and services right across the world.

A team of researchers, working on the MIDAS project are designing a system to use anonymised data to help make healthcare policy, and are interested in understanding what people who give their data to the NHS think about this, and wish to ask which information you think might be acceptable to use, and also what model of consent you might think is appropriate.

For example, researchers might what to use your data to create a research registry. This is a database that gathers all your clinical data in the hospital over time, which can then be anonymised and exported to researchers to look at in a specific and detailed way for research purposes.

For example, does having a cardiac CT give a better diagnosis than a treadmill and thus lead to a better outcome for a patient? With a registry you may be able to answer this question.

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Therefore we wish to randomly give 100 patients a questionnaire to understand what patients/ clients like yourself think is acceptable when using data for healthcare research and how you might be best informed by this.

This questionnaire will have a unique identifier known only to the research team, and at no time will the information you give be identifiable.

This should take no more than 2 hours in total to complete the consenting process for the study and completing the questionnaire. You can complete the questionnaire during your hospital visit or return in a stamped addressed envelope.

Type of Research Intervention
This project will require you to read the questionnaire and answer the questions. How to answer the questionnaire is explained on the questionnaire form. These questionnaires will then be looked at in a group and analysed to see if any themes/ patterns emerge.

Participant Selection
As you are a patient in the South Eastern Trust and being seen at the cardiology clinic we wanted to ask you to participate in this research as the cardiology service is research active and we feel that this gives a representation of the general population that use the current service within the Trust. The questionnaire will include a section asking questions such as your age, sex etc, i.e. basic demographic data. This will enable us to understand how representative those patients participating are.

Voluntary Participation
Your participation in this study is entirely voluntary and whether you choose to participate or not will have no bearing on the care that you receive. If you wish to not proceed at this point please inform a member of the team and we ensure that you are not approached again in relation to this project.

Procedures
We are keen to try and understand what might either help or hinder patients/ clients of the health service allowing their data being used for research purposes. To gain an insight into this, we want to ask users of the health service a number of questions about what they think might be acceptable use and how best they might be informed about this use.

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The design of the study means that you will be asked to complete a questionnaire and return this to the research team.

There is a total of 1 questionnaire throughout the study and we anticipate that it will take approximately 2 hours to review your involvement in the project, consent (if you prefer you can take the information away from your appointment and return the consent form and questionnaire in the stamp addressed envelope. If you do need clarification then we will record this contact to include in our analysis of the project. A member of the research team will be on hand to assist at clinic or will be contactable by phone email as and when you require.

Duration
Your inclusion in the study will be limited to approximately 2 hours over a period of time that you choose (if for example you chose to review the project at home and return by post).

Risks
We do not anticipate that there is any risk in participating in the study, except for the loss of time and effort required in reading the information and answering the questionnaire. All information recorded in the questionnaires will be anonymous.

Benefits
There will be no direct benefit to you in participating in the study but the information coming from this study may enable us to tailor information and how we gain access to this data in the future.

Reimbursements
There will be no reimbursement for the study. Initial contact will be made at your cardiology appointment, and follow up if any, can be by post and phone call. You will be supplied with prepaid envelopes to return the required questionnaire (and consent if needed).

Confidentiality
All data gathered will use a unique identifier to organise and anonymise the questionnaires. The research team will have a key, to check who has been approached and returned the questionnaires. The team will phone once after two weeks to remind you to return the questionnaire, if after this time no questionnaire is received you will be withdrawn from the study and all data destroyed. All data will be stored physically in locked filing cabinets and locked offices. This will be stored until

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February 2020 when it will be destroyed as the MIDAS project will end at this point. Electronic data will be stored on password protected, encrypted devices that are only accessible by the research team. All electronic data will be deleted at the end of the MIDAS project (or for those who do not respond removed from the project database after 4 weeks post approach/ consent).

Sharing the Results

A final report will be provided to each participant at the end of the project. The findings will be used to assess the feasibility of creating a model of approach/ consent/ appropriate use which will be used for the MIDAS projects overall outcomes.

The information may also be used to help inform the current Honest Broker Service model and engagement within the Encompass programme with end users.

Right to Refuse or Withdraw

You have the right to withdraw from the project at any time, but the team will use the information gathered for analysis. At no time will you be personally identifiable in any analysis or publication.

