Comment to the Guidelines on Consent under Regulation 2016/679 by Article 29 Working Party

Finnish Social Science Data Archive (FSD) welcomes the high priority Article 29 Working Party has placed on updating the guidelines regarding the concept of consent to consider the changes introduced in the Regulation (2016/679). FSD provides digital research data for learning, teaching and research purposes. The archive is a national resource center that operates as a separate unit of the University of Tampere. In addition to archiving and dissemination of data, key services include data-related information services and support for research data management. This comment has been discussed in Nordic cooperation with representatives of NSD-Norwegian Centre for Research Data and Swedish National Data Service SND.

Although the processing of personal data for research purposes can be based on several legal grounds pursuant to Article 6(1) of the Regulation, informed consent is at the very heart of research involving human subjects. OECD has set several recommendations regarding consent in scientific research. One of these is that consent should be ‘future-proofed’ to enable future research projects to use the data. This issue is closely connected to concepts of purpose limitation and transparency – in addition to the ‘specific’ and ‘informed’ elements of consent.

Regarding future research, Recital 33 affirms that it is not always possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. However, the new guidelines on consent by WP29 are rather ambiguous in terms of how Recital 33 should be applied in practice. Legal certainty has been established as a core principle by the European Court of Justice. Processing personal data based on the data subject’s consent should be subject to clear evaluation criteria. Considering that privacy, data protection and consent are closely related to ethical principles covering scientific research, it is paramount for the data controllers in the research sector to have clear guidelines on the appropriate consent practices.

This comment focuses on the following topics:

1. Consent for scientific research and Recital 33
2. Relationship between Article 11 and withdrawal of consent
3. Refreshing consent
4. Demonstrating valid consent when transitioning from the framework of the Directive 95/46/EC
5. Interaction between different legal grounds for processing personal data

The adopted interpretations on the provisions concerning the concept of consent should reflect the significance given to consent as a lawful basis for processing personal data in Article 8 of the Charter of Fundamental Rights of the European Union (2000/C 364/01). A genuinely free and informed expression of the data subject’s wishes should be respected as a manifestation of the research subject’s human dignity and right to integrity of the person (Articles 1 and 3 of the Charter respectively). There has been a tendency for supervisory authorities to apply strict interpretations on consent even in the absence of any complaints from data subjects.

Admittedly data subjects may need the expertise provided by data protection professionals to safeguard them especially if a data processing operation contains technical elements that are hard for the layperson to understand, such as complicated algorithms. Yet, imposing restrictions on data subjects to give their consent

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consent should adhere to the principle of proportionality and the risk-based approach adopted in the Regulation.

On a general note to the approach and structure chosen in the new guidelines, WP29 has chosen to build on the earlier opinions and the new guideline “expands and completes” earlier opinions. Furthermore, the earlier opinion remains relevant when consistent with the new legal framework (p. 4). In this respect, it would be beneficial to have a separate annex in the guidelines to codify all existing praxis by WP29 on the concept of consent.

1. Consent for scientific research and Recital 33

There has been a considerable amount of interest and discussion regarding Recital 33 of the Regulation, and its implications for obtaining a consent for scientific research. Namely, this has concerned whether it is possible to obtain a form of broad consent. The exact wording of the recital states that data subjects “should be allowed to give their consent to certain areas of scientific research”.

Information Commissioner’s Office published a draft guidance on consent for public consultation in March 2017. Regarding Recital 33, the draft guidance stated that “if you are seeking consent to process personal data for scientific research, you don’t need to be as specific as for other purposes.” According to the summary of the consultation responses in this regard, there had been expressed “the need for more detailed guidance on the naming of parties and the future purposes of the processing at the time of data collection.” Rather similar critique can be applied to the present draft opinion by WP29.

WP29 states that the Recital 33 “does not disapply the obligations with regards to the requirement of specific consent”. Additionally, the draft opinion states that “where purpose for data processing … cannot be specified at the outset, Recital 33 allows as an exception that the purpose may be described at a more general level” (p. 27–28). WP29 has in its earlier opinion on purpose limitation stated that “future research”, without further detail, doesn’t satisfy the requirement for a purpose to be specific. Recital 33 doesn’t warrant such broad purpose, but nonetheless blurs the line of when a purpose is adequately specific.

