

# NEWSLETTER

# CONTRACT

CONSENT IN A TRIAL & CARE ENVIRONMENT

## EDITORIAL

### Why CONTRACT ?

Consent is a fundamental ethical and legal concept of our society and culture. Having the right to refuse or to agree with an offer is a very basic sign of a subject's freedom and autonomy. Protecting this right to give or refuse consent is therefore an important goal of national and European legal regimes and the autonomy standing behind the right to consent is protected (and limited) by a complex set of rules and fundamental rights. Some of these rules are of European, others of national character. Many of them are very old and stable and go back to the roots of European private law in the period of the Roman Empire, others are very new and subject to permanent change.

CONTRACT focuses on a defined and important area of the topic: We analyze how the European Data Protection Directive and the Clinical Trials Directive understand and protect informed consent and which impact these concepts have on the success of translational medical research. Both men-

tioned Directives define (informed) consent. However, the definitions as well as the legal concepts behind them differ significantly. CONTRACT helps to understand how the differing concepts of informed consent have consequences on the patient's (data subject's) and researcher's (data controller's) rights and duties. It shows how new legal approaches can help to support translational research and to protect patients' rights at the same time. The project is in close contact with stakeholders from all affected interest groups: patients, researchers, regulatory authorities, political bodies, patient organizations etc. The research community is supported by a helpdesk offered by CONTRACT and by intense interaction using all available means of communication.

This newsletter seeks to give an overview about all the different CONTRACT activities and the people performing them. We would love to hear from you, would appreciate your feedback and are looking forward to cooperating with you in order to support Europe as a world-leading research area in the best interest of the patient.

Sincerely yours  
*Nikolaus Forgó*  
 Project Coordinator

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# Life and Achievements

## Results from the CONTRACT electronic questionnaire

by Yvonne Braun, CONTRACT project team member



Informed consent (IC) is a legal requirement in clinical research in Europe (Clinical Trials Directive, Data Protection Directive, Good Clinical Practice Directive). CONTRACT aims to investigate legal, ethical, technical and clinical aspects of IC in research projects focusing on vulnerable patient groups, in particular the pediatric population. In order to identify the main issues, difficulties and best practice cases regarding the handling of IC a survey amongst stakeholders was conducted.

For this purpose an online questionnaire was developed and different interest groups in the clinical research and care environment (e.g. physicians, care providers, clinical research project members, computer -, legal -, ethical experts, and policymakers) were invited to complete this online survey (<http://www.contract-fp7.eu/>). The questionnaire comprises a general section to be completed by all participants and 5 sections (clinical care, research, IT, legal/ethical issues, handling of IC)

addressed to specific stakeholders only.

So far (as of 5th of September 2011) a total of 203 individuals have participated of whom 58 submitted a complete reply to the questionnaire. Due to the low number of respondents a detailed analysis comparing different countries/ stakeholders is not yet possible at the moment and thus only general answers are provided:

People from 21 different European and 3 Non-European countries participated at the survey. The majority of the participants are very experienced with handling of IC (mean 9.1 years). Most of the respondents (60%) are employees of academic institutions. 19% answered in the role of basic researchers, 17% as chairmen of trials and legal experts, respectively, 16% as clinicians and 9% as computer scientists.

The survey revealed that the majority of the participants are very familiar with legal requirements regarding the IC procedures.

Furthermore, people are generally comfortable with informed consent process and medical and legal information provided through the IC are considered sufficient and should not be described in too much detail. The vast majority insists on different proceedings regarding informed consent in clinical care and clinical research.

Regarding the individual sections of the IC in care and research, the already existing legal requirements (purpose of the trial, voluntary participation, foreseeable risks, data protection, benefits for patients) are considered very important.

The role, attitude and experience of the physician are considered indispensable in obtaining IC. A personal discussion with the physician as well as a patient information sheet (PIS) should be the basis for decision making regarding trial/ treatment participation. The size of PIS should not exceed 5 pages and the patient/subject should not be asked for more than 3 different ICs at the

same time. Ideally, the patients/subjects should be given at least 24 to 48 hours to reflect before signing IC, as is the current practice according to the respondents. Reconsent is important from a legal point of view (mean 3.18) and should be obtained in view of about half of the participants.

Almost 50% of the participating coordinators of trial and care projects have already drafted an IC, most of them by the means of IC templates. A lot of them experienced difficulties within the IC procedure. About 60% had to rework the ICs after ethical review, although in their opinion all legal and ethical requirements had been addressed and it was assumed that a major part of the patients/ subjects would completely understand all listed items. In general, IC templates are considered helpful and people are willing to pay for a template service.

