BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

BBMRI-ERIC CONTRIBUTION TO THE PUBLIC CONSULTATION ON THE WMA DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATA-BASES AND BIOBANKS

2015--06--12

This contribution to the works of the WMA is made on behalf of the pan-european BBMRI-ERIC Infrastructure and includes works from its National Nodes and from the BBMRI-LPC.

We fully support the need for additional ethical guidance regarding Health Databases and Biobanks from the WMA, particularly in light of its long-standing tradition and accomplishments in furthering human rights in medicine, health care and research. A Declaration aimed at providing ethical guidance to research making use of data and samples obtained from human beings would in principle be a welcome addition to currently existing guidelines.

That being said, we have a number of major reservations in the ethical perspective taken in the current Draft Declaration. Our primary reservations relate to the overly dominant role accorded to the principle of autonomy in the Draft Declaration as a whole. In our view, Health Databases and Biobanks also play a constitutive role in furthering goals of public health, particularly in solidarity-based health care systems, should therefore also be regarded as instrumental for furthering justice, equity and solidarity in addition to principles of autonomy, privacy and confidentiality.[1] In our view, such principles are taken insufficiently into account in the current Draft Declaration.

Taking these principles into account in particular would mean reconsidering the currently proposed nearly universal consent requirements for research using data and samples obtained from human beings. Consent is neither sufficient nor always necessary as an ethical principle, and will even be detrimental to some forms of research using Health Databases and Biobanks, particularly in public health research.

A second reservation to the perspective taken in the Draft Declaration pertains to the emphasis put on direct and individual obligations of those contributing to or working with Health Databases and Biobanks, particularly obligations of physicians. Health Databases and Biobanks should not just be regarded as stand-alone entities in their own right, but rather as embedded in healthcare organizations as well as part and parcel of and feeding data and samples into research networks.[2] In order to bring ethical guidance to the burgeoning field of data- and sample-driven research, the ethical obligations involved

[1] Prainsack B, Buyx A. Solidarity in Contemporary Bioethics – Towards a New Approach. *Bioethics*. 2012;26(7):343-350. doi:10.1111/j.1467-8519.2012.01987.x; Prainsack B, Buyx A. A Solidarity-Based Approach to the Governance of Research Biobanks. *Med Law Rev*. 2013;21(1):71-91. doi:10.1093/medlaw/fws040; Knoppers BM, Chatwick R, Human genetic research: emerging trends in ethics, Nat. Rev. Gen. 2005, 6 1):75-79.

[2] Kaye J. From single biobanks to international networks: developing e-governance. *Hum Genet*. 2011;130(3):377-382. doi:10.1007/s00439-011-1063-0; Knoppers BM, Harris JR, Tassé AM, et al. Towards a data sharing Code of Conduct for international genomic research. *Genome Medicine*. 2011;3(7):46. doi:10.1186/gm262; Kosseim P, Dove ES, Baggaley C, et al. Building a data sharing model for global genomic research. *Genome Biology*. 2014;15(8):430. doi:10.1186/s13059-014-0430-2; Knoppers BM, Harris J et al., A human rights approach to an international code of conduct for genomic and clinical data sharing, Hum Gen, 133(7): 895-703.

should be framed in a more layered, distributed and process-oriented fashion as well. Moreover, contrary to the suggestion made in article 14 of the Draft Declaration, the inclusion and distribution of health data and samples in such wider arrangements need not be construed as constituting a breach of confidentiality per se, provided additional safeguards are in place.

Thirdly, full and irreversible anonymization[3] is problematic for several reasons and should not be recommended anymore as a privileged method to protect confidentiality and privacy:

