

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 2 October 2014

T-PD-BUR(2014)RAP33Abr

**BUREAU OF THE CONSULTATIVE COMMITTEE OF THE CONVENTION
FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO
AUTOMATIC PROCESSING OF PERSONAL DATA
[ETS No. 108]
(T-PD-BUR)**

33rd meeting of the Bureau

Paris, 30 September – 2 October 2014

ABRIDGED REPORT

Directorate General Human Rights and Rule of Law

The Bureau of the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD-BU) held its 33rd meeting in Paris from 30 September to 2 October 2014 with Mr Jean-Philippe Walter (Switzerland) in the chair. The agenda, as adopted by the T-PD Bureau, and the list of participants are set out in Appendices I and II.

The Bureau of the T-PD:

1. examined the working document to be discussed at the forthcoming and last CAHDATA meeting (1-3 December 2014) in order to agree on the position of the T-PD Bureau on the proposals and reiterated the concern expressed by the T-PD during its Plenary regarding the risk of lowering the level of protection which the T-PD had achieved in adopting its modernisation proposals in 2012;
2. examined the draft Explanatory Memorandum of the revised Recommendation on the processing of personal data in the context of employment, prepared by the Secretariat, which will be amended on the basis of the discussions and will be transmitted to the T-PD delegations for comments (amending proposals) before its transmission to the CDMSI;
3. discussed the needs and possible options regarding the work on the use of personal data in the police sector and decided to propose the preparation of a practical guide on the use of personal data by the police, instructing its Secretariat to initiate the selection of an expert;
4. took note of the information provided on the questionnaire on the protection of medical data and of the fact that, further to a joint meeting of the Bureaux of the T-PD and DH-BIO which was held on 30 September 2014, it was agreed to facilitate direct contact between each delegations of the respective committees in order to support coordination at national level;
5. took note of the information provided by the Secretariat on the automatic inter-state exchanges of personal data for administrative and tax purposes and agreed that in order to promote dissemination of the relevant opinion of the T-PD, various actions should be taken at national level, notably by T-PD delegations;
6. discussed on actions to be taken by the Committee with regard to the topic of 'big data' and agreed that a more flexible approach should be applied, such as a report, focusing on the questions of anonymisation, discrimination and use of the data for marketing purposes. It further agreed that experts should be selected for this task and instructed the Secretariat to take the necessary actions in this respect;
7. took note of the information provided concerning the cooperation with other Council of Europe bodies and institutions and, in particular, of the work in the field of Internet Governance in relation to ICANN's procedures and policies and the upcoming ICANN 51 meeting (12-15 October) where the T-PD will be represented by Ms. Alessandra Pierucci. The work of the Cybercrime Committee was also discussed and the possibility of a letter jointly signed by the Chair of the T-PD and the Chair of Article 29 Working Party in response to the case-scenarios presented in June (during the Conference on Article 15 safeguards and criminal justice access to data of 19-20 June 2014);
8. held a joint meeting with the Bureau of the DH-BIO on the morning of 30 September 2014 and discussed issues of common interest and opportunities for future cooperation, where the respective committees presented their current activities and notably the revision of Recommendation (97)5 on the protection of medical data, big data and employment and agreed to consider the possibility of

further collaboration as regards emerging technologies, as well as the development of tools, such as guidelines or codes of best practices to facilitate the implementation of existing principles in specific fields of common relevance;

9. adopted an opinion (see appendix III) on the working document on research on biological materials of human origin (DH-Bio) and instructed its Secretariat to transmit the opinion to the DH-Bio within the set deadline;

10. took note of the information provided by the observers attending the meeting;

11. took note of the exchange of views that the Chair will have with the Group of Rapporteurs on Legal Co-operation of the Committee of Ministers on 7 October, with a view to underlining the importance of the work and notably regretting the inadequacy of the resources allocated to this file;

12. confirmed that its 34th meeting would be held in Strasbourg from 16 to 18 December 2014.

APPENDIX I.