The vast majority of the participants prefer a paper based informed consent form (ICF), as less than 50% of the patients/subjects are considered to be able to sign ICFs electronically. About half of the respondents supported the alternative for the patients/ subjects to choose between paper and electronic IC, with the possibility to withdraw by any way. The electronic form should be built up on a modular base comprising at least modules for care, trial, research, bio banking, data storage and transfer. So far, IT systems in the clinical care and

trial environment (hospital information-/ , electronic health record-/ , clinical trial management systems) seem to be mainly used to archive rather than to actively manage consent issues.

With regard to the results of the legal and ethical issues section, about half of the respondents are involved in projects where different national and international legal and ethical requirements have to be taken into account throughout the IC procedure. The national implementation of EU regulations caused indeed some difficulties within European projects, amongst others a considerable rise in administrative overhead and thus cost and delays in study start. Also different data protection requirements were not easy to coordinate. A harmonization of laws and regulation is strongly recommended.

The common IC practice in dealing with vulnerable subjects complies with legal requirements of EU (see Clinical Trials Directive (DIRECTIVE 2001/20/EC)). Certain evaluation criteria to measure the vulnerable patient's capability to understand the implications of the assent are applied by the majority of the participants. If conflicts between consent of legal representative and assent of subject arise, the vulnerable subject will not be admitted to the trial in most cases.

There is a preference towards predetermined IC procedure vs. a negotiable procedure. The re-

ention period of ICFs is not handled consistently with the majority archiving ICFs 10 – 15 years or indefinitely.

Almost all patients/subjects are informed about their rights concerning IC either by written consent or by a personal conversation with the responsible physician. It is not common practice to involve further institutions/ specialists to inform patients/subjects about risks, dangers and aims therapy/ trial. A slight majority grant patients/subjects access to their personal data after signing IC. Also it is common to share non – personal data about trial subjects mainly within the same country or within EU and to a smaller extent outside the EU. In general, the patients are informed about data sharing.

Normally, the same levels of data security are applied throughout all participating trial sites. With respect to data protection, the majority of the participants confirmed the presence of specific data security policies and a data protection officer.

In the future it is hoped, with further stakeholder feedback, that we shall be able to define best practice cases in dealing with IC solely based on the survey. A higher number of participants are urgently needed. For this purpose the questionnaire remains online (<http://www.contract-fp7.eu/>). Your participation in the survey is highly appreciated.



# A major success: **CONTRACT's** **first stakeholder workshop**



by **Matthew Pediaditis**, CONTRACT project team member

The first CONTRACT's stakeholders' workshop took place in Hannover, Germany, on the 15th of September 2011 and was a major success. Experts from the legal, medical and ICT related academic community (K.U. Leuven, Leibniz University Hannover, Saarland University, Stockholm University, TEI Crete, University of Oslo, University of Cambridge), as well as representatives of major organizations and industrial representatives (ECRIN, EORTC, TMF, SIOP, Custodix) and EU projects (BBMRI, EHR4CR, ENCCA and p-MEDICINE) from eight European countries gathered to exchange knowledge and experience on issues related to the impact of the Clinical Trials Directive (CTD) and Data Protection Directive (DPD) on translational research and clinical trials.

The workshop also discussed the results from the questionnaire which was conducted during the initial phase of CONTRACT. Two sessions were held in series, the first consisting of seven guest presentations and two CONTRACT project presentations, each followed by a short discussion, and the second, consisting of an extended in depth discussion.

The participants agreed that the CTD has resulted in reduced trial participation rates, increasing costs and declining patient survival rates. This is a clear indication that the regulation has to be changed. "There is a need to make it much easier to enroll patients into academic trials" was the general message

behind each discussion in the workshop. Moreover, the regulation doesn't specify what "informed" means and it doesn't give outline of consent. This has led to an inconsistent interpretation of what informed consent means in practice by local ethics committees. The informed consent document might not always necessarily be the long comprehensive document as we know it today, addressing all possible cases. Ethics committees play therefore a major role in the way the informed consent is prepared.

Encouragement of participation in clinical trials and research is connected to giving people a choice – helping the patients – instead of defining a legal process. Creating awareness on this subject is important and implies fully informing the involved persons, quite a difficult task, which might be facilitated if there is an easy to access information desk so that participants know that the information exists, is valid, and that it can be read anytime. The most important issue here is building up trust between the patient and the physician. Patients are generally not able to adequately judge whether a treatment is good or bad for them. Accordingly, a respectful and open approach to providing information is arguably as important as the actual content of the information. Another problem is that it requires time to process the given information in order to make a decision, which is a problem in urgent life threatening situations.

