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HRA response to the ICO's Consultation on draft guidance on the use of anonymisation and pseudonymisation for research purposes

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The Health Research Authority (HRA) welcomes the opportunity to comment on the ICO’s draft guidance on the use of anonymisation and pseudonymisation for research purposes. Clear and consistent guidance in this area has an important role in enabling the responsible use of health and social care data for research, while maintaining the confidence of patients and the public.

The HRA is a statutory body that regulates and approves health and social care research in the UK. Our core purpose is to protect and promote the interests of patients and the public in health and social care research. Most of our functions apply to research undertaken in England, but we work closely with the other UK nations to support a coordinated UK-wide research system. Our functions include ethical review and approval of research, study-wide governance review, including information governance, and coordinating and standardising research regulatory practice.

The issues addressed in this guidance are directly relevant to the regulatory framework within which health and social care research takes place. We welcome the development of research-specific guidance and there is much that is helpful in the draft, including its recognition that controller and processor roles need to be considered in relation to particular processing activities and that organisations may have different roles at different stages.

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Our principal request is that the final guidance more clearly reflects the organisational and regulatory structure of health and social care research and aligns its treatment of controller roles, joint controllership and the “whose hands” assessment with the ICO’s existing guidance.

In particular, we consider it important that the final guidance:

- recognises the established role of the research sponsor;
- distinguishes individual researchers from the organisations on whose behalf they act;
- avoids treating necessary or interdependent decisions across a research pathway as sufficient, without more, to establish joint controllership;
- distinguishes substantive determination of research processing from decisions about whether data may be made available and from operational implementation;
- reflects the ability of SDE/TRE operators to act as processors where they implement processing on behalf of controllers;
- makes clear how controller, joint-controller and processor status affects the subsequent “whose hands” assessment;
- distinguishes access to information within a secure environment from the subsequent disclosure of information or controlled outputs from that environment; and
- makes clearer, at each stage, which organisation the guidance is addressing and what assessment that organisation is expected to undertake.

These issues are likely to become increasingly important as health and social care research makes greater use of SDEs, TREs and federated approaches involving several organisations with different but interdependent functions. We expand on each of these points below.

We also think it is important to recognise the boundary of this ICO guidance. Data protection is only one part of the legal and governance framework for health and social care research. Questions about the circumstances in which pseudonymised information remains confidential patient information, and what confidentiality route supports its use or disclosure, are separate from the UK GDPR analysis.

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HRA has a statutory role in providing regulatory guidance for health and social care research, including guidance on good practice and on the requirements applying to those conducting research, to which NHS trusts and foundation trusts in England must have regard under section 111(6) and (7) of the Care Act 2014. HRA has previously exercised this role in translating data protection requirements into health and social care research-specific guidance, working with the ICO and the wider health and care IG system.

HRA also has a distinct role in the wider confidentiality and research-governance framework, including through its Confidentiality Advisory Group (CAG) where relevant. We therefore think there is likely to be a continuing need for a health and social care research-specific layer of guidance explaining how the ICO's data protection framework applies within established research arrangements and interacts with those separate requirements. We would welcome working with the ICO on how these respective pieces of guidance fit together.

1. Organisational roles and the role of the research sponsor

The draft frequently refers to the “researcher”. We suggest that it should distinguish more clearly between the individual researcher and the organisations involved in sponsoring and undertaking the research.

Under the [UK Policy Framework for Health and Social Care Research](#), all health and social care research must have a research sponsor. The sponsor is the organisation or partnership that takes overall responsibility for proportionate and effective arrangements being in place to set up, run and report the research study. The sponsor is not necessarily the organisation employing the individual researcher.

This distinction is particularly important when applying the controller analysis in the draft. HRA guidance ([Controllers and personal data in health and care research - Health Research Authority](#)) and the HRA's UK Study-Wide Governance Criteria ([section 5.1 on Assessment of IG, Data Protection Compliance and Data Security](#)) set out the established position that the sponsor is the controller for data processing in a research study. They explain that the sponsor determines, amongst other things, what data are processed, the purposes of the processing, how the data are processed and stored, and retention periods. The Criteria also recognise that joint controllership can arise where the facts support it. This established position on controllership was developed previously in consultation with the ICO.