Who to Contact

For further information about the project please contact:
Paul Carlin, Innovation, Research and Development Manager at South Eastern Health and Social Care Trust
02891553101
paul.carlin@setrust.hscni.net

For advice that is impartial and outside of any project influence please contact:
Laura Moore, Data Manager, South Eastern Health and Social Care Trust
laura.moore@setrust.hscni.net

This proposal will be reviewed and approved by ORECNI before the project is allowed to commence. ORECNI, is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about ORECNI please contact Dr Siobhan McGrath, siobhan.mcgrath.hscni.net, tel:02895361400

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

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Meaningful Integration of data analytics and service (MIDAS)
Acceptability Pilot (MIDAS-APP) Consent form

MIDAS-APP V1 27/07/2019 consent form

This consent form will only be signed after you have read and agreed that you understand the information that the Health Care Professional (HCP) has shared with you and after you have read the MIDAS-APP V1 27/07/2019 Participant Information Sheet.

This consent form is a record that you agree to take part in the research project that will ask you to answer a questionnaire that will capture demographic data, attitudes to consent and use of personal data for research purposes.

Please read the statements below carefully and initial each box:

1. I confirm that I have read and understood the information sheet MIDAS-APP V1 27/07/2019 for the above study. This has also been explained to me and I have had the opportunity to ask questions.

Please initial box ☐

2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

Please initial box ☐

3. I understand that sections of my medical notes may be looked at by staff involved in the study or from the sponsor and regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to those records.

Please initial box ☐

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4. I understand that i will not be offered any payment for taking part in the study

Please initial box ☐

5. I agree to take part in the above study.

Please initial box ☐

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out or witnessed the information sheet being read by the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. **They will be required to complete the questionnaire**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Consent Form has been provided to the participant.

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Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____
Date _____
Day/month/year

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7 Appendix 3

Honest Brokers Service Model

In Northern Ireland the Business Services Organisation (BSO) has established an Honest Broker Service (HBS) for Health and Social Care (HSC). The aim is to enable non-identifiable data that is stored in the regional data warehouse and gathered from the 6 healthcare Trusts (operational units of management, geographically boundaried within Northern Ireland) to be safely shared with a variety of researchers outside and internal to the HSC family. Provision also exists for the use of the data by the Trusts for operational use, service development and evaluation, outside of a formal programme of research. This thus maximises use that allows for planning, commissioning of services and public health monitoring. As data is anonymised and managed centrally it can be aggregated and potentially pseudonymised for linkage with other datasets, for example prescribing data. This falls within current legislative bounds as acceptable as the data is reviewed and stratified to minimise re-identification through linkage, by the HBS itself. Data scientists prepare the data and any project is reviewed by an expert panel for use/ linkage risk (with technical review from the data-science team).

There is a governance structure that ensures adequate oversight and adherence to good practice and legislative frameworks, including confidentiality requirements, data protection legislation and the Information Commissioner's Office Codes of Practice.

The service operates within the umbrella of a Memorandum of Understanding (MOU), that exists between the Trusts and BSO (Appendix 1).

The MIDAS Context

The MIDAS project has enabled a variety of partners to share good practice, both technically and operationally, and it in this latter category that the HBS model exists. There is an opportunity to examine the transferability of the model to another jurisdiction. To this end, colleagues in the Basque region have expressed an interest and the HBS is currently refining the Standard Operating Procedures that provide the operational framework that the service operates on.

We will over the next 4 months August - January 2020 examine the utility and feasibility of this adoption using a standardised questionnaire that is currently being developed.

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The suite of documents for review by the Basque region is currently being finalised, and will include:

- HBS Application form
- HBS review form
- HBS working group Terms of Reference
- HBS Governance board terms of reference

These documents are currently under review.

Conclusion

This document forms an interim step to provide the agreed outstanding Work Package 2 outputs. It is a pragmatic approach to meet the current resourcing, political and outstanding project elements that will inform the overall outputs from the MIDAS project.

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8 Appendix 4

MEMORANDUM OF UNDERSTANDING (MOU) FOR AN HONEST BROKER SERVICE FOR HEALTH & SOCIAL CARE INFORMATION

Agreed and signed off: September 2013
Last updated: April 2018
Review date: May 2018

Memorandum of Understanding (MOU) for an Honest Broker Service for Health Information

MEMORANDUM OF UNDERSTANDING (MOU) FOR AN HONEST BROKER SERVICE FOR HEALTH & SOCIAL CARE INFORMATION

1. This Memorandum of Understanding (MOU) is established for the purposes of informing the development of an Honest Broker Service for Health and Social Care (HSC). The Honest Broker service enables the provision of anonymised, aggregated and in some cases pseudonymised data from the Regional Data Warehouse, (held within Business Services Organisation BSO), to the Department of Health (DoH) and HSC organisations (listed below). It also provides a service to researchers carrying out approved health and social care related research (see section 14).