> First, it weakens the usefulness of data analysis and interpretations to produce high quality research, since any loss of information due to the anonymization procedure leads inevitably to deficits in obtaining comprehensive scientific results.
>
> Secondly and even more important, anonymization does not strengthen, but to the contrary weakens the rights of the donors, since they lose their right to withdraw their consent. This is not at all compensated by the effect of anonymization, since effectively anonymizing biosamples and/or genetic data, which is rich enough to single out a person, belongs to the past. The Art 29 Working Party under the EU Data Protection Directive has stated in its Opinion on Anonymization Techniques (p.10): "Genetic data profiles are an example of personal data that can be at risk of identification if the sole technique used is the removal of the identity of the donor due to the unique nature of certain profiles. It has already been shown in the literature that the combination of publically available genetic resources (e.g. genealogy registers, obituary, results of search engine queries) and the metadata about DNA donors (time of donation, age, place of residence) can reveal the identity of certain individuals even if that DNA was donated 'anonymously'." Indeed, re-identification techniques are constantly progressing. The field needs further debate. But it is quite clear, that anonymization of such data cannot be recommended any more as general means to protect donor's privacy without a feeling to betray donors. Next generation sequencing makes it more and more affordable and achievable to extract this data from biosamples.
>
> Thirdly the donors / patients cannot be contacted any more in case of incidental findings. Beyond the ethical issues around feeding back incidental findings, it cannot be seen as solution to anonymize and thus exclude any feedback. Especially in cases of changes in oncological treatment protocols, which need readily to be returned for the benefit of the donors / patients (well-being), pseudonymization is highly preferable and can already be seen as prevailing practice.

Finally, we fully subscribe to the need to pay heed to principles and arrangements of governance in the context of this Declaration. At the same time, we believe that principles have evolved further in a number of areas. In our view, the Declaration could be expanded to reflect current principles and practice of governance even better, particularly in areas of transparency, accountability and public and patient engagement.[4]

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[3] In the meaning of the Council of Europe Convention n°108 on data protection; of the EU Directive 95/46/EC and the Proposal for a General Regulation on Data Protection, EP amended version of 12 March 2014, e.g. rec.23.

[4] Chalmers D, Burgess M, Edwards K, Kaye J, Meslin EM, Nicol D. Marking Shifts in Human Research Ethics in the Development of Biobanking. *Public Health Ethics*. 2015;8(1):63-71. doi:10.1093/phe/phu023.

The following recommendations reflect these broader comments and suggesting ways in which the Declaration might be improved upon to accommodate these comments, while also suggesting further points for clarification in areas such as terminology relating to identifiability.

Textual convention in this contribution:

- Additions or proposed changes are marked in **bold**
- Deletions proposed are marked in ~~**bold strikethrough**~~
- Separating line between comments where several aim the same article "-------"
- Contradictory views between National Nodes of the BBMRI-ERIC are quoted as discrepancy plus author of the comments.

Reference within the text	Comment	Proposal
2. This declaration provides additional principles for the ethical use of data in Health Databases and human biological material in Biobanks, referred to hereafter as biological material, used for research or for other purposes.	What kind of "other purposes"? It is not clear, what "other purposes" means and why it is included. Do the other current practices of quality management, system improvement, technological validation using biological samples and health data are considered through the declaration? --- The article is using the expression "biological material" to refer both to data in Health Databases and human biological material in Biobanks. This expression is too restrictive and seems only to refer to the sample and not to the data. A biological resource, including of human origin, is made by a biological sample and associated data. This should be clarified and corrected accordingly throughout the text. --- As articles 2, 3 and 7 address definitions of a health database, a biobank and biological resources, we suggest that they be united as article 2 for enhancing clarity.	Insert: **"used for research, clinical care, quality assessments or health policy management purposes"**. --- From an ethical point of view, the expression "biological material" should be replaced by **"human biological resources"** to refer to the human ~~**material**~~ **samples** and the data. This should be done throughout the text. --- We advise to have a specific article / table with the definitions.
3. A Health Database is a system for collecting, organizing and storing health information. It enables the information to subsequently be retrieved in a structured man-	The term "Health Data Base" is quite vaguely defined, is really any data base containing health data in the scope of the declaration?	*No specific proposal*

