

*Human knowledge and skills alone cannot lead humanity to a happy and dignified life. Humanity has every reason to place the proclaimers of high moral standards and values above the discoverers of objective truth.*  
*Albert Einstein*

## 1 Aim

With this scoping paper, the ETHICAL consortium aims to start and to shape the debate on ethical implications of data collection, use and storage in medical and biometric applications.

The project objective is to facilitate debate and discussion amongst the scientific community and society towards an international consensus on a roadmap for the protection of personal rights by safe-guarding the ethical use of person-identifiable biological data.

## 2 Method

The ETHICAL consortium has conducted a scientific review of relevant literature to launch the international debate. As one outcome, the consortium has chosen a set of questions, each of them supported by one or more background papers. The questions are foreseen to be debated in expert communities and will be the subject of face-to-face expert meetings. This scoping paper provides the leitmotif of this debate but not the supporting documentation.

## 3 Definitions

Ethics is the branch of philosophy dealing with the finding of what is acceptable and what is right and appropriate. Ethics changes depending on the society to which it applies.

ETHICAL project vision: An international consensus on the ethical use of personal data as a basic human right in the information society.

ETHICAL project mission: To be an effective mechanism for members of society's engagement in enhancing the debate on ethical implications of data collection, use and retention in medical and biometric applications so as to create a consensus and a roadmap towards a secure environment and simultaneously not compromise human rights.

ETHICAL consortium: An international team with members predominantly from the European Union, but also from Ukraine, Malaysia and Chile

## 4 Scope and preliminary position

Shared values such as the respect for privacy shape the moral identity of a particular society. They also provide the foundation for trade-offs between different values, which have to be made. The rapid developments of information and communication technologies – whilst creating new business opportunities and services – pose constantly new threats and risks for privacy. At the same time, issues surrounding the protection of privacy, are in all modern societies are subject to both legislation and to ethical principles.

Thus this scoping paper is based on the following assumptions:

- ⇒ Ethics addresses principles of right and wrong. Some of these principles are used as a basis for laws.
- ⇒ Laws are tools to implement ethical principles in a given society at a given time and to provide society with means to prosecute infringements. Laws are official statements that enforce behaviour in society. Not adhering to laws may result in prosecution by legal authorities.
- ⇒ An ethical dilemma is a choice which has to be made and is not covered by a law.

Hence the ETHICAL consortium concludes that ethics will be the main guidance

- ⇒ for subjects where legislation does not yet exist,
- ⇒ for subjects where legislation is incomplete or must remain ambiguous and
- ⇒ for subjects that are outside the scope of legislation.

For practical purposes, one additional observation might help to understand the need for ethical consensus for emerging research and application fields: The constitutions and laws of states reflect a consensus that has been – often over many years – built in to the societies. Hence some legislation may be understood as “crystallised” ethics.

## 5 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 effected 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.

## 6 Expected Outcomes

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.

For 2) and most particularly for 3) ethics should be implemented in a way that makes it useful for everyday decision making in science and society.

The ETHICAL international dialogue, e.g. via the Delphi process and real-time debates will elicit input for codes of conduct, guidelines, and governance methods which reflect identified ethical principles.

*We invite experts worldwide to join the ETHICAL dialogue on ethical questions in biomedicine and biometrics at [ethical-fp7.eu](http://ethical-fp7.eu)*