APPENDIX TWO:
SUGGESTED QUESTIONS TO PUT TO ICBs OR TO SUBMIT AS FOI REQUESTS

Theme 1: GOVERNANCE

1.1 Overall structure

[These questions assume that ICBs will have similar structures for data governance or uses similar names for their committees and sub-committees, which may not always be the case. Initial information to help adapt these questions about an ICB's structure should be available in its Governance Handbook.]

Q: Which boards, committees, sub-committees and working groups across the ICS play a role in

a) the ICS's *collection, processing, sharing, and use* of patients' data, and
b) *governing* the ICS's use of patients' data?

Q: Please explain

a) how these Boards, committees, sub-committees and groups relate to or engage with the public, which of these are open to the public, and how the public can access the meetings and/or papers of these bodies;
b) if none of these is open to the public, and the papers are unpublished, how is accountability to the public regarding the use of their data to be established?

Q: What access do the various bodies across the ICS have to social care data, and how is this access governed?

1.2 The Digital Board

Q: Please provide the Terms of Reference (ToR) for the Digital Board (or whichever body deals with the development of the ICB's Digital Strategy; investment and funding bids for the ICS's digital schemes; and aligning digital solutions across the ICS). If ToR are not available, please provide details of the Board's responsibilities and membership, plus details of any representatives on the Board from private companies or the ICS's commercial 'partners'.

1.3 The Information Governance sub-committee

Q: Which private companies – including technology, commercial or research 'partners' - are represented on the Sub-Committee; what is the rationale for their membership; and how does the sub-committee deal with conflicts of interest?

Q: Please explain:

a) Whether the ICB transfers personal data abroad, and if so, what type of data is transferred, to whom is it sent, and for what purposes?
b) What form does this data take (e.g. anonymised, pseudonymised, aggregated)?
c) What safeguards are in place to prevent the selling on, or out of contract processing of patient data that is transferred abroad?
d) What processes are in place to ensure patients' informed consent for this transfer?

1.4 The Digital Transformation Board

Q: What are the terms of reference of the Digital Transformation Board or where can these be found?

Q: Please provide details of any representatives on the Board from private companies or industrial, technology, commercial or research 'partners'.

1.5 The Data Usage Committee
Q: Please supply the Data Usage Committee's terms of reference. If these are not yet published in final form, please explain:

- to whom is the DUC accountable?
- what are its responsibilities?
- which ICS and non-ICS bodies, groups or committees does the DUC relate to?
- which roles are represented on the DUC?
- which external bodies or organisations, including private companies or the ICS's industrial, technology, commercial or research 'partners', are represented on the DUC?
- how is the public represented on the DUC, beyond Healthwatch?

Q: Does the ICB's DUC publish its minutes, and a full list of Approved Data Usage Requests. If not, what steps is the ICB taking to make the work of the DUC and its decision making more transparent to the public?

1.6 The Business Intelligence Committee
Q: Please provide details of the work of the Business Intelligence Unit, including its core responsibilities, to whom it is accountable, and its relationship to any external partners. What access does it have to confidential patient information (CPI) and on what legal basis?

Q: Which organisations are providing risk stratification services to the ICB? Are they on NHSE's List of Risk Stratification Approved Organisations?

Q: Which organisations are providing population health analytic services to the ICB? Are they approved and listed on the Risk Stratification or any similar Register?

Q: How has the ICB informed patients that any opt out they may have registered has been maintained, despite their CPI being requested following any task-related approval by the Confidential Advisory Group (CAG)?[1] As the nature of Population Health Management requires individuals' CPI to provide what is felt to be appropriate care, please tell us how many people have opted out of this particular use of their data following your application of section 251?

1.7 The Population Health Management and Inequalities Board
Q: Please provide the terms of reference for the PHMIB. If these are not yet published in final form, please explain:

- to whom is the Board accountable?
- which ICS and non-ICS bodies, groups or committees does the Board relate to?
- which roles are represented on the Board?
- which external bodies (including private companies, industrial, technology, commercial or research 'partners') have representatives on the Board and what is the rationale for this?
- Which company is providing data analytics? Has it received CAG approval for the analyses?

