

EUROCOURSE and ENCR Working Party

Position paper on the Commission's proposal for a General Data Protection Regulation

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Summary

This paper explores various elements of the Commission's proposal for a new general data protection regulation all of which are important to cancer registration and public health research in general. We recommend that thorough attention is given to it during the coming negotiations of the draft regulation in both the Parliament and in the Council, and in the national parliaments when they interact with their governmental representatives in the Council.

Organising data protection in the EU by means of a comprehensive, binding regulation implies a sidelining of Member States' data protection provisions. National data protection guarantees are complex and nuanced, not least with regard to population-based disease and cancer registration, linked activities and research in public health. Applying exactly the same rules to all kinds of data, even when limited to research use, and in all Member States may limit the possibility to adapt to the special conditions that apply in different contexts and impose restrictions on data flow within EU.

The main concern of the EUROCOURSE and ENCR Working Party is the delicate balance to be found between respecting the national values and interests to conduct valuable register-based research on public health, on the one hand, and protection of individuals with regard to the processing of personal data and on the free movement of such data, on the other hand.

Throughout this paper the Working Party points out and comments on important articles, some of which can be preserved as they are, such as art.17 and especially art. 83, which provides an exemption to the principle of explicit consent for processing data for historical, statistical and research purposes. Recommendations and suggestions for change are made in respect to other articles, when necessary to protect cancer-registration and public health research.

The Working Party is alarmed by the extensive delegation of power to the Commission to adopt Delegated Acts. Such acts can either further or jeopardize cancer registration and public health research. The Working Party would welcome guarantees that the empowerment of the Commission to adopt delegated acts will not prevent public health research, clinical research, cancer registration or linked activities. Further, safeguards must ensure that any such delegation will not lead to an utterly disproportionate effort for epidemiological research using record linkage in countries that have facilitated this. 'Harmonisation' which can lead to more data sharing across Europe, but also to lesser data to be shared because of undue hindrances to collect data at the national level will weaken European research.



Hans H. Storm

Chairman, Working Group on Confidentiality of the European Network of Cancer Registries in the framework of the EUROCOURSE project.

Introduction

EUROCOURSE¹ and ENCR² Working Party have followed the revision of the European Data Protection Directive (95/46/EC) leading to the Commission's proposal for a new General Data Protection Regulation with great interest. We welcome the overall intention of the EU to protect personal data and to facilitate a free flow of data within the EU.

Research in public health is a fundamental pillar for the planning, management and evaluation of healthcare systems, as well as for disease prevention. The main roles for population-based cancer registries are measuring the public health impact and the burden of cancer, cancer survival and cancer control. During the last 50 years the benefits of collecting and using complete records on morbidity and mortality have been shown repeatedly. The importance of cancer registries is increasing in both planning and quality assessment of health care, and further with the European initiative to create large scale biobanking facilities in countries where data from biobanks can be combined with health data from population registries.

Cancer registers are proved to be vital resources in cancer prevention, and due to important results from register based epidemiological research it has been possible to protect human health and avoid premature deaths. Solid experience with register-based public health research in the Nordic countries demonstrates that it is possible to unite protection of personal data while also ensuring access to data for research purposes for the benefit of public health - without unnecessary obstruction, delay and increased costs for research.

Population-based cancer registries in the EU are of incontestable value for research into many aspects of cancer, which will most likely remain a key public health problem for many years, amongst other factors, as a result of the ageing of the population. Any harmonization of data protection must, therefore, protect the capacity for research done to protect public health, monitoring of health care and the safety of health interventions.

The Directive has been transposed very differently into Member State law. If a new General Data Protection Regulation implies a harmonisation of European data protection measures to conform to the legislation in force in the Nordic countries, favourable to public health research and known to be productive without posing risks to the security of personal data, then research collaboration in Europe will improve substantially and a high level of quality in public health research throughout the EU is secured.

The possibility to establish and maintain large multinational databases linked to individual persons and the conduct of joint research projects in the EU will be invaluable for research into for example rare cancers, more nuanced correlations between socioeconomic or environmental change and cancer, or the impact of reorganization of health services on patterns of survival. It would, in sum, if facilitated both legally and financially endow EU with a major competitive advantage within public health research globally.

