

BBMRI-ERIC joint comments to the Article 29 Working Party Guidelines on Consent under Regulation 2016/679 (wp259) and Transparency under Regulation 2016/679 (wp260)

What is BBMRI-ERIC?

BBMRI-ERIC (www.bbmri-eric.eu) is set up as a **distributed research infrastructure for biobanks and biomolecular resources** in most, if not all European Member States. Currently, BBMRI-ERIC consists of **19 Member States and one International Organisation**, making it one of the largest research infrastructures in Europe:

Members: Austria, Belgium, Czech Republic, Estonia, Finland, France, Germany, Greece, Italy, Latvia, Malta, the Netherlands, Norway, Poland, Sweden, and the United Kingdom.

Observers: Cyprus, Switzerland, Turkey, IARC/WHO

Since December 2013, BBMRI is a research infrastructure under the ERIC legal framework that shall establish, operate and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. BBMRI-ERIC operates on a non-economic basis.

The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values.

Nationally, biobanks may be governed by a single law (e.g. Finish Biobank Act) or a set of laws and regulations (e.g. France) and appear in various forms across Europe such as clinical biobanks, disease-specific or population-based cohorts. They may be governed by patient organisations or within the clinical setting and are operated in the intersection between health care and research.

Why BBMRI-ERIC is interested in the Guidelines?

The Draft Guidelines deal with consent and not the other legal bases for processing of personal data for research purposes. Our perspective to the draft Guidelines is focused on health research.

Structure of our reply

BBMRI-ERIC welcomes the draft Guidelines on Consent under Regulation 2016/679 and the possibility for public consultation by the Working Party 29.

Our comments focus in particular on scientific research (7.2) and are divided in three sections:

1. A joint statement on behalf of BBMRI-ERIC
2. Country experts/National Node specific comments;
3. Noted version of the Guidelines with comments from BBMRI-ERIC country experts/National Nodes.

BBMRI-ERIC encouraged the National Nodes to further submit their country specific statements directly to the Working Party 29, especially as the short time span made it difficult for a Pan-European, multi-stakeholder organization to conclude on a joint statement in all important details. The joint statement represents the most critical shared viewpoints across countries. Our comments focus in particular on the scientific research paragraph (7.2).

We argue that the final Guidelines should take into account:

- the interconnected nature of healthcare and health research,
- that health research already builds on a set of well-established governance principles, international and European rules (e.g., Declaration of Helsinki) that complement data protection law,
- that health research relies on competent and independent ethic review boards as key custodians designed to protect patients/research participants and have set up appropriate modes of governance specially when considering data reuse,
- that appropriate safeguards (including access control, pseudonymisation) are already a standard in health research especially when the research is based on broad consent,
- that due to the stated goal of the GDPR to facilitate research (provided appropriate safeguards pursuant to Article 89) data subjects should not be deprived of the option to give their broad consent,
- that appropriate information for research participants and patients about the research in question may consist of different means for different research participant and patient groups,
- that quality assurance and reproducibility of research results depend on the reliable availability of data on a large scale,
- that the requirement of a granular re-consent system may result in a selection bias (e.g., resulting from non-responders due to a frequent re-consent system; 'consent fatigue'), and
- ultimately, that the progress in healthcare through research is in the public interest.

Country expert/National Node specific comments

In each BBMRI-ERIC Member country a National Node has been established that coordinates the national biobanks and biomolecular resources and links its activities with the pan-European activities of BBMRI-ERIC. National Nodes are supported by the BBMRI-ERIC Member country and may or may not have legal personality.

The following comments to the Guidelines represent the explicit viewpoints and considerations from Member State experts or its National Nodes in its entirety collected via the BBMRI-ERIC Common Service ELSI:

- France: 3
- Germany: page 5
- The Netherlands: page 9¹
- Poland: page 21
- Sweden: page 22
- Italy: page 24²

Viewpoints and comments may differ from country to country. Consequently, particular concerns and questions raised represent the viewpoint of a specific country/National Node or national expert and are highlighted as such by indicating the member state in the section below (Germany, Sweden, Italy, The Netherlands, Poland, France) as well as directly in the guidelines (Malta, Greece, The Netherlands, United Kingdom).

¹ The co-signed comments on guidelines on consent and transparency (WP259 and WP260) from Health-RI, COREON, BBMRI-NL, Parelsnoer Institute (PSI) and the NFU have been submitted by BBMRI-NL.

² Countries listed in alphabetical order, except Italy as its comment refers to Sweden's comment.

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The efforts from Art.29 data protection Working Party to set up guidelines as regards to consent are welcome.

Nevertheless, it is important to consider the following points in the finalization of the guidelines in order to ensure both clarity and common understanding of the provisions dedicated to the GDPR implementation for health research purposes.

1. Biobanks and Health Research Databases are infrastructures established on the long term thus necessitating due consideration as to their special needs in terms of data protection governance which depart from the needs of research projects. In this regard, it seems important to acknowledge the essential role of competent Ethics Committees that assess the circumstances in which personal data, mostly sensitive (health, genetic etc.), can be processed for research purposes, in particular where researchers as data controllers inscribe in exemptions fixed by European or National laws.
2. Consent requirements are also detailed into other pieces of Regulation such as in the EU Clinical Trial Regulation and the EU Medical Device Regulation. While the GDPR refers to these special laws as applying first (by citing the Clinical Trial Regulation) we would be grateful if the Guidelines could also explicitly refer to them in order to have a clear view on the legal hierarchy to consider in research settings.
3. As regard to the ban to swap the legal basis of a processing during the processing, it is unclear to know whether this only covers Art.6 or includes legal basis fixed in Article 9 regarding the processing of special categories of personal data. This should be clarified for a better understanding of the guidelines in the research context.
4. While we recognize the ban to swap legal basis (of Art.6 or Art.9) in the course of a given processing as a principle ensuring legal certainty for data subjects and efficient safeguards against abusive “function-creep”, in our special field (research biobanking), we would ask to clarify in the guidelines that a swapping should be allowed for reusing the data already processed for another research purpose under conditions of lawfulness, fairness, minimisation and transparency as to the data subjects. This cover in particular swapping between Art.6(1)(a) and Art.6(1)(e), and Art.9(a) and Art.9(g)(i)(j).

