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Ethical issues form

Proposers are requested to fill in the following table

Does your proposed research raise sensitive ethical questions related to:	Yes	No
Human beings	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Human biological samples	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Personal data (whether identified by name or not)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Genetic information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Animals	<input type="checkbox"/>	<input checked="" type="checkbox"/>

I am required to declare that the proposed research does not involve:

- the use of human beings for reproductive purposes;
- the use of human beings for human cloning or for the production of human embryos which could be used for reproductive purposes;
- the use of human embryos for the purposes of research or for the production of human beings which could be used for reproductive purposes;
- the use of human embryos which could be used for reproductive purposes.

National Regulations on Ethics and Research in

Malta



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**National Regulations
on Ethics and Research in**

Malta

by
Pierre Mallia

European Commission contacts:
Barbara Rhode, An Baeyens and David Coles
Brussels, 2003

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Foreword

I welcome the preparation of this comprehensive report on national regulations on ethics and research in Malta. It provides a useful overview of the legal and enforcement structures in place and identifies the scope of greater efforts, which need to be made to strengthen them. It is particularly important in view of Malta's accession to the EU in May next year and our increasing involvement in scientific research through a new National Programme for Research, Technological Development and Innovation (RTDI) and our active participation in the EU Framework Programmes for Research and Technological Development.

The report is timely as we are currently formulating the national RTDI strategy. Efforts will be made to give the issue of ethics and research a central place in the strategy and its implementing programme. Appropriate attention will be given to promoting awareness of national regulations on ethics and research among our scientists and to implement an appropriate policy of oversight in publicly funded and private research investments.

We shall try to understand the public concerns about genomics assisted clinical procedures, stem cells and artificial organs, genetically modified organisms, but we also have a sincere appreciation for the potential benefits to society at large. We commit ourselves to a proper discussion of the issues without hindering beneficial progress.

I congratulate the Directorate-General Research on this initiative. This publication is a highly useful guide for comparing national responses to the issue of ethics and scientific research. We will be studying the regulations and implementing structures in other candidate countries and Member states with the aim of emulating best practice.

A handwritten signature in black ink, appearing to read 'Louis Galea'. The signature is fluid and cursive, with a large loop at the end.

*Hon Louis Galea B.A., LL.D., M.P.
Minister of Education*

Introduction

The European Commission is committed to ensuring that research funded under the 6th Framework Programme respects ethical principles. What legal requirements do researchers have to respect in European Commission funded research projects?

The text of the 6th Framework Programmes makes reference to the following international texts:

- The Charter of Fundamental Rights of the European Union
- European Union directives
- Convention of the Council of Europe on Human Rights and Biomedicine (1997) and the additional protocol on the Prohibition of Cloning Human Beings (1998)
- UN Convention on the Rights of the Child (1989)
- Universal Declaration on the human genome and human rights adopted by UNESCO (1997)
- Helsinki Declaration

These regulations and texts are all well known and can be consulted on the website http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html.

Apart from such European legislation and international texts, the Specific Programme for research, technological development and demonstration 'Integrating and strengthening the European Research Area' (2002-2006) requires also that "In compliance with the principle of subsidiarity and the diversity of approaches existing in Europe, participants in research projects must conform to current legislation, regulations and ethical rules in the countries where the research will be carried out.

In any case, national provisions apply and no research forbidden in any given Member State will be supported by Community funding in that Member State. ⁽¹⁾"

The specific regulation of ethical issues is a matter of subsidiarity. Rooted in the cultural background of the nation state, there are many ethical rules and guidelines in the national legal system that the scientists have to apply when conducting research in a country.

The guide for proposers of the 6th Framework Programme requires applicants to identify whether workpackages contain one or more of the five following ethical issues, namely whether the research work involves

- humans,
- human tissue,
- personal or private data,
- genetic information,
- or animal experimentation.

Detailed information on how these issues are handled has to be given, including the explanation of the applicable national legal background. Such projects that contain ethical issues may be submitted to an ethical review if they have been shortlisted after the scientific evaluation. When co-operating in a European research consortium, it is important that researchers from partner countries have easy access to the national regulations on those five areas, where ethical issues

(1) See Annex 1.

may arise. It is an advantage if researchers not only understand the regulation of their own countries, but also those of potential partners and when they seek to collaborate.

This document is part of a series that aims to make the regulatory situation in the accession and candidate countries more transparent and better accessible to scientists in Europe.

