ABHI Response to ICO Research Provision

Submitted 22nd April 2022

Q1: On a scale of 1-5, to what extent do you agree or disagree that the guidance is clear and easy to understand? Please explain your reasoning for your choice.

☐ 1 – Strongly disagree ☐ 2 – Disagree ☐ 3 – Neither agree nor disagree ☒ 4 – Agree ☐ 5 – Strongly agree

Comments:

Generally, the guidance is clear and easy to read. Highlighting relevant provisions and the further reading links are welcome. Would welcome further, more complex examples, also examples of when something is not research and why.

Q2: Do you think the draft guidance will help you to carry out your research while complying with your obligations under data protection law? If no or unsure, please explain why.

☐ Yes ☐ No ☒ Unsure

Comments:

Gathering together all elements related to research into one piece of guidance is welcome. However, as commented in Q1 it would be useful for the guidance to include more complex worked examples where the position is less clear cut. Where possible some decision trees to support determination would be useful

Q3: To what extent do you agree or disagree that the guidance gives a useful definition of archiving purposes in the public interest?

☐ 1 – Strongly disagree ☐ 2 – Disagree ☒ 3 – Neither agree nor disagree ☐ 4 – Agree ☐ 5 – Strongly agree

Q4: To what extent do you agree or disagree that the guidance gives a useful definition of scientific or historical research purposes?

☐ 1 – Strongly disagree ☐ 2 – Disagree ☒ 3 – Neither agree nor disagree ☐ 4 – Agree ☐ 5 – Strongly agree

Comments:

Data processing is frequently needed as a precursor for research, for example data processing may be required to clean and curate data into a suitable format for research and to put it into a suitable secure environment for research. We would suggest that the guidance should explicitly state that these types of data processing activities which are required in order for research to take place effectively and securely are within the definition of scientific or historical research purposes.

We welcome the clarification that scientific research should be construed broadly and that this includes research carried in commercial settings, and technological development and demonstration. We recommend also making explicit reference to the following activities

- research that informs policy and practice (e.g. research to inform making a health service change that does not necessarily result in a publishable report);
- the application and explanation of scientific research; and showing replication/reproducibility of research.
- development of Artificial Intelligence (AI) as part of the technological development as it holds an increasingly important role in the HealthTech sector.
- research on real-world evidence (outside of formal clinical trials) and secondary use of clinical trials data

We recommend clarifying that the processing of personal data by HealthTech companies for purposes of developing their products, services, and therapies can be regarded as scientific research, by adding a sector-specific example, such as

Example

An international medical technology company develops, manufactures, and places on the market medical devices for use on patients by Healthcare Organisations (HCOs) and HCPs.

In the course of providing its services to HCOs and HCPs, it collects intra-operative videos from laparoscopic towers.

The MedTech company would like to use the videos – once all Real-World Identifiers have been removed – to advance its research and development program on robotic and digital medical devices. It aims to improve the reliability of diagnostic and therapeutic interventions on patients, utilising AI learning techniques. The company has a robust and effective data management framework for research activities.

The processing of this personal data shall be regarded as scientific research.

Q5: To what extent do you agree or disagree that the guidance gives a useful definition of statistical purposes?

☐ 1 – Strongly disagree ☐ 2 – Disagree ☒ 3 – Neither agree nor disagree ☐ 4 – Agree ☐ 5 – Strongly agree

Q6: Do the definitions of these terms fit with your understanding of these concepts? If unsure or no, please explain why.

☒ Yes ☐ No ☐ Unsure Comments: Yes, subject to comments made above.

Q7: Do the definitions capture the key features of each of the types of research-related purpose? If unsure or no, please explain why.

☐ Yes ☒ No ☐ Unsure

Comments:

Not all features of scientific research are captured, please see our response to Q4.

Q8: Do these definitions help you determine whether your processing can make practical use of the research provisions in your day-to-day work? If unsure or no, please explain why.

☐ Yes ☐ No ☒ Unsure

Comments:

Please see our response to Q4.

Q9: Are there any factors that you use to determine whether processing is for research-related purposes which you expected to see in the guidance? If yes, please give details.

☒ Yes ☐ No ☐ Unsure

Comments:

Please see our response to Q4.