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Comments on The Article 29 Working Party Guidelines on Consent under Regulation 2016/679 (wp259) and on the Guidelines on Transparency under Regulation 2016/679 (wp260).

The guideline explicitly refers to **medical research** and should offer paths and solutions to facilitate research for the sake of our patients. Therefore, some basic assumptions of The Art. 29 WP Guidelines cannot remain unchallenged.

In particular, some key points need to be addressed in the light of the current challenges and opportunities medical research has to face today:

1. How biomedical research is nowadays carried out?

Unfortunately, the currently proposed guidelines seem to assume research scenarios and research methods, that belong to the past. Healthcare and biomedical research including clinical trials have always been closely linked. However, in the current era of precision medicine, the same methods and resources are used for the identification of individual therapeutic treatment options in many disease-areas, particularly in cancer. Vice versa, the data obtained or derived from the clinical course of patients are feeding biomedical research data bases as a basis for the progress, *inter alia* serving to develop and/or optimize individualized treatment options.

Many European and global collaborations aiming at exchange of research data have been funded and promoted by the EU. Disease-specific or more general research and infrastructure networks have been set-up and research resources including biomedical databases have been established. All these infrastructures depend heavily on the **lawfulness of data re-use and data exchange**.

Real world data are more and more required to demonstrate long-term effects of drugs and therapies (outcomes-based healthcare) by EMA and FDA. Healthcare providers and patients have realized that traditional clinical trials represent only a very limited part of the truth: Study-populations are highly selected and often do not represent real world settings. In addition, only sparse data are available on the long-term well-being and quality of life of study participants, if only data collected during a specific trial are taken into account. The pharmaceutical industry currently counteracts such obvious drawbacks by changing the setting of clinical trials: study programs (series of clinical trials with one drug or several members of a drug-family) or umbrella studies (with drugs targeting different paths, alone or in combination) etc. are initiated in order to prolong observation intervals and/or to switch more rapidly to promising treatment regimes.

Data protection is considered the main hurdle in making progress in various fields of biomedical research. Often data from various sources are needed to gain medical/scientific knowledge, but in many cases restricted underlying (e.g., mostly study-specific) consents make it impossible to conduct cross-border research or to widen the disease-area(s) addressed by biomedical research.

Currently huge amounts of so-called legacy data are gathering dust in archives and remain unused due to the legal uncertainty instead of being leveraged for the sake of progress in research. Legal uncertainty causing bureaucratic burden and endless negotiations with various partners is always mentioned, if a survey asks, what the roadblocks for research projects are. The currently proposed Art. 29 WP-Guidelines will not be helpful in reducing this burden and thus will not contribute to facilitate medical research: As the Art. 29 WP-Guideline explicitly states, that “swapping” between different legal grounds for data processing is forbidden, a researcher has to choose the appropriate legal basis for his project in advance. As a result, it could even be risky to ask research participants for consent, if he/she could use another legal gateway. The decision, which legal ground to choose, often needs the involvement of a lawyer and causes red tape without benefit for research participants. Asking them for consent should always be a good choice as long as it is made clear in the consent process, that other legal grounds for using the data for research might exist and that withdrawal of consent therefore may have limited effect.

2. Data re-use is ethically required

Data re-use is an **ethical requirement** in order to avoid unnecessary repetition of the same studies/ examinations and/or analyses (and recapture duplicate data). The ignorance and non-use of available medical or diagnostic knowledge may lead to inadequate patient care which may even bring harm to the patients. Access to this information (e.g., on new diagnostic methods, the appropriate dosage of a drug or potential (late) adverse events) without unnecessary data protection restraints is essentially required. How could we explain to parents of a child who has been harmed by a drug that has been classified not harmful in clinical trials but later on harmful in observational registries/long term surveys? This still happens too often due to a lack of data availability.

Effective pharmacovigilance requires access to as much clinical and research data as possible. Pharmacovigilance is a permanent process and its typical assumption is: we do not know, what we are looking for, otherwise we would have prevented it.

3. How to keep research participants being involved?

In biomedical research, health data and human biological materials are generally pseudonymized and - for good reasons - very rarely anonymized: on the one hand, in reality it is often hardly possible to anonymize data in a fashion that they are still useful for future research, and on the other by employing various anonymization tools data may be de-identified to an extent, that the result bears the risk of generating false positive or negative results and/or associations (genetic data). And most important, anonymization generally hinders the addition of important clinical/diagnostic follow-up data to a same case, thus hindering a potential gain in medical/scientific knowledge.

In general, it is not desirable to anonymize research data from a patient’s perspective because any feedback of incidental/unsolicited findings or any re-contact is impossible, including advances in drug-therapy, diagnostic methods etc. Deleting the identity of patients in a database is the opposite of keeping them involved in medical progress. First, it hinders the collection of additional health data including current health problems/ newly acquired diseases/ risk factors. Ethically even more important is the exclusion of anonymized donors/patients from potential therapeutic/diagnostic benefits gained from clinical studies/medical research including novel diagnostic methods/parameters. In the end, anonymization cuts all direct information on progress in medical research.

4. Useful communication with patients instead of fulfilling formal requirements

Research plans and even research aims are mostly extremely complex and hardly explainable to research/study participants in the granularity, the Guideline seems to require. Therefore, **independent ethics committees** have been installed to additionally protect individuals.

Patients and healthy volunteers are very often research oriented and wish their data to be used in order to advance the progress in medical research and treatment. Many of them are not interested in being overly and/or systematically re-contacted and confronted with complex research information. The tendency in designing ICFs therefore is, to make the text as concise as possible using lay language. Otherwise, people feel bad while signing a consent that keeps being mysterious or unclear to 60-80%.

Forcing people to learn or actively participate in things or processes, they are not interested in, is a burden for both the patient and the clinical researcher. In addition, there is often a lack in time or (medical/scientific) education of next-door patients/donors to fully understand the scope and/or procedures of clinical/medical research. Instead, (medical) research institutions, clinical data bases and/or clinical biobanks should make detailed information on their research aims, current stage and results of their research (topics) publicly available, so that the general public and/or the research- or study-participant himself can take notice/get the desired information(s) whenever they wish.