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Many of the matters identified in the draft as indicators of controllership will therefore already have been determined by the sponsor through the protocol and study design - for example, the research purpose, the population or cohort to be studied, the data required, linkage requirements, retention and whether re-identification is required.

The individual carrying out the analysis, their employing organisation and the sponsor may all be different. We therefore recommend that the guidance introduces and defines the research sponsor where relevant and makes clearer that the controller assessment should focus on the organisation that in fact determines the relevant purposes and essential means, rather than assuming this is the individual researcher or their employer.

It is therefore important that the guidance does not imply that an individual researcher or their employing organisation is the controller simply because they undertake the research, employ the investigator, provide an honorary contract or provide access to systems. Those factors may be relevant context, but are not determinative in themselves. The assessment should focus on which organisation or organisations, in practice, determine the purposes and essential means of the relevant processing.

2. Joint controllership and “converging decisions”

We would welcome further clarification of the section on joint controllership, particularly the concept of “converging decisions”.

The draft explains that joint controllership can arise where parties make decisions about different aspects of processing which complement one another so that the processing could not take place without the influence of all parties. It gives as an example one organisation determining governance and assurance measures and another determining core design parameters and the release model.

We are concerned that this could be read too broadly in the health and social care research context. A research sponsor, a data-providing organisation and an SDE/TRE operator may all make decisions which are necessary for research to take place. However, the fact that those decisions are necessary, complementary or interdependent should not, of itself, mean that those organisations jointly determine the same processing.

The analysis should remain focused on whether, as a matter of fact, the parties’ decisions, taken together, amount to joint determination of the purposes and essential means of the particular processing activity under consideration. Different organisations can have important and necessary responsibilities at different stages, or in relation to

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different aspects of an overall research pathway, without necessarily becoming joint controllers for the same processing.

This distinction is particularly important because the controller analysis has direct consequences for anonymisation. The ICO's existing anonymisation guidance makes clear that the "whose hands" approach applies where information is disclosed to an organisation which is not acting with the disclosing organisation as a joint controller or as its processor. Where information is personal data in one joint controller's hands, the ICO's existing guidance treats it as personal data in the hands of the other joint controllers regardless of their own technical or contractual ability to identify the people concerned.

The consequences of characterising organisations as joint controllers therefore extend beyond the allocation of accountability obligations. If joint controllership is inferred too readily, it may have a significant downstream effect on whether information or research outputs can be treated as anonymous from the perspective of another organisation.

For that reason, we think the final guidance needs particular precision around "converging decisions". Interdependence is commonplace in regulated research and should not itself become a proxy for joint determination.

3. Distinguishing research decisions, data-access decisions and implementation

Related to this, we suggest that the guidance distinguishes more clearly between:

- determining the substantive purpose and essential means of the research;
- deciding whether data controlled by another organisation may be made available for a proposed use, and subject to what conditions; and
- administering or technically implementing an approved use.

For example, the sponsor determines the research purpose, population or cohort, data required, linkage and analysis. A data-providing controller, potentially informed by a Data Access Committee (DAC) or other governance process, may separately decide whether and on what conditions data it controls can be made available for that proposed research. An SDE/TRE operator may then provision the approved data and implement the required access, security, pseudonymisation and output controls.

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Those decisions may all be necessary for the research to proceed, but that does not, of itself, mean that the data-providing controller has jointly determined the sponsor-controller's research processing or that the SDE/TRE operator is a joint controller.

The distinction between deciding and approving is particularly important. A data-providing controller may make a controller decision about whether and on what terms its own data are made available, without thereby co-determining the subsequent research processing undertaken by the sponsor-controller. Similarly, an SDE/TRE operator may administer an access process or implement an approval against established criteria on behalf of a controller without acquiring an independent research purpose.