It was generally accepted that the role of patient organizations is very important in assisting patients making a choice on informed consent. The decision is a personal matter and the patient is making it on his/ her own, but guidance from somebody with experience would help substantially. On the other hand, withdrawal of consent is a very important feature. Its practical implication is that it limits the amount of information required to be delivered to the patient upfront as long as he/ she may change his/ her mind at any time.

Finally it was felt that the availability of e-consent is one of the most anticipated technical solutions to managing informed consent documents and to gaining informed consent, as it can provide a more flexible and dynamic way of informing participants while enhancing the feeling of trust. It could give the possibility to withdraw at any time, so that broad

consent scenarios could be supported. Several challenges related to managing e-consent were discussed, with the issue of electronic signatures being one of them.

The key message taken by the project consortium from the workshop is the fact that there is a great will in the community to collaborate and cooperate in creating a more consistent picture of informed consent and that the project could act as a catalyst towards achieving this.

As a result of this very fruitful workshop, the CONTRACT project – during its second year of implementation - should focus on integrating the input provided by the community, as well as continuing to extend the number of the participating organizations.

## Dissemination

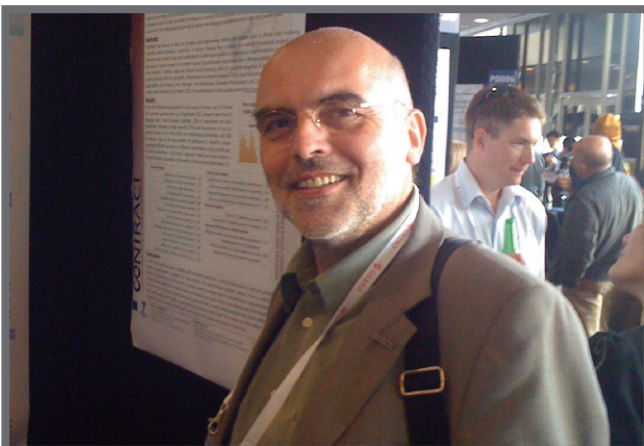


On 24 & 25 January 2012 the Annual Conference of European Forum for Good Clinical Practice (EFGCP) in the Résidence Palace in Brussels, Belgium took place. Participants of the conference discussed, in the words of the organiser, „ways to improve the information provided and see how sponsors, researchers and research participants can work together to influence law, policy and ethics and hence change these regulatory requirements and current culture.“

The CONTRACT Project was present and conference participants could inform themselves about the project by reading the project poster, as well as by having a chat with Magdalena Góralczyk from Leibniz Universität Hannover, who represented the CONTRACT consortium at this event.

The CONTRACT Project was present and conference

EFGCP is planning to write a report on the conference where a detailed account of the conference will be given.



From the 25th to the 30th of October, the 43rd Congress of the International Society of Paediatric Oncology did take place in Auckland, New Zealand. Prof. Dr. Norbert Graf from the University Hospital Homburg, member of the CONTRACT consortium participated and presented the first results of the questionnaire to an interested audience of Paediatricians, Nurses and Parents groups. In front of the poster many lively discussions took place and people expressed their willingness to contribute in filling out the questionnaire, as all agreed that Informed Consent is a major issue that needs to be standardized around the world.



# Feature Article

## Informed consent in translational research

by Magdalena Góralczyk, Nikolaus Forgó and Griet Verhenneman, CONTRACT project team members



It is generally known that participation in translational research is subject to informed consent. Less well known is the legal basis on which this requirement to obtain informed consent is actually based. In the operational guideline of Trouet (2007)<sup>1</sup> and the recent analysis of Doppelfeld (2010)<sup>2</sup> medical scientific research is used as an umbrella term covering research and experiments on man with the aim to obtain biological or medical knowledge, but a widely accepted definition of this concept does not exist. Both authors do agree that under the umbrella of scientific research a distinction has to be made between the scientific use of human biological material, research on existing data and clinical trials. The category of clinical trials can in its turn be divided in the clinical trials involving medicinal products and those not involving medicinal products. The clinical trials involving medicinal products can finally be split into interventional and non-interventional or observational clinical trials. Drafting an informed consent form for the participation in translational research will consequently firstly require you to decide on or specify the type of research you will be performing.