In general, such details should not be a mandatory part of an ICF, but should rather be offered to those, who really want to get informed on particular research issues. An ICF should rather contain the means and procedures, how such information can be accessed.

The same way should be taken regarding future research and data re-use. **Research participants should be allowed to give their consent in a rather broad manner** as long as they get more detailed information on demand. This would ensure the fundamental right of research participants/donors to withdraw their consent as soon as they feel uncomfortable with biomedical research using their data and/or biomaterials and wish no further involvement. There is no need in order to accomplish the principle “data control by the data subject” to force participants/donors - against their will and conviction - to decide repeatedly on each and every single (betimes complex) research step with often varying granularity dependent on the nature of this step.

Appropriate communication with **research participants/donors** means to explain the risks and benefits of dedicating sensible health data to biomedical research databases/clinical biobanks and to respect their wishes. This comprises to provide as much information as they would like to obtain and not bother them with “you have to understand” obligations (which generates a feeling of being responsible for something, they are often not capable to decide on). The responsibility for the proper use – of course, taking reasonable expectations of participants/donors into account – the integrity and protection of the health data/biosamples lies with the researcher and cannot *via* consent be imposed on the research participant/donor. Appropriate governance and safeguards (including an involvement of independent ethics committees) as well as information on request should therefore replace an **overflow of mandatory information** (e.g., in an ICF) and an **“obligatory” over-collection of re-consents** (including dynamic options), which are mostly considered mere formalities then real patient/donor-protection or -involvement.

5. Missing obligatory involvement of independent ethics committees as key custodians for individuals/patients participating in medical research.

In line with the proposed Art. 29 WP-Guidelines the purpose of the collection, storage and intended use of (health) data and/or human biological materials by a medical research project, (biomedical) research data base and/or clinical biobank should be – in general - specified as exactly as possible. Such purposes might be, e.g., the conduct of a particular clinical study, or research focused on a specific disease (i.e. lung cancer) or on well-defined disease-entities (e.g., cardio-vascular diseases or brain disorders).

On the other hand, biomedical research data bases and clinical biobanks must be prepared to satisfy **future medical questions** and meet future challenges in public health by **permitting broad use of health data and human biological materials**, including cross-border exchange and cross disease-area(s) use of data and/or biomaterials. The ethical framework should enable biomedical data-bases/ clinical biobanks to fulfil their key missions based on the arguments (i) **opening new vistas for medical research**, and (ii) **supporting optimization of public health care**.

However, as a pre-condition for the legal validity of a donor's broad consent the unpredictability of future use of his/her data and/or biological materials must be compensated by appropriate measures and procedures. In this regard, **independent ethics committees** are of paramount relevance for both (i) the assessment of a (biomedical) research data base or a clinical biobank itself (during set up and operation), and (ii) the assessment of individual biomedical research projects later on requesting "broad consent" health data/biosamples as a general pre-condition for the release and delivery of such data/samples. **This important role and task of independent ethics committees as key custodians for individuals/patients participating in medical research has been fully neglected by the proposed Art. 29 WP-Guidelines and must be added therein!**

In addition, in case of broader consent(s) independent ethics committees will check whether patients/donors have been informed in an understandable manner and unambiguously on the broad scope of the future use of his/her health data and/or biological materials including the option of cross-border or disease-overlapping medical research.

However, in line with the proposed Art. 29 WP-Guidelines (even under the conditions of a broad consent) the donor should be given the possibility to exclude certain research fields and/or procedures from the future use of donated health data and/or biological materials at least to some extent, preferably during the **initial** consenting procedure, thereby securing and documenting the donor's wishes from the very beginning of his/her data or bio-sample donation on.

This fact fits, but is not at all identical, to a so-called dynamic consent, which is **almost impossible to achieve for clinical data warehouses/biobanks having access only to pseudonymized data and biomaterials**. From a logistical point of view such attempts are far away from every day practice/ feasibility for biomedical research data bases and/or clinical biobanks hosting data and materials from several hundred thousand or millions of pseudonymized donors: This is almost due to the fact that each modification of consent requires an involvement of the respective local data custodians/ protection officers. which appears logistically not feasible on a case by case-basis.

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Comments on the guidelines on consent and transparency (WP259 and WP260)³

Executive Summary

Health RI, COREON, BBMRI-NL, PSI and NFU represent Dutch clinicians, medical scientists, epidemiologists, academic hospitals, health registries, biobanks, both clinical biobanks and population cohorts and associated organisations. Our perspective is that of health research, excluding clinical trials on human subjects as defined in Regulation EU 536/2014.

At the outset, we kindly remind the article 29 Working Party of the extensive debate between the European research and patient communities and the EU legislator during the genesis of the GDPR (hereinafter: the Regulation) which has resulted in the stated goal of the Regulation to facilitate the processing of personal data for scientific research, as is evident from, inter alia, the following:

- a. The Regulation explicitly allows processing for research purposes, provided appropriate conditions and safeguards are in place to protect the rights and freedoms of data subjects;
- b. The Regulation explicitly leaves the setting of these conditions and safeguards to the Member States, within the general confines of the Regulation;

³ The co-signed comments on guidelines on consent and transparency (WP259 and WP260) from Health-RI, COREON, BBMRI-NL, Parelsnoer Institute (PSI) and the NFU have been submitted by BBMRI-NL

- c. The Regulation explicitly exempts research from the principles of purpose limitation, storage limitation if certain conditions are met, and within limits and subject to nuances, also subject to national law, the information requirement, the right to erasure and the right to object;
- d. The Regulation explicitly allows the subsequent processing of personal data for research purposes by the same controller without a separate legal base. The allowed subsequent research is not limited to any specific research but applies to research in general;
- e. The Regulation explicitly allows data subjects to give general consent rather than specific consent, for processing for research purposes, provided data subjects are offered the option to give specific consent; and
- f. The Regulation explicitly recognises (existing) registries and explicitly facilitates the use thereof for scientific research, without requiring that the research be specified or requiring consent, subject to the conditions of national law.

Key reasons for the Regulation approach towards scientific research include the need to avoid selection bias (due to non-responders in a consent system), the importance of registries and population cohorts for public health research, the interdependence of health research and healthcare and the impossibility to identify ex ante the specific purpose of research, which is inherent to the conduct of science and the trend in health research, supported by the European Commission, that research data should be 'FAIR': findable, accessible, interoperable and reusable.