Since the draft opinion doesn’t introduce any concrete examples, and focuses more on appropriate safeguards, there remains ambiguity on the proper application of Recital 33 when obtaining consent for scientific research. It should be noted that WP29 seems to clearly indicate that another controller can rely on the original consent if the controller has been previously named (p. 13–14). Against this background, it would be beneficial for WP29 to elaborate in more detail:

1) Is Recital 33 meant to be applied only in the context of a single data controller’s research activities or is it possible to obtain a consent for a research area in a way that it covers multiple controllers, assuming appropriate safeguards are in place?
2) What is the exact interpretation for the term “areas of scientific research”?
3) Considering that the draft opinion places importance on whether the data falls within the scope of Article 9, is there a difference in the following scenarios:
   a. a research deals with medical data (and hence falls within the scope of Article 9)
   b. a research project where the processed personal data consists only of qualitative interviews, and the personal data doesn’t fall within the scope of Article 9

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4 Opinion 03/2013 on purpose limitation, p. 15–16.
The draft guidelines additionally state that “[m]oreover, the controller may apply further safeguards” when research purposes cannot be fully specified, and refers in the same paragraph to Article 89 (p. 28). It would be desirable for WP29 to elaborate what kind of impact rigid safeguards on low-risk data would have on interpretation of Recital 33. For instance, how would the requirement for “specific” be interpreted in the following scenario:

Research project processes low-risk personal data that falls far from the scope of processing activities that are “likely to result in a high risk” as further clarified by WP29 in an earlier opinion on DPIA. Additionally, the research data doesn’t fall within the scope of Articles 9 or 10. The non-sensitive research data is minimized via various anonymization techniques. Appropriate technical and organisational measures are in place to prevent combining and linking the data. However, the data cannot be guaranteed to be fully anonymous. What are the limits of consent in terms of Recital 33 in this case, taken into the nature of low risk to research participants? This would apply for instance to survey data and oral history interviews for future research, preventing unnecessary collection of new personal data.

The draft opinion contains total of 17 examples. Since Recital 33 contains new elements, it would be appropriate to have clear examples to illuminate how obtaining consent for scientific research differs from other sectors. The issue would be best solved by clear guidance on European Union level instead of leaving the interpretation to national data protection authorities.

2. Relationship between Article 11 of the Regulation and the withdrawal of consent

In accordance with Article 7(3) the data subject shall have the right to withdraw his or her consent at any time. The draft guidelines by WP29 discusses the topic of withdrawal of consent to some extent. However, a topic the draft guidelines doesn’t comment on is the relationship between Articles 7(3), 5(1)(c) and 11. Article 5(1)(c) limits the processed personal data to what is adequate, relevant and limited to that what is necessary in relation to the purposes for which they are processed. Furthermore, Article 11(1) calls for controllers – when the processing of personal data no longer requires the identification of a data subject – to be no longer obliged to maintain or acquire additional information to identify the data subject for the sole purpose of complying with this regulation.

For a data subject to be able to withdraw their consent, the data subject needs to be identified. Hence, there seems to be an internal conflict between the requirement to freely withdraw a consent and the minimization principle manifested in Articles 5(1)(c) and 11. The lex specialis connections regarding Article 11 are in many cases extremely blurry. As an example of a situation that would require further clarification is given in the next example regarding a survey research:

A survey research is conducted on behalf of the controller by a company acting in the capacity of a processor. The legal basis for the data processing is data subject’s consent. The rights and duties between the controller and the processor are stipulated in a contract that fulfills the criteria of Article 28. As per the contract, the processor delivers to the controller data that is void of direct identifiers. The processor’s activity ends, and no further information is retained or delivered. The data possessed by the controller no longer permits withdrawal of consent as the data subjects can no longer be identified with adequate certainty. **Is consent as a legal basis invalid or does Article 11(1) apply to the situation?**

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5 Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is “likely to result in high risk” for the purposes of Regulation 2016/679.
The scope of Article 11(2) is limited to Articles 15 to 20 although some of the referred articles, f.ex. 17(1)(b), are connected to consent. It would seem that Article 11(2) doesn’t concern with the issue of validity of consent, but Article 11(1) is open for interpretation. In any case, the relationship between Article 11 and the requirements for valid consent should be further elaborated in the WP29 guidelines on consent.