AGENDA

Strasbourg, 30 September 2014

T-PD-BUR33(2014)OJ_En

BUREAU OF THE CONSULTATIVE COMMITTEE OF THE CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO AUTOMATIC PROCESSING OF PERSONAL DATA [ETS n° 108] (T-PD-BUR)

33rd meeting, Paris, Council of Europe, room 02

**From 30 September 2014 – 9:00 am
to 2 October 2014 – 4:00 pm**

DRAFT AGENDA

1. OPENING OF THE MEETING

- T-PD-BUR(2014)RAP32Abr Abridged report of the 32nd Bureau meeting
(25-27 March 2014)
- T-PD(2014)RAP31Abr Abridged report of the 31st Plenary meeting
(2-4 June 2014)
- T-PD(2014)WP Work programme of the T-PD
- T-PD(2014)Rules T-PD's rules of procedure

2. ADOPTION OF THE AGENDA

3. STATEMENT BY THE SECRETARIAT

4. MODERNISATION OF CONVENTION 108

Scientific Expert: Ms Cécile de Terwangne, Professor Law Faculty, CRIDS Research Director, Namur University (FUNDP)

Required action: The Bureau will examine the working document to be examined at the forthcoming and last CAHDATA meeting (1-3 December 2014) in order to agree on the position of the T-PD Bureau on the proposals.

- CAHDATA(2014)03 Working document - Convention 108 with Additional Protocol and Modernisation Proposals
- T-PD(2012)04REV04 Final document on the modernisation of Convention 108
- Resolution on the revision of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, European Conference of DPAs

5. EMPLOYMENT RECOMMENDATION

Required action: The Bureau will examine the draft Explanatory Memorandum of the revised Recommendation on the processing of personal data in the context of employment, prepared by the Secretariat for its transmission to the CDMSI.

- T-PD(2014)08 Draft Recommendation on the processing of personal data in the context of employment
- T-PD-BUR(2014)02 Draft Explanatory Memorandum of the revised Recommendation on the processing of personal data in the context of employment
- T-PD-BUR(2010)11FIN Study on Recommendation (89)2 on the protection of personal data used for employment purposes and to suggest proposals for the revision of the above-mentioned Recommendation by Giovanni Buttarelli

6. DATA PROTECTION AND POLICE

Required action: The Bureau will discuss the follow-up.

- T-PD(2013)11 Recommendation (87)15 – “Twenty-five years down the line”: Final Report

7. PROTECTION OF MEDICAL DATA

Required action: The Bureau will take note of the information provided by the Secretariat and will discuss the follow-up.

- T-PD(2014)07 “Medical technologies and data protection issues”
Questionnaire
- Recommandation N° R (97) 5 sur la protection des données médicales

8. AUTOMATIC EXCHANGE OF DATA

Required action: The Bureau will take note of the information provided by the Secretariat and will discuss the follow up (means to promote dissemination of the opinion and other steps to take in respect of this topic).

- T-PD-BUR(2014)01 Report on the implications for data protection of the growing use of mechanisms for automatic inter-state exchanges of personal data for administrative and tax purposes, as well as in connection with money laundering, financing of terrorism and corruption
- T-PD(2014)05 Opinion on the implications for data protection of mechanisms for automatic inter-state exchanges of data for administrative and tax purposes

9. BIG DATA

Required action: The Bureau will take note of the information provided by the Secretariat and will discuss the follow-up.

- Working Paper on Big Data and Privacy Privacy principles under pressure in the age of Big Data analytics
- Big Data and Data Protection ICO
- Preliminary Opinion of the European Data Protection Supervisor Privacy and competitiveness in the age of big data: The interplay between data protection, competition law and consumer protection in the Digital Economy
- Executive Office of the President, “Big Data and Privacy: A Technological Perspective” Report to the President
- Report of workshop on Privacy, Consumers, Competition and Big Data 2 June EDPS

10. COOPERATION WITH OTHER COUNCIL OF EUROPE BODIES

Required action: The Bureau will take note of the information provided by the Secretariat

- Steering Committee on Media and Information Society (CDMSI)
- Internet governance
 - CoE experts report "ICANN's procedures and policies in the light of human rights, fundamental freedoms and democratic values"
- Cybercrime Committee (T-CY)
- PACE

11. JOINT MEETING WITH DH-BIO BUREAU (NB. – 30/09 morning)

Required action: The Bureau will hold a joint meeting with the Bureau of DH-BIO to discuss issues of common interest to the two committees in respect of future co-operation.