If, on the other hand, data protection measures are harmonised to conform to more restrictive interpretations of the Directive, such as exist in some European countries, then the regulation will introduce expensive and complex procedures for research into public health. In short, this would regrettably imply adherence to the lowest common denominator for epidemiological

¹ EUROCOURSE: EUROpe against Cancer: Optimisation of the Use of Registries for Scientific Excellence in research, EUROCOURSE is funded within the 7th Framework Programme of the Directory General Research of the European Commission under number LSSH-CT-2008-219453.

² ENCR: European Network of Cancer Registries.

research activities, leading to the abandonment of valuable research projects, with serious consequences for policy interventions that influence the lives of all European citizens.

General concerns - the choice of type of legal act

The need for creating common standards across the internal market (e.g. harmonising data protection across Member States) is one of the intended objectives of replacing the Data Protection Directive 95/46/EC with a General Data Protection Regulation (Article 1). A Regulation will be binding by itself across the EU and does not need implementing legislation by the member states.

Comments and suggestions:

EUROCOURSE and ENCR Working Party have followed the revision of the Directive with great interest. The Commissioner for EU Justice has stated that Directive 95/46/EC has stood its test but that there is a need for reduction of legal fragmentation in the EU. Nevertheless, the Working Party finds it important to pay attention to crucial differences in approaches to research and in research cultures across the Member States, and the fact that the current Directive has been implemented differently.

The Directive has been implemented rather differently in the member states, perhaps even most of all relating to the research exemptions embedded in the Directive. Though there are some publications which describe these differences, a comprehensive evaluation of those differences has never been performed. Such a comprehensive evaluation should also take into account how the use of personal data for quality assurance in patient care and public health has led to the increased performance of the health care systems, and to international publications from which health care in other countries has profited.

Epidemiological research using record linkage should remain possible in countries which have facilitated this. Below under the comments to Article 83 we will discuss that it is an illusion that this can be done with solely anonymous or pseudonymised data. If the Regulation, together with the delegated acts of the Commission, would make epidemiological research impossible or extremely costly, legislation on the national level should prevail.

The Working Party agrees that in principle a more harmonised regime could strengthen the possibilities of data sharing across the EU in the sense of assembling data in pan European epidemiological research projects. For such projects data need to be assembled at the national level first of all, using linkage of the national records by which the relations between exposure, disease, treatment regimes and outcomes can be ascertained.³

Given the present differences in data protection legislation some countries can only participate in the pan European research either with extra costs involved or with less data, either quantitatively and/or qualitatively. A restrictive regulation thus only *seemingly* facilitates pan national and European research. It will be difficult to answer more intricate research questions, such as in rare cancers or rare exposures. Overall European epidemiological research would suffer. Any harmonisation should respect the present possibilities for epidemiological and public health research as they exist most of all in the Nordic countries.

³ We are aware of Directive 2011/24/EU on the application of patient's rights in cross border health care.

Commentaries and suggestions concerning specific articles

In the following sections a range of articles of the draft regulation - critical to the European epidemiological research community - are scrutinised.

1. Processing of health data without data subjects' consent

The bearing principle for the processing of personal data is that of explicit consent. For reasons which have been described elsewhere⁴, for most public health research purposes it is very difficult or virtually impossible to obtain from every data subject in the population studied. The present Directive allows for important exceptions from this principle, which is vital for public health research.

According to the draft regulation any processing of personal data concerning health is prohibited. However, crucial exemptions from which cancer registration and public health research can benefit are allowed for when:

- g) processing is necessary for the performance of a task carried out in the public interest, on the basis of Union law, or Member State law which shall provide for suitable measures to safeguard the data subject's legitimate interests; or
- h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81; or
- i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83.

(Article 9.2)

Comments and suggestions:

EUROCOURSE and ENCR Working Party strongly advise that the provision to conduct epidemiological research without the data subjects' consent is maintained.

It is vital for cancer registration and public health research that the exemptions enshrined in Article 9.2 are maintained in the regulation adopted. Otherwise it will be virtually impossible to use cancer registration data for public health purposes.