In view of the above, we submit the following:

1. The Guidelines (both WP 259 and WP 260) should refer to and achieve the stated objective of the Regulation to facilitate (health) research, as evidenced above.
2. The Guidelines should respect and reflect the room the Regulation explicitly leaves to the Member States to set the conditions and safeguards for processing personal data for research purposes.
3. WP 260 remarkably does not mention the last sentence of article 5.1.b, stating that further processing for research is by definition not incompatible the original purpose. This blind spot of the WP is reflected in example 15 in WP 259.
4. WP 260 conflates transparency to specified data subjects and transparency in general. General transparency is part of the social license of biomedical research (as is also shown by the websites in the following text). Individual transparency cannot always be achieved and the Regulation leaves room for a balance. The examples given in WP 260 are extreme in that respect and deny that the balance is much more subtle.
5. The interpretation of 'specified purpose' required for consent under both Article 6(1)(a) and Article 9(2)(a) in the Draft paragraph on Scientific Research is too narrow and amounts to a misinterpretation of both the wording (Provisions and Recitals) and the aim of the Regulation to facilitate the processing of personal data for purposes of scientific research if certain conditions are met. The intention of Recital 33 seems to be denied in WP 259. Research per se can qualify as a specified purpose in the context of the consent requirements of the Regulation. Given the option to narrow down consent and given the stated goal of the Regulation to facilitate research

provided safeguards pursuant to Article 89 are met, data subjects cannot be deprived of the option to give broad consent.

6. There can be no care or cure without research combined with reuse of data for registries and vice versa. Patients also expect this. Given the mutual interdependency ('marriage') of care and research, the interpretation of the consent requirement in the health research context by the Guidelines should reflect the general pro research objectives and provisions of the Regulation. Otherwise, health research will be mired in controversy over conflicting interpretations, depending on the applicable legal base, and so be blocked or significantly delayed.
7. Consequently, the WP 259 should nuance the current ban on 'swapping' between legal bases. Legal bases of health care delivery, registries and research are often intertwined and can corroborate each other, due to the fact that healthcare and health research are already intertwined.
8. Additionally, it should be possible that in cases where current research is based on consent which does not meet the present standards, the new basis can be a research exemption, if allowed by national law.
9. WP 259 discusses withdrawal of consent for research in a different more restrictive way than from withdrawal of consent for other purposes. In the context of research the WP again seems to deny the existence of an article of the GDPR relevant for research namely article 17.3.d.

We have substantiated our submissions in our detailed comments below. That text also gives more insight in particularities of biomedical research, relevant in this context. We may kindly refer to that detailed text.

Introduction

Undersigned welcome the opportunity to comment on the article 29 Working Party (hereinafter: WP) draft guidelines on consent and transparency under the GDPR (hereinafter: the Regulation).

Undersigned are Dutch organisations for observational research and biobanks and their affiliated legal counsel. Research with data to improve health is at the very heart of our activities whether long with lasting cohort studies, biobanks and registries⁴ or shorter studies to investigate a specific public health issue.

Much of that research is based on informed consent and a long lasting relation with the participants. Other research is not. There is sufficient evidence that clinical registries, such as cancer registries, would become biased if their data would be based on informed consent and invaluable information would be lost, to the detriment of future patients and prevention. We underscore this point, as we want to avoid too strong a dichotomy between both regimes for research data. Both should be subject to the same governance of responsible use, ethical vetting, inclusion of patient organisations as our primary stakeholders, research integrity and data protection. Also transparency should apply to both, hence we will discuss both draft Guidelines on consent and transparency in the same document.

The nature of biomedical research data

Before continuing we would like to underscore some salient facts about the data under discussion.

There can be no doubt that these data are usually very sensitive. Hence all precautions are taken to ensure data security. Data protection by design and by default are deployed along the chain of research data. As usually there is a chain of data, from the primary sources to intermediary databases, linking with other databases and outcomes. With active participants, contact details are kept separately from the research data with different access rules.

Yet data protection by design and by default can rarely lead to anonymisation of the data until they are published as statistical findings. Several factors due to the nature of research contribute to this, in addition to the high threshold before data can be considered anonymous.⁵ One of those factors is that research data need to be sufficiently granular in order to avoid false correlations. Another factor is that there should always be trail back on the data in order to validate the research done. Lastly in many cases there should be a possibility to get back to the participant for feed-back of results which are deemed especially relevant for his or her health. The researcher will not be able to do this by the way, amongst other reasons because the participant's identity will always be masked as follows from the privacy by design principle.

Obviously we are very well aware of methods to exchange data for research where the datasets are analysed on the spot and only outcomes will reach the researcher, such as 'datashield'. In such a way anonymisation can be reached for this specific research yet, the datasets to be analysed will still contain personal data and must be sufficiently structured and compatible to allow for this method.

⁴ See also Recital 157 of the Regulation.

⁵ It should be noted by the way that the position of the WP of 2014 on anonymisation techniques has been, in terms of empirical research (see the later text) been 'falsified' to a large extent by the decision of the Court of Justice of the EU in the Breyer case. However, we noted that the WP still only referred to the Opinion on anonymisation techniques in WP 259.

Another aspect of these research data is that large numbers of data subjects need to be involved. Too often research findings have been published based on too small samples or biased samples of the population and then proved not to be corroborated in further research or even plainly false.

In that context there is quite a lot of traffic of research data in Europe, with millions of Europeans involved. As far as we know, a data breach resulting from these processing operations has not been reported. Which in a sense is understandable as research is dependent on the trust citizens have in this societal activity. Hence the many precautions as mentioned already.

Particularly relevant to the consent issue is that biomedical research data need to be “FAIR”. Meaning: findable, accessible, interoperable, and reusable.⁶ Datasharing is becoming the norm.⁷

Also this aspect combines various necessities of research data. One of the more mundane is that public funds should not be invested in research which has been done already. Another is that participants should not be harassed with questions if the research has been done already. Or, in the case of clinical trials, even subjected to the dangers which are inherent to those in phase 1-3 trials. Another extremely important reason is that this kind of empirical research must be validated. Other researchers should have access to the original data to scrutinise those. Many journals require that the original data will be submitted to them or can be accessed before accepting a publication. Most funders require the data to be FAIR.

