

Questions for the Delphi online process

Set 1: Biomedicine Domain (8 priority questions, 7 optional)

Set 2: Biometrics Domain (8 priority questions, 5 optional)

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The following questions are based on the status quo of the international scientific debate on ethics for data use. Experts are invited to join and enhance this debate in a multi-step Delphi process. Input is particularly welcome in order to establish ethical guidelines on international data use.

Invitation: Need for Action

This debate on the ethics of data collection, use and retention in medical and biometric applications must be launched now, because the quality and the quantity of usage of medical and in particular genetic data as well as of biometric markers is fast evolving everywhere in Europe and worldwide.

The aspects of privacy that are affected by the protection of data are crucial both in the area of biometric and health applications. Today's networked environments change the reference framework for privacy. Whilst innovative information and communication services are constantly improving people's lives and generate growth throughout the global economy, they also create new risks. The crucial issue of protecting personal data becomes more complex. Processing personal data over distributed networks poses the threat of misuse. What should be defined as minimum and optimal standards to preserve privacy and how technology can assist in the protection of integrity and privacy of data are critical questions.

The lack of harmonisation and standardisation of international ethical principles has the potential to lead to the abuse of data collection, use and retention by exploiting differences between societies with regard to established ethical standards. These developments raise various problems affecting the daily life of more and more citizens and therefore answers are needed.

Often achievements in emerging fields of medicine and technology will be "moving targets" for legislation since the fast progress may raise societal questions, which need to mature – with the support of ethics – before legislation can be defined, agreed and adopted.

The international debate is expected to focus on issues which:

- 1 are already resolved – in some states – by existing legislation
- 2 are not yet resolved by legislation but are expected to be included in legislation
- 3 cannot be resolved by legislation and require some kind of ethics-based governance or code of conduct to be addressed.

We invite experts worldwide to join the ETHICAL dialogue on ethical questions in biomedicine and biometrics at ethical-fp7.eu

Biomedicine Domain

1. [priority question] **For what purposes should government be allowed to share its biomedical data with private organisations?**

- ⇒ For many legitimate reasons, the government collects a large amount of data about its citizens. These data can be used to provide medical or social services or protection against crime and national security breaches. The government, of all actors, has the broadest scope for collecting data. It is not clear that industry actors have the same purposes and goals. Many government industry collaborations, such as MyKad (Thomas, 2004; Kassen, 2010) and deCODE (Wylie and Mineau, 2003; deCODE, 2010), have diffuse or multiple purposes. For what purposes should government and industry share medical or biometric data, and should they cease to share data after this purpose has been fulfilled?

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2. [priority question] **How should the rights of the community (Public Health) be balanced against the rights of the individuals? Should public health data use be subject to different ethical standards than medical data use?**

- ⇒ It is often assumed that only those who use data have the responsibility to protect and respect individuals' privacy and confidentiality. Do data subjects also have a responsibility to share their data under certain circumstances? For instance, withholding data that might provide public health officials with useful information on the outbreak of an infectious disease might be considered unethical. Further, should individuals receiving public medical care be obligated to provide their data to the state? Which ethically takes precedence: individuals' rights to control data held about them or the public's right to benefit from these data?

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3. [priority question] **To what extent should the purpose of the application influence how ethical an instance of data collection, use, or retention is? How do we ascertain if a purpose is ethical or not?**

- ⇒ There are many stages and dilemmas of medical and biometric applications during which ethical concerns might arise. Medical research, surveillance and profiling, and identification systems are three applications that involve ethical dilemmas. It is important to note that the purposes of these applications may be vastly different. Some argue that concern for ethics hinders medical and life sciences research (Menon and Cash, 2006; Smith-Doerr, 2009). Medical research can, in turn, improve or save lives. Surveillance applications, on the other hand, may have less dramatic benefits. Does the purpose of the application determine whether or not it is ethical?

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4. [priority question] **Should international sharing of biomedical data be harmonised? Who should have the authority to oversee this process?**

⇒ One of the aims of EU Directive 95/46/EC was to harmonise data protection legislation across the EU, but this goal has not been entirely met (Pouillet, 2006; Kuner, 2009). While harmonisation is an ideal for some, it is not clear that universal data protection policies are feasible or desirable. For instance, should all countries have the same minimum age of consent for participation in medical research studies?