Screening and other public health interventions are examples of interventions that would be difficult to monitor and evaluate if the exemption is not maintained. The extensive data linkages done in the Nordic (and other) countries for public health research would become impossible, both in terms of organization but also in the cost of obtaining individual consent or the bias in the data such consent would create. In this context, it would be bizarre if the European Council Recommendation on cancer screening (OJEU 2003/878/EC 16 Dec 2003) is ignored. This recommendation states that the quality and impact of cancer screening should be monitored from linkages between population-based screening registries and cancer registries.

⁴ Van Veen, Patient data for health research, MedLawconsult, November 2011. The Working Party does however not agree with van Veen's conclusion that opt-out for registry data should be applied for all registries.

1.1 Processing of personal data concerning health

According to article 81.1 processing of personal data concerning health must be within the limits of the Regulation and in accordance with point (h) of Article 9.2.

Further, any processing must be on the basis of Union law or Member State law which shall provide for suitable and specific measures to safeguard the data subject's legitimate interests, and be necessary for:

- (a) *the purposes of preventive or occupational medicine*, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies; or
- (b) *reasons of public interest in the area of public health*, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia for medicinal products or medical devices; or
- (c) other reasons of public interest in areas such as social protection, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system.

(Article 81.1)(Italics added)

Article 81.2 specifies that processing of personal data concerning health is allowed for when:

“[...] necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies, is subject to the conditions and safeguards referred to in Article 83.”

1.2 Processing for historical, statistical and scientific research purposes

According to article 83.1 processing of personal data may be processed for historical, statistical and scientific research purposes if:

- (a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;
- (b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner.

(Article 83.1)

Comments and suggestions:

The article mentioned above includes important components required for cancer registration and most uses of cancer registry data for research. It is of utmost importance that Article 83.1 is maintained in the adopted regulation. If not, cancer-registration and public health research will terminate abruptly.

Cancer registration should first of all fall within the ambit of art. 81, 1 under b. Detailed cancer registration will give a first indication of the influence of environmental factors on the

onset of cancer and also of the safety and efficacy of treatment regimes. Further analysis of the data by linking with other registries would then fall under the ambit of art. 83.

Dealing with data protection in the EU by means of a comprehensive, binding regulation implies a sidelining of Member States' data protection provisions, as the Regulation would enjoy primacy. Article 81 mentions suitable measures to safeguard the legitimate interests of the data subject at the level of member states. Art. 83 does not.

One of the safeguards at the national level is the ethical review of public health research where such research is conducted without the data subjects' consent, as is currently mandatory in several Member States at either National or regional level.

Data protection rules on the Member State-level are complex and nuanced also with regard to public health research. We strongly suggest that Member States legislators are empowered to maintain or adopt concrete measures on ethical vetting of public health research, carried out without the need for the data subject's consent.

Ethical vetting at Member State or regional level offers data subjects a guarantee that the use and reuse of their personal data for research purposes is in line with societal values at the given point in time.

Further, we suggest that Member State influence on processing of data for research purposes is strengthened by a change in Article 83. It should be stated that:

Within the limits of Regulation, especially this article, Member States may adopt specific regulations concerning the processing of personal data for scientific research purposes, in particular public health research (see also hereinafter about delegated acts)

This would be similar to the proposed Article 82.1 concerning processing in the employment context.

More specific about article 83, when will it apply?

The processing of data for historical, statistical or scientific research purposes under art. 83, hence without explicit consent, is only allowed if these purposes cannot be otherwise fulfilled by data which does not or do not longer permit the identification of the data subject.

Some groups claim that all health research can be performed with anonymised or pseudomised data, using constructions by Trusted Third Parties (TTP). Though the Working Party endorses Privacy Enhancing Technologies (PET) as a way to further privacy and data security, we strongly warn against the following aspects of this trend.

The first is the illusion that all good public health research can be performed with anonymised or pseudomised data. This type of research often involves the assessment of the risk of disease in which the impact of exposure to a substance (e.g. asbestos) on the risk of disease (e.g. mesothelioma) or consequences of modern technology (e.g. mobile phones) must be measured in very large populations of individual persons over several decades. Disease risks can often only be discovered by research of this type, and it is not possible to do it without access to and repeated linkage of data which must be considered indirectly identifiable according to present standards or simply identifiable.