ner. A Biobank is a collection of biological material and associated data from different individuals. Health Databases and Biobanks are both collections of information on individuals, and both give rise to the same concerns about autonomy, privacy and confidentiality.		
4. In health care provision, health information is gathered by physicians or other members of the medical team to record health care events and to aid physicians in the ongoing care of their patient. This declaration is intended to cover any use of health information beyond the individual care of the patients.	This article is focused on health information used in patient care and overlooks other current practices of quality management, system improvement, and technological validation (cf. comments and proposals regarding article 2). These also apply to the use of biological samples used for these purposes.	Include other contexts where health data are collected, namely, collection performed by qualified research team (not only medical team) in the frame of an approved scientific research protocol (which can include healthy volunteers and not only patients) and data collection for registries used for public health policy and management purposes. Additionally or in a different article, provisions should be redacted by focusing on samples' sources. This means samples that are collected in clinical routine or in a research protocol and biobanks used for health research and other purposes.
5. Respecting the dignity and autonomy of individuals, physicians have specific	Physicians are appointed as stewards having specific obligations to guaranty protecting privacy and dignity. This task should not be appointed to the individual physician, but to the organiza-	Respecting the dignity, **privacy** and autonomy of individuals, **those involved in, contributing to or working with Health Databases and Biobanks** have specific obligations, both ethical and legal, as stewards protecting information provided by ~~**their**~~ patients**, donors and participants**.

obligations, both ethical and legal, as stewards protecting information provided by their patients.	tion (eg hospital/research institute). Organizations must provide the infrastructure and practical necessities (IT, information, etc.) for physicians and researchers to be able to guarantee that the privacy, autonomy and dignity of patients are respected. Moreover, not all people whose data and/or tissue are involved will be patients. We suggest a wider scope for this article. --- The article refers to physicians which have specific obligations to respect the dignity and autonomy of individuals. Maybe just talking about physicians is too restrictive and the article should refer to other stakeholders who are in charge to protect the information of the patients. The article should also refer to the data controllers working with the Health databases and fit to the existing legal state of art.	--- Add the "**data controller**" as a person who have obligations to protection the information provided by the patients. "Respecting the dignity and autonomy of individuals, physicians and **data controllers** have specific obligations, both ethical and legal, as stewards protecting information provided by **the** patients".
6. Ongoing improvements in the understanding of diseases and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions can be significantly accelerated through research using data from Health Databases and Biobanks.	Some insights into health and disease would not just be slowed down but simply be impossible without Health Databases and Biobanks. For instance, reliable figures on incidence and prevalence of disease can only be gathered through Health Databases. We suggest a slightly different wording acknowledging this crucial role.	Ongoing improvements in the understanding of diseases and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions **are made possible and** can **often** be significantly accelerated through research using data from Health Databases and Biobanks.
7. Biological mate-	We should integrate the specificities related to	"[…] including genetic information**~~, about that individual~~ that is rich enough to**

rial refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual.	the potential change of status of samples and related data given that a lot of data and samples that seem now innocuous may turn out to be personally significant in the future or regarding specific processing activities for the initial donor or relatives for example. --- A definition of genetic information should be placed in definitions. This is important as it is becoming the topic that causes concern for privacy but there are differences in somatic and germ line genetic information which affects the matter of living and diseased individuals and therefore should be well defined.	**single out an individual**" --- A definition of genetic information should be placed in definitions.
8. Health Databases and Biobanks that exclusively contain fully anonymised and non-identifiable data and biological material are not the subject of this declaration.	Why are "anonymised" biobanks and data bases excluded? The terminology with respect to anonymity and identifiability is ambiguous and unclear in its implications depending on how one defines 'identifiability'. This article can be read as stating that Health Databases and Biobanks containing 'pseudo-anonymous data' are not the subject of the declaration. Such a reading, however, seems in contradiction to article 9 and to the current state-of-art in data protection law. --- Biobanking raises many questions, not only those regarding data protection (see for example article 22 (ownership and IP.) The article looks oriented to health databases or biobanks that are ONLY and TOTALLY made of	"Health databases and Biobanks, **or the sole sub-part(s) of them,** that exclusively contain **anonymous data** and **human** biological **samples (fully anonymised, irreversibly de-identified and non-identifiable)** are not the subject of this declaration, **excepted articles 20 and 22 to 27 where relevant for the database or biobank.**" --- Insert definitions based on the legal advances in EU law regarding "pseudonymous/pseudonymised data" and "anonymous/anonymised data". Harmonise the vocabulary with other articles.