This also means that it never can be fully predicted where the data will end.

Many of these aspects are also reflected in most of the contributions to “The Ethics of Biomedical Big Data”.⁸ It should be mentioned that at page 1 the editors express their concern about the version of the European Parliament (hereinafter: EP) of the draft Regulation “which may drastically restrict information-based medical research utilising aggregated datasets...”, which was the then last version of the Regulation when the book was finalised. The final version became more nuanced.

Yet, as will be shown below, it seems as if the WP wants to go back to the EP version.

The nature of this kind of empirical research

Connected to the last point is that it also never can be fully predicted for which specific research protocol the data will be used if data are collected for longer lasting cohort studies. This type of research is very different from normative research with which you might be more familiar. Without going into an epistemological discussion between empirical biomedical research and normative analyses, there is a much larger element of surprise and even serendipity involved in the former kind of research. Datasets might even be analysed without a prior hypothesis but to be surprised by new correlations.⁹ Resistance to such attitude of being able to be surprised, is an attitude of bias.

It seems to us that the analyses of the WP do not show this attitude of wanting to be surprised which lies at the very heart of scientific inquiries.

⁶ <https://www.dtls.nl/fair-data/>

⁷ C. Ohmann et., *Sharing and reuse of individual participant data from clinical trials: principles and recommendations, at BMJ open*, <http://bmjopen.bmj.com/content/7/12/e018647>.

⁸ B.D. Mittelstadt, L. Floridi (eds), Springer, 2016.

⁹ Of course, in next steps it must be researched whether those correlations are also causal correlations or random.

Transparency

In general

We readily agree that transparency is paramount to fair data processing. Research should strive for the greatest possible transparency, whatever the legal basis. It is part of our social license. Given the pseudonymisation procedures, often article 11 of the GDPR will apply to the research database. Yet, this does not mean that the research database should not have an internet site where the purpose and governance is explained.¹⁰ Such a website is not the only way transparency can be reached. Often patient organisations will be invited to participate in one of the governance committees, the researchers might interact with participants directly such as on annual meetings of the patient organisation and etc.

Transparency towards the data subject and in general

Most of the recommendations in the draft Guidelines relate to 'transparency' towards the data subject concerned. The transparency referred to in the previous section relates to transparency in general, towards whomever this may concern or all possible data subjects.

WP260 does not always clearly distinguish between these two variants of transparency. An example is the box 'example' on p. 26. While previously all examples referred to notices to the data subject concerned, suddenly a shift is made to transparency in general.

As we argued already, there should always be transparency in general yet this must be distinguished from the notifications as seems to be meant in article 14.

Layered transparency and consent

We welcome that the WP tries to navigate a way out of the inherent paradox in the Regulation (even though without acknowledging that there is paradox) between the fact that the information should be concise and understandable while at the same time the amount of information to be provided is huge.

In observational research we generally tend not to 'legalise' our notifications. Research is not offering a service to clients for a fee or for free and then wanting the clients data. If based on consent, we always ask for an active act to contribute. There will be an appeal to the general interest or to that of the specific patient population) pursued in this research. However, this appeal is very different from that of commercial offerings of for example social media which offer or seem to offer direct benefits to their users. Legalising informed consent could very well have a deterrent effect on the initial willingness to contribute. The same, however, applies to too complex consent mechanisms.

Layered information levels where data subject can click through and 'privacy portals' could offer a good solution. Yet, these portals may also come at a price for health research and might not be used by most patients or participants who, against a background of general transparency and trust in research, for very different reasons will have other concerns than to navigate through these portals.

We also wonder whether the WP does not increase the information to be provided beyond what is required by the Regulation. At p.9 it is said that language qualifiers such as 'may' etc. should be avoided. Possibilities of 'further use' of the data are inherent in research but also in the source databases in health care, such as patient records. The point is that it cannot be predicted in advance whether the data of a particular individual

¹⁰ An example is <https://www.nivel.nl/nl/NZR/clone-of-over-nivel-zorgregistraties>. This database is composed of pseudonymised data of health practitioners operating in the first tier of the Dutch health care system. The database is filled by informed opt-out (following from the Dutch research exemptions on informed consent).

in a large dataset will be used for research but that it is clear that at least some of the data of some individuals will be used once. And then it cannot be predicted in advance for which specific research project other than that it will research to improve health (prevention or treatment) or the health care system.

Hence, these language qualifiers could be very apt to describe a potential situation for each particular individual and hence in the context of individual transparency while the general transparency, in a sub layer, could describe some possible scenarios.

Further processing

At p. 20 further processing is discussed. We note that the WP does not mention the second half of article 5.b namely that “further processing for research purposes in accordance with article 89.1 is not considered incompatible with original purpose” and only mentions article 6.4. We are seriously worried the WP masks or even seems to deny the decision of the legislator here (which was also part of Directive 95/46/EC). Earlier we mentioned ‘bias’ as one of the most serious sins for researchers. We may only hope that omitting 5.b last sentence was an unfortunate mistake and is not a sign of bias by the WP.

Though this does not mean that general transparency should not apply to this further processing. But in that case in general terms as discussed above as it cannot be predicted beforehand whether the data will be actually used for research or for which research.

Disproportionate effort (article 14.5 under b)

As within the context of research a new controller would usually receive data which are stripped of directly identifying personal identifiers, this situation is particularly relevant for research.

At p. 27 an example is given of disproportionate effort in the sense of article 14.5 under b. However, the example is detached from real life scenarios in research and extreme. Most people would consider the example given by the WP an example of simply being (completely) impossible to provide information and/or falling under the ambit of article 11, apart from the fact that most subjects in the dataset might be deceased and would be out of the remit of the Regulation anyhow.

If the dataset had been assembled 20 years ago and contained 5000 data subjects, the effort to notify them might also be disproportionate. It should be noted efforts to notify might run contrary to the data minimisation principle.