2. The MOU should be reviewed and kept up to date by the Honest Broker Advice Service (HBAS) in conjunction with the Honest Broker Governance Board (HBGB).

3. A definitions document is provided at Appendix

4. This MOU has been agreed and signed off by:
• Health and Social Care Board (HSCB)
• Business Services Organisation (BSO)
• Belfast Health and Social Care Trust
• Northern Health and Social Care Trust
• Southern Health and Social Care Trust
• South Eastern Health and Social Care Trust
• Western Health and Social Care Trust
• The Department of Health (DoH)

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• Public Health Agency (PHA)
• Northern Ireland Ambulance Service Health and Social Care Trust (NIAS)
• Northern Ireland Blood Transfusion Service (NIBTS)
• NI Guardian Ad Litem Agency (NIGALA)
• NI Medical & Dental Training Agency (NIMDTA)
• Northern Ireland Practice & Education Council for Nursing and Midwifery (NIPEC)
• NI Fire & Rescue Service (NIFRS)
• Health & Social Care Regulation and Quality Improvement Authority (RQIA)
• NI Social Care Council (NISCC)
• Patient and Client Council (PCC)
(See section 15- MOU Sign Off).

5. Assumptions
The Honest Broker Service will only provide data in anonymised, aggregated and, where necessary, pseudonymised formats, in line with Data Protection, confidentiality requirements and the ICO's Codes of Practice.

Memorandum of Understanding (MOU) for an Honest Broker Service for Health Information.

Organisations subject to the MOU should ensure that their Privacy Notices or Fair Processing Notices make service users aware of the uses of their data, including secondary uses.

The Honest Broker Service has been developed in line with the ICO's Anonymisation: Managing Data Protection Risk Code of Practice[2] and Data Sharing Code of Practice.

6. Scope
The MOU covers the provision of an Honest Broker Service to fulfil 2 purposes:
1) The provision of (or access to) anonymised/ pseudonymised data from the Regional Data Warehouse to other organisations within the HSC family, including DoH (see Appendix 3) 2) The provision of anonymised data from the Regional Data Warehouse for approved HSC related research (see Appendix 4).
This MOU does not cover the sharing of patient identifiable information.[4]
While this is the initial scope for the service which is to be provided by the Honest Broker, the service should be reviewed following a period of time after its establishment, to assess its value and to consider potential development of the service.

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7. Purpose of an Honest Broker Service

Currently the HSC Trusts (Belfast Trust, Northern Trust, Southern Trust, South Eastern Trust and Western Trust) hold information within the Regional Data Warehouse. This information is used by the individual Trusts, but is not shared across Trusts. The Department, the Health and Social Care Board (HSCB) and PHA require access to data for various purposes including planning, commissioning of services, performance management and public health monitoring.

An Honest Broker Service can help to ensure that this data is shared, within the HSC family, including DoH, in anonymised or pseudonymised formats, thus strengthening the protection of health and social care data and patient confidentiality, whilst maximising the uses and health service benefits which can be gained from sharing this information safely.

Previously information was not provided from the Regional Data Warehouse to researchers. The Honest Broker Service enables the safe and secure provision of anonymised data to researchers for approved health and social care related research, which is in the overall interest of public health and the development of health and social care related policy.

ICO's Privacy Notices Code of Practice - https://ico.org.uk/for-organisations/guide-to-data-protection/privacy-notices-transparency-and-control/

ICO's Anonymisation: Managing Data Protection Risk Code of Practice- https://ico.org.uk/media/1061/anonymisation-code.pdf

3 ICO's Data Sharing Code of Practice - https://ico.org.uk/media/for-organisations/documents/1068/data_sharing_code_of_practice.pdf

4 The sharing of patient identifiable information must be managed in accordance with the 'Code of Practice on Protecting the Confidentiality of Service User Information' and the 'DHSSPS & HSC Protocol for Sharing Service User Information for Secondary Purposes', which are available from the Department's website https://www.health-ni.gov.uk/publications/doh-hsc-protocol-sharing-service-user-information-secondary-purposes