We welcome the parts of the draft which already support this distinction. It recognises that applying anonymisation or pseudonymisation techniques and carrying out output checking can be processor activities where they are undertaken in accordance with controller-agreed steps, parameters or controls.

We suggest that the ICO frames this analysis around the particular activity and function being undertaken rather than around labels such as "TRE" or "SDE". Those terms cover a wide range of operating models. Operating an SDE/TRE, administering an access process, applying controller-established access criteria, providing technical and security controls, pseudonymising data and undertaking disclosure or output checking do not, in themselves, mean that the operator determines the purposes and essential means of the research.

4. Controller checklist and service provider decision-making

We suggest reconsidering the formulation that "you are a controller if you answer yes to any" of the questions in the controller checklist.

The list contains matters which may be strong indicators of controllership, but it also includes decisions about anonymisation techniques, technical and organisational measures, platforms, governance and implementation. Depending on the circumstances, some of these may legitimately be decisions made by a processor using its specialist expertise while implementing requirements already substantively determined by a sponsor or another controller.

We therefore suggest presenting the checklist as a set of indicators to be considered in the round, and in relation to a defined processing activity, rather than suggesting that any single positive answer necessarily establishes controllership. The key question remains who in fact determines the purposes and essential means of that processing.

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In particular, it would be helpful to distinguish between substantively determining an essential matter and operationally implementing another controller's decision.

The same point applies to the suggestion that insufficient controller oversight of an anonymisation or pseudonymisation service provider is likely to make the provider a joint controller. Insufficient oversight may indicate that the factual relationship needs closer examination, and may raise a separate accountability or compliance issue, but should not itself determine the provider's status. The substantive question remains whether the provider in fact determines the purposes and essential means of the relevant processing.

5. Clarifying the sequence and intended actor

A cross-cutting difficulty is that it is not always clear who "you" refers to in the draft. At different points it appears capable of referring to the data-holding controller, an SDE/TRE operator, or the researcher/research organisation. This is particularly difficult where the guidance also requires roles to be assessed for each processing stage.

We recommend that the final guidance sets out a clearer sequence, for example:

- identify the particular processing activity and stage;
- identify the organisations involved and their controller/processor roles for that activity;
- identify the organisational perspective from which any identifiability assessment should be undertaken; and
- where relevant, separately consider the information or output that is subsequently made available or disclosed to another organisation.

The existing flowchart could usefully be aligned to these stages. This would help distinguish, for example, processing identifiable source data to create a research dataset, linkage or pseudonymisation within an SDE/TRE, researcher access or querying, and the subsequent release of outputs.

A clearer sequence would also help address uncertainty about who particular statements in the guidance are directed to and when each assessment is required.

6. The 'whose hands' assessment: organisational perspective

We welcome the draft's emphasis on assessing identifiability in context. We nevertheless recommend a clearer cross-reference to the ICO's existing anonymisation

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guidance when explaining the “whose hands” approach, particularly its qualification concerning joint controllers and processors. The existing guidance expressly states that the approach applies to disclosure to an organisation which is not acting with the disclosing organisation as a joint controller or as its processor. ([ICO](#))

Access and analysis within an SDE/TRE

We also suggest that the research-specific guidance is clearer about the organisational level at which the “whose hands” assessment should be undertaken. The draft refers in its TRE example to the “researcher (or their organisation)”. In health and social care research, however, the researcher may be employed by a university, NHS organisation or other research organisation while a different organisation acts as the research sponsor and, as such, the controller for the research processing.

Where a researcher accesses information within an SDE/TRE on behalf of the sponsor-controller, the researcher’s access should not in itself be taken to mean that the researcher’s employing organisation represents a separate set of “hands” for the purposes of the identifiability assessment. The guidance should make clear how the controller and processor relationships for that processing determine the relevant organisational perspective, including how additional information available to the sponsor-controller and means reasonably likely to be used by it should be taken into account. The assessment should not turn only on what the individual researcher personally knows or can see.

Although “whose hands” is useful shorthand, in an SDE/TRE context it should not be understood as necessarily involving the physical transfer or receipt of the underlying data by another organisation. A researcher may access and analyse information while it remains within the secure environment.