A more real life scenario would involve a balancing. Often article 11 would apply. If not, whether notification is disproportionate should also be seen in the light of the purposes of the new controller. The new controller might be a data repository for research data which stores data for validation purposes and possible follow-up studies following from the original research after the funding for the original research has ended. An example could be the data of the Dutch ‘hunger winter study’.¹¹ If there is still an active communication with the participants, they could be informed. But if the cohort is resting for a while, it would be sufficient as an aspect of general transparency that the new custodian of the dataset is announced on the website.

Recipient

Recipient is not defined in the Regulation. The WP states that a ‘processor’ is to be considered a recipient. That seems logical. There is a kind of a data transfer, from the controller to the processor, even though when the controller uses a SaaS or PaaS solution, the data would first of all be stored at the processor. Yet,

¹¹ <http://www.hongerwinter.nl/item9b87.html?id=32&language=EN>

the data processor is processing personal data on behalf of controller (article 4.8) and can only act (as a processor) within the specific conditions of the contract or other legal act between controller and processor (article 28.3).

Actually the same would apply to any employee who has access to the data of the controller. It would be helpful if the WP would clarify whether or not those are considered recipients as well.

The granularity of transparency

If the internal employees or whoever will be granted have access to the data based on a contract with the controller at the premises of the controller, would be considered recipients as well, the granularity of transparency will become a puzzle which is impossible to solve.

As with consent the WP not unexpectedly chooses in general for granularity for the information to be provided. At the same time this granularity can obfuscate conciseness. Layering the information cannot always remediate this problem. Not without reason the legislator has chosen for 'or categories of recipients' in article 13.1 under d without showing any preference for mentioning recipients by name or by category. However, WP260 prefers that recipients are mentioned by name and places the burden of proof that they cannot be mentioned by name on the controller.¹² Again, the WP chooses for an overly restrictive interpretation or even seems to deny the choice of the legislator.

Obviously this granularity would be completely impossible if internal employees would be considered 'recipients'. But also mentioning processors by name would more often than not be impossible and might even confound the issue at hand. In the context of research, there might be a platform to process research data together with other researchers, which could be chosen at a later moment than the notification to the data subjects. The platform could deploy sub-processors. The platform might change such as moving from a dedicated server at one of the participating research organisations to the European science cloud.

It might very well be said that it is completely irrelevant to data subjects which specific processor is contracted within the broader context of general transparency.

Consent

In general

WP259 quite rightfully mentions that informed consent is not the only basis for processing personal data. Especially in the context of research another legal basis will be appropriate as was recognised explicitly by the legislator in the final version of the Regulation. This should then also be based on Union or national law and is beyond the competence of the WP. Consent on the other hand has an autonomous meaning in the Regulation and clarifications about the meaning and implications are helpful.

Yet, if the bar for consent is set too high and the implications, especially of withdrawal of consent, too drastic, the WP shouldn't be surprised that the consent option is used as little as possible.

In this context we wonder whether the strong separation which the WP makes between legal grounds is not detrimental to the aims of fairness of processing. WP states that one should choose one legal ground. Though we agree that one cannot swap from legal ground retroactively (if the first chosen proves to be

¹² Amongst others at the scheme at p. 32.

invalid), one should be able to swap prospectively. Current research which is based on a consent modality which does not meet the standards of after 25 May 2018, can then be based on a research exemption if so allowed by national law.

Additionally, it might also be argued that certain legal grounds can corroborate each other. A case could be that a health care provider reuses data for research (based on 5.1.b), then takes 6.1.e as legal ground and as they are health data uses a soft consent mechanism, such as opt-out, if not all of these data are being processed by the same health care professionals who would have access to the data if these data were solely processed for diagnosis and treatment following from national law and professional secrecy in that context (articles 9.2.h and 9.3).

If on the other hand the WP would argue that only national legislation for research following 9.2.j could be a basis for this kind of processing, and that the mentioned 'opt-out', is a way to comply with the last part of 9.2.j, we might end into a kind of dichotomy which does not do justice to fluid boundaries between treatment and research. The members of the WP should be well aware that if they would need health care, their options for their treatment will be based on research and not on normative convictions.

The granularity of the information to be submitted for informed consent, also in the context of Recital 33

We readily admit that in the research context, if consent is being used, such as by asking healthy volunteers to submit data or tissue, the consent should be voluntary and not connected with other issues.

We also agree that sufficient information should be given and that because of the amount of information required by the Regulation, that this can only be layered information. If potential participants do not delve in the deeper layers, the consent should still be valid. Not to delve deeper, is their choice. The WP is somewhat ambiguous about this issue.

Of more importance is that not all information can be precise.

In some research with volunteers it is essential that the information they submit will be combined with data from other sources, such primary health care records, cancer registries or completely different records from mobile phone providers¹³ and etc. It cannot be said beforehand which databases and these might also change. It should be sufficient to give examples. In the context of general transparency, they could be mentioned by name but then given the limited resources for research updating the website might not be the first priority.

If it is not essential to the research that data submitted by volunteers will be combined (in other words, that without this combination, participation is senseless) then the participants should be given a choice. But again the categories of databases can be mentioned and some by example but not all by name. And from Recital 157 it follows that such registries even should be used for research.

Even more important is that the nature of the research can usually only be described in broad terms. These terms have tended to become broader. A fine example is the pan-European EPIC study.¹⁴ This not primarily because researchers want more leeway but as there is a much more intricate relation between various phenotypes of disease, lifestyle, environment and (epi)genetic¹⁵ factors than ever previously thought of. By

¹³ To assess the risk of cancer by using mobile phones, the Amigo study.

¹⁴ <http://epic.iarc.fr/>

¹⁵ See also the hunger winter study mentioned at footnote 11.

fixating it on one subtype of research, the project is usually already outdated at the start.¹⁶ Biomedical research does not ‘narrow down’ as is presumed by the WP and might be the case in biased research but expands. An example is the discovery of the BRCA 1 and 2 genes in hereditary breast cancer. On further analysis it proved that the relation is much more complex and that also other genes can be involved in hereditary breast and ovarian cancer.¹⁷

Additionally, the research databases with data from volunteers are a resource which may last over centuries and which will be used for a host of specific research protocols, depending on our increased understanding and open questions and leading to better understanding of those open questions (but which at the same time might lead to more questions). Again the EPIC study is a case in point but there are many more examples. Though active participation has been closed for quite some time and many participants will have deceased, the data and samples are still being used for research.