	anonymous data and material, what about the other parts of a health database (respectively the part of a biobank) that is meeting the definition of pseudonymised data and thus still be personal data (cf. EU draft General data protection Regulation, Article 4)? ---------- ***This comment relates together to articles 8; 9 and 17:*** The handling of full anonymisation is not "state of the art", since NGS allows for quite affordable sequencing. Full genome is certainly not fully anonymisable. Other de-identifying measures such as pseudsonymisation are preferable and they preserve the rights of the donor much better (e.g. withdrawal of consent). In addition anonymisation reduces the usability for research. ---------- Is forensic material covered?	---------- Specify the scope of the declaration. ---------- Specify in the scope of the declaration
10. Physicians, administrators, medical researchers and health policy makers must observe the provisions outlined in this Declaration.	WMA documents cannot be binding for anybody else than medical staff. ----------**Discrepancy**---------- This article is providing very useful information about the scope of the principles that apply not only to physicians but also to administrators, legal researchers and health policy makers which have to respect specific rules of medical/research sectors and, for administrators, secrecy. Therefore, it should appears sooner in the text.	*No specific proposal* ----------**Discrepancy**---------- Insert the content of article 10 after the definitions of article 3 for enhancing clarity about the scope of the Declaration.

Article 11 and 12?	These articles appear to be missing	These articles appear to be missing
14. Confidentiality is essential for maintaining trust and integrity in the patient-physician relationship. Knowing that their privacy will be respected gives patients the confidence to share sensitive personal information with their physician. The privacy of a patient's information is secured by the physician's duty of confidentiality.	Patients (especially in academic centers) are often treated by an interdisciplinary team of physicians to make a diagnosis, some whom they never see or speak (pathologist, clinical chemist, researchers). It is therefore unrealistic to think that their information will only be shared (seen and used) by their main physician. Patients should be informed that their information will be stored in the IT systems of all the different health departments involved (or in the one EHR if applicable) and can be used for research by the organization as a whole. It is the responsibility of the organization to make sure that all the departments are actually able to protect the privacy of the patient. Often an intermediary biobank or biobank manager can be put in place to facilitate relationships between both researchers, patients/ participants and the physicians in this process. We therefore suggest a more general wording tailored to Health Databases and Biobanks. Privacy and confidentiality in the patient-physician relationship as such is already covered by other Declarations and does not require explicit mention here. --- Furthermore, Health Databases and Biobanks are not just a matter of patients-physician relationship. They also involved healthy subjects and researchers, and trust regards the health system at large ---	Confidentiality is essential for maintaining trust and integrity in ~~**the patient-physician relationship**~~ **Health Databases, Biobanks and the uses to which data and samples collected through them are put.** Knowing that their privacy will be respected gives patients**, donors and participants** the confidence to share sensitive personal information ~~**with their physician**~~. The privacy of a patient's information is **notably** secured by the physician's duty of **medical secret and by the other data controller's duties of confidentiality and professional secret**.

	Health Databases and Biobanks should not just be regarded as stand-alone entities in their own right, but rather as embedded in healthcare organizations as well as part and parcel of and feeding data and samples into research networks.[5] In order to bring ethical guidance to the burgeoning field of data and sample-driven research, the ethical obligations involved should be framed in a more layered, distributed and process-oriented fashion as well. Moreover, contrary to the suggestion made here, the inclusion and distribution of health data and samples in such wider arrangements need not be construed as constituting a breach of confidentiality per se, provided additional safeguards are in place. --- This article only talks about the physician's duty of confidentiality in order to guarantee that the privacy of patient's information is secured. But he is not the only one to ensure such an obligation. Insert in the article a reference to a data controller in the meaning of European law which also guarantee that patient's information are secured in a logical chain described within governance schemes and policies.	
15. Individuals must be given the opportunity to decide	Mandating consent for all Health Databases, as this phrasing suggests, will demonstrably introduce bias into such systems[6] and would jeopard-	We suggest a wording which leaves open the possibility of 'thick' opt-out mechanisms, subject to oversight by an ethics committee. E.g.:

[5] Kaye J. From single biobanks to international networks: developing e-governance. *Hum Genet*. 2011;130(3):377-382. doi:10.1007/s00439-011-1063-0; Knoppers BM, Harris JR, Tassé AM, et al. Towards a data sharing Code of Conduct for international genomic research. *Genome Medicine*. 2011;3(7):46. doi:10.1186/gm262; Kosseim P, Dove ES, Baggaley C, et al. Building a data sharing model for global genomic research. *Genome Biology*. 2014;15(8):430. doi:10.1186/s13059-014-0430-2.