[1] "For researchers intending to access confidential patient information without consent in England and making an application through the Confidentiality Advisory Group (CAG), the standard condition of CAG's advice is that the wishes of people who have withheld or withdrawn their consent (i.e. opted out) are respected. Therefore, it has taken the position that it will advise applicants that it is not in the public interest to override any opt-out in anything other than the most exceptional circumstances, e.g. serious public safety concerns." (NHS HRA website accessed 1st May 2023).

- how is the public represented on the Board, including but also beyond Healthwatch?

THEME 2: USE OF PATIENTS' DATA

2.1 Data services

Q: Which supplier systems currently provide data sets for the data service/SDE used by the ICB? How can their data controllers be contacted? Does the data controller of each supplier carry out a Data Protection Impact Assessment, and where can the public access these?

Q: Do subscribers to the data service/SDE become data controllers for the data they receive – in which case how can these data controllers be identified by the public?

Q: Is the data service provider categorised as an 'NHS accredited secure data environment (SDE)" as described by the Department of Health and Social Care's *Secure data environment for health and social care data – policy guidelines*?[2] If not, how does it fit with DHSC policy for SDEs to become the default way to access NHS health and social care data for research and analysis?

Q: What is the relationship of the data service to the Data Services for Commissioner's Regional Office (DSCRO)?

Q: We understand that disclosure of anonymised or aggregated data to the data service by GPs, hospital trusts and other data controllers is lawful provided that anonymisation takes place at source. What steps has the ICB taken to ensure that the anonymisation of the data that it draws on for analytic purposes has been undertaken at source?

Q: Does the data service share patient identifiable data with third parties? If so, for what purposes and what is the legal basis for sharing such information?

Q: If the data service shares patient identifiable data with third parties, do these include private companies (including those such as technology, industry, and research companies working in partnership within the ICS)?

Q: The National Data Guardian and Caldicott Guardian Chair of Council have recently expressed concerns that sharing information from local record sharing programmes with SDEs for purposes other than direct care may be happening without ensuring that their activities do not breach confidentiality. Please explain:

- How does the data service used by the ICB ensure confidentiality during this process?
- How does the ICB ensure that confidential patient information used for direct care purposes at the end of a processing chain (eg following risk stratification) is not based on prior unlawful disclosure and processing?[3]

Q: Have any applications been made to the CAG for support under Section 251 of the NHS Act 2006 to share confidential patient information from the local care record with the data service? If so, what are the CAG reference numbers?

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[2] https://www.gov.uk/government/publications/secure-data-environment-policy-guidelines/secure-data-environment-for-nhs-health-and-social-care-data-policy-guidelines

[3] https://www.nhsdatasharing.info/CLoC/DDSdataflow.pdf

Q: Which occupational groups are trained and authorised to
a) have access to patients' data, and
b) to conduct dataset linking within the data service? What form of training is recognised, and what is the process for authorising/verifying those who are carrying out dataset linking? What degree of probity is legally required contractually?

Q: What are the governance arrangements for the data service and to whom is the service accountable?

Q: What Data Sharing Agreements, signed in the past 18 months, underpin the use of, and access to, patients' personal data via the data service? Please give details of the particular projects and the specific policies in place in respect of people's rights and consent.

Q: When and how are patients proactively informed about their right to opt out of their data being collected and shared at local and national levels? What information is kept, including the numbers of those who have chosen to opt out, that shows patients have been given a choice by all ICS organisations?

2.2 Population Health Management and risk stratification

Q: Please explain

- Which underlying causes of ill health is the ICB currently tackling using population health management?
- Which data sets are being used?
- How is the ICB tackling these causes of ill health? and
- What new funding has been secured for tackling these inequalities, and if there is no new funding, which existing services are losing funding in order to finance these activities?

Q: How does the ICB ensure that the public understands the proposed use of their data for risk stratification purposes? At what point in the collection of a patient's data are they given an explanation of risk stratification; information about who the data controllers and processors are; the type of data used; and the individual's rights, e.g. to access the data or to object.