The Maltese text has been written by Dr. Pierre Mallia and subsequently approved by the Ministry of Education of Malta. The Commission has been promoting this project and is now dedicating a publication to the accession and candidate countries in order to facilitate their participation in the 6th Framework Programme. The project has been co-ordinated for the Commission by Alexandra Bitusikova, An Baeyens and David Coles. The responsibility and credit for the contents rest with the author and the Ministry of Education of Malta. ■



Barbara Rhode
 Head of Unit "Ethics and Science"
 Research Directorate-General

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1. International instruments in Maltese law

The scientist involved in any aspect of research must be aware of local as well as international legislation, codes or ethics and other guidelines that are relevant for the pursuit of research. The research scientist in Malta should be guided by the following:

1. Acts of Parliament and Subsidiary legislation that impinge on research;,
2. Regulations which the Minister(s) may promulgate from time to time;,
3. Other directives, including those issued by individual institutions (Department of Health, hospitals, University departments etc);
4. International Conventions and Directives to which Malta has signed or is in the process of signing;,
5. International guidelines which, while not binding, indicate a level of practice that should

be emulated (e.g.g. Helsinki Declaration, UNESCO, CIOMS);

6. Finally, requirements by international publishers of research manuscripts.

International instruments may be incorporated within Maltese law, usually with some modifications which are relevant to local conditions. It is to be noted, however, that there may be differences between a published EU directive and the specific wording of the Maltese legislation. Note should also be taken of the fact that preambles and recitals do not usually find their way into local legislation, and therefore, when these differ or add substantially to the substance of the text, then one may find deficiencies and differences between the two.

2. National overview

Maltese legislation is silent on a number of topics relating to research. On other occasions, legislation refers more particularly to the outcomes of research and to research products rather than to the conduct of the research itself. This is particularly the case for genomic research, where the Patents Act is the only legislation, which deals primarily with patenting rather than with the research as such. One obvious exception to this is the Animal Welfare Act (2000), which deals specifically and in detail with animal experimentation.

1) Overview of national legal structure

In Malta, there are several aspects of legislation that impinge on research, even though there is no specific legislation that deals with the subject comprehensively - apart from research involving animals. The scope of this paper is to outline the various aspects of legislation that are relevant.

2) Research Ethics Committees (falls under the Medical Council)

In Malta, there is no specific legislation relating to

the establishment and functions of research ethics committees. Reference is made to research ethics committees in the Data Protection Act. Concerning processing of data relating to research and statistics, the Data Protection Act states: Article 16. (2b) "in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner for the purposes of this paragraph". The Animal Welfare Act also refers to 'ethical rules and standards which may be drawn up by the Council' (Art. 33 (1), implying the existence of an animal research ethics committee).

In Malta, there are the following **ethics committees**:

1. *The Bioethics Consultative Committee*

This committee is in the first instance an advisory body to the Minister of Health. Its role in research is limited to formulating guidelines to be followed by various institutes and individuals, as well as to pronounce its views on questions relating to research ethics as the need arises. It is not involved in the ethical assessment of individual research projects. Its members are appointed by the Minister for Health for the duration of one year.

2. *Research Ethics Committee, Medical School
University of Malta*

This body was set up by the Faculty of the Medical School. It examines research projects of a biomedical nature submitted to it. Researchers however have no obligation to submit their project to this body. It reports to the Faculty of Medicine but has no authority to supervise the research projects it has authorised.

3. *Other research ethics committees*

The only other research ethics committee has been set up by the Senate of the University of Malta to deal with non-biomedical issues (social sciences, psychology etc). Again there is no legal obligation on the part of researchers to submit their research for scrutiny by this body.

3) Projects or procedures that should be submitted to ethics committees

Research relating to biomedical issues should all go to a medical research ethics committee, while all other research involving human beings should go to the University Research Ethics Committee. As mentioned already, there is currently no obligation on the part of researchers to submit their research project for approval to an ethics committee. Note, however, that research involving animals is now covered by the Animal Welfare Act which specifically requires such approval, as mentioned above.

3. Research involving human subjects

1) Laws regarding informed consent

The issue of informed consent in research is not dealt with in Maltese legislation. Malta is expected to sign and ratify the Council of Europe Convention on Human Rights and Biomedicine in the near future, following which the relevant articles relating to research will apply to Malta.