3. Refreshing consent

The draft opinion suggests that consent should be refreshed at appropriate intervals as a best practice (p. 20). In the same context it is suggested that all information should be provided again to the data subject. These suggestions for a best practice are mentioned in a paragraph following a comment on the time limit of a consent. The time limit of a consent is linked to the context, the scope of the original consent, the expectations of the data subject and the changes in processing operations. However, the suggestion to refresh the consent doesn’t seem to be clearly linked to any qualifying criteria.

To prevent divergent interpretations and unnecessary fragmentation in the member states, it would be advisable to reconsider the suggestion. In its current form it is also prone to cause information fatigue and confusion for the data subjects. This is not to say that refreshing consent might not be warranted in some circumstances, equal to the criteria set out for the consent time limit. However, the data subject has always the right to withdraw his or her consent based on Article 7(3). From this viewpoint, it might be more apt to consider this as an issue of transparency regarding the right to withdraw consent – not that of a valid consent (as it currently seems to be presented in the draft opinion) – and hence removed or further qualified.

Additionally, the term “best practice” indicates that the requirement doesn’t strictly result from the Regulation. This leads to uncertainty what ramifications, if any, not adhering to the suggestion leads to. This is especially problematic since if a legal basis of processing activity is disqualified on the grounds of a best practice, the controller is subsequently in material breach of Articles 6 and 5(1)(a) of the Regulation. It is questionable if this is an adequate basis – especially when considering the maxim of legal certainty – for the resulting civil, administrative and criminal sanctions.

4. Demonstrating valid consent when transitioning from the framework of Directive 95/46/EC

As recital 171 of the Regulation states, consent based on the old framework does not need to be renewed insofar as it fulfills the conditions for a valid consent in the Regulation. Since consent, based on the implementation of Article 7(a) of the Directive to national legislations, has often been used as a legal basis for lawful processing of research participant’s personal data, the issues relating to transition from the Directive to the Regulation have substantial practical importance. Long research projects, where the consent has been obtained a long time ago, and where there is still a legitimate reason to process non-anonymized data, are most likely not uncommon. One crucial issue is the level of granularity required from previous documentation to demonstrate that the previously given consent is valid under the Regulation.

WP29 has in their previous opinion on consent stated that general accountability obligation requires that controllers must be able to demonstrate that a consent has been obtained. To fulfill this obligation, the controllers should place practices and mechanisms to seek and prove unambiguous consent. However, even though controller’s have had the obligation to demonstrate consent, this has not been as strictly stipulated as in the Regulation, and it seems to have been more of an issue of proof in the case of a dispute. For instance, WP29 has stated earlier that it has been a “good practice” to “create and retain evidence”. Although Article 6(2) of the Directive imposed on the controller an obligation to demonstrate compliance with the general principles set out in Article 6(1), the earlier framework seems to have had a different type

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6 Opinion 15/2011 on the definition of consent, p. 36-37.
7 Ibid. p. 21.
of accountability. This can be seen for instance by observing WP29’s earlier proposal for a new statutory accountability principle.  