[6] Emam KE, Jonker E, Moher E, Arbuckle L. A Review of Evidence on Consent Bias in Research. *The American Journal of Bioethics*. 2013;13(4):42-44. doi:10.1080/15265161.2013.767958.

whether their identifiable information will, or will not be included in a Health Database or their biological material in a Biobank. As part of the consent process, individuals must be informed about the purpose of the Health Database or Biobank, the nature of the data or material to be collected and about who will have access to the Health Database or Biobank.	ize if not outright destroy disease registries. Moreover, various European countries such as the Netherlands, Belgium, Denmark and Sweden explicitly allow for use of tissue left over and stored after treatment, provided that additional safeguards to protect privacy and confidentiality are in place, opportunities to opt out of such residual or secondary use are available, and sufficient information about these practices is provided to patients.[7] Research among participants has even shown that such systems are preferred by most patients over systems of informed consent.[8] These may even be considered ethically preferable to consent under particular circumstances.[9] Patient material is always stored in hospital biobanks/archives in the event that another diagnosis later on in life should be necessary (primary re-use). This is especially the case for pathology tissue. These samples are also used for research (secondary use) under the circumstances that there is enough tissue left over and privacy and dignity is guaranteed. It would not be responsible to not store these samples, as it is in the interest of the patients themselves. Giving patients the possibility to opt-out for secondary	15. Individuals must be given the opportunity to decide whether their ~~**identifiable**~~ information **and/or their biological sample will be excluded from or** will, or will not be included in a Health Database or ~~**their biological material in**~~ a Biobank. As part of **this** ~~**consent**~~ process **and as far as provided under national law**, individuals must be informed about the purpose **or categories of purposes** of the Health Database or Biobank, the nature of the data or material to be collected and about **entities** ~~**who**~~ **that** will have access to the Health Database or Biobank. They must also be informed about the governance arrangements and the means that will be used to protect the privacy of their information. **For biobanks, donors shall also be informed that if the biological specimen donated to the biobank is ineligible the biobank has no obligation to carry out the storage of the sample.**

[7] Veen E-B van. Europe and tissue research: a regulatory patchwork. *Diagnostic Histopathology*. 2013;19(9):331-336. doi:10.1016/j.mpdhp.2013.06.017.
[8] Vermeulen E, Schmidt MK, Aaronson NK, et al. Opt-out plus, the patients' choice: preferences of cancer patients concerning information and consent regimen for future research with biological samples archived in the context of treatment. *J Clin Pathol*. 2009;62(3):275-278. doi:10.1136/jcp.2008.061069; Hoeyer KL. Donors Perceptions of Consent to and Feedback from Biobank Research: Time to Acknowledge Diversity? *Public Health Genomics*. 2010;13(6):345-352. doi:10.1159/000262329.
[9] Giesbertz NAA, Bredenoord AL, Delden JJM van. A Thick Opt-Out Is Often Sufficient. *The American Journal of Bioethics*. 2013;13(4):44-46. doi:10.1080/15265161.2013.767962.

	use for research purposes is the best thing to do. It is also not possible to inform individuals in those circumstances 'as a part of the consent process. It is however possible to inform individuals about the *purpose* of the Health Database or Biobank (e.g. via clear information on the website) in general. The obligation to provide information about the *nature* of the data or material is also provided under article 12 of the European Directive on the Protection of Personal Data (Right of subject access), as well as in many national laws. --- Individuals should be given the opportunity to decide for every kind of information, not just for "identifiable" information. --- There is an important link between article 15 and Article 18. Does Article 18 on broad consent implicitly excludes conditions of detailed purpose and scope in article 15? --- Suggest a clarification/separation between conditions of living and diseased, as conditions for direct consenting would obviously not apply to diseased.	--- Specify the link --- Plan specific provisions about deceased persons and link with national laws and governance mechanisms where individual autonomy cannot anymore exercise. Respect for privacy must continue after the death of the patient/donor/research participant.
16. Individuals have the right to solicit and be provided with information about their data and its use as well as to request	This wording suggests obligation for providing and correcting individually tailored information for all Health Databases and Biobanks. This would amount a huge administrative, logistic and financial burden in many cases, particularly those cases where data is collected, stored and used in	16. Individuals have the right to solicit and be provided with information about their data and its use as well as to request necessary corrections of mistakes or omissions **for Health Databases and Biobanks serving purposes of individual care**.