The Data Protection Act defines "consent" as "any freely given specific and informed indication of the wishes of the data subject by which he signifies his agreement to personal data relating to him being processed". This does not refer specifically to research, but to any collection of data from a data subject. This also includes processing operations in cases of research.

Other Guidelines include:

- a) The "Patients' Charter of Rights and Responsibilities" issued by the Hospital Management Committee (St Luke's Hospital). This refers to informed consent to be given by a patient in hospital. It does not specifically deal with research involving such patients.
- b) The "Patient Charter" issued by the Malta College of Family Doctors refers to the right of a patient to "give or withhold your consent to medical or other care and treatment". It also advises patients that they can "Choose whether or not you wish to take part in research or student training".
- c) Bioethics Consultative Committee: "Guidelines Relating to Consent of Patients to medical intervention". These guidelines request specifically that consent of patients to research is necessary

and that research should not normally be carried out on those unable to express their consent.

2) Other legal requirements for research

The Data Protection Act provides for the processing of data concerning research and statistics Art. 16. states that

- (1) Sensitive personal data may be processed for research and statistics purposes, provided that the processing is necessary as stipulated in article 9(e).
- (2) If the processing referred to in subarticle (1) has been approved:

...

- (b) in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner for the purposes of this paragraph; the provisions of subarticle (1) shall be deemed to be satisfied".

This is the only reference to the establishment of a research ethics committee relating to research involving human beings, and to the requirement for research projects to be submitted to it by the researcher.

3) EU regulations and directives:

- Charter of the Fundamental Rights of the European Union (200/C/364/01).
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

4. Children and others unable to consent

The age of consent for most procedures in Malta is 16 years. However, there are other legislations in which the minimum age is 18 or even 21 years. None of these laws specifically refer to the age of children for the purposes of giving consent for participating in research.

Consent in relation to therapeutic procedures is also to be found in the Mental Health Act, which refers to consent with respect to those who cannot give consent by virtue of having a mental disability. Again no specific mention of research is made in this legislation.

5. Research involving human biological material (blood, organs, tissues, cells, dna)

Although there are no specific references to the use of human biological material for research, the following provisions of the Patents Act (Chapter 417, 2000) dealing with the patentability of tissues (human or animal) have relevance:

- Art. 4 (4) states: "A method for the treatment of the human or animal body by surgery or therapy and a diagnostic method practiced on the human or animal body shall not be regarded as an invention capable of industrial application ..."
- Art. 5 states that "a patent shall not be granted in respect of:
 - (b) the human body, at the various stages of its formation and development from the moment of conception, and the simple discovery of one of its elements;
 - (c) processes for cloning the human body, processes for modifying the germ line genetic

identity of the human body and uses of the human embryo for industrial or commercial purposes".

In other words, these procedures are not prohibited as such; however, financial gain resulting from application of these procedures is prohibited.

It is to be noted that recital 26 of Directive 98/44/EC (relates, in case of patent applications based on human biological materials, to the opportunity for the sources to express their free and informed consent if) has not been incorporated in the Maltese Data Act.

6. Research involving human embryos

Laws relating to embryos and foetuses can be found in the following legislation:

- Criminal Code, Chapter 9, articles 241 and 242 contains penalties for procuring miscarriage;
- Patents Act (2000), Chapter 417, Art. 4 (5b) defines the human body at the various stages of its formation from the moment of conception.

1) Definition of 'embryo'

This term is not defined anywhere in the legislation. However, Art. 4(5b) of Chapter 417 of the Patents Act denies patents relating to "the human body, at the various stages of its formation and development from the moment of conception", implying that the embryo may be defined as from conception.

2) Use of human embryos in research

There is no specific prohibition relating to the use of embryos in research, as long as these are not obtained through an abortion. However, Art. 5 (c) of the Patents Act (Chapter 417, 2000) states that "patents shall not be granted for uses of the human embryo for industrial or commercial purposes".

3) Approval of research on embryos

There is no specific requirement that research should be approved by a research committee (see above under Section 3. Research involving persons).

4) Permitted sources of embryos

Apart from naturally miscarried foetuses, there are no permitted sources of embryos.

5) Research involving stem cells

There is no legislation controlling the use of stem cells.

6) Law regarding human reproductive cloning

Cloning as such is not prohibited by law. However, Art. 4 (5bc) of the Patents Act (2000) states that "no patents granted in respect to processes for cloning the human body..."