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5. [priority question] **It has been suggested that the public should learn to deal with a certain low level of risk to their personal data. Who would decide how low is low enough, and what would their criteria be?**

⇒ Some argue that the most ethical approach to data management is to quantify and reduce risk (Navarro, 2008) using anonymisation and pseudonymisation, among other techniques. This approach assumes that risk is inevitable and, to a certain extent, acceptable; no database containing identifiable medical data can be completely secure. Long-term retention of data may increase the risk of unintended disclosure. Therefore, is it ethical to collect and hold data insecurely? Is a formal and standardised risk balancing approach ideal, and, if so, who should decide what level of risk is ethical?

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6. [priority question] **Would it be ethical to collect and analyse DNA from every newborn?**

⇒ In many countries, blood samples are systematically collected from newborns, creating a biobank that might allow analysis of the DNA of a large part of the population (Boudewyns, Declau, Smets, Ursi, Eyskens, Van den Ende, and Van de Heyning, 2009). Though these samples are primarily used to diagnose diseases, there is the possibility that they might also be used for other purposes, such as the identification of criminals in forensic investigations. In addition to such “function creep,” the creation of a DNA biobank might bespeak the assumption that everyone is in some way guilty. However, there may also be ethical justifications for the systematic collection of DNA from newborns that should be considered.

7. [priority question] **What would be the ethical requirements for the access and control a patient should have to his/her medical record in a foreign country?**

⇒ Medical data may be transferred across national borders for many reasons. For example, a patient requiring urgent medical treatment while abroad may need their records sent from their home country. Individuals may contribute their medical data to a clinical trial with research

centres in more than one country. When data are transferred, their management may be subject to different laws and procedures. Ethical violations may arise from the policy gaps between different jurisdictions. In particular, it may be more difficult for data subjects to obtain access to their data and to exert control over them. Should there be ethical requirements protecting data subjects' access to and control over data sent abroad, and if so, what should they be?

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8. [priority question] What would be the ethical requirements to ensure that citizens and patients have an appropriate level of health literacy? e.g. before being involved in medical research and/or before providing informed consent on the secondary use of their medical data?

⇒ Informed consent means that subjects are aware of what their participation involves and agree to it. However, to understand what is being consented to requires that the subject fully understands the implications of what they are committing to. Is it therefore ethical to accept consent when the level of understanding and literacy of the consenting party is uncertain?

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Biomedicine domain: seven additional questions (9 - 15)

9. Should the data subjects receive some compensation for the use of their data if others are profiting from it?

⇒ Commercial biobanks created or maintained, at least in part, by a private organisation do not always share benefits with data donors (Cambon-Thomsen, Rial-Sebbag, and Knoppers, 2007; Gitter, 2010). Other government-industry collaborations may similarly make money from individuals' medical or biometric data. Should individuals receive money for their data if their data are used to generate profits? Should government-industry collaborations seek to compensate participants "in kind," rather than in cash?

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10. Are there circumstances under which it is acceptable to use medical data for financial gain?

⇒ In the case of collaborations between government and industry, there may be a mismatch between the goals of the partners. In most situations, both government and industry partners aim to fulfil the stated goal of the partnership, but private sector partners may additionally seek economically viable products, patents, or procedures. If intentions matter, then their access to personal data for profits or gains might be said to be unethical. On the other hand, industry partners are often asked to collaborate because their participation can bring an influx of capital and spur innovation. In the case of biotechnology projects in developing countries, collaborations between organisations may be vital to the success of the project (Rausser, Simon,

and Ameden, 2000; Thorsteinsdóttir, Melon, Ray, Chakkalackal, Li, Cooper, Chadder, Saenz, Paula, Ke, Li, Madkour, Aly, El-Nikhely, Chaturvedi, Konde, Daar, and Singer, 2009). Are there justifications for using medical or biometric data for profit?

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11. Is it appropriate to transfer health data between countries where benefit is disproportionate?