8. Benefits of Providing an Honest Broker Service

The Honest Broker Service provides:

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• streamlined, secure processes for data sharing for the HSC and the Department, creating efficiencies and ensuring full benefits of data sharing for the benefit of public health and well being
• Trusts and others who feed into the Regional Data Warehouse with assurances that the data for which they are responsible will only be made available in an anonymised format in a secure environment to accredited researchers for formally approved purposes
• data to researchers, which could contribute to improved health and social care outcomes and practices and associated benefits for health and social care policy development
• better data security and less data travel
• dedicated research coordinators, who are located at BSO offices, to assist researchers with projects and provide advice and support
• statistical disclosure control to protect patient confidentiality.

The Honest Broker Service enables the BSO to maximise data security in the Regional Data Warehouse, while removing the need for excessive procedures across the HSC for access to anonymised/pseudonymised data. Agreement for the Honest Broker Service, via this MOU, should reduce the need for the current number of Data Access Agreements across the HSC, where anonymised and pseudonymised information is required. It provides greater protection of service user information, by increasing the use of anonymised and pseudonymised service user information, whilst supporting the needs of secondary users.

9. Role of BSO & the Department (DoH)
As the Regional Data Warehouse resides within BSO, the Honest Broker Service has been established within BSO, with some resources being provided by the Department for the research support role. In providing the Honest Broker service BSO perform the role of ‘data processor’, acting on behalf of each of the signatory organisations, (data controllers), who feed data into the Regional Data Warehouse. They carry out the service of taking the data and anonymising or pseudonymising it before providing it to researchers, HSC organisations or the Department.

BSO do not make independent decisions about the further processing of personal data outside of the terms of their engagement under this MOU. If any queries or activity arise which are not included in the instructions under which BSO operate within this MOU, BSO must contact the relevant data controller and seek instructions on how to proceed.

In fulfilling the data processor role, BSO agree to comply with the obligations, equivalent to those imposed on all of the data controllers, by the seventh principle of the Data Protection Act (DPA).

Therefore they must ensure that,
“Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data”.

BSO ensure that when processing personal data on behalf of the signatory organisations, all of the security considerations of the seventh principle of the Data Protection Act (DPA) are met.

In providing an Honest Broker service, BSO will:
• Implement systems and processes for ensuring that the data outputs are appropriately anonymised.
• Where pseudonymisation techniques are used, BSO as Honest Broker must ensure appropriate disclosure control to protect the identity of individuals and must ensure that any codes or algorithms used to pseudonymise data are appropriately security controlled and accessed only by authorised staff. Routine and regular audits should be carried out to ensure this is the case.
• Ensure that data is held and used in a secure manner and is only accessible by authorised personnel.
• Ensure that appropriate vetting and training methods are implemented for staff.
• Ensure that all requests for access to health and social care data are documented and monitored appropriately.
• Remind recipients of their obligations under the law before they access the data.

In supporting the Honest Broker Service, the Department may provide information/statistical expertise to:
• Ensure that recipients of data have the necessary support to handle and understand the data.

10. How the Honest Broker Service Works
BSO, which currently hosts the Regional Data Warehouse on behalf of the Trusts (and the Board), provides a service to process requests for health and social care data which are submitted from within the HSC family (which includes all HSC organisations and the Department). Separately from this they also manage a process for dealing with requests for anonymised data from researchers.

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In the majority of cases the outputs provided by BSO are anonymised health and social care data from the Regional Data Warehouse and this will always be the case for research requests.

The Honest Broker Service provides a safe and secure environment in which the service user data can be processed (and in some cases linked to other data), before being provided in an approved format to the requestor.

Appendix 2 provides a diagrammatic overview of how the Honest Broker Service works.

11. Provision of Pseudonymised data

On occasion the BSO are required to provide the Department and HSC organisations with pseudonymised health and social care data where this is justified, (for example where there is a need to track trends, which would require a unique identifier).

The pseudonymised identifier must be unique to each individual patient/service user. The method of applying the pseudonymised identifier is via re-coding techniques which are applied to the current Health and Care Number (HCN).

The unique identifier must:

• Remain consistent throughout the life care of an individual patient.

• Consistently be applied across all systems to enable patients to be tracked across all elements of their care and throughout the lifetime of their care.