necessary corrections of mistakes or omissions.	a distributed fashion. It would be almost impossible to provide each individual with information in which research their data or samples are used and what the outcomes are in all cases. We would suggest delimiting the scope of this article to Health Databases and Biobanks serving purposes of individual care.	
17. Individuals must have the right to, at any time and without reprisal, withdraw their consent for their identifiable information to remain included in a Health Database and their biological material to remain in a Biobank.	See comments for article 15. --- We suggest a different approach to this issue by providing some additional practical details. --- "Right to at any time and without reprisal withdraw" raises questions about prior use of data. There are needs to insert some limitations / provisions as it is impossible to un-use data and samples that have been published. It would also be unethical and a waste of research to do this. Does this article permit the removal also from national registries such as cancer registries, which are important for social and economical aspects of national health care systems. Therefore this article needs to be more articulated to limit the conditions under which this can happen. These would be outlined in the consent. --- "Individuals […] at any time without reprisal…" The word reprisal seems to be a bit strong and irrelevant for the purpose of this article. "*Reprisal*" should be replaced by the words "harmful consequences".	17. Individuals must have the right **to apply to the chief processor**, at any time and without **harmful consequences**, to withdraw their consent for **or opt out of** their identifiable information to remain included in a Health Database and their biological material to remain in a Biobank. **Withdrawal of consent should automatically entail deletion of all identifiable data and destruction of biosamples.** **Where destruction is impossible and justified by legitimate interests of the responsible persons, the full and irreversible anonymisation of the biological resources must be implemented by the destruction of data and keys enabling decoding/reidentification of samples and data in order to maintain them for scientific purposes in the same Database/Biobank**. **Any results already obtained from such biological resources can remain in the system and can be the basis for publications.** **Provided that they comply with law and regulation, any limitation to the right to withdraw must be outlined in the consent process.**

Between art 18 and 19		An article should be added between art 18 and 19 to foresee the case where data / biological samples have been already collected and it is not possible to (re)contact the subjects to ask for their inclusion in databases or biobanks.
18. If Health Databases and Biobanks are established to allow for multiple studies and if, during the consent process, all principle information about future use is provided, all relevant safeguards are secured, the use of health data or biological material is transparent, and if all use is explicitly approved by a dedicated, independent ethics committee, then conditional broad consent is acceptable. In contrast, blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable.	The term 'all principle information' is ambiguous and the article does not leave room for Health Databases and Biobanks which are exempt to requirements of consent. Moreover, the article does not leave sufficient scope to adopt opt-out systems for residual use of data and samples procured in health care, as explained in previous comments. In such cases, future use is by definition unknown at the outset. Given our remarks on article 21, and given that that article already covers the situations circumscribed in this article, we suggest erase the mention of a dedicated ethics committee in this article. --- The terms "conditional, open, blanket consent" are not as commonly used in the same manner as the Declaration seems to assume and need definitions. --- This is the most important article. The issue of blanket consent needs to be sorted out. There are different views. 1) favour patients knowing the future use of banked specimens – at least the general information, as to areas of research / type of studies / who will benefit/ which third parties are involved	If Health Databases and Biobanks are established **principally** to allow for multiple **research** studies and if, during the consent process, **as far as provided under national law**, **sufficient ~~all principle~~** information about future use is provided, all relevant safeguards are secured, and if the use of health data or biological **samples** is transparent**~~, and if all use is explicitly approved by a dedicated, independent ethics committee~~**, then conditional broad consent is acceptable. In contrast, blanket or open consent for future use of health data or biological material not envisaged at the time of collection is not ethically acceptable **if the purpose of collection of data and samples is primarily related to research**. **If Health Databases and Biobanks are established on the basis of data and tissue collected for other (usually care-related) purposes and if sufficient information about such collection, storage and use is provided, all relevant safeguards are secured, the use of health data or biological material is transparent, then an opt-out system is acceptable.** **The involvement of a competent ethics committee can be required by law, notably to decide whether a new individual information process is necessary regarding the context and type of consent used.** --- It should be described what "open", "blanket" or "broad" consent means, preferably in a table of definitions. --- Agreement on this point will be difficult. There should be the possibility of different types of banked resources, some obtained via "conditional broad consent", and other tissue obtained only with specific consent.