⇒ If data sharing is to be equitable, it must be done in such a way as to reflect fairness and impartiality. This implies that all participants should receive appropriate benefit from the collaboration. On the other hand, it can be difficult to provide equal benefit, for instance, in the hypothetical case of exported medical data being used to develop medicines that are only available in the country to which the data were sent. Is equal benefit an ethical requirement?

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12. Are there circumstances under which international medical data sharing should be obligatory?

⇒ An important question regarding the balancing of ethical rights and obligations is whether there are circumstances under which it would be unethical not to transfer medical and biometric data. For example, should a nation make a breakthrough in the treatment of a given medical condition, does that nation have an ethical obligation to share that information freely? A further example may be seen in the transfer of biometric data which may have public benefits in terms of national security, but some individuals may be unfairly profiled or discriminated against as a result of this transfer.

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13. Which ethical issues do you perceive around the ownership of medical information? What are the criteria for data ownership and what does data ownership imply?

⇒ The question arises as to who owns medical data: do they belong to those who provide, collect, view, process, physically possess, or share them? According to US law, healthcare practitioners and insurance providers own the physical units in which data are stored, though ownership of electronic health records involves a “hierarchy of overlapping rights” (Hall and Schulman, 2009, p. 1283). Others have proposed that medical records should be co-owned by clinicians and patients (Sadan, 2001) or that medical records should be publicly owned (Rodwin, 2009). Clarification of the concept of ownership and its ethical implications is needed.

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14. What would be the minimum requisite provision for medical data integrity required for data transfer between countries?

- ⇒ Many international laws and guidelines, such as EU Directive 95/46/EC and the APEC Privacy Framework, specify that data should have a certain level of quality or integrity in order to be legitimately retained (European Union [EU], 1995; APEC, 2005). Does it follow that, in order for data to be transferred across borders, they should meet certain standards of accuracy, recency, and completeness? Is this minimum level of quality or integrity higher for data that will be transferred than for data that remain in one country?

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15. What would be the ethical implications of the fact that biomedical research is financed both by public and private funds.

- ⇒ There is an argument for saying that if an individual benefits from public funding that is paid for or subsidised by the State, then that individual has an obligation to support State biomedical research for the benefit of the greater good assuming explicit consent. Equally if, with appropriate briefing regarding the use of their personal information, an individual chooses to take part in private research either freely or with some form of incentive, they can be said to have explicitly chosen to do so. Either scenario seems ethical. However, if a public body provides a private organisation with data collected from individuals given as part of a public or State initiative, can this be considered ethical without consent or recompense (given profits are likely to accrue to the company). But, if the research results in a life-saving drug or procedure for the benefits of society as a whole, is the action then ethical?

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Biometrics Domain

1. [priority question] **Should international sharing of biometric data be harmonised? Who should have the authority to oversee this process?**

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2. [priority question] **For what purposes should government be allowed to share its biometric data with private organisations?**

⇒ For many legitimate reasons, the government collects a large amount of data about its citizens. These data can be used to provide medical or social services or protection against crime and national security breaches. The government, of all actors, has the broadest scope for collecting data. It is not clear that industry actors have the same purposes and goals. Many government industry collaborations, such as MyKad (Thomas, 2004; Kassen, 2010) and deCODE (Wylie and Mineau, 2003; deCODE, 2010), have diffuse or multiple purposes. For what purposes should government and industry share medical or biometric data, and should they cease to share data after this purpose has been fulfilled?

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3. [priority question] **Under which requirements would it be ethical to use biometric identification data for purposes of daily living like paying in a super-market or for identification at airports?**

⇒ Biometrics has the potential to make many everyday activities simpler, more convenient, and more “modern.” Debit cards and PINs may be easily forgotten, while fingerprints are always on hand. Furthermore, biometrics can provide more accurate identification at airports, in online transactions, and in forensic investigations. Disney World has used fingerprint information to verify identities associated with tickets to the theme park (Harmel, 2006; Clodfelter, 2010). If such biometric applications should be allowed to proceed – and it is not clear that they should – then what ethical standards should they be held to? For how long should such biometric information be retained by the data controllers?