Recital 33 recognises this situation. It is extremely worrisome that the WP seems to deny the choice of the legislator at p. 27/28. After the extreme and ‘neoliberal’¹⁸ position regarding research of the EP, the final Regulation with amongst other the active involvement of patient organisations, is much more nuanced, whether the WP likes this or not.

Broad consent is a feasible option under the Regulation, if certain conditions are met. We briefly mentioned them already in the Introduction. Just as people should have an option to narrow down, people such have an option for broad consent if they choose so. The GDPR requires that consent for the processing of special categories of data must be for ‘one or more specified purposes’ (Article 9(1)(2)(a)). The GDPR explicitly recognises scientific research *as such* (in general) as a specified (and legitimate) purpose. In other words, under the GDPR, research in general qualifies as a ‘specified purpose’ in its own right; the GDPR does not require to spell out the details of the research. Hence too narrowed down is We would gladly expand on those in an open dialogue with the WP.

We are obviously aware of the ‘dynamic consent’ approach in the context of research. Yet, the feasibility of this approach still has to be proven for long lasting cohorts which need to encompass many others than the frontrunners in new gadgets and against the experience of consent fatigue and/or simply losing interest to click once more, also because of changes in lifestyle and circumstances for participants during the long duration of those cohorts. We have discussed general transparency already and obviously withdrawal from the cohort or opt-out for parts of the research of cohort, should be feasible and always has been feasible.

The consequences of withdrawal of consent

Regarding data for research the WP takes an inconsistent position. In the section on research the WP mentions that withdrawal should lead to deleting the data or anonymization if the researcher still wants the data to be used for research. Yet, earlier the WP makes clear that data processing before withdrawal is

¹⁶ Again we see a difference here with normative studies as mentioned in the introduction.

¹⁷ Couch FJ, Wang X, McGuffog L, Lee A, Olswold C, Kuchenbaecker KB, et al. (2013) Genome-Wide Association Study in BRCA1Mutation Carriers Identifies Novel Loci Associated with Breast and Ovarian Cancer Risk. PLoS Genet 9(3): e1003212. doi:10.1371/journal.pgen.1003212

¹⁸ As negating the public interest aspect of research and relying on individual choice while many data, especially regarding health, could be generated because of our solidarity based systems in Europe and are based on earlier research to which many have contributed.

considered lawful and makes a link with article 17 whether the data should also be deleted.¹⁹ This difference is peculiar and we may only hope that this is not another example of a seemingly anti-research position of the WP.

After withdrawal the data should obviously not be used for any further research and if data have been transmitted further in the research chain, the new controllers should be notified. Yet, the original data may be kept to be used to validate the original research, as that is inherent to the original consent.²⁰ Deleting data should be seen in the context of article 17.3 d. If the outcomes of the original research would become obsolete because of the deletion of the data, then that research would be seriously impaired.

At the same time we would like to underscore that researchers try to accommodate as much as possible the withdrawals. These are rare but a participant might simply not want to be bothered by questionnaires anymore. In that case the approach is more nuanced than that of the WP. The link between the participant's directly identifying data will be deleted. The data will be 'flagged' as not to be used for new studies. And, as said, possible other controllers, will be notified.

Miscellaneous

At example 15 (at p. 20) it is mentioned in a sub-sentence that only patients who voluntarily agreed to be on a list of candidates will be approached for *this* research purpose. Apparently the WP presupposes various lists for various specific purposes to which patients should 'volunteer'. Someone's admission to health care would become very complicated because of the need for such lists.

It should be mentioned again. Health care and research are intertwined. Article 5.1.b clearly states that 'further use' of data for research is not incompatible with the original purpose. That is how patients are selected to be invited for a specific project, sometimes using a processor, like even a call centre, which will contact the selected patients. Patients often even expect that, such as when they are eligible to take part in a clinical trial which might help their condition. It should also be mentioned that, as also follows from Recital 50, that if health care data are further processed by the health care provider, no separate legal ground is necessary.

We strongly advise that the WP deletes this sub-sentence in example 15.

Concluding remarks

All health care is based on research and the reuse of data. Not to reuse data, whether research data or from the health care system, will lead to 'harm'.²¹ In the European context health care systems are solidarity based and patients do not only expect that they will profit from advances in health care but, as patient organisations have pointed out during the discussions, they also expect that data will be reused, if that is done in a responsible way.

In the version of the EP of the Regulation the balance was lost, undermining solidarity and health research and hence also health care and health protection. The final version leaves many aspects of the balance to

¹⁹ After withdrawal of consent there might be or might not be a need to keep the original data. That assessment should be made in the context of article 18.3.d most of all. The right to delete data requires a separate act of the data subject but might be implicit in the withdrawal of consent.

²⁰ See the Introduction about the need of validation of research.

²¹ K.H. Jones et al, The other side of the coin: Harm due to non-use of health-related data, *Indertijd.J. of Medical Informatics*, 97 (2017) 43-51.

the member states within in the boundaries of the Regulation which was also amended in this respect in comparison to the EP version.

We are aware that the WP might have preferred the EP version. However, it would be unacceptable if the WP would deny the choice of the legislator by an overly restrictive interpretation of the (amended) clauses in the Regulation relating to research. Above we gave examples of how the WP even fails to mention certain relevant clauses. It should not be a surprise that this gives rise to concern, both about the democratic attitude of the WP and about a possible anti-research stance.

We sincerely hope that this concern proves to be ill founded. We can easily be proven wrong if the WP would add the relevant but as yet missing explicit research clauses (5.1.b and 17.3.d) in final version of both Guidelines and would nuance many of its comments in the context of research.

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In the part: 3.3.1: "Minimum content requirements for consent to be 'informed'" is lacking any information about potential commercial uses and commercial products that may arise from research conducted using subject's data and about potential benefits for participants. OECD Guidelines on Human Biobanks and Genetic Research Databases states (p.4.H): "The operators of the HBGRD should provide participants with information about commercial products that may arise from research conducted using its resources, including human biological materials, data derived from the analysis of samples, data or other information provided by or about the participant. Information should also be provided on the benefits, if any, the participant may receive".