- Draft agenda and Working document (*to be issued later*)

12. OPINION

Required action: The Bureau will examine the draft opinion submitted for adoption

- T-PD(2014)xx Draft opinion – on the working document on research on biological materials of human origin (DH-Bio)
- DH-BIO/INF(2014)3 Working document on research on biological materials of human origin

13. OBSERVERS

Required action: The Bureau will take note of the information provided by the observers

14. OTHER ISSUES

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DRAFT ORDER OF BUSINESS

	30 September 2014	1 October 2014	2 October 2014
<i>Opening</i>	9:00 am	9:30 am	9:30 am
<i>Morning</i>	Item 11	Item 5	Item 4
<i>Lunch</i>	01:00-2:30 pm	01:00-2:30 pm	01:00-2:30 pm
<i>Afternoon</i>	Items 1,2,3,5	Items 5 and 6-14	Item 4
<i>End</i>	6:00 pm	6:00 pm	4:00 pm
<i>Informal gathering</i>	8 pm		

APPENDIX II.

LIST OF PARTICIPANTS

Strasbourg, 2 October/octobre 2014

T-PD-BUR33(2014)LP_Final

**BUREAU OF THE CONSULTATIVE COMMITTEE OF THE
CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD
TO AUTOMATIC PROCESSING OF PERSONAL DATA
[ETS 108]**

**BUREAU DU COMITE CONSULTATIF DE LA CONVENTION
POUR LA PROTECTION DES PERSONNES A L'EGARD DU TRAITEMENT
AUTOMATISE DES DONNEES A CARACTERE PERSONNEL
[STE n° 108]**

(T-PD-BUR)

33rd meeting / 33^{ème} réunion

LIST OF PARTICIPANTS

LISTE DES PARTICIPANTS

**30 September / septembre – 2 October / octobre 2014
Paris, Room / salle 2**

Directorate General of Human Rights and Rule of Law /
Direction Générale Droits de l'Homme et Etat de droit

MEMBERS OF THE BUREAU / MEMBRES DU BUREAU

BELGIUM / BELGIQUE

Joëlle Jouret, SPF Justice, Direction générale de la législation et des libertés et droits fondamentaux, Service des droits de l'homme, Cellule vie privée, 115 boulevard de Waterloo, 1000 Bruxelles

GEORGIA / GEORGIE

Nino Sarishvili, Head of International Relations and Communications Department, Office of the Personal Data Protection Inspector, 7, Ingorokva Str., 0105, Tbilisi Georgia

ITALY / ITALIE

Pierucci Alessandra, (first vice-chair), Piazza di Monte Citorio 121, 00186 Rome

LUXEMBOURG (apologised/excusé)

Gérard Lommel, Président, Commission Nationale pour la protection des données (CNPD), 41, avenue de la Gare, L-1611 Luxembourg

PORTUGAL (apologised/excusé)

João Pedro Cabral, Legal Adviser, Directorate General of Justice Policy, Ministry of Justice, Avenida D. João II, n.º1.08.01 E, Torre H, Pisos 2/3, 1990-097 Lisboa

SERBIA / SERBIE (apologised/excusée)

Nevena Ružić, (second vice-chair), Head of Office, Commissioner for Information of Public Importance and Personal Data Protection, 42 Svetozata Markovica, 11 000 Belgrade

SPAIN / ESPAGNE

Agustín Puente Escobar, Director, Agencia Española De Protección De Datos, State Attorney -Head of the Legal department, C/Jorge Juan, 6, 28001 Madrid

SWITZERLAND / SUISSE

Jean-Philippe Walter, (Président), Préposé fédéral à la protection des données et à la transparence (PFPDT), Chancellerie fédérale, Feldeggweg 1, 3003 Berne

MEMBERS OF THE T-PD / MEMBRES DU T-PD

CZECH REPUBLIC / RÉPUBLIQUE TCHÈQUE

Hana Štěpánková, Head of the Press Department, Spokeswoman, Office for Personal Data Protection Pplk.Sochora 27, 170 00 Prague 7

MONTENEGRO

Zora Cizmovic, Ministry of Interior of Montenegro, Head of the Section for Personal Data Protection and Free Access to Information, Blvd. Svetog Petra Cetinjskog No 22, Podgorica

Jelena Matovic, Ministry of Interior of Montenegro, Department for International Cooperation and European Integration, Advisor - Interpreter

SWEDEN / SUÈDE

Naiti Del Sante, Legal advisor, Division for Labour Law and Work Environment, Ministry of Employment, 103 33 Stockholm