The second aspect of this trend is that it often ignores that source data (such as from electronic health care records) are sometimes inaccurate and therefore need to be checked. This can only be done by allowing researchers to interact with the data sources about particular patients. One way pseudonymisation can create highly unreliable research databases.

The third aspect is that of costs. These TTP constructions are very costly and consume funds which otherwise could have been dedicated to proper research. Again, data security is of paramount importance. However, no breaches of data security have been reported from countries which have held diseases registries over a very long time without using TTP constructions.

2. The right to be forgotten and erasure

Article 17.1 of the proposed regulation specifies the data subject's right to be forgotten and to erasure. This entails the right to obtain from the controller the erasure of personal data relating to them and the abstention from further dissemination of such data. The registries, however, can benefit from article 17.3 (b) and (c) of the proposed regulation. These sections exempt data processors from the obligation to carry out the erasure without delay for reasons of:

- b) for public interest in the area of public health in accordance with Article 81;
- c) for historical, statistical and scientific research purposes in accordance with Article 83.

(Article 17.3)

In conclusion, cancer registries must be able to operate without the obligation of erasure of personal data on the data subject's request.

Comments and suggestions:

As stated above, it is of great importance to future epidemiological research that storage, use and reuse of data across generations is made possible across the EU.

It is vital that the proposed exemptions from Article 17.1 of the draft regulation are maintained. Otherwise databases will potentially lose their value for research and public health, including the use of historical series.

3. Health data as a special data category

The proposed regulation acknowledges that unauthorised processing of some types of data is more likely to harm the data subject than others. Amongst other types of data 'data concerning health' is introduced as a separate and special category of personal data (Article 4.12, Article 9.1). Data concerning health is defined as "*any information which relates to physical or mental health of an individual or to the provision of health services to the individual*" (Article 4.12).

A more comprehensive account of the scope of data concerning health is found under point (26) in the comments to the draft regulation:

“Personal data relating to health should include in particular all data pertaining to the health status of a data subject; information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance, including biological samples; identification of a person as provider of healthcare to the individual; or any information on e.g. a disease, disability, disease risk, medical history, clinical treatment, or the actual physiological or biomedical state of the data subject independent of its source, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test.”

The definition of health data in the draft regulation comprises, amongst other factors, any information which relates to physical health of an individual (Article 4.12) and the physiological or biomedical state of the data subject (point 26).

Comments and suggestions:

The proposed Regulation also gives a definition of ‘genetic data’ (art. 4.10). Comments have already been made that this definition is too broad and should include ‘found on the basis of professional genetic analysis’ or a similar expression.

Genetic data are considered part of the ‘sensitive data’ to which the special provisions of art. 9 apply. It is remarkable that in art. 9.2.h which refers to art. 81 (legitimate use of personal data for health care) only ‘data concerning health’ are mentioned and not genetic data. Such data become increasingly important for diagnoses and treatment in health care, unless one considers genetic data to be a species of the genus ‘health data’. That is the most logical assumption, given the broad definition of health data.

On these grounds we assume that genetic information of any kind is included in the definition of health data and welcome a confirmation on this point. The working party would be happy that ‘genetic exceptionalism’ in the context of health care and research is no longer part of the Regulation. We warn against this ‘genetic exceptionalism’ as genetic data are not more sensitive as some other health data such as about carrying infectious diseases. To consider genetic data as a special category in the context of health care might also fuel unwarranted fears among the public and could create unwarranted barriers for research. At this point in time research into genetic data has shown that they are far more complex than previously thought, such as the discovery of epigenetic changes, and do not easily fit into a model of one dimensional genetic determinism as often perceived by the lay public.

