Strasbourg, 22 October 2013

T-PD(2013)10rev

CONSULTATIVE COMMITTEE OF THE CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO AUTOMATIC PROCESSING OF PERSONAL DATA

(T-PD)

OPINION FURTHER TO A DH-BIO REQUEST CONCERNING THE ON-GOING REVISION OF RECOMMENDATION (2006) 4 ON RESEARCH ON BIOLOGICAL MATERIALS OF HUMAN ORIGIN

Directorate General Human Rights and Rule of Law

1. At its meeting of 28-30 May 2013, the Committee on Bioethics (DH-BIO) decided to consult the Consultative Committee of the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (T-PD) with regard to two provisions contained in the preliminary draft of the revised Recommendation (2006) 4 on research on biological materials of human origin[1].

2. The Consultative Committee (T-PD) has examined the proposed provisions of Recommendation (2006)4 and its compatibility with Council of Europe standards on data protection, in particular with the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108, hereafter "Convention 108").

Article 3 on identifiability of biological materials

3. In relation to Article 3 the TP-D was asked to consider whether the notion of non-identifiability was valid and, consequently, whether the distinction made in Article 3 between 'identifiable' and 'non-identifiable' biological materials remained relevant.

4. Article 2 of Convention 108 defines "Personal data" as *any information relating to an identified or identifiable individual*. Identifiable individual means a person who can be identified without unreasonable time or efforts. The notion of 'identifiable' does not only refer to the individual's civil identity as such but also to what may allow to *individualise* or *single out* and thus allow to treat differently, one person among others.

5. Where an individual is no more identifiable, data are said to be anonymous and are not covered by Convention 108. Data that appear to be anonymous (unaccompanied by any obvious identification data) may nevertheless lead to an indirect identification with the piecing together of informative data (example of deidentification of DNA Samples). This is the case where for example, alone or through the combination of physical, physiological, genetic, mental, economic, cultural or social data it is possible for the controller, or any legitimate or illegitimate actor, to identify the person concerned (in particular when the data was made publicly available).

6. When data are made anonymous, necessary means, including technical ones, should be put in place to avoid re-identification of individuals and preserve anonymisation. The anonymity of data should be regularly re-evaluated in time as in light of the fast pace of technological development, what could at a point in time be considered 'unreasonable' could after some time be considerably facilitated by technology and enable identification with reasonable ease.

Conclusion

7. In light of the above, the T-PD considers that the issue raised deserves further reflection. Indeed, due to the rapid advances in technology, it is difficult to ensure that data which have been anonymised will no longer allow a re-identification of the data subjects if they are combined with other data and therefore additional safeguards should be put in place.

8. It recommends to all stakeholders to promote suitable measures to guard against any possibility that the anonymous data may result in the re-identification of the data subjects. Separation of identifiers and data relating to the identity of the persons could be an appropriate security measure to introduce, as well as other technical and organisational

[1] Questions of DH-Bio and relevant draft provisions of the revised recommendation (2006)4 are provided in the appendix.

measures to prevent any unauthorised person from having access to the data and to provide traceability of access and use of the data.

Article 23 on Transborder data flows

9. Acknowledging the general data protection principle that transborder flows of personal data can only occur if in the recipient state an appropriate level of protection is guaranteed, the DH-Bio Committee suggested to introduce the provision that, where an appropriate level of protection is not guaranteed by domestic law, the transfer of biological materials and/or associated data can still occur on the basis of safeguards provided in a bilateral contract between the sender and the recipient of the biological material and/or associated data.

10. The T-PD was asked to consider the admissibility of such provision, as well as to provide some clarification with regard to the exact meaning of the notion of '**enforceable instruments**' as referred to in article 12(3)b of the modernised Convention 108[2].

11. The notion of '**enforceable instruments**' will be clarified in the Explanatory Report of modernised Convention 108 but aims at referring to the fact that relevant instruments need to be complied with, and that the non-voluntary compliance with the legal instrument may result in action from an authority entrusted with the task of enforcing the instrument in question or, if no longer possible, imposing as consequence a penalty as well as, eventually the duty to indemnify those eventually armed by non-compliance.

12. As provided in the draft explanatory report[3] of the modernised Convention 108, the following elements should be considered in relation to the notion of "appropriate level of data protection":

- An appropriate level of data protection can be ensured provided that the persons involved in the transfer (legal as well as natural persons) provide sufficient guarantees, such as approved standardised safeguards binding both the controller who transfers data and the recipient who is not subject to the jurisdiction of a Party. The adoption of common approved standardised safeguards should be sought.