The draft’s healthcare TRE example usefully illustrates this issue. The researcher does not have direct access to the pseudonymised data, undertakes analysis through the secure environment and receives outputs only after automated and manual checking. The draft concludes that the data accessed and analysis output may be anonymous from the researcher’s perspective where neither the researcher nor their organisation has additional information or reasonably likely means of identification.

It would be helpful for the ICO to clarify how that conclusion should be applied where the researcher is accessing the SDE/TRE on behalf of a sponsor-controller that is not the researcher’s employing organisation, including whether and how information available to that controller and means reasonably likely to be used by it should form part of the identifiability assessment. This clarification may affect whether information

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accessed within the SDE/TRE can properly be regarded as anonymous for the relevant research processing under data protection law.

The common law duty of confidentiality involves a separate assessment, which we address in section 7 below.

Outputs disclosed from an SDE/TRE

A separate issue arises where outputs are subsequently disclosed from the SDE/TRE to another organisation. The status of those outputs may then need to be assessed from the perspective of that recipient organisation, taking account of the information available to it and the means reasonably likely to be used by it to identify individuals.

The status of source data held or processed within the environment, information accessed or analysed within the environment, and outputs subsequently disclosed outside it need not therefore be the same. A disclosure-controlled output may be anonymous for one independent recipient while being personal data for another organisation that has additional information or other reasonably likely means of identification. This is consistent with the ICO's existing guidance that the same information may be personal data in one organisation's hands while being anonymous in another's, subject to the important exception for processor and joint-controller relationships.

The draft itself demonstrates the other side of this distinction in its healthcare TRE example: where the TRE operator is acting as processor and holds the additional information necessary for re-identification, the information is personal data from the perspective of both the TRE operator and its controllers.

A further worked health and social care research example

We strongly recommend including a further worked example based on a typical sponsored health and social care research arrangement involving an SDE.

For example, a pharmaceutical company sponsors a multi-site health research study. The sponsor determines the research question and protocol, including the population or cohort to be studied, the health data required, the linkage and analysis to be undertaken, the duration of the research and any need for follow-up or re-identification.

Researchers undertaking the study may be employed by NHS organisations or universities which are not themselves the sponsor. Their employment of researchers, or the fact that those researchers undertake study activities, does not of itself mean that those organisations determine the purposes and essential means of the sponsor's research processing.

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An NHS organisation holds existing patient information for the purposes for which it collected or otherwise processes that information and is controller for that processing. It has separate responsibilities in deciding whether the proposed use or making available of that information for research is lawful and appropriate.

Approved data are made available through an SDE operated by another organisation. The SDE operator provisions the approved research workspace, applies pseudonymisation where required, authenticates users, manages access in accordance with agreed governance arrangements, operates technical and security controls, logs activity and checks outputs against established disclosure-control requirements.

On these facts, the sponsor is controller for the research processing; the NHS organisation may separately be controller for processing undertaken in relation to its existing data and decisions about making those data available; and the SDE operator may act as processor in implementing the processing within the secure environment.

These roles should not become joint controllership simply because the research depends upon all of them. Joint controllership may arise where, on the facts, two or more organisations' decisions amount to joint determination of the purposes and essential means of a particular processing activity. Where it does arise, it should be identified and described in relation to that processing rather than assumed to extend across the research pathway as a whole.

It would also be helpful for the example to recognise that these functions do not necessarily always sit in different legal entities. For example, the sponsor may itself host or operate an SDE. The analysis should therefore follow the actual functions and decisions being undertaken for the particular processing activity rather than the organisational label.

We suggest that any worked example follows the processing through its different stages, including the status of the source data, access or analysis within the secure environment, and any subsequent release of outputs. This would help demonstrate how controller and processor roles, identifiability and the “whose hands” assessment interact across a realistic research pathway.

7. Wider health and social care research framework

We also suggest a short signpost making clear that the guidance addresses the data protection position. A conclusion that information is anonymous for UK GDPR purposes, or a particular allocation of controller and processor roles, does not itself

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determine whether separate requirements relating to confidentiality, research ethics and research governance have been met.

