# Consultation response: stakeholders consultation on draft AI Ethics Guidelines

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making science work for health


**Submitted to**
EU High Level Expert Group on Artificial Intelligence

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The PHG Foundation is supportive of the aims of the High Level Expert Group on AI in formulating draft guidance that sets a benchmark for high standards which can be adopted throughout Europe. However, we have some concerns that this approach is predicated upon an exceptionalist view of AI.

## Introduction: rationale and foresight of the guidelines

### Health applications

Our experience of the regulation of genetic and genomic tests is that there are a lot of parallels between the proposed uses of AI and genomics: with both technologies – there is potential to generate potentially predictive and sensitive data which could be used in discriminatory ways. On the other hand, many genetic and genomic tests are uninformative, are routine, and do not yield sensitive data. Regulating all genetic/genomic tests on the basis that they are sensitive does not adequately distinguish between the different uses to which genetic/genomic tests might be put.

The same arguments can be made in relation to AI. Many applications of AI technologies pose no prospect of harm or benefit. We have some concerns that the tone of the ethics guidance is that AI is necessarily exceptional. We would like to see more consideration of the view that some applications of AI may be routine and may yield uninformative data. In such cases it might be neither proportionate or rationale to seek to impose an exceptionalist regulatory framework.


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...We suggest that insufficient attention has been given to guiding developers and users as to how they should prioritise these principles when they conflict.

There are, of course, some applications which require extreme levels of oversight; multidisciplinary expertise, and careful transparency. Mandating the same levels of oversight to all AI applications might risk burdening the sector with excessive levels of regulation.

## Chapter 1

The PHG Foundation acknowledges the importance of the long list of fundamental rights, principles and values that have been identified. However we suggest that insufficient attention has been given to guiding developers and users as to how they should prioritise these principles when they conflict. By way of example, in medical ethics, medical research and the cases of withholding and withdrawing treatment are seen as paradigm examples of where harm could be caused to the individual, but where an action or omission is justified because it is mandated by other principles (such as respect for autonomy). It would be helpful for the guidance to include examples of where challenges might occur and how these potential conflicts might be resolved (e.g. the principle of non-maleficence: "Do no Harm", page 9).

Whilst we note that these guidelines are not intended to address legal and regulatory issues, there does however appear to be an assumption that informed consent will be the legal basis for data processing at numerous points. For example, in Chapter 1 there is reference to the need to obtain 'informed consent' and similarly a right for data subjects to opt-out of their data being processed through automated processing.

We note that if data is processed through a legal basis other than consent (such as legitimate interest or public interest under Article 6 of the GDPR) and data is used for secondary purposes such as research, that there will not necessarily be an obligation to seek consent, so a right to opt-out will not be engaged. It would be helpful if these guidelines were to clarify how conflicts between these ethical and legal principles, such as the one described, might be reconciled with each other.

## Chapter II

Section 4 refers to the need for an internal and external (ethical) expert. It is not clear whether the group are advocating for both an internal and external expert. Nor is it clear how independent that expert should be (and whether, like the Data Protection Officer under the GDPR) such a person is expected to have expertise in both AI and ethics. An independent ethical committee might be a better way of capturing expertise both in technological capacity and ethical issues – such a multidisciplinary group would be well equipped to advise on the ethical issues that might arise in response to a technological challenge (p. 8).

Our view is that it would be better to consider the ethical and legal frameworks together than in isolation. A framework for proportionate and responsive regulation is already in place ...

## Chapter III Assessing Trustworthy AI

In view of AI's context-specificity, any assessment list must be tailored to the specific use case in which the AI system is being deployed'. (p28) The PHG Foundation has considerable expertise in assessing the impact of novel technologies for health services and health systems. We are engaged in active research which is exploring various aspects of AI use within healthcare, including for diagnosis and treatment (such as pathology, imaging) but also for screening for rare genetic diseases. Much of this work is available on our website at www.phgfoundation.org

Our view is that it would be better to consider the ethical and legal frameworks together than in isolation. A framework for proportionate and responsive regulation is already in place in the form of the EU General Data Protection Regulation, EU Medical Devices Regulations and EU Privacy Regulations. These are supplemented by industry standards such as IEC 82304 which operate across sectors (such as wellbeing apps and medical uses) [noted at p21]. These already take account of contextual issues such as the potential for interoperability and operating environment.

We think it might be premature for the high level ethics group to require developers and users to have additional 'ethics' expertise in the form of internal and external experts, before account is taken of the scope and impact of existing regulations (as is planned in phase 2 of activity of this group).