Q10: Is the section of the guidance on appropriate lawful bases when processing for research-related purposes helpful? If unsure or no, please explain why.

☐ Yes ☐ No ☒ Unsure

Comments:

In general, we welcome the ICOs explicit acknowledgment that 'research related purposes shall de facto be considered as compatible with the original purpose for which the data was initially collected'. In such a case, according to Recital 50 of the UK GDPR, controllers should be able to further process the data for research related purposes without needing a new lawful basis.

However, it is unclear to us why the ICO outlines an approach that a new lawful basis (i.e., new consent) would necessarily be required for the further processing of data for research related purposes if the original lawful basis was consent. This approach would exclude, in all circumstances, the applicability of the intended purpose compatibility provided under Article 5(1)(b) of the UK GDPR, which would be inconsistent with the position taken by the European Data Protection Board (EDPB) in Opinion 3/20191. Controllers should be able to further use data for research related purposes without the need for a new lawful basis – irrespective of the initial lawful basis – as long as they have appropriate safeguards in place in accordance with Article 89 of the UK GDPR and they ensure that the processing is otherwise fair and lawful.

We would recommend that the guidance does not include reference to consent as an 'automatic' limitation of the applicability of the intended purpose compatibility.

(1 See Opinion 3/2019 concerning the Questions & Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (art. 70.1.b) adopted on 23 January 2019, para. 31.)

In the HealthTech sector there are often collaborations between commercial and academic organisations. In practice this can lead to issues with identifying the appropriate lawful basis under Article 6 occurs for projects with more than one Controller. It is not always clear whether both parties can rely on public interest in respect of the same research project. We would welcome guidance stating that for collaborations between academia and commercial entities for research purposes, public interest can be an appropriate lawful basis for both parties.

Q11. Is the section of the guidance on the compatibility of research with your original purpose helpful? If unsure or no, please explain why.

☐ Yes ☐ No ☒ Unsure

Comments:

The confirmation that processing data for a new research related purpose is automatically considered compatible with the original purpose is helpful. • In our experience much of the reluctance and delays to sharing data comes not from concerns about identifying a lawful basis but from concerns that the data controller will unintentionally breach data protection legislation and face large fines from the ICO. This is a particular concern for smaller organisations or those that do not have significant information governance and legal resource.

See also comments in Q10

Q12. The guidance provides a definition of when processing for research-related purposes is in the public interest. Does this definition help you determine whether or not your processing is in the public interest? If unsure or no, please explain why.

☒ Yes ☐ No ☐ Unsure

Comments:

Q13. Does the section on exemptions help you determine when you may apply the exemptions for research-related purposes? If unsure or no, please explain why.

☐ Yes ☐ No ☒ Unsure

Comments:

Further to answer to Q1, more examples would be helpful including more complex examples. and also, scenarios when each of the exemptions would apply and would not apply.

Q14. Does the section on appropriate safeguards contain sufficient detail for your processing? If unsure or no, please explain what else you think this section should cover.

☐ Yes ☒No ☐ Unsure

Comments:

The five safes framework was developed by the social science community and is widely respected and adopted in the health data research community and beyond. It would be helpful for the guidance to reference this framework as an exemplar model for implementing safeguards.

Q15: Does the guidance contain enough examples? If unsure or no, please give details of further scenarios you would like us to consider.

☐ Yes ☒ No ☐ Unsure

Comments:

As noted previously, it would be helpful to have more examples (see also specific suggestion given in Q4) generally but, in particular, multiple examples of when each of the exemptions for research-related purposes would and would not apply.

Q16: Did you find the examples in the guidance useful or not useful? Please give details as to why/why not.

☐ Useful ☐ Not useful ☒ Unsure

Comments:

Some elements are very useful in guiding the reader in the right direction, but it does not always have enough detail to support practical implementation. As noted in response to Q15 further examples would be helpful. The examples currently chosen are quite obvious, it would be more useful to have more complex examples and explanations.

Q17: Is there anything that you think hasn't been covered that should be? If yes, please give details.

☐ Yes ☒ No ☐ Unsure

Q18: Please provide any further comments or suggestions you may have about the drafts.