4. Purpose of collecting data and time limits for storage

Any regulation on the scope or purpose of collecting data or time limits for storage is of importance to register-based research. Point (30) in the Recitals to the draft regulation concerns both issues:

“Any processing of personal data should be lawful, fair and transparent in relation to the individuals concerned. In particular, *the specific purposes for which the data are processed should be explicit and legitimate and determined at the time of the collection of the data.* The data should be adequate, relevant and limited to the minimum necessary for the purposes for which the data are processed; this requires in particular ensuring that the data collected are not excessive and that the period for which the data are stored is limited to a strict minimum. Personal data should only be processed if the purpose of the processing could not be fulfilled by other means. Every reasonable step should be taken to ensure that personal data which are inaccurate are rectified or deleted. In order to ensure that the data are not kept longer than necessary, *time limits should be established by the controller for erasure or for a periodic review.*” (Italics added)

This recital should be read in conjunction and as an explanation of article 5(b).

4.1 Scope of purpose for the collection of data

In accordance with the current Directive the collection of personal data must be for a specified, explicit and legitimate purpose (Article 5(b)). That said, it isn't specified to what extent or how widely such a purpose can be defined. The basic principle is that data can only be used for the purpose it was collected for.

Comments and suggestions:

Purposes for future uses of register data, even after many years, are plentiful and cannot be predicted, other than it will be health research. Eurocourse distinguishes at least 6 types of research programs – e.g. risk assessment by linking of cancer data to exposure or life style, mass screening evaluation, quality of care assessment, survivorship studies, prognostics, and health economics - in which registry data are used or whereby the registry functions as a sampling frame. It is therefore vital that collected health data can be processed for any purpose that isn't irreconcilable with mentioned purpose for which the data were initially collected. Full use of health data for register-based research within this very broad purpose must be allowed for, respecting the ethical vetting of the Member States involved.

Increasingly, collection and use of biological samples, with the development in technology for analysis and register linking, can provide new answers and information on disease, treatment and prevention in the future.

4.2 Time limits or periodic review

Withdrawing or deleting all or parts of register data relating to health will undermine the ability to conduct important public health research or monitoring.

Cancer Registries can, however, benefit from Article 5 (e) concerning the principles relating to personal data processing and storage since:

“[...] personal data may be stored for longer periods insofar as the data will be processed solely for historical, statistical or scientific research purposes in accordance with the rules and conditions of Article 83 and if a periodic review is carried out to assess the necessity to continue the storage”.

Comments and suggestions:

It is of great importance to future epidemiological research that storage, use and reuse of data across generations is made possible across the EU, such as in the European Diet and Cancer Study (EPIC). This study of over 350.000 Europeans provides knowledge on cancer and heart diseases in relation to diet and is able to confirm beliefs and refute misbeliefs about the impact of diet, physical activity etc.. EURO COURSE and ENCR therefore fully support and appreciate the proposed regulation on data storage.

Earlier versions of the draft regulation included an article concerning change of purpose of the processing of data. The final proposal doesn't include such a specific article. But there is a clear opening to use or reuse data for compatible purposes first of all in Article 5. b and 6.2. We assume that “Processing” in article art. 6.2 also means ‘Further processing’ and welcome a clarification on this point.

EURO COURSE and ENCR do, however, suggest a change of wording in Article 5.b since the term compatible purpose has shown to be highly contestable in practise. EURO COURSE and the ENCR therefore propose that the term “incompatible” is changed to “irreconcilable” in mentioned article.

This would also have consequences for article 6.4

5. Right of access for the data subject

Article 15 provides the data subjects' right of access to their personal data.

Research data are collected from different sources of data; sources from which the data subjects can gain access to their personal data.

For linked research databases it would involve a disproportionate effort to back track data on individual data subjects, since information on the single data subject consists of data linked from different sources and is not directly identifiable.

However, those research databases could profit from article 10 which states that:

If data processed by a controller do not permit the controller to identify a natural person, the controller shall not be obliged to acquire additional information in order to identify the data subject for the sole purpose of complying with any provision of this Regulation.

Comments and suggestions:

Article 10 is extremely important for research databases and we strongly recommend that it shall be maintained. There have been comments that the article is superfluous. These com-

ments are based on the assumption that the Regulation would not apply for data, which are in some way pseudonymised. That view is mistaken. The Regulation has a broad definition of personal data and, rightly or wrongly, in practice a very high threshold is being used by Data Protection Authorities, based on perceived risks of disclosure, before data can be considered anonymous.