UNITED KINGDOM / ROYAUME-UNI

Daniel Johns, EU and International Data Protection Policy Ministry of Justice

OBSERVERS / OBSERVATEURS

TURKEY / TURQUIE

Abdullah Aydin, Counsellor, Ministry of Justice, Turkish Embassy in Paris

ASSOCIATION EUROPEENNE POUR LA DEFENSE DES DROITS DE L'HOMME / EUROPEAN ASSOCIATION FOR THE DEFENSE OF HUMAN RIGHTS (AEDH)

Marise Artiguelong, Déléguée, AEDH, Rue de la Caserne 33 – 1000 Brussels, Belgium

EUROPEAN DATA PROTECTION SUPERVISOR (EDPS) / LE CONTRÔLEUR EUROPEEN DE LA PROTECTION DES DONNÉES (CEPD)

Alba Bosch Moliné, Acting head of international cooperation, Policy & Consultation Unit, Postal address: Rue Wiertz 60, B-1047 Brussels, Office address: Rue Montoyer 30, B-1040 Brussels

EUROPEAN COMMISSION / COMMISSION EUROPEENNE

Katerina Dimitrakopoulou, Policy Officer, Directorate C: fundamental rights and Union citizenship, Unit C3 Data Protection, 1049 Bruxelles, Belgium

Lukasz Rozanski

FRENCH-SPEAKING ASSOCIATION OF PERSONAL DATA PROTECTION AUTHORITIES / ASSOCIATION FRANCOPHONE DES AUTORITÉS DE PROTECTION DES DONNÉES PERSONNELLES (AFAPDP)

Floriane Leclercq, Chargée de mission, Commission nationale de l'informatique et des libertés, 8 rue Vivienne - CS 30223 - 75083 PARIS Cedex 08

INTERNATIONAL CONFERENCE OF DATA PROTECTION AND PRIVACY COMMISSIONERS / CONFERENCE INTERNATIONALE DES COMMISSAIRES A LA PROTECTION DES DONNEES ET DE LA VIE PRIVEE

Laurent Lim, CNIL, Juriste chargé de mission, Service des affaires européennes et internationales

SCIENTIFIC EXPERTS / EXPERTS SCIENTIFIQUES

Cécile de Terwangne, Professeur à la Faculté de Droit, Directrice de recherche au CRIDS (Centre de Recherches Informatique, Droit et Société), Facultés Universitaires Notre-Dame de la Paix (FUNDP), Rempart de la Vierge n°5, 5B-5000 Namur, Belgique

SECRETARIAT

**Directorate General Human Rights and Rule of Law
Direction Générale Droits de l'Homme et Etat de Droit**

Data Protection Unit / Unité de la protection des données

Sophie Kwasny, Secretary of the T-PD / Secrétaire du T-PD

Maria Michaelidou, Programme Advisor / Conseillère de programme

INTERPRETERS / INTERPRETES

Ms Eline Aitken
Mr Claudien Pierson
Ms Marianne de Susbielle

APPENDIX III.

OPINION ON THE DRAFT RECOMMENDATION ON RESEARCH ON BIOLOGICAL MATERIALS OF HUMAN ORIGIN

The DH-BIO is currently re-examining Recommendation (2006) 4 on research on biological materials of human origin. In this context, it has already sought the opinion of the T-PD on specific issues and the comments of the T-PD have been taken into account in the drawing up of a draft revised Recommendation. In March 2014, this draft Recommendation was made public in the form of a working document for consultation. At its 5th plenary meeting held from 5 to 7 May 2014, the DH-BIO agreed to ask the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (T-PD) for its comments on the whole working document.

The Bureau of the Consultative Committee welcomes the opportunity to comment on the draft revised Recommendation. The Bureau has examined the relevant provisions and their compatibility with the standards of the Council of Europe in the field of data protection, in particular the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108, hereafter "Convention 108") and its Additional Protocol, as well as the relevant recommendations.

General comments

The Bureau of the Committee welcomes the reference, in the new 8th recital of the preamble, to the right to privacy and to the protection of personal data.

It should be underlined that a new recommendation must be entirely consistent with the principles already set forth by the Committee of Ministers with regard to the protection of personal data in this field, in particular, with Rec (97) 5 on the protection of medical data,¹ Rec (92) 3 on genetic testing and screening for health purposes,² Rec (83)10 on the protection of personal data used for scientific research and statistics,³ Rec(2002)9 on the protection of personal data collected and processed for insurance purposes⁴ and Rec (2010)13 on the protection of individuals with regard to automatic processing of personal data in the context of profiling.⁵

In order to avoid any contradiction with the existing legal framework in the field of data protection in a sector which the Council of Europe considers particularly sensitive because of the potentially high risks of discrimination against individuals, a reference to such relevant standards should be included in the Recommendation.

