Dear Sir/Madam

WMA consultation: Declaration on Ethical Considerations Regarding Health Databases and Biobanks

The British Medical Association (BMA) is an apolitical professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care. We have a membership of over 154,000, which continues to grow every year.

The Association welcomes the opportunity to respond to the WMA.

We have had the opportunity to comment on this draft declaration at various stages and iterations before this public consultation. After further consideration and a wider consultation with members we have made a number of observations and recommend some changes to the draft declaration to reflect our views more accurately.

Overall we believe that the declaration could benefit by strengthening the safeguards and protections for both patients and doctors regarding the collection and use of health data for secondary uses. For example, we suggest highlighting the role of statutory powers, including legislation, guiding and directing health data. Currently the draft relies too much on dedicated independent ethics committees overseeing the governance and regulation of health data, which have a critical role in some circumstances, but may not provide enough protection for patients and doctors in all circumstances. The BMA believes that there are statutory and ethical guiding principles and directives in place in the UK which could be used to strengthen this declaration. We have mentioned a few of these in our previous responses and highlight some of these again below.

In addition to comments on the declaration text we also recommend some structural and wording changes, as outlined below.

**Paragraph 2:** Replace the end of the last sentence with ‘used for research or for other purposes beyond direct patient care.’ The BMA also recommends the declaration defines what ‘other purposes’ means.

Chief Executive: Keith Ward
We have recently worked on outlining a vision around the uses of secondary data for research and other purposes which include areas such as education, innovation and the effective management of healthcare resource. We would happily provide further information about our work if you would find that helpful.

**Paragraph 5:** Insert ‘of confidentiality’ after ‘obligations’. Insert ‘to protect’ after ‘as stewards’ and remove ‘protecting’. Delete ‘their’.

**Paragraph 6:** Suggest this becomes paragraph three to improve flow of text. And paragraph three becomes paragraph six.

**Paragraph 8:** We recommend explicit definitions of anonymous and non-identifiable data and biological material to accompany this declaration. A definition will clarify the meaning ascribed in the context of this document.

**Paragraph 15:** There may be limited occasions when individuals cannot choose whether to have their information held in a database, i.e. public health legislation or other statutory or public interest requirements.

**Paragraph 17:** Replace paragraph with ‘Individuals must have the right to, at any time and without reprisal, withdraw their consent for the use of their identifiable information and/or biological material’. In some instances it may be very difficult for health databases or biobanks to fully delete the data/material. But it must stop any future collection and use of data.

**Paragraph 18:** We would like to see definitions of ‘conditional broad consent’ and ‘blanket and open consent’ to demonstrate the difference between the two and to avoid confusion amongst readers.

**Paragraph 19:** Replace first sentence with ‘In the event that anonymous data will not suffice, the requirements for consent may be waived if there is specific legal provision to do so.’ Insert ‘or other statutory and competent body’ after ‘ethics committee’ in second sentence.

**Paragraph 20:** Replace paragraph with ‘A statutory and competent body, or independent dedicated ethics committee must approve the establishment of health databases and biobanks used for research or other purposes’. Move this paragraph up before paragraph 19.

**Paragraph 21:** Insert ‘A statutory and competent body, or’ before ‘The Ethics committee’. Delete ‘and decide on the type of consent necessary’ – we consider that, except where legally justified, all Health Databases and Biobanks that collect identifiable information related to secondary uses should be based on informed consent. We believe this is set out in paragraph 15 and the Helsinki declaration.

**Paragraph 23:** Delete and see paragraph 26.
Paragraph 24: Delete ‘those health’ as the BMA recommend all who contribute to or work with health databases and biobanks should be covered in this statement. Delete ‘make themselves aware of’ and replace with ‘follow’.

Paragraph 25: Replace ‘physician’ with ‘professional’ as it is not always the case, nor practical to have a physician appointed to safeguard databases or biobanks.

Paragraph 26: Replace first sentence with ‘health databases and biobanks must be appropriately managed and safeguarded and governance arrangements must include:’. Add new sub point 26.10. ‘Publication of research outcomes from the use of health information or biological material must be made freely available to participants and the wider public in an easy and understandable way’. We also suggest introducing a new sub point 26.11 that recommends a strong patient voice to be included in the governance arrangements. Draft example: “Arrangement for a strong patient voice representation to be included.”

We hope that our submission is useful – please do not hesitate to contact us for more information if you would find that helpful.

Yours sincerely

Hilary Lloyd
Policy Director