In health and social care research, these requirements operate alongside data protection law. HRA's study-wide governance framework ([section 5.1, as above](#)), for example, considers data protection alongside the common law duty of confidentiality and, where relevant, mechanisms such as section 251 support.

This distinction is particularly important for pseudonymised health information. Whether information remains personal data under UK GDPR and whether it remains confidential patient information under the common law duty of confidentiality are separate legal questions applying different tests. The ICO guidance should therefore avoid being read as resolving the confidentiality position merely because it has reached a conclusion about anonymity under data protection law.

We think a short signpost would help prevent conclusions in the anonymisation guidance being taken as resolving those wider requirements, including the standard for anonymisation under the common law duty of confidentiality. HRA has previously published guidance on this distinction, developed in consultation with ICO colleagues, along with other members of the Health and Care IG Panel Working Group, and the NHS England IG team - [Types of health and care information and the legal frameworks protecting them - Health Research Authority](#).

This provides an established precedent for HRA working with the ICO and the wider health and care IG system to translate data protection requirements into the health and social care research context. We think there is likely to be a similar need here, particularly in explaining how the ICO's position interacts with research sponsorship, research governance and the common law duty of confidentiality. HRA, including through CAG where relevant, would be well placed to lead or coordinate that work with the ICO and other UK partners.

8. Terminology

We welcome the draft's recognition that secure access, pseudonymisation and output checking can be used together to minimise identification risk. We also welcome the clear statement that a TRE/SDE is not itself an anonymisation technique and that the status of information held within the environment must be assessed in context.

Consistent with our comments above, we suggest that this distinction is applied consistently throughout the guidance and that the labels "TRE" or "SDE" are not used as shorthand for the status of the information being processed. The analysis should

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instead follow the particular data, processing activity, organisational roles and safeguards.

We also encourage the ICO to use terminology consistently throughout the guidance, particularly where the same information may have a different status from the perspective of different organisations or at different processing stages. Clear use of “personal data”, “pseudonymised data” and “anonymous information”, with explicit identification of the relevant organisational perspective, would help avoid confusion in practice.

Conclusion

The HRA welcomes the ICO’s development of specific guidance in this area and supports its overall direction. The section on synthetic data is particularly helpful in making clear that synthetic data should not automatically be treated as anonymous and that identifiability must be assessed in context.

Our main concern is that some of the draft’s core concepts could be applied in ways that do not map cleanly onto the established [UK Policy Framework for Health and Social Care Research](#) and the wider research governance requirements that sit alongside it. In particular, greater clarity on the sponsor model, the test for joint controllership, the distinction between substantive research decisions and operational implementation, and the organisational perspective relevant to the “whose hands” assessment will be important if the guidance is to support rather than create uncertainty in increasingly complex research data environments.

This is particularly important as HRA works with HDRS and partners, through its role in coordinating and standardising regulatory practice across health and care research, to support clear and consistent expectations for research sponsorship, data protection and confidentiality that are aligned with other research governance requirements as national arrangements develop. Greater clarity now will help avoid these issues having to be resolved inconsistently or retrospectively as HDRS develops.

We recognise that the ICO may wish to keep its guidance at a relatively high level. If so, it is particularly important that the guidance is clear both about the boundary between the ICO’s data protection guidance and the more detailed health and social care research guidance that may need to sit alongside it, and about how the two interrelate, including in relation to the common law duty of confidentiality and wider research governance.

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The HRA has an established statutory role in providing research-specific regulatory guidance, and we would welcome working with the ICO on this interface. This could include developing a health and social care research worked example and, where appropriate, further sector-specific guidance led or coordinated by HRA, with CAG involvement as relevant.

We propose that this could be taken forward through the Health and Care IG Panel Working Group, enabling HRA, the ICO and other members, including the National Data Guardian and NHS England's IG team, to develop the approach collectively, with input from other key stakeholders. HRA could also use the Four Nations policy lead network that it manages to connect this work across the UK and support a consistent approach.

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