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4. [priority question] **When would it be ethical to collect and store multiple biometric identifiers on a person and for how long should these identifiers be retained?**

⇒ The ethical collection of multiple biometric identifiers might imply that the individual being enrolled is fully informed regarding all of the purposes for which the data are being used. It also implies that once such information is given, there can be no change to the use of such information unless specific and informed consent is given. One example of misuse is that during the 2001 SuperBowl in Tampa Bay (Arge, 2001), attending fans had been unknowingly matched against a database of alleged criminals using facial recognition technology. They had not been told that their images were being scanned. One possible answer to the issue of using biometric identifiers for legal and practical purposes may be through restrictions on the length of time such data can be held. A practical example is the use of fingerprints at airports to match passengers to their luggage. Once the operation is complete, the data are immediately destroyed.

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5. [priority question] **Are there circumstances under which it is acceptable to use biometric data for financial gain?**

⇒ In the case of collaborations between government and industry, there may be a mismatch between the goals of the partners. In most situations, both government and industry partners aim to fulfil the stated goal of the partnership, but private sector partners may additionally seek economically viable products, patents, or procedures. If intentions matter, then their access to personal data for profits or gains might be said to be unethical. On the other hand, industry partners are often asked to collaborate because their participation can bring an influx of capital and spur innovation. In the case of biotechnology projects in developing countries, collaborations between organizations may be vital to the success of the project (Rausser, Simon, and Ameden, 2000; Thorsteinsdóttir, Melon, Ray, Chakkalackal, Li, Cooper, Chadder, Saenz, Paula, Ke, Li, Madkour, Aly, El-Nikhely, Chaturvedi, Konde, Daar, and Singer, 2009). Are there justifications for using medical or biometric data for profit?

6. [priority question] **What would be crucial ethical issues around the ownership of biometric information?**

a) What are the criteria for data ownership?

b) What does data ownership imply?

⇒ The ownership of biometric data presents as many ambiguities as does the ownership of medical data. According to Chandra and Calderon (2005) and Liu (2009), there are no clear legislative guidelines on the ownership of biometric data. The issue is complicated as ownership claims may apply to both the tangible biometric template as well as to the “underlying information” (Chandra and Calderon, 2005, p. 106). Without a coherent legal perspective, one must approach this question from an ethical standpoint. Who is the rightful owner of the templates, databases, and information associated with a biometric application? What are the criteria and implications of ownership?

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7. [priority question] What would minimum requisite provisions for data integrity required for data transfer between countries?

- ⇒ Many international laws and guidelines, such as EU Directive 95/46/EC and the APEC Privacy Framework, specify that data should have a certain level of quality or integrity in order to be legitimately retained (European Union [EU], 1995; APEC, 2005). Does it follow that, in order for data to be transferred across borders, they should meet certain standards of accuracy, recency, and completeness? Is this minimum level of quality or integrity higher for data that will be transferred than for data that remain in one country?

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8. [priority question] What would be the primary ethical requirements for the governance of biometric identification systems?

- ⇒ Contemporary security policies are characterised by a focus on sophisticated technologies using biometrics as a security enabler. A globally well-known example is the usage of biometric data – particularly finger prints – by the US immigration offices. Adding digitised images and eventually finger prints to passports is becoming standard practice in the European Union (EU) and many developed countries. Thus biometrics is accepted as the ultimate technology to identify people with certainty (Ceyhan 2008). Yet the biometric identifiers like fingerprints or iris scans do never make up for identification alone, they are used within an identification management system. Possible governance principles for the design of identification management systems in general could be a) proven, sufficient level of reliability of identification; b) easy usage fit for daily live; c) respecting guidelines of a given society which identifiers should be kept distinct (e.g. taxation, social security, healthcare) and d) efficient mechanisms to prevent identity theft and for the victims of identity thefts to recover their functioning in society. For identification management systems involving biometrics Mordini & Petrini (2007) suggest the following basic principles: 1) no personal data can be collected without explicit and legitimate purpose; 2) collected personal data should be minimised to that data which is minimal necessary; 3) obtaining and processing the biometric data should observe moral and religious interests of the humans in question. More recently, Sutrop (2010) has suggested that “public trust” (p. 102) is an essential ethical requirement for the governance of biometric identification systems and Zhai and Renzong (2010) have put forth nine principles for ethical governance of biometrics, including responsibility and respect.