Secondly you need to determine who you will involve in your research. Here a distinction has to be made between participants able to consent for themselves and participants not able to consent, such as children. Given that informed consent is in many situations considered the most important condition

for participation in medical scientific research, and this condition cannot be fulfilled as usual by children, the Ethics Working Group of the Confederation of European Specialists in Paediatrics (2003)<sup>3</sup> stresses that medical scientific research should never be carried out in a paediatric population if it can also be carried out in an adult population.

Depending on the above two factors, a) the type of scientific research you are performing; and b) the participants you are involving; the legal framework consisting of international, European and national laws, codes and good practices applicable to your informed consent form will differ. Nevertheless, many of the same general requirements apply to all types of informed consents: the consent has to be given freely, after having been duly informed.

In the CONTRACT project, as it currently stands, we have opted to focus, in the first instance, on the informed consent form for clinical trials and the informed consent form for data protection involving children.

### **Informed consent for children's participation in clinical trials**

The only legal regulation on informed consent for clinical trials in Europe is the 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, or for short “the Clinical Trials Directive”. As the title of this legal document already partly suggests, this Directive applies however only to one type of clinical trial: interventional clinical trials involving drug research. For the requirements on informed consent in other types of clinical trials, one has to rely on general principles, good practices and/or national legislation. The Clinical Trials Directive defines “informed consent” as “a decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation”. One of the goals of the CONTRACT project is the word-by-word analysis of this key definition and the in-depth study of the implications thereof for clinical trials involving children. The 2001/20/EC directive is currently however under review. In the following paragraph we signal some of the most often mentioned potential obstacles to informed consent in paediatric trials.

The most often signalled obstacle is definitely the difficult, voluminous and contingent information that minors and their parents are confronted with. Pinxten, Nys and Dierickxs (2010)<sup>4</sup> for example found that the overload of information makes it difficult or even impossible for minors and their parents to make a well-considered decision, and may tempt them to leave the decision to someone else. Nevertheless and even though the consent process should always be designed to discover and promote the will of the child-participant, the Ethics Working Group of the Confederation of European Specialists in Paediatrics (2003) considers it to be best to include all of the information and considerations generally accepted for seeking informed consent of adults<sup>5</sup>. Pinxten, Nys and Dierickxs (2010) also indicate that for children and their parents it is hard to grasp the distinction between research and therapy.

Robinson and Andrews (2010)<sup>6</sup> furthermore highlight that the choice of the Directive to refer to national legislation for a definition of the patient unable to consent and legal representative has caused difficult challenges for international trials. They found that the majority of Western European countries does allow family members to consent on behalf of the patient in so far no other legal representative was appointed earlier. In a number of these countries, a legal representative scheme or hierarchy is enacted by law, while other countries recognize anyone ‘linked to the subject by family reasons or fact’. Some countries also allow as a last step in the hierarchy the consent of the healthcare professional acting in the best interest of the patient unable to consent. These national differences were also recognized as an obstacle in paediatric research during the first CONTRACT stakeholder workshop (September 2010, Hannover). Additionally to the different representation schemes it was noted that national legislation also differs with regard to the age at which a patient is considered to be able to consent for himself and the evidence or documents required to prove this relationship.

Welzing et al. (2007) finally indicate that also the aspects of data protection and its specific regulations are experienced as a major difficulty when drafting informed consent forms<sup>7</sup>. These aspects are further described in the next section.



## Data protection aspects in translational research

The Clinical Trials Directive obliges all the persons involved in conducting clinical trials not only to follow the rules of the Directive but to act in observance of the trial subject's privacy and his right to protection of data. As a result the conduct of clinical trials is also subject to the additional rules found in the Data Protection Directive. Unfortunately the latter Directive does not contain specific regulations dedicated only to processing of personal data of trial subjects. When all of this is looked through the lenses of different national legislations the divergences multiply.

The situation is complicated due to a plethora of reasons – firstly the data flows in modern clinical trials are very complex<sup>8</sup>; furthermore the national implementations of both the Data Protection Directive, as well as the Clinical Trials Directive are very diverse<sup>9</sup>. All this together brings difficulties in recognising both which persons involved in the trial have obligations according to the data protection regulations, and what those obligations actually are.

Both the Clinical Trials and the Data Protection Directives provide a set of roles – in the former Directive, the main persons involved are the sponsor and the investigator. In the latter, the main roles in-

troduced are those of data controller and of data processor. In the complex environment of a clinical trial, in which often there are many units processing the data, distinguishing between these roles can be difficult.