- The level of protection should be assessed on a case-by-case basis for each transfer or category of transfers. Various elements of the transfer should be examined such as, in particular: the type of data; the purposes and duration of processing for which the data are transferred; the respect of the rule of law by the country of final destination; the general and sectoral rules of law applicable in the State or organisation in question; and the professional and security rules which apply there.

- The assessment as to whether there is an appropriate level of protection must take into account the principles of the Convention, the extent to which they are met in the recipient State or organisation – in so far as they are relevant for the specific case of transfer – and how the data subject is able to defend his or her interests where there is non-compliance.

[2] Corresponds to the modernisation proposals adopted by the Consultative Committee at its 29th plenary meeting of 27-30 November 2012.

[3] Draft explanatory report of the modernised convention 108 (T-PD-BUR(2013)3ENrev2), as submitted to the 30th Plenary meeting of the T-PD (15-18 October 2013).

Conclusion

15. The T-PD supports the provisions, as it was proposed by the Committee on Bioethics and invites the Committee to review these provisions after the adoption of the amending protocol to Convention 108.

APPENDIX[4]

At its last meeting (28-30 May 2013), the Committee on Bioethics (DH-BIO) decided to consult the Consultative Committee of the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (T-PD) with regard to two provisions contained in the preliminary draft of the revised Recommendation (2006) 4 on research on biological materials of human origin.

(1) **Article 3 – Identifiability of biological materials**

Biological materials referred to in Article 2 may be identifiable or non-identifiable:
i. *Identifiable biological materials* are those biological materials which, alone or in combination with associated data, allow the identification of the persons from whom the materials have been removed, either directly or through the use of a code.
In the latter case, hereafter referred to as "coded materials", the user of the biological materials may have direct access to the code or, alternatively the code may be under the control of a third party.

ii. Non-identifiable biological materials, hereafter referred to as "anonymised materials", are those biological materials which, alone or in combination with [associated] data, do not allow, with reasonable efforts, the identification of the persons from whom the materials have been removed.

Question with regard to Article 3:

During the discussion concerns were raised about the continuing validity of the distinction between 'identifiable' and 'non-identifiable' biological materials. It was pointed out that – due to rapid advances in genomic technology, use of increasing amounts of associated data, increased linking of databases and increased exchange of data – the possibility to re-identify biological materials that were considered non-identifiable/anonymised has significantly increased and that, as a result, non-identifiability of biological materials may possibly no longer be guaranteed. The Committee would like to know whether the TP-D still considers the notion of non-identifiability valid and, consequently, whether the distinction made in Article 3 between 'identifiable' and 'non-identifiable' biological materials remains relevant.

(2) **Article 23 – Transborder flows**

1. Biological materials and associated data should only be transferred to another state if an appropriate level of protection is ensured by the law of that state or by legally binding and enforceable instruments adopted and implemented by the persons involved in the transfer.

2. The transfer of the biological materials and/or associated data should be done under appropriate safety conditions.

3. A documented agreement between the sender of the biological material and/or associated data, on the one hand, and the recipient, on the other, should be signed. Appropriate consent or authorisation, including, where appropriate, any relevant restriction established by the person concerned, should be included in the agreement.

Question with regard to Article 23:

[4] Request transmitted on 9 July 2013 by the Secretariat of the DH-BIO to the Secretariat of the T-PD.

Acknowledging the general data protection principle that transborder flows of personal data can only occur if in the recipient state an appropriate level of protection is guaranteed, the Committee discussed the possibility to introduce the provision that, where an appropriate level of protection is not guaranteed by the law of that state, the transfer of biological materials and/or associated data can still occur on the basis of safeguards provided in a bilateral contract between the sender and the recipient of the biological material and/or associated data. The Committee would like the opinion of the T-PD with regard to the admissibility of such provision. Taking into account that Article 3, paragraph 1 has been redrafted along the lines of the proposals for modernisation of Convention No. 108, contained in document T-PD(2012)4Rev4 as adopted by the T-PD at its 29th Plenary meeting, it would also be important for our Committee to obtain some clarification with regard to the exact meaning of the notion of 'enforceable instruments' as referred to in paragraph 1.