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Biometrics domain: five additional questions (9 - 13)

9. What are the most crucial ethical implications of the risk of errors in biometric features for biometric identification?

⇒ Biometric identification systems are said to have two error rates: a false match rate, which summarizes how often a non-matching biometric will be deemed a match, and a false non-match rate, which summarizes how often a matching biometric will be deemed not to match (INCITS, 2007). In 1999, the probability of either error occurring in many biometric systems was estimated at 0.1% (Ashbourn, 1999). However, biometric error rates have been shown to vary widely, with false non-matches estimated to occur between every one in 1000 to every one in five times that a biometric template is presented to the system (Cavoukian and Stoianov, 2007, as quoted by the Irish Council for Bioethics, 2009, p. 9). Error rates vary between different types of biometric (Jain, Ross and Prabhakar, 2004; Jacobs and Poll, 2010) and decrease as technology improves. For a particular hand geometry recognition system implemented in a private gym, the two error rates were said to be equal at 0.1%, though this claim has been difficult to verify (Tilburg Institute for Law, Technology, and Society, 2009). Do the designers of biometric identification systems have the responsibility to create trustworthy systems? Further, error rates may vary unfairly between different groups of people, such as those of different racial backgrounds (Irish Council for Bioethics, 2009). Are there other ethical implications or justifications for error in biometric systems?

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10. How could/should ethical challenges arising from religious concerns towards the use of biometric identification be addressed?

⇒ There are ways in which biometrics may be unacceptable to those with certain religious beliefs. Those who, for religious purposes, wear face or head coverings may be embarrassed or inconvenienced by enrolment or verification in facial recognition systems (Wickins, 2007). Those of other religions may object to the collection of biometric templates on spiritual grounds; it has been noted that some Christians might believe that biometrics are the “mark of the beast” (Woodward, Webb, Newton, Bradley, Rubenson, Larson, Lilly, Smythe, Houghton, Pincus, Schachter, and Steinberg, 2001; Hitchcock, 2009, p. 74). How should such religious objections to biometrics be addressed?

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11. In your opinion, does biometric identification raise the same issues regarding data privacy and data security as other forms of traditional personal identification?

⇒ General rules for identification management systems like sufficient level of reliability and keeping identifiers for different sectors of society distinct apply also for systems involving biometrics. Yet the lifelong persistency of most biometric identifiers raises additional issues since the persistency of an identifier is strongly linked with risks of identity theft and privacy violation. For example: Every individual has characteristic retinal vascular pattern, which can be used to

uniquely identify this human. Specific dangers lie in a potential identity theft; if for example a high resolution retinal angiogram gets stolen from an ophthalmologist, criminals might be able to fake an object, which gets accepted by scanner devices. In addition popular movies suggest that the use of fingerprints or iris scans as biometric identifiers can be cheated with cut off fingers or eyeballs resulting in fears. Even if fears are mostly irrational since non-vital specimen only work in science fiction this could lead to the request for effective public information.

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12. To what extent could it be ethical that the human body is reduced to an assortment of biometric features?

- ⇒ One goal of biometrics is to obtain suitably accurate representations and measurements of individuals' body parts to authenticate or verify identities later. These biometric representations can come to define the body itself (Irish Council for Bioethics, 2009). One pervasive image is of bodies imprinted with bar codes (for instance, see Irish Council for Bioethics leaflet, p. 5), symbolising "machine readable bodies" (van der Ploeg, 2007, p. 46). This informatisation can lead to the oversimplification of identification and depersonalisation of bodies – what McCullagh calls "taking the person as a mere thing" (2005, p. 8). Does biometrics "reduce" the body in these ways or are these threats minimal?

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13. How should security and privacy be balanced in biometric identification applications?

- ⇒ Presently and in the future, biometrics may be used to ensure secure identification in airports and homes as well as at workplaces and national borders. Digital devices and networks may be accessed using biometrics. Biometrics can therefore provide security, but, because biometric applications involve the collection of personal data, it is often argued that this security comes at the expense of privacy. Some argue that security and privacy can be balanced in biometric systems (Irish Council on Bioethics, 2009), but it is not clear how this balance should be struck and which should be prioritized.

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