It is to be noted that the Bioethics Consultative Committee (Malta) has issued a document Ethical Considerations relating to Human Reproductive Technology, which gives guidelines relating to procedures on embryos, including the use of embryonic tissues for research and therapy.

7. Personal data

Legislation relating to data protection is contained in the following legislations:

- Chapter 440 of the Data Protection Act, 2002
- L.N 16 of 2003 – Data Protection Act (Cap 440) Processing of Personal Data (Telecommunications Sector) Regulations 2003
- Chapter 422 of the Malta Statistics Authority Act
- Chapter 377 of the Professional Secrecy Act, 1994
- Constitution of Malta
- Chapter 418 of the Malta Communications Authority Act, 2000.
- Chapter 399 of the Telecommunications (Regulations) Act, 1997
- L.N 19 of 2003 – Telecommunications (Regulation) Act (CAP 339) (Personal Data and Protection of Privacy) Regulations, 2003
- Chapter 350 of the Broadcasting Act, 1991
- Medical Council Regulations
- Chapter 319 of the European Convention Act 1987 (European Convention for the Protection of Human Rights and Fundamental Freedoms), to become and be, enforceable as, part of the Law of Malta.

1) Definition of personal data

The Data Protection Act defines “personal data” as “any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity”.

Moreover, “sensitive personal data” are defined as “personal data that reveals race or ethnic origin,

political opinions, religious or philosophical beliefs, membership of a trade union, health, or sex life.”

The Malta Statistics Authority Act (Chapter 422, 2000) defines “confidential data” as “data obtained by the National Statistics Office for the production of official statistics when such data allow statistical units to be identified directly or indirectly, thereby disclosing individual information”.

2) Regulatory approach to data rendered anonymous

Identifiable data are defined in the Data Protection Act (see the above-mentioned definition of “Personal data”).

In the Data Protection Act, the “processing” and “processing of personal data” mean “any operation or set of operations which is taken in regard to personal data, whether or not it occurs by automatic means, and includes the collection, recording, organisation, storage, adaptation, alteration, retrieval, gathering, use, disclosure by transmission, dissemination or otherwise making information available, alignment or combination, blocking, erasure or destruction of such data”.

It is to be noted that this Act does not refer to anonymisation of data as such.

Art. 26 of the Data Protection Act refers to security measures relating to the processing:

“(1) The controller shall implement appropriate technical and organisational measures to protect the personal data that are processed against

accidental destruction or loss or unlawful forms of processing thereby providing an adequate level of security that gives regard to the:

- (a) technical possibilities available;
 - (b) cost of implementing the security measures;
 - (c) special risks that exist in the processing of personal data;
 - (d) sensitivity of the personal data being processed.
- (2) If the controller engages a processor, the controller shall ensure that the processor:
- (a) can implement the security measures that must be taken;
 - (b) actually takes the measures so identified by the controller."

These measures do not specifically mention anonymisation. However, Art. 8 (b) of this Act states that: "the appropriate safeguards are in place where personal data processed for historical, statistical or scientific purposes may be kept for a longer period than is necessary having regard to the purposes for which they are processed". The appropriate safeguards may also include anonymisation of personal data.

3) Fundamental rights and privacy

The preamble of the Data Protection Act states as follows: "To make provision for the protection of individuals against the violation of their privacy by the processing of personal data and for the matters ancillary thereto." This implies that this Act is meant to protect the privacy of individuals.

■ *Consent by data subject necessary*

According to Art. 9 of the Data Protection Act

sensitive personal data may be processed only if a number of criteria are met, including the provision that "the data subject has unambiguously given his consent".

■ *Revocation of consent by data subject*

This is covered by Art. 11 of the Data Protection Act: "(1) In those cases where the processing of personal data is made in terms of article .9(e) and (f), the data subject, except where otherwise provided in any other law, shall be entitled to object at any time to the controller on compelling legitimate grounds to the processing of such data.

(2) Saving the provisions of art. 10, where the processing of personal data takes place with the consent of the data subject, the data subject may at any time revoke his consent for compelling legitimate grounds relating to his particular situation."

■ *Sensitive data*

In the case of sensitive data, the Data Protection Act states in Art. 12.

(1) Subject to the other provisions of this Act no person shall process sensitive personal data: Provided that such personal data may be processed in those cases provided for under sub article (2) and under Arts. 13 to 16 or as may be prescribed by the Minister having regard to an important public interest.