The draft opinion gives some flexibility in terms of complying with the requirement of Article 7(1) of the Regulation. The draft opinion states that

a) controllers are free to develop methods that are fitting in their daily operations,

b) the requirement to demonstrate consent shouldn’t lead to excessive additional data processing,

c) GDPR doesn’t prescribe how this should be done in detail; and

d) the controller must be able to prove that data subject consented in a given case. (p. 20)

As an example of non-adequate demonstration in context of an old consent the draft opinion states that “all presumed consents of which no references are kept will be automatically below the consent standard” (p. 30). Since in many cases the researchers have tried to minimize data collection, there may be cases where no strict documentation on individual basis exists (for instance when an oral consent has been obtained systematically, but no individual records exists). Although it’s clear having no documentation at all does not satisfy the requirement of Article 7(1), it remains ambiguous if the following scenario would satisfy the requirement of Article 7(1):

A research project consists of qualitative interviews with the research participants. The participants were given an information sheet on the research prior to the interviews and the data subjects orally consented to the data processing. However, there is no case-by-case demonstration of this. Instead, only the general method to inform the participants and obtain consent has been recorded as part of the research plan. Is the documentation (without taking into account here if the consent is de facto valid based on other requirements in the Regulation) enough to fulfill the requirement of Article 7(1) in the transition phase?

It would be beneficial to have in the guidelines examples that deal with more borderline cases for the controllers to be able to appropriately determine the validity of a previous consent. Although it is possible to change the legal basis for processing during the transition phase (as indicated on p. 30.), it may not be possible in every case. Furthermore, since it may take time to obtain new consents, it would be imperative to have clear criteria to evaluate the need to obtain new consents well in advance of 25 May 2018.

The issue on required level of documentation concerns also consents that are obtained now with compliance with the Regulation in mind. The draft guidelines give flexibility for complying with Article 7(1) without giving explicit guidance on what is adequate level documentation from a consent, it is unclear how “methods that are fitting in their daily operations” is to be interpreted and for instance especially in the context of scientific research. As an example:

A research project conducts face to face survey interviews with research participants. Information is given in advance of the interview, and time and date for the interview is settled. When the interview takes place, the interviewer first asks the participant if the information is read and understood, if the participant has any questions, and accordingly, if he/she gives their consent to participating in the research project.

After this assurance, the interviewer ticks off that the participant has received information and has given his/her consent (orally) together with time and date for the consent in

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his/her record. The record is linked to the identity of the participant by pseudonymisation. Will this documentation fulfill the requirement of Article 7(1)?

5. Interaction between different legal grounds for processing

In scientific research there is essentially a distinction between the act of consenting to participate in a research project and the act of consenting to processing of personal data. In case consent is deemed inappropriate in a research context for processing personal data, yet the data is collected directly from the data subject with his or her active participation, the situation may be slightly confusing for the research participant. We may have a situation where the research participation is based on informed consent, but the data processing is based de facto on f.ex. Article 6(1)(e) which sets out processing that is necessary for the performance of a task carried out in the public interest as a legal basis for processing personal data.

Although it is more connected to the concurrent consultation on the guidelines on transparency, it would be advisable for WP29 to elaborate on the application of Article 13(1)(c) in such situations to ensure adequate transparency on the relatively complex construct. It may be confusing for research participants to grasp the differences in consenting to participate on one hand and the legal basis for processing personal data on the other hand. Although Article 89 does not allow for derogations from the provisions on consent, the Regulation is nonetheless based on risk-based approach. A flexible interpretation of consent in terms of data processing for scientific research purposes, assuming appropriate safeguards are in place, would make consent more often a viable option for legal basis for data processing. Having both the participation and data processing based on consent might be beneficial for the data subjects as it might be more transparent by the virtue of situation being easier to understand.

Summary

The draft guidelines by Article 29 Working party on consent provides valuable information for interpreting the changes introduced in the Regulation. However, the guidelines should be further refined to answer additional questions that have been overlooked. The main suggestions in this comment to the guidelines are the following:

- More in-depth analysis of Recital 33 with focus on practical application and examples
- Elucidation of the relationship between withdrawal of consent and Article 11
- Clarification of the level of detail required from documentation from previous consents to evaluate the need to obtain new consent
- Elaborating in more detail the requirements for documentation to generally demonstrate compliance with Article 7(1)

On behalf of Finnish Social Science Data Archive,

Antti Ketola
Lawyer, FSD