In addition the relationships between all the actors are governed by contractual obligations, protocols, as well as forms of informed consent.

Consent is another focal point of the problems as both Directives require consent, but the definitions of consent differ. Therefore there is no clear consensus as to what the informed consent form should look like – should the consent for data processing be a part of the consent for participation in clinical trial, or rather a separate document? How far-reaching is the requirement of explicit consent? Although some clarifications have been brought by the art. 29 Data Protection Working Party in their opinion on definition of consent<sup>10</sup>, further consideration of this and other pressing issues will hopefully take place in the upcoming revisions of both Clinical Trials Directive and Data Protection Directive. One of the most important aims of CONTRACT is therefore to support the European legislator in mastering the legal transition process necessary for a better understanding of informed consent and for fostering European clinical research in the best interest of patients.

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<sup>3</sup>D. Gill on behalf of Ethics Working Group of the Confederation of European Specialists in Paediatrics 2003, "Guidelines for informed consent in biomedical research involving paediatric populations as research participants", *Eur J Pediatr*, 162:455-458.

<sup>4</sup>W. Pinxten, H. Nys, K. Dierickxs 2010 "Frontline ethical issues in pediatric clinical research: ethical and regulatory aspects of seven current bottlenecks in pediatric clinical research", *Eur J Pediatr*, 169:1541-1548.

<sup>5</sup>D. Gill on behalf of Ethics Working Group of the Confederation of European Specialists in Paediatrics 2003, "Guidelines for informed consent in biomedical research involving paediatric populations as research participants", *Eur J Pediatr*, 162:455-458.

<sup>6</sup>K. Robinson, P. JD Andrews 2010 "(More) trials and tribulations": the effect of the EU directive on clinical trials in intensive care and emergency medicine, five years after its implementation", *J Med Ethics*, vol 36, 6, 322-325.

<sup>7</sup>L. Welzing et al. 2007 "Consequences of Directive 2001/20/EC for investigator-initiated trials in the paediatric population – a field report", *Eur J Pediatr*, 166:1169-1176.

<sup>8</sup>K. van Quatherm, 'Controlling personal data – the case of clinical trials', *P&I* 2005, p. 155-161

<sup>9</sup>Beyleveld, Deryck, D. Townend, S. Rouille-Mirza, and J. Wright. *Implementation Of The Data Protection Directive In Relation To Medical Research In Europe (Data Protection and Medical Research in Europe)*. Aldershot: Ashgate Pub Ltd, 2005.

<sup>10</sup>Available online: [http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2011/wp187\\_en.pdf](http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2011/wp187_en.pdf)



# **Feature Article:** A concise data protection and privacy literature overview with a focus on informed consent for data processing and medical research.

by Magdalena Góralczyk, Nikolaus Forgó and Griet Verhenneman, CONTRACT project team members

The publications concerned with the Data Protection Directive can be generally divided into three categories – the first category is publications from the European bodies – those are the documents on state of compliance of the national member states law with the Directive, as well as opinions on the different notions introduced in the directive. A second interesting source of information are the EU Framework projects, which are concerned with the EU legislation and its influence on the different forms of research. Finally there is a wide range of publications from scholars concerned with commenting both upon the Directive, as well as its transpositions in the national legislation of the various EU Member States. The more prominent examples from each of these categories will be introduced below.

## **From the EU bodies**

The richest source of information is the art. 29 Working Party – an institution consisting of the Data Protection Authorities from every Member State of EU, which publishes opinions on implementation of the Directive. Opinions of the Working Party are held in high regard both by courts and scholars.

Among other documents the Working Party introduced: Opinion 1/2010 on the concepts of "controller" and "processor" from 16 February 2010 and Opinion 15/2011 Consent from 13 July 2011.

Additionally until the year 2008 yearly reports were published concerning the situation regarding the protection of individuals with regard to the processing of personal data in the EU and in third countries.

## **Projects sponsored by the EU**

Privereal – Privacy in Research Ethics in Law – Privereal was a project focusing on examining the influence which country implementations of the Data Protection Directive have had on medical research,

including the role of ethics committees. As an outcome of the project, the following books were published:

- Beyleveld, D., D. Townend, S. Rouille-Mirza, and J. Wright. *The Data Protection Directive And Medical Research Across Europe (Data Protection and Medical Research in Europe: Privereal)*. Aldershot: Ashgate Pub Ltd, 2005.