As discussed already, data in research databases will often be considered personal data according to that high threshold. Data subjects in those databases will be distinguished from each other by some sort of pseudonym but not having names and addresses. The databases are used to find meaningful patterns between risks and disease and between treatment and outcomes. Without discerning data subjects from each other such analyses are not possible. Identification is something completely different from this distinguishing which risk factors and diseases belong to data subject a and which to data subject b. These distinctions will not lead to conclusions on individual data subjects but to meaningful general research outcomes. Researchers are not allowed to identify the data subjects behind pseudonyms and the research data attached to those. Hence what art. 10 basically does is solve the paradox that in order to notify data subjects on data about him or her in the database, the controller should do what he is not allowed to, namely to identify that data subject.

If a data subject wants to know what data are about him or her in a research database, this data subject should be able to contact the data source. EURO COURSE and ENCR suggest that research databases are to inform what sources they use to collect research data and what the data is used for. This information shall be provided as a general basis, on homepages etc., with a reference to the source providing the data. Detailed information on the content of the data should be provided from the original data source.

6. Controller and processor

Among the general obligations concerning controller and processor are provisions for joint controllers (Article 24). The article clarifies the responsibilities of joint controllers as regards their internal relationship and towards the data subject.

Comments and suggestions:

Joint controllers can prove a valuable addition potentially helpful in joint research projects with regard to synergy effects, efficiency and use of often scarce research funds.

7. Data protection impact assessment

Article 33 introduces the obligation of controllers and processors to carry out a data protection impact assessment prior to data processing which fulfils certain criteria. By their very nature cancer registries and following research would fall into those criteria.

The national supervisory authority must be consulted about such proposed processing and can prohibit it (art. 34.4).

It is important to ensure that these articles will not lead to more bureaucracy and obstacles to register-based research. The draft regulation, though, raises more questions than it answers on this matter.

Comments and suggestions:

EUROCOURSE and ENCR are concerned with the consequences of Articles 33 and 34. The register-based research community has guidelines to follow on impact assessments prior to carrying out studies. The guidelines are well functioning, highly operative and accommodate protection of private data. It would be a disaster for research if national supervisory authorities, which usually don't have any expertise on health research and whose governance in the sense of accountability to stakeholders as researchers and their allies, the patient organisations, would be allowed to implement their own ideas about what research complies with the Regulation and what research does not.

8. European Data Protection Board

A European Data Protection Board is setup in Article 64 of the draft regulation and Article 72 provides for rules on the confidentiality of the European Data Protection Board.

Comments and suggestions:

Due to the double role of the members in both the National as well as the European context their independence, as stated in Article 65 is doubtful. Although it seems reasonable to meet and discuss matters of concern this setup may lead to national interest bias.

Additionally the actual role of the board is not sufficiently clear.

Further we are concerned with the principle and rules of confidentiality of the European Data Protection Board. Conclusions and overall topics for the discussion must be made public. Openness and public access as a governance principle encourages motivated and informed discussions as well as conclusions.

9. The authority of the Commission to issue delegated and implementing acts

The draft regulation empowers the Commission to adopt delegated acts in 26 instances in accordance with Article 290 of the Treaty of Lisbon (TFEU) and to adopt implementing acts in 19 instances in accordance with Article 291 TFEU. The implications of this empowerment are potentially substantial and create an unfortunate degree of uncertainty with regard to the consequences of the regulation, which on these grounds will come out as a black box.

This is highly undesirable for future research and investment in research. Allowing the Commission to amend, supplement or delete elements of the legislative act will require thorough attention from stakeholders in the research community as well as Member States and EU-institutions.

9.1 Examples

Article 9 sets out the general prohibition for processing special categories of personal data and the exceptions from this general rule. Article 9.3 empowers the Commission to:

“ [...] adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria, conditions and appropriate safeguards for the processing of the special categories of personal data referred to in paragraph 1 and the exemptions laid down in paragraph 2.”

(Article 9.3) 5

Article 81 obliges Member States, further to the conditions for special categories of data, to ensure specific safeguards for processing for health purposes. Article 81.3 empowers the Commission to adopt delegated acts:

“for the purpose of further specifying [...] criteria and requirements for the safeguards for the processing of personal data for the purposes referred to in paragraph 1”.