¹<https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=564487&SecMode=1&DocId=560582&Usage=2>

²<https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=573883&SecMode=1&DocId=601492&Usage=2>

³<https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=602986&SecMode=1&DocId=680204&Usage=2>

⁴<https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=543727&SecMode=1&DocId=295736&Usage=2>

⁵[https://wcd.coe.int/ViewDoc.jsp?Ref=CM/Rec\(2010\)13&Language=lanEnglish&Ver=original&Site=CM&BackColorIntranet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383](https://wcd.coe.int/ViewDoc.jsp?Ref=CM/Rec(2010)13&Language=lanEnglish&Ver=original&Site=CM&BackColorIntranet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383)

The Bureau of the T-PD would suggest that a general reference be included in the Recommendation to Convention 108, its additional protocol and other relevant legal instruments of the Council of Europe in the field.

In view of the sensitive nature of the data covered by the draft instrument, it is strongly recommended that greater emphasis be placed on data protection principles in the recommendation.

It is also suggested that further references be made to the relevant national rules/legislation in member states in the field of data protection and to specify more clearly in the recommendation the role of states in regulating research facilities.

Specific comments on the text

Preamble:

In addition to the reference to the importance of the right to private life and to the protection of personal data in the new 8th recital, there should also be a mention of the fact that the processing of personal data must comply with the general principles set forth in Convention 108 and its Additional Protocol, and in the relevant recommendations of the Committee of Ministers in this field (see general comments).

Recital 10: In the phrase “Taking into account the development of new technologies, in particular in the field of genetics, which increase *issues* regarding (...)”, it is suggested that the word “issues” be replaced by “risks”.

Recital 13: it is suggested to add at the end of the sentence “ensuring the protection of the human being **and his or her rights and fundamental freedoms**”.

Recital 17: it is suggested that “*good* and transparent governance” be replaced by “ethical and transparent governance”.

With regard to the recommendations made to the governments of member states, in the second recommendation referring to codes of good practice, it should be made clear whether these codes are in addition to the first recommendation, if necessary adding “and” at the beginning of the sentence. If such is not the case, this would appear to limit the scope of the first recommendation which provides for the adaptation of laws.

CHAPTER I – Object, scope and definitions

A reference to the protection of individuals with regard to the processing of personal data could be introduced in Article 1, which could read as follows: “right to respect for private life, **to the protection of personal data** and other rights and fundamental freedoms (...)”.

The aim of Article 2.3 is to extend the protection of biological material to associated personal data. However, this article is ambiguous as it refers to the treatment of biological materials and the processing of data which are two different aspects although linked by a single set of rules. Accordingly, they need to be differentiated. It is suggested that the wording be changed as follows: “The collection, storage and use of biological materials of human origin may be accompanied by associated personal data. Where in this Recommendation provisions make reference to biological

materials of human origin these extend, where relevant, also to associated data **which in all cases should be adequately protected in accordance with the data protection principles**".

CHAPTER II – General provisions

The question of the anonymisation of the data is addressed in various sections of the Recommendation, with precise requirements (see articles 3, 7, 13.3, 14.5 and 17.3). The Bureau of the T-PD suggests that a specific part of the general provisions be devoted to this particularly important issue. Accordingly, it is suggested that the following text be included: "Regarding anonymised data, in light of the risks implied by the re-identification of the persons, all possible measures preventing such risks, both of a technical and organisational nature (regarding for instance the issue of access to anonymised data) have to be taken and be regularly reviewed".

Article 4: There is a need for further explanations regarding minimal risks and minimal burdens. The explanatory memorandum should provide the necessary clarifications. It should be specified who evaluates these risks and how the application of the principle of proportionality is to be made.

Furthermore, a paragraph should be inserted on the risks to minors, on account of the specific safeguards that are necessary.

Article 7: It is proposed that the first paragraph be reformulated as follows "Biological materials should be anonymised **unless impossible with regard to** the research activities concerned".

Regarding paragraph.2: The procedure for justifying research by researchers is not specified in this article. The text could be much clearer, possibly by referring to national texts and procedures.