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ACGT - Advancing Clinico-Genomic Clinical Trials on Cancer – the ACGT project aimed at developing support tools in support of cancer research. The project had a strong focus on data protection, which resulted in a data protection framework, which was also published:

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tion Management Association. Medical records and the law. Sudbury, Mass: Jones & Bartlett Learning, 2006.

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### **A concise literature overview with a focus on informed consent for clinical trials in paediatrics.**

Many institutions, companies and people are confronted with the issue of obtaining or giving informed consent for clinical trials. Not surprisingly, guidelines, recommendations and good practices have been developed internationally, both by official bodies and through scientific research. In Europe the informed consent for participation in an interventional clinical trial involving medicinal products has for the last 10 years been regulated in addition by Directive 2001/20/EC. Publications on informed consent for clinical trials vary from practical guides on how to draft informed consent forms, over ethical and legal publications, to study results reporting on good practice cases or research with informed consent forms. Publications on informed consent specifically in paediatrics do exist, but are rather rare. We introduce the most prominent and recent examples of publications in these three categories below.

### **Guides to informed consent for clinical trials**

- The World Health Organisation has published several templates for informed consent on its website, including templates for the Informed Consent for Clinical Studies and Informed Assent for Children/minors, [http://www.who.int/rpc/research\\_ethics/informed\\_consent/en/](http://www.who.int/rpc/research_ethics/informed_consent/en/).

- Marshall, P., (2007) “Ethical challenges in study design and informed consent for health research in resource-poor settings”, WHO publication: Special Topics in Social, Economic and Behavioural (SEB) Research report series; No. 5, TDR/SDR/SEB/ST/07.1.

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- AMA Guidelines on informed consent, Code of Medical ethics and Policy Finder, available through organisation website: [www.ama-assn.org](http://www.ama-assn.org).

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- Pinxten, W., Nys, H. and Dierickxs, K. (2010) “Frontline ethical issues in pediatric clinical research: ethical and regulatory aspects of seven current bottlenecks in pediatric clinical research”, *Eur J Pediatr* 169:1541-1548.

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# Community View

## The challenges for data protection in contemporary healthcare activities

by Peter Singleton, Director at Cambridge Health Informatics



### What is “personal data” ?

The EU DP Directive presumes a single category of “personal data”, whereas the reality is a little more complex: aggregated “personal data” is no longer “personal”, but may nevertheless have identification risks where small numbers are concerned; data may be de-identified (“pseudonymised”) so that it is no longer possible for the data controller to identify a person’s record (perhaps in response to a subject access request), but it is still deemed “personal data”.

A large data-set of individually “unidentifiable” records almost certainly has one or more records that could be identified, either by some chance occurrence of values or by determined application by a “hacker”. Any rich data-set (as often used in healthcare) will have many unique records, though not necessarily identifiable as such.

The EU DP Directive needs to be revised to make clear what obligations or restrictions apply to what sorts of data that fall within the broad remit of “personal data”. That all “personal data” needs some measure of protection is indeed appropriate, but the legal basis needs to be better grounded in the level of risk and appropriate safeguards.

### Medical data re-use

DP Legislation presumes a rather simple “supply chain”: data subject: data controller: data processor, where the data controller is the supplier of the products or services to the end-user/data subject. Other actors may be involved, but usually as agents or data processors on behalf of the data controller. The consumer may, of course, have multiple relationships with different suppliers/data controllers to gain an overall service or set of products.

In healthcare, the situation is much more complex. There may be a “primary supplier” or payor (an insurance company or state health-care) who pays for or even commissions services for the patient. While historically their involvement was often only financial, so detailed care information was not necessary, nowadays there is far more emphasis on “smart commissioning” to get high-quality care for the patient at the most effective price.

Even this is a simplification of actual practice, where clinical governance is a separate strand within professions and across organizations, involving various regulatory bodies (e.g. NICE, GMC, BMA, MDU, etc., in the UK); individual professions have a duty



of confidence around what patients may tell them (as well as broader expectations of medical confidentiality, of course); as well as government initiatives which may require the sharing of medical data to measure progress towards various policy goals.

Furthermore, there is an urgent need to learn from the experience of healthcare delivery – within teams, within organizations, and across healthcare economies. Currently, this tends to be the role of medical research, but should really just be part of wider clinical practice with medical research just being the more “scientific” aspect of a wider process of quality improvement, identifying what works and what doesn’t.

The problem with the current framing of DP (and ethics review as well) is that explicit consent is often required for every use of medical data in a separate project – no matter how well controlled and vital. This increases costs for medical research and means that many routine uses and possible studies either never get done, are significantly delayed, or are less effective than they might otherwise be.