• Be meaningless to any person outside of the approved staff within the Honest Broker Service and the original Data Controller. The Data Controller may need to link the unique identifier to the HCN and associated data in order to deal with validation queries from organisations using the unique identifier, such as the Department and HSCB. This will ensure that identification of patients and service users outside of the Honest Broker Service or beyond the original Data Controller is prevented.

12. Requests for data from within the HSC or by the Department

• The process for ‘Internal’ requests received from HSC organisations and the Department is mapped at Appendix 3.

• These are submitted and handled through one point of contact within the Honest Broker Service (within BSO).

• Requests are submitted using the HSC/DoH Application for Data form.

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• The Honest Broker ensures that all requests are valid requests (i.e. needed for legitimate purposes) and are for anonymised data.
• If a request is made for pseudonymised data the Honest Broker ensures that appropriate justification has been given for the need for a unique identifier; otherwise the data is provided in anonymised format.
• The Honest Broker has the responsibility of gathering the relevant data and anonymising or pseudonymising that data appropriately.
• Checks are made before the data is shared to ensure that it has been appropriately and correctly anonymised or pseudonymised to ensure that no individual may be identified. (An appropriate checking and approvals process has been implemented by BSO).
• The Honest Broker ensures that only authorised and trained staff access the data and that these staff are fully aware and compliant with data protection and confidentiality obligations. Staff are made aware of disciplinary actions which will be taken as a result of a breach of the terms of the Honest Broker Service, data protection, confidentiality and security.

13. HSC & DoH User Responsibilities

As users of the Honest Broker Service, organisations to which this MOU applies will:
• Ensure they request the minimal amount of data required for the purpose.
• Provide adequate justification when pseudonymised data is required.
• Apply appropriate retention and disposal to the information they receive.
• Will not attempt to identify individuals from the data they are provided, either by using the data they already hold within their organisations, or by linking that data to data received as part of separate requests to the Honest Broker Service.

14. Research and Development Uses

One of the objectives of the Honest Broker Service is to facilitate scientifically sound research through the appropriate use of health and social care data. By providing data for these purposes in anonymised format, the rights of individuals will be respected with adequate privacy protection.

Researchers will only have access to anonymised data and be subject to an obligation not to attempt to re-identify individuals; this and other obligations are outlined in a Research Access Agreement and Disclosure Policy Agreement which researchers must sign before gaining access.
• The Honest Broker process for handling research requests is mapped at Appendix 4.
• Completed applications must provide clear evidence of the value of proposed study to health and social care related research and policies.
• Any decisions taken in relation to unsuccessful applications are fully documented.

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• The Honest Broker provides an appeals process for unsuccessful applications.
• Before the data is gathered researchers are asked to sign off an Access Agreement which stipulates the terms and conditions of their use of the anonymised data, including sanctions for misuse, to ensure they will use the data only for the purposes intended and outlined in their application. This must be signed by all researchers involved. An Institutional Signatory is also required by a representative for the organisation with ultimate responsibility for research team members.
• The data is gathered by the Honest Broker and anonymised before it is provided to the researcher in a project specific dataset. The dataset is checked and approved before the researcher is given access. A safe setting/ 'safe haven' will be used for provision of the anonymised data.
• A member of staff from the Department's Information Analysis Directorate may on occasion be appointed to act as a research support contact for the researcher. Their role will be to help guide the researcher in navigating, using and understanding the data provided to them and in ensuring the researcher interprets the data accurately before it is published.
• Outputs from these analyses will normally be released once cleared by the research support contact and by an appointed contact within BSO.
• All research outputs will be checked by the research support contact and an appointed contact within BSO before they are released.
• The Honest Broker Governance Board is responsible for overseeing the Research Approvals process. Details of the composition of the HBGB and its roles and responsibilities are provided in the HBGB Terms of Reference at Appendix 5.

15. MOU Sign Off

The MOU has been signed off by the Chief Executives, or equivalent, within each organisation and by the Permanent Secretary of the Department of Health.
In signing the MOU, organisations agree to the establishment of an Honest Broker Service under the terms set out in this MOU. Organisations also agree to abide by the expectations set out for them in relation to their use of the Honest Broker Service and how they handle the data they receive.
The MOU and associated arrangements should be reviewed annually by the Honest Broker Advice Service, in consultation with the organisations included in the MOU.
The MOU Sign Off page is provided at Appendix 1.