Article 8: A reference to the protection of personal data should be added in paragraphs 1 and 2 of this Article. The principle of confidentiality given in paragraph 1 should not be linked solely to the need to comply with the rules on the protection of private life. Furthermore, paragraph 2 should not refer exclusively to the need to ensure confidentiality; it should also refer to the integrity of biological materials and the integrity and quality (as provided for by Article 5 of Convention 108) of the associated personal data. It is suggested that the wording be supplemented as follows: "appropriate security measures **and strict certification measures...**".

Article 9: it is recommended to add, in complement to the reference to general information "on the nature and objective of research collection", a reference to the risks arising from such collections.

CHAPTER III - Information and consent

Article 11.1: It is suggested that the following be added: "the conditions **and duration** applicable to the storage". It is furthermore proposed to introduce a specific reference to the information which should be provided to the data subject with regard to the disclosure and access to materials and the information they contain.. Finally, information regarding the risks at stake should also be provided.

Article 11.4: It is suggested that the following wording be used: "free, specific, informed and **explicit** consent". The proof that such a consent has been given should be available at all times.

Article 12: The removal of biological materials from persons not able to consent for storage for future research should as a principle be prohibited by law, which can stipulate that where necessary the authorisation should be sought from the legal representative.

In the 3rd paragraph, a similar comment than the one made in respect of Article 4 should be made, and more precisely that further clarifications on the evaluation of the risks and the application of the principle of proportionality would be welcome in the explanatory memorandum of the Recommendation.

Article 13: Concerning the information provided to the persons concerned in paragraphs 1 and 2, the draft is ambiguous and it is proposed to replace “whenever possible” by “subject to the provisions of Articles 14 and 15”. Further clarification needs to be given as to what “beforehand” means and in particular when this information must be provided.

Article 14.2 seems to raise a contradiction is so far as it would appear difficult to provide the information and obtain the appropriate authorisation “before”, as the material was removed (previously) for other purposes as stated in the first paragraph.

Article 15 raises the particular issue of the rights of the living parents of the deceased persons. The use of ‘should’ in paragraph 2 furthermore brings uncertainty in respect of the strength of the authorisation (or absence thereof) and could be understood as recommending an ‘opt-out’ system.

Article 16.1: It is recommended that the wording be more specific with regard to what might constitute “limitations on withdrawal of his or her biological material”. It should be pointed out that, in principle, there should be no limitation on withdrawal of consent by the persons concerned.

CHAPTER IV – Use of biological materials in a research project

Article 17.2.ii.a: In the phrase “evidence is provided that sufficient efforts have been made to contact the person concerned”, it is suggested that the word “sufficient” be replaced by the word “reasonable”.

Article 19.2: “Availability of results”. It is suggested that the second paragraph be supplemented by the following: “Appropriate measures (...) in reasonable time **with due respect for the right to private life and to the protection of the associated personal data of the persons concerned**”.

Article 20.3 should make clear that any change in the purpose should be strictly limited to ‘compatible’ uses of the data as the principle of purpose limitation implies that the data cannot be ‘further processed in a way incompatible’ with the purposes for which the data was collected (compatible use). Further processing for a different purpose does not necessarily mean that it is incompatible, but compatibility needs to be assessed on a case-by-case basis, taking into account all relevant circumstances and the expectations of the person concerned.

Article 21.2: The sentence should be supplemented by the following: “... and be given by a healthcare professional”.

Article 22.2: It is suggested that the second paragraph be supplemented by the following: “**Appropriate access by researchers to collections of biological materials must, in all cases, comply with the relevant restrictions specified** by the person concerned”. Indeed, while stating that measures should be taken to facilitate access by researchers to collections of biological materials, reference should be made to the need to comply with data protection standards in this field.

Article 22.4: In addition to the traceability of the uses granted by the collection, reference should be made to the researcher's commitment not to use the data for purposes other than those specified by the person concerned and not to communicate the data to third parties.

Article 23.1: In the sentence: "if a comparable level of protection is either ensured ...", it is suggested that the words "a comparable" be replaced by the word "**an appropriate**" and that a reference to Convention 108 be introduced, which could for instance read as follows "Biological materials should only be transferred to another **State in compliance with the relevant provisions of Convention 108 and its additional Protocol**, implying that an **appropriate** level of protection (...)".

Article 24: In paragraph 1, the text stipulates that the oversight mechanism is applicable to the 'establishment' of the collection of biological materials. It is suggested that the scope of the oversight mechanism also includes the subsequent stages in order to also cover all operations carried out on these materials, with particular attention to data protection aspects, in the context of the rights and interests of the persons concerned.