The EU Article 29 Data Protection Working Party has already identified that gaining consent for recording data in EHRs is not appropriate and that there should be explicit legislation in each EU member state, detailing likely use and expected protection. This should allow more effective review of healthcare in practice rather than just in the laboratory (e.g. clinical trials, where consent is usually appropriate), removing a barrier to better understanding of medicine and its delivery and allowing a reduction in the number of unnecessary deaths, poor outcomes, and spiraling costs of healthcare.

## Experience with computer assisted design of informed consent documents

by Roland Krause and Dr. Annette Pollex-Krüger at TMF e.V.

The development of an online wizard by TMF e.V. Berlin for the web-based design of informed consent forms ([www.tmf-ev.de/pew](http://www.tmf-ev.de/pew)) was driven by the following considerations: Informed consent is not limited to a pure signed paper; it rather involves two essential parts: a document and a process. The informed consent document provides a summary of the clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation, etc.) and explains the rights as a participant. It is designed to begin the informed consent process, which consists of conversations between the patient and the research team. In order to create such a document, a variety of information is required.

The informed consent process provides the participant with ongoing explanations that will help make educated decisions about whether to begin or continue participating in a trial. Researchers and health professionals know that a written document alone may not ensure that a patient fully understand what participation means. Therefore, before the participants makes a decision, the research team will discuss with them the trial’s purpose, procedures, risks and potential benefits, and the rights as a participant. Before, during, and even after the trial, a participant shall have the opportunity to ask questions and raise concerns. Thus, informed consent is an ongoing, interactive process, rather than a one-time information session.



A general framework for an informed consent regarding clinical research requires that the data and/or material must be collected, processed and stored only for a defined purpose, for a restricted time frame, and for explicitly listed users. All these conditions must be mentioned in the patients' information. Extending these restrictions is possible in certain circumstances, but only by applying additional safeguards and conditions in a rigid organizational framework, where the risk of re-identification is strictly controlled. The TMF approach overcomes the barriers for keeping data indefinitely by additional safeguards. The additional safeguards are: Establishing the medical research network as a legal instance with clear accountability, Offering state-of-the-art information and communication security, including Public Key Infrastruc-

ture (PKI) techniques and access control, dividing informational powers by designating information and procedures to several independent parties; in particular, the establishment of Trusted Third Parties (TTPs) and separate storage of data, medical images, biomaterial, and corresponding analysis results, and the use of pseudonymization.

TMF has therefore developed an online wizard for the web-based design of informed consent forms ([www.tmf-ev.de/pew](http://www.tmf-ev.de/pew)) based on the book Patient Information and Consent: TMF Checklist and guidelines. The wizard guides the user through the compilation of the documents and proposes model/generic texts. It contains all required information (legal principles, opinions of ethical committees, etc.) However, the wizard does not "self-generate" documents; the output

needs to undergo careful adaptation to each research project.

Further developments may cover: Rules for patients not capable of consent, i.e. poly-traumatic patients, unconscious patients or those patients with dementia as well as children. In Germany, as a result of the federal distribution of competencies, many different laws with different regulations and limitations for research exist; this is especially the case for studies where only indirect benefit is expected. It is therefore desirable that uniform rules are drafted and, moreover, Standardisation within Europe in this field is needed, e.g. in accordance with the Oviedo Convention of the Council of Europe.





# Upcoming Events

## CONTRACT and Academic GMP organize a joint conference

by Matthew Pediaditis, CONTRACT project team member

CONTRACT and Academic GMP join forces and will be hosting together a conference that will take place on October 11-12, 2012 in Brussels. Academic GMP (Grant Agreement No: 260773) and CONTRACT are both running within the research area HEALTH.2010.4.2-6, Impact of EU legislation on health research. Academic GMP investigates the impact of EU regulation on the development of Advanced Therapy Medicinal Products (ATMP) in academia. The theme of the conference will be “The Impact of EU legislation on Therapeutic Advance”.

The European Union has actively pursued and enhanced regulation of scientific research and medical treatment during the last decade. The Directives 2001/20/EC on Clinical Trials, 2001/83/EC on a community code for medicinal products, 2002/98/EC on Blood and Blood components, 2004/23/EC on Human Tissues and Cells, 2005/28/EC on Good Clinical Practice and the regulation 1394/2007/EC on advanced therapy medicinal products are examples of these activities.

They have a goal in common that is easily understandable and clear: Protecting patients from risks that scientific research and medical treatment might cause on the one hand and fostering research and care on the other hand.