Appendix 1

MEMORANDUM OF UNDERSTANDING (MOU) FOR AN HONEST BROKER SERVICE FOR HEALTH & SOCIAL CARE INFORMATION

SIGN OFF

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I (print Name), Chief Executive/ Chief Officer for (print Name of Organisation) agree to the establishment of an Honest Broker Service under the terms of this MOU. In signing this declaration, as the accountable officer for my organisation, I agree that my organisation will abide by the terms of the MOU. I agree that my organisation will handle the data it receives from the Honest Broker Service in line with the requirements set out by the MOU. I will ensure that staff within my organisation who use the Honest Broker Service, or data from the Honest Broker Service, are aware of their responsibilities and that they are provided with relevant training and awareness to enable them to comply with the MOU.

As users of the Honest Broker Service, my organisation and staff will:
• Ensure they request the minimal amount of data required for the purpose.
• Provide adequate justification when pseudonymised data is required.
• Apply appropriate retention and disposal to the information they receive.
• Will not attempt to identify individuals from the data they are provided, either by using the data they already hold, or by linking that data to data received as part of separate requests to the Honest Broker Service.

I will ensure that staff are made aware that disciplinary action will be taken as a result of any breach of this MOU and that where breaches occur relevant action is taken.

If I have any concerns over the processing of my organisation's data by BSO, I can request BSO to cease processing the data. I can also request that BSO provide information about their processes for anonymising and pseudonymising the data provided by my organisation.

Appendix 2 – How the Honest Broker Service Works
Customers Assessment of Honest Broker (HB) access requests Data Sources
Customers can access their 'own' data for patient care purposes
Trusts
HSCB
PHA
DoH
Other
Researchers
Outputs: Validated outputs are returned to the customer. Regular

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these will fall into three broad categories dependant on the original request and HBGB assessment. All outputs will be assessed outputs do not need and scored for disclosure risks. Outputs will be: to go through HBGB each time
a) summarised statistics; b) anonymised data; or c) pseudo-anonymised data (specialised anonymisation software may be required).
Current data access continues for A ‘Safe Haven’ will be provided within the Honest Broker Service based at BSO.
existing customers, but should be reviewed to ensure sharing meets the requirements of the MOU.
Honest Broker Advice Service Staffed by Statisticians and IT staff Develops, maintains and manages HB access protocols. Provides advice and support to customers. Provides secretarial support to the Honest Broker Governance Board (HBGB) to enable informed decision making. Maintains records of requests received.
Memorandum of Understanding (MOU) for an Honest Broker Service for Health Information [9]
Honest Broker Governance Board See Honest Broker Governance Board (HBGB) Terms of Reference- Appendix 6, MOU HBGB will assess HB access requests from customers and will decide whether they need modified or if they are appropriate. HBGB may apply disclosure restrictions or other controls as appropriate.
Data available to HB 1) BHSCT, NHSCT, SEHSCT, SHSCT, WHSCT data already contained within HSC Regional Data Warehouse. 2) Primary care data relating to pharmacy, dental, ophthalmic and patient registrations in FPS data warehouse.
(The above represents the data which will be provided at the outset. Further data sources may be made available as the HB service develops).
HB Advice Service (HBAS) will:
• manage agreements with data suppliers and HB users
• help customers understand the limitations of the data and what data is available
• develop the data available to include new sources over time
• assist customers prepare their submissions for HBGB
• assess and score outputs for risk of disclosure
• develop a ‘safe haven’ for HB customers (where customers can query the anonymised data but are not allowed to extract record level data)

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Appendix 3 – Internal HSC/ DoH Request Process

Return to organisation to follow current procedures for secondary uses or change request to have data either anonymised or pseudonymised

Information required is identifiable

onest Broker checks request is for
her anonymised or pseudonymised
data

accuracy of data

Pseudonymised
data
Pseudonymised
data

Anonymise
data

Apply unique
identifier

Gather and check

Provide data and ensure
appropriate disclosure controls
are in place
Request from DoH or
HSC organisation for
data

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Test data against the risk of identification, check and approve disclosure

No

Is the request justified – have you got a valid reason to provide a unique identifier?

