Correspondence: BBMRI-NL
p/a Lygature
Jaarbeurs, Beatrix building 6th level
Jaarbeursplein 6
3521 AL Utrecht, The Netherlands
erna.erdtsieck-ernste@lygature.org

To: European privacy supervisors of the Article 29-working group (WP29)

By mail:
JUST-ARTICLE29WP-SEC@ec.europa.eu
presidenceg29@cnil.fr
cc: guidelines@autoriteitpersoonsgegevens.nl

Subject: Consultation. Comments by Health-RI, COREON, BBMRI-NL, PSI AND NFU on guidelines on consent and transparency (WP259 and WP260)

Utrecht, 22 January 2018.

Dear Working group

Below you will find the comments on guidelines on consent and transparency (WP259 and WP260) from Health-RI, COREON, BBMRI-NL, Parelsnoer Institute (PSI) and the NFU.

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;
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.

Health-RI, BBMRI-NL:
Prof.dr. G.A. Meijer (NKI-AvL)
Scientific Co-Director BBMRI-NL, co-chair Health-RI

COREON:
Dr. M. Schmidt (NKI-AvL)
Chair a.i. Federa-COREON

Parelsnoer Institute:
Prof.dr. G.A. Zielhuis (RadboudUMC)
Director Parelsnoer Institute

NFU:
Prof.dr. E.J. Kuipers
Chair NFU

This consultation is supported by VSOP: The Dutch national patient umbrella organization for rare and genetic disorders.

Juridical advisors
Mr. E.B. van Veen (MLC Foundation)
Mr.Dr. J.A. Bovenberg (Advocaat, Legal Pathways)

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 registries[1] 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.[2] 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.

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.

[1] See also Recital 157 of the Regulation.

[2] 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.

Particularly relevant to the consent issue is that biomedical research data need to be "FAIR". Meaning: findable, accessible, interoperable, and reusable.[3] Datasharing is becoming the norm.[4]

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".[5] 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.[6] 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.

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.[7] 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

[3] https://www.dtls.nl/fair-data/
[4] 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.
[5] B.D. Mittelstadt, L. Floridi (eds), Springer, 2016.
[6] Of course, in next steps it must be researched whether those correlations are also causal correlations or random.
[7] 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).

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 predicted in advance whether the data of a particular individual 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 used once. And then it cannot be predicted in advance for which specific research project other than that it will research to improve to 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 scenario's.

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'.[8] 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 of PaaS solution, the data would first of all be stored at the processor. Yet, 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.[9] Again, the WP choses 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.

[8] http://www.hongerwinter.nl/item9b87.html?id=32&language=EN

[9] Amongst others at the scheme at p. 32.

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 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 providers[10] 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.

[10] To assess the risk of cancer by using mobile phones, the Amigo study.

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.[11] 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)genetic[12] factors than ever previously thought of. By fixating it on one subtype of research, the project is usually already outdated at the start.[13] 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. [14]

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'[15] 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, peole such have an option for braod 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 explictly 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 put 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 considered lawful and makes a link with article 17 whether the data should also be deleted.[16] This difference is peculiar and we may only hope that this is not another example of a seemingly anti-research position of the WP.

[11] http://epic.iarc.fr/

[12] See also the hunger winter study mentioned at footnote 8.

[13] Again we see a difference here with normative studies as mentioned in the introduction.

[14] 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

[15] 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.

[16] 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.

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.[17] 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'.[18] 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 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.

[17] See the Introduction about the need of validation of research.

[18] 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.