(2) Sensitive personal data may be processed if the data subject:

- (a) has given explicit consent to processing; or
- (b) has made the data public."

■ *Other protection measures for the data subjects*

- Information to data subject

Art. 19 of the Data Protection Act states that

"The Controller or any other person authorised by him in that behalf must provide a data subject from whom data relating to the data subject himself are collected, with at least the following information, except, where the data subject already has it:

- (a) the identity and habitual residence or principal place of business of the controller and of any other person authorised by him in that behalf, if any;
- (b) the purposes of the processing for which the data are intended; and
- (c) any further information relating to matters such as:
 - (i) the recipients or categories of the recipients of data;
 - (ii) whether the reply to any questions made to the data subject is obligatory or voluntary, as well as the possible consequence of failure to reply; and
 - (iii) the existence of the right to access, the right to rectify, and, where applicable, the right to erase the data concerning him, and, insofar as such further information is necessary, having regard to the specific circumstances in which the data is collected, to guarantee fair processing in respect of the data subject."

■ *Prior checking by the Commissioner*

Art. 34 of the Data Protection Act states as follows:

"(1) (a) Processing of personal data that involves particular risks of improper interference with the rights and freedoms of data subjects shall be submitted for prior checking to the Commissioner."

■ *Further confidentiality protection*

Further protection to confidentiality is provided by the Professional Secrecy Act (1994). This Act interprets Section 257 of the Criminal Code (Chapter 9) and defines persons covered by this Act, namely, persons who, by reason of their calling, profession or office, fall within the scope of section 257 of the Criminal Code". These include the following:

"members of a profession regulated by the Medical and Kindred Professions Ordinance, advocates, notaries, legal procurators, accountants, auditors, employees and officers of financial and credit institutions, trustees, officers of nominee companies or licensed nominees, persons licensed to provide investment services under the Investment Services Act, 1994, stockbrokers licensed under the Malta Stock Exchange Act, insurers, insurance agents, insurance managers, insurance brokers and insurance sub-agents, officials and employees of the State."

It is to be noted that scientists as such are not mentioned, although medical scientists are included in the Medical and Kindred professions Ordinance. Authority to disclose such secret information is only possible when ordered by a Court.

Further regulation of data transmission is available in the Malta Communications Authority Act (Chap 418, 2000), which defines "communications" to include "telecommunications, postal services, data protection, electronic commerce, internet services, and such other matters as the Minister may by Order from time to time prescribe".

Chapter 399 of the Telecommunication (Regulation) Act (1997) states in Art. 38 "(2b) prescribe measures to be taken by authorised providers for the purpose of ensuring the inviolability of the telecommunications transmitted and their confidentiality and the protection of privacy in relation to any telecommunications service including data protection measures and matters related to the use of information obtainable in the telecommunications sector for the purpose of direct marketing". The Malta Communications Authority Act (Chap 418, 2000) sets up an Authority whose function is "the protection of the right to privacy".

4) Conditions for data processing

Art. 7. of the Data Protection Act requires that "The controller shall ensure that:

- (a) personal data is processed fairly and lawfully;
- (b) personal data is always processed in accordance with good practice;
- (c) personal data is only collected for specific, explicitly stated and legitimate purposes;
- (d) personal data is not processed for any purpose that is incompatible with that for which the information is collected;
- (e) personal data that is processed is adequate and relevant in relation to the purposes of the processing;
- (f) no more personal data is processed than is necessary having regard to the purposes of the processing;
- (g) personal data that is processed is correct and, if necessary, up to date;
- (h) all reasonable measures are taken to complete, correct, block or erase data to the extent that such

data is incomplete or incorrect, having regard to the purposes for which they are processed;

- (i) personal data is not kept for a period longer than is necessary, having regard to the purposes for which they are processed.

5) Processing for historical purposes, etc.

According to Art. 8 of the Data Protection Act, "the processing of personal data for historical, statistical or scientific purposes shall not be regarded as incompatible with the purposes for which the information was collected:

Provided that the Controller shall ensure that:

- (a) the appropriate safeguards are in place where personal data processed for historical, statistical or scientific purposes may be kept for a period longer than is necessary having regard to the purposes for which they are processed; or
- (b) personal data kept for historical, statistical or scientific purposes shall not be used for any decision concerning a data subject."