Gather and check

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Appendix 4 – Research Request Process

Research Request Received by Honest Broker Service*

***If the request is a non-research request from within the HSC family they should follow the internal process for making non-research requests to the HBS (see Appendix 3 of the Honest Broker MOU).**

Appendix 5

Honest Broker Governance Board - Terms of Reference

Membership

The Honest Broker Governance Board will require representation from the Data Controllers of the data held within the Regional Data Warehouse, as well as representation from the main users of the data from within the HSC family. It is recommended that membership should be as follows:

• A representative from each of the 5 Trusts, 1 of who should be an Information Governance lead within 1 of the Trusts. A Representative from the Business Services Organisation, which will be delivering the Honest Broker Service.

• A Representative from the Department's Information Analysis Directorate (IAD), which will deliver part of the research support service and will be a key user of the service from within the HSC family.

• A Representative from the HSC Board, which will be a key user of the service from within the HSC family.

• A Representative from the Public Health Agency, which will represent researchers and others using the service within the HSC family.

• A Representative from the Patient and Client Council, which will represent patients and clients whose data is held within the Regional Data Warehouse.

• A Clinician (whose role shall be to input her/his clinical expertise).

• A Personal Data Guardian Representative. It is recommended that this person should also be the Chair of the HBGB.
• An Operations Research Manager from the Trusts.
• A representative from the Office for Research Ethics Committees Northern Ireland (ORECNI).
• At least one lay representative.

Secretariat:
Honest Broker Advice Service.
Memorandum of Understanding (MOU) for an Honest Broker Service for Health Information [12]

Roles & Responsibilities
• Discuss and consider the risk, cost and feasibility of health and social care related research projects which are submitted to the Honest Broker service, for pre-existing data held within the Regional Data Warehouse.
• Approval of data extraction and provision in appropriate format.
• Communicate decisions in relation to the research applications back to the applicants, including conditions of access, disclosure controls, or information about why any application has been declined.
• Provide advice to researchers of any modifications which need to be made to their application.
• Ensure meetings of the HBGB are minuted by the HBAS and that records of all decisions are maintained.
• To be assured that the management of Honest Broker data for a researcher is compliant with best practice.
• To maintain oversight of the working of the Honest broker service (HBS) and review relevant performance metrics.

Appeals
Any appeals by researchers will be referred to the Honest Broker Research Appeals Panel (HBRAP), which will make a final decision.

Meetings
Meetings of the HBGB will be organised by the HBAS when research project applications have been received by the HBAS. When it is not possible to arrange a meeting within a reasonable timeframe – the approvals process will be completed by correspondence. The HBGB should aim to meet at least twice a year.

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Quorum of membership
A meeting of the Honest Broker Governance Board cannot take place unless there is present at minimum, the Chair/Deputy Chair, 1 HSC Trust voting member (or her/his nominated Deputy) and 3 other voting members (or their nominated Deputies).
For the purpose of review and approval of an Honest Broker Research Application Submission, a meeting consisting of at least the Chair/Deputy Chair, 1 HSC Trust voting member (or his/her nominated Deputy) and 1 other voting member (or her/his nominated Deputy) must be convened. This meeting may happen physically, by teleconference or by email correspondence.

Modifications to Existing Projects
The HBAS will, on behalf of the HBGB, process Project Modification requests submitted by researchers. This will enable HBAS staff to amend existing project datasets and/or project end dates, where appropriate. The HBGB will be informed of any Project Modification requests.

Reporting and Documentation
The Research Approvals principles used to assess a project will be provided as an annex to the Research Application Form and will be made available to researchers as part of the application process. Documentation of decisions, actions and the minutes of meetings will be provided by the HBAS.
Details of all approved projects will be made available on the BSO website.

Appendix 6 – Definitions
Anonymisation The process of rendering data into a form which does not identify individuals. Pseudonymisation The process of distinguishing Individuals in a dataset by using a unique identifier which does not reveal their ‘real world’ identity. Data Processor Any person (other than an employee of the data controller) who processes the data on behalf of the data controller. Data Controller A person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed. Data Protection Act (DPA).

The main UK legislation which governs the handling and protection of information relating to living people. Personal Data which relates to a living individual who can be identified-
(a) From those data, or (b) From those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and

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includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual. Processing of Data In relation to information or data, means obtaining, recording or holding the information or data or carrying out any operation or set of operations on the information or data, including—
(a) organisation, adaptation or alteration of the information or data, (b) retrieval, consultation or use of the information or data, (c) disclosure of the information or data by transmission, dissemination or otherwise making available, or (d) alignment, combination, blocking, erasure or destruction of the information or data. Re-identification The process of analysing data or combining it with other data with the result that individuals become identifiable.