In addition to those provisions directly targeting

medical research, additional pieces of legislation shape the innovation trajectory in many ways, affecting researchers, clinicians and patients. The situation is complex and – in the view of many – unsatisfactory for many different reasons. It is foreseeable that the framework will become even more complex when upcoming, technically and ethically challenging therapeutic advances become subject to more intense regulations.

**The aim of the workshop will be to critically analyze and better understand the impact of European legislation on the patients’ situation on the one hand and the European (academic) research environment on the other hand.**

The conference will unite participants from different European projects dealing with interdisciplinary issues of legal regulation of medical research and treatment.

Target groups will be members of the European Parliament, policy makers and regulatory authorities in the member states, (academic) researchers and patient organizations, as well as the general public.

For the final location and conference agenda, stay in touch through [www.contract-fp7.eu](http://www.contract-fp7.eu) and [www.academic-gmp.eu](http://www.academic-gmp.eu), or subscribe to this newsletter.



# CONTRACT People



**Prof. Dr. Nikolaus  
Forgó**

is a full Professor for Legal Informatics and IT-Law and since 2007 Head of the Institute for Legal Informatics (IRI) at the Leibniz Universität Hannover. He is the coordinator of CONTRACT, thus responsible for the overall management of the project, including the coordination of all legal, financial and administrative aspects of the project. He is the leader for WP1: "Coordination and Project Management" and WP3: "Status in Europe". Professor Forgó has significant experience in the management of EU-level projects, such as within the FP6 Integrated Project AGCT (work package leader), within FP7 in the projects P-Medicine, EURECA, CONSENT and PONTE and others, as a member of the scientific advisory board of the Network of Excellence "Virtual Physiological Human" and also in the coordination of diverse national and international projects.



**Magdalena Góralczyk**

is a member of the Institute for Legal Informatics (IRI), Leibniz Universität Hannover (LUH) and part of the coordinator team of CONTRACT Project. Together with Prof. Forgó she is responsible for the project as a whole and therefore her tasks focus on coordination and management of the work of the whole consortium. Furthermore, as LUH was the leader of WP3 - "Status in Europe" - she was responsible for the first stage of the legal analysis done in the project.

Magdalena has been part of the IRI team since October 2008. Before that she read law at Silesia University, Poland and La Sapienza Università di Roma, Italy and graduated in 2008. Currently, next to her work in CONTRACT and other projects of the Institute, she is busy with her Ph. D. thesis in the field of data protection.



**Prof. Dr. Norbert M.  
Graf**

is a Professor of Paediatrics, the director of the Department of Paediatric Oncology and Haematology at the Saarland University in Germany, and member of the Faculty of Medicine of the same University. Prof. Graf's main contribution to CONTRACT focuses on the clinical aspects, providing insights and feedback on how the Data Protection Directive finds application in real-life clinical trial settings, in particular in terms of informed consent. He is the leader for WP2: "Problem Analysis". Prof. Graf is a member of the German Society of Paediatrics, the Austrian Society of Paediatrics, the Association of Paediatricians in Germany, the German Society of Paediatric Oncology and Hematology (GPOH), the German Cancer Society, the Cancer Society of the Saarland, Germany, the German TNM Committee, representative for the German Paediatricians, the European Bone Marrow Transplantation, the International Society of Paediatric Oncology (SIOP), the Paediatric Society of Bone Marrow and Stem Cell Transplantation, the European Haematology Association and is an Associate Member of COG (Children's Oncology Group, USA).



**Griet Verhenneman**

is scientific researcher at Interdisciplinary Centre for ICT and Law (ICRI) at Katholieke Universiteit Leuven. Within the CONTRACT project Ms. Verhenneman studies the legal frameworks for informed consent in care, research and data protection together with the legal team of IRI. She is leading WP4: Policy Recommendations and Guidelines. Ms. Verhenneman has sound experience with research on ICT-law, eHealth and the law especially. She contributed to different Belgian and European projects amongst which the FP7 TAS3 project on secure data sharing in an e-health and work-related context and the IM3 project on medical mobile monitoring, the TransCare project on eHomecare and the Share4Health project which aimed to build a common patient-centric and community-centric healthcare IT platform including innovative security and privacy solutions, all supported under the Flemish IBBT framework. In 2010 she was awarded the prize for Best Young Presenter at the Fitce Congress in Santiago, Spain for her presentation entitled "Consent, an Instrument for Patient Empowerment?". Currently Griet is preparing a PhD on the patient's right to privacy and autonomy in personalized healthcare.