Above statement, its part or minimum requirement (e.g. "The information about the policy in regards to intellectual property and policy on the commercialisation of its resources" should be used in the part 3.3.1 "Guidelines on consent...".

Sweden

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Comments on The Article 29 Working Party Guidelines on Consent under Regulation 2016/679 (wp259) and on the Guidelines on Transparency under Regulation 2016/679 (wp260).

Introduction

The Guidelines lay out the principles of informed consent as a lawful basis for processing personal data in a clear and consistent way in agreement with the GDPR and its Preamble. This guidance as well as the guidance on how to interpret the new principle of transparency is helpful for the planning and carrying out of research that involves the use of personal data. Regarding *scientific research* we propose some clarifications and examples along the lines suggested below.

1. The concept of '*scientific research*'

We agree that '*scientific research*' should be reserved for research projects set up in accordance with relevant sector-related methodological and ethical standards. We propose that the guidance here also should explicitly state that the concept of research should be interpreted in a wide sense, also covering the collection and integration of personal data in databases. This is of direct relevance when setting up biobanks and cohorts for future research purposes, e.g. in epidemiological biomedical and social science research.

2. General scientific purpose with specification of process

We welcome the specification based on Recital 33 regarding the possibility to ask specifically for consent where the purpose is described at a general level. We agree that this possibility should not be used in order to circumvent requirements of specifying the purpose when that is possible and consistent with the scientific objectives. However, general consent is essential for the possibility to search for mechanisms (e.g. genotypes, biomarkers and environmental factors) related to health and disease in epidemiological research. It would be helpful if the guidance could include some examples to help researchers understand where the limits are to be drawn.

In order to guide researchers as well as ethical review boards the guidance could here also explicitly refer to The Charter of Fundamental Rights of the European Union (2010/C 83/02). As indicated in the beginning of the guidance document regarding consent, the charter emphasizes the right of each individual to integrity within the fields of medicine and biology, implying a free and informed consent according to the procedures laid down by law (Article 3). Article 8 of the Charter grants the individual the right to the protection of personal data implying that the processing of such data requires consent of the person concerned or other legally-recognized means. These articles conform with the European Convention for the Protection of Human Rights and Fundamental Freedoms, the Social Charters adopted by the European Union and by the Council of Europe.

In addition, and as a route to understand the importance of the principle of proportionality (Article 4 of GDPR), it could be mentioned that the Charter of Fundamental Rights of the European Union also lays down

rights of each individual to social security benefits and social services in cases of illness (Article 34) and the rights of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices (Article 35).

The purpose of research may when appropriate be described in general terms for areas of research. Two examples are research regarding rare diseases and research investigating the effects of drugs for pregnant women and their fetuses. There is a clear lack of scientific evidence with no or little treatment available for patients (often children) with rare diseases and since patients are few scientists need to collaborate across borders. The consequence of having insufficient evidence on the effects of drugs given to women before or after conception is that they and their fetuses are exposed to risks in association with ordinary treatment or that treatment given is suboptimal because doctors take a risk averse approach, despite lack of evidence of the risk to the fetus and knowledge about the benefit for the pregnant woman. In both these cases, the patients' rights to welfare and medical treatment in accordance with Article 34 and 35 of the Charter of Fundamental Rights of the European Union are not respected.

We suggest that the guidance document in providing these kinds of examples should make a distinction between the purpose of research and the research process. The purpose may be described in general terms, e.g. research in order to understand hereditary and environmental factors related to rare diseases and research in order to understand the benefits and risks of drug treatment in pregnant women. However, one may be more specific concerning how the research is going to be carried out, the research process.

Information may be given on, e.g. who the data controller is, that the research is a collaboration with partners in several (named) countries, that biosamples and personal data will be shared among research partners, that the research involves genetic information, that personal data will be added by using named public or research based registries, foreseen secondary uses of data, that the research involves collaboration with pharmaceutical companies, how to withdraw consent, etc. The information may also include clear and specified description of how the privacy of the data subjects is protected, e.g. means for pseudonymization, in accordance with the principle of transparency.

3. Lawful basis

We support the view that one should not be able to change lawful basis within the premises of GDPR, e.g. by referring to a public interest just because one did not succeed in obtaining informed consent. We appreciate, however, also the possibility suggested in the guidance document that if a controller finds that the consent previously obtained in accordance with Directive 95/46/EC will not meet the standards of GDPR one may assess whether the continuous processing may be based on another lawful basis, taking into account the conditions set by the GDPR.

4. Opt-out

The guidance document states that one may not use pre-ticked opt-out boxes but suggest that there are other legitimate opt-out constructions. Since opt-out is in some instances, e.g. in registry based research, a valid and acceptable information and consent procedure to be selected after an assessment of the balance between scientific value, practical circumstances and privacy concerns, it would be helpful if the Article 29 Data Protection Working Party could give some examples of acceptable opt-out constructions.

Italy

Contacts

BBMRI.it comments to Mats Hansson's (Sweden) suggested comments

BBMRI.it comments represent the conclusion of 3 working groups including clinicians, scientists, biobanks, research organization, patient association, regional and national government, representatives of biotech industries.

Comments on The Article 29 Working Party Guidelines on Consent under Regulation 2016/679 (wp259) and on the Guidelines on Transparency under Regulation 2016/679 (wp260).

Ad 1. The concept of '*scientific research*'

BBMRI.it agrees with the proposal to interpret the concept of research in a wide sense, also covering the collection of personal data in databases.

Ad 2. General scientific purpose with specification of process

Highlighting patient/citizen representatives' comments (informed consent cornerstones are: intelligible purpose, granularity, consent clearly distinguishable from the other matters) BBMRI.it welcomes the specification based on recital 33 regarding the inclusion of personal data in scientific projects on the basis of consent with a well-described purpose. When research purposes cannot be fully specified, within a framework of informed consent process intended as a dynamic and participatory process, BBMRI.it considers reasonable to describe the purpose of research in general terms of area of research and to update consent for subsequent steps in the project. Moreover, when the purpose can be described only in general terms, bbmri.it agrees on the fairness to distinguish on the purpose of research and on the research process, in order to inform of the area of research in general term, but specifically on the process.