(Article 81.3)

Article 83 sets out specific conditions for processing personal data for historical, statistical and scientific research purposes. Article 83.3 empowers the Commission to adopt delegated acts:

“[...] further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.”

(Article 83.3)

Comments and suggestions:

We are worried by the extensive delegation of power to the Commission. It is of general concern to us that the empowerment of the Commission to adopt delegated acts in Articles 9.3, 81 and 83 may lead to additional legislation (on for example encryption, TTP's or pseudonymisation of data) hampering the possibilities to conduct register-based research in countries proved excellent in this or imposing bureaucracy in the pursuit of greater legislative coherence across the EU. We have discussed the illusion that TTP constructions will lead to sophisticated research already in the section discussing article 83, and possibly make public health research an unreliable basis for health policy. False conclusions may have severe consequences for large populations if interventions are based on those, e.g. vitamin A supplementation for smokers rather increased than decreased their lung cancer risk.

The 25-person Steering Board of EURO COURSE and the ENCR Working Party are not familiar with any breaches of confidentiality in population-based cancer registration, linked activities and the systematic use of population-based health data in those countries which allow such research. The existing regulation functions well in such countries and fulfil the need for data protection. This demonstrates that it is not necessary to introduce binding comprehensive regulation at the European level with regard to concrete measures and mechanisms for the processing of personal data for research purposes unless that would allow such registries and research in those countries where this is not possible at the moment.

We question the extensive delegation of power to the Commission and advocate that the regulation is clear on all points. The Working Party demands guarantees that any empowerment of the Commission to adopt delegated acts will not prevent cancer registration or linked activities. Further, safeguards must ensure that any such delegation will not lead to an utterly disproportionate and costly effort for epidemiological research using record linkage in countries

that have facilitated this, or fail to strengthen possibilities for international data sharing across the EU.

In particular, article 9.3 is of concern here. By this delegation the Commission might even reverse the possible positive aspects of the Regulation which we have discussed before. Member State regulation on this issue differs very much, and since the regulation will sideline Member States' data protection provision on this matter, it is likely that detailed provisions adopted by means of delegated acts are called for.

Excessive regulation on this issue can easily disable public health research or even simple monitoring of the cancer burden, with disastrous consequences for public health information.

How these delegated acts will be drafted is of also concern in this context. With the Lisbon system and the new category of Delegated Acts the comitology committees cease to exist as the requirement to get the approval of Member States. Although the Commission uses other forms of groups, notably expert groups, it is not entirely clear how the experts are chosen. Member States will have to monitor how the Commission consults experts and have the possibility of making this compulsory by putting such a provision in the legislative act.

Particular concern is raised about undue influence of IT companies and privacy enhancing services, which have strong vested interests in lobbying for costly but unnecessary privacy enhancing technologies, yet have no interest in public health which should nevertheless be the primary concern of the EU.

EUROCOURSE and ENCR Working Party invite for a maximum level of consultation with experts from the EU research community on any acts, if the wide authority of the Commission to issue those Acts would be maintained in the final Regulation.

We further suggest that in such a case any delegated acts must take into account professional guidelines already adhered to by the EU research community, such as ENCR's *Guidelines on confidentiality and ethics for population-based cancer registration and linked activities in Europe, (1992, 1995, 2002 and 2012)*.

The same suggestions are made for:

- Article 23 (which sets out the obligations of the controller arising from the principles of data protection by design and by default),
- Article 14 (which specifies the controller's information obligations towards the data subject), Article 15 (on the data subject's right of access to their personal data),
- Article 30 (obliging the controller and the processor to implement appropriate measures for the security of processing) and
- Article 33 (introducing the obligation of controllers and processors to carry out a data protection impact assessment prior to risky processing operations).

It should further be noted that researchers in public health are in general not in the position to monitor policy processes and use lobbyist as some other groups are. Hence the powers of the Parliament, where such lobbying usually will take place, to revoke delegated acts, is of little avail to public health researchers. If on the other hand, the Commission would embed them early on in the drafted process, balanced delegated legislation might be achieved.