6) Criteria for processing

Following Art. 9 of the Data Protection Act, "personal data may be processed only if:

- (a) the data subject has unambiguously given his consent; or
- (b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract; or
- (c) processing is necessary for compliance with a legal obligation to which the controller is subject; or
- (d) processing is necessary in order to protect the vital interests of the data subject; or

(e) processing is necessary for the performance of an activity that is carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data is disclosed; or

(f) processing is necessary for a purpose that concerns a legitimate interest of the controller or of such a third party to whom personal data is provided, except where such interest is overridden by the interest to protect the fundamental rights and freedoms of the data subject and in particular the right to privacy”.

According to the Malta Statistics Authority Act:
 “Art. 41 (1) No information obtained in any way under this Act which can be related to an identifiable person or undertaking shall, except with the written consent of that person or undertaking or the personal representative or next-of-kin of that person, if he be deceased, be disseminated, shown or communicated to any person or body except
 (a) for the purposes of a prosecution for an offence under this Act, or
 (b) to officers of statistics in the course of their duties under this Act”.

7) Data protection Act: processing concerning research and statistics

“Art. 16. (1) Sensitive personal data may be processed for research and statistics purposes, provided that the processing is necessary as stipulated in article 9(e).

(2) If the processing referred to in subarticle (1) has been approved:

(a) in the case of statistics, by the Commissioner himself;

(b) in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognised by the Commissioner for the purposes of this paragraph; the provisions of subarticle (1) shall be deemed to be satisfied.

(3) Personal data may be provided to be used for the purposes referred to in subarticle (1), unless otherwise provided by applicable rules on secrecy and confidentiality.”

Art. 23 (2) of the Data Protection Act contains further provisions as follows:

“The provisions of article 21 shall not apply when data is processed solely for purposes of scientific research or is kept in personal form for a period which does not exceed the period necessary for the sole purpose of compiling statistics: Provided that the provisions of this subarticle shall not apply where the data is used for taking measures or decisions regarding any particular individual or where there is a risk of breaching the privacy of the data subject.”

(Note Art. 21 as referred to above states “(1) The controller of personal data at the request of the data subject shall provide to the data subject, without excessive delay and without expense, written information as to whether personal data concerning the data subject is processed: Provided that a request by the data subject under this subarticle shall only be made by the data subject at reasonable intervals.” etc)”.

8. Genetic information

Genetic information is regulated by the following legislation:

- Chapter 16 of the Civil Code;
- Chapter 417 of the Patents Act 2000.

1) For paternity testing

Art. 70(1)(d)) of the Civil Code states that genetic data may be used as evidence in paternity cases. "The husband can repudiate a child conceived in wedlock... if he proves that during the said time the wife had committed adultery or that she had concealed the pregnancy and the birth of the child, and further produces evidence of any other fact (which may also be genetic and scientific tests and data) that tends to exclude such paternity."

Moreover, Art. 70 (3) states that "The court may in an action of disavowal invite all or any of the parties including the child whose filiation is in dispute to submit to the tests necessary to establish the genetic proof that may be relevant to the case. The court shall be entitled to draw such inferences as may be justified by the refusal to submit to such tests. Where the child whose filiation is in dispute is a minor, the court itself shall determine whether the child shall submit to the tests".

2) Genetic Manipulations

Genetic manipulations that modify the germ line genetic identity of the human body are not prohibited as such. However, the Patents Act (Chapter 417, 2000) states that patents shall not be granted for:

"5 (c) processes for cloning the human body, processes for modifying the germ line genetic identity of the human body and uses of the human embryo for industrial or commercial purposes".

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This report is part of a series, in which the legal framework for ethical issues of accession and candidate countries is made accessible. This will allow researchers to fulfil the ethical requirements under the 6th Framework Programme. In particular, information is provided with regard to humans, human tissue, personal or private data, genetic information and animal experimentation.

Dr. Pierre Mallia is a family doctor and is specialised in clinical and biomedical ethics obtaining his doctoral degree from Nijmegen, Holland. He is on the National Bioethics Consultative Committee and is President of the Malta College of Family Doctors. He is also on the executive Council of the European Society for Philosophy in Medicine and Health Care. He has published three books on bioethical issues and numerous papers in peer reviewed journals. He is also a lecturer in the Dept. of Family Medicine at the University of Malta.