Q: What are the conditions set by the CAG allowing the ICB to carry out risk stratification? Please provide a copy of the Risk Stratification Assurance Statement.

Q: Please provide a practical example of how Population Health Management is being used to reduce health inequalities and what steps are being taken to monitor and evaluate its effectiveness.

THEME THREE: THE LEGAL BASIS FOR THE USE OF PATIENTS' DATA

3.1 The common law duty of confidentiality

Q: Population Health Management requires identifiable patient level data. To be lawful, this requires an application to the Confidentiality Advisory Group for support under Section 251 of the NHS Act 2006 to temporarily lift the Common Law Duty of Confidentiality. Has the ICB made an application/s for this specific purpose and if so, what are the CAG reference numbers?

Q: Please provide evidence to demonstrate that the ICB has complied with the existing section 251 exemption conditions and controls in its use of confidential patient information for all purposes that do not constitute direct patient care, including

- risk stratification and
- Population Health analytics.

Plus, if linked social care data (which is not covered by CAG) has been used, please provide evidence of the necessary legal basis relied on for such use.

Q: Please inform us how many patients' data were excluded from risk stratification and analysis due to their opting out? If none, then has a specific exclusion been applied, and if so, by which authorized body?

3.2 The UK GDPR and right to know

Q: A key transparency requirement under the UK GDPR[4] gives individuals the right to be informed about the collection and use of their personal data when the data is being collected.

How is the ICB ensuring that patients and other individuals are made aware, *at the point of data collection*, that their personal data is to be collected for non-direct patient care, and informed about the purposes for which it may be used? Will it be made clear that their data will be used not only by the ICB, but other organisations as well, such as other ICBs?

3.3 The Data Protection Act (DPA 2018) and 'substantial public interest'

Q: If the ICS or the data service it uses is relying on substantial public interest conditions set out in the DPA (2018) to process special category data, please explain *how* such processing is in the public interest.

3.4 Data confidentiality and the ICB

Q: How is the ICB ensuring *independent* oversight of the way it uses confidential patient information?

Q: Patients' medical records often contain special category data that is subject to additional protections. How does the ICS's, or its data service's, processing of special category data comply with Article 9 (3) of the UK GDPR, requiring such data to be processed by a professional who is subject to an obligation of professional secrecy (such as a doctor, nurse or clinical scientist) or others owing a legal duty of confidentiality?

Q. Please provide the data service's Appropriate Policy Document covering the processing of special category data.

THEME FOUR: PATIENT AND CITIZENS' ENGAGEMENT

Q: Please explain how the public is represented, beyond Healthwatch, in ICB decision-making about digital and data matters, and how the public can get involved. What methods are used to ensure meaningful consultation and engagement with a fully diverse range of citizens?

Q: Which committees, sub-committees and groups dealing with patients' data include:
a) a Data Champion
b) a representative from Healthwatch and/or
c) a lay member?

Q: Please explain

[4] https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-be-informed/

a) How does the ICS ensure that
    - individuals are aware that they may raise an objection to their data being, collected, shared or processed at local and national levels, and
    - that they are informed about how they can do this?
b) Where the objection concerns a specific health and social care provider, how are individuals supported in finding the relevant data controller to contact?
c) What information, including the numbers of those who have chosen to opt out, is kept to show that patients have been given a choice to opt out by all of the ICS's organisations?

THEME FIVE: PRIVATE COMPANY INVOLVEMENT

Q: Do the different companies that supply data derived from primary and hospital care to the data service used by the ICB have access to the detail of individual patient records?
If so,

- what requirements are placed on them to ensure that they do not use this data for their own purposes, and
- what monitoring takes place to ensure they comply with any such requirements?

Q: A significant number of companies listed on the HSSF for 'Informatics, Analytics and PHM Digital Tools' have parent companies that have been required to pay colossal fines for violations of contracts. What processes has the ICB put in place to ensure that it does not procure services from companies with a history of customer protection and contract violations?

Q: Are any private companies that provide the ICS's IT data platforms or that collects, aggregates, processes or otherwise deals with patients' data potentially able to access individual patient records as part of the delivery of their service?