	in research 2) Art 18 as it stands seems limited and does not take into account the new IT / socio-economic tools that could transform research subjects into research partners over a long period of time. Should also emphasise the governance and privacy protection clause used at end of article 15. --- It is part of the autonomy of the donor to consent, after appropriate information, also to yet unknown projects. Therefore it is not necessary that the use of health data or biological material has to be explicitly approved by an ethics committee. This means that e.g. each project in which epidemiological data are analyzed by external users has to be approved by an ethics committee. --- The importance of appropriate training/education of professionals that gather the informed consent and those that administrate consents should be addressed.	Could formulate minimum dataset to be provided for the donor prior to consent for banking their tissues – maybe with opting out clauses from specific type of research e.g. on embryonic stem cells
19. In the event of a clearly identified and immediate threat where anonymous data will not suffice, the requirements for consent may be waived to protect public health. An independent, dedicated ethics commit-	The wording in this article is not in line with WHO International Health Regulations and national public health regulations concerning communicable diseases. The WHO International Health Regulations (2005), for instance, suggest a lower threshold for notifiable reporting and place the burden of responsibility on States Parties. --- Public health authorities want to intervene earlier and always follow the trail of just 1 patient	In the event of a clearly identified ~~**and immediate**~~ threat where anonymous data will not suffice, the requirements for consent may be waived **by appropriate legal authorities** to protect public health **in line with national and international health regulations**. ~~**An independent, dedicated ethics committee**~~ **Where, national laws does not allow such a waiver of consent,** an independent **competent** ethics committee should confirm that each exceptional case is justifiable.

tee should confirm that each exceptional case is justifiable.	backwards. Only then it can be decided whether the threat is also immediate. --- The pathogens are found in the lab. There is by definition a collection there. With a possible highly contagious pathogen, it needs to be a biosafety level 4 lab. The genetic code of the possible new pathogen will be shared in order to alert other labs and public health agencies. Ethical committees play no role here. A delay on samples collection can really represent a missed opportunity for outbreak response. You may need some time to obtain an approval by ethical committee and in the meantime you will not be allowed to start the collection.	
20. A dedicated independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes.	As an example, the Belgian Act on HBM indicates that (in the future), an ethics committee will need to provide a *positive advice* on the *aims and activities* of a biobank (Art.21 Act on HBM), not an approval of establishment. In addition, in Belgium, the biobank does not have to obtain an accreditation or approval from the Belgian Federal Medicine Agency. It only has to *notify* the Medicine Agency of its establishment and activities (future art. 22, § 1, first section of the Act on HBM). Therefore, the WMA declaration is stricter than the future law in Belgium on HBM. --- It refers to a "dedicated" ethics committee… what does it mean? Dedicated to what? The requirement for the ethics committee to be	A ~~dedicated~~ **competent** independent ethics committee **(for biobanks) or a committee charged with equivalent responsibilities (for databases, such as a privacy committee or data access committee)** must **approve** the **establishment** or the aims and activities of Health Databases and Biobanks used for research and other purposes.

	independent looks sufficient. --- Will this Ethics Committee work exclusively with Biobanks ? It shall also be planned that an existing Ethics Committee with other duties such as University Research Ethics Committee, or a Medical School Research ethics committee or a national health ethics committee can be involved. --- Ethics committees approve use of biobank's resources but with regards to health databases, a data access committee should evaluate access as the expertise is different. Otherwise the ethics committee needs to have an IT / data expert.	
21. The ethics committee must approve all use of data and human material (…)	"The" suggests that the ethics committee in charge of approval of use should be the same committee as that of approval of establishment. Moreover, actual use of data or tissue is often decided by other bodies than ethics committees strictly speaking. Since in most cases of residuary material no consent on the secondary use is required the ethics committee will handle the request for such use without assessing the type of consent in advance. --- Unclear how often and at what stages the research ethics committee has to be involved. --- Is the assumption that ethics committees may withdraw approval and halt research?	21. ~~**The**~~ **A** ~~**dedicated**~~ **competent** ethics committee **or a committee charged with equivalent responsibilities regarding data** must approve ~~**all**~~ **each or categories of** use of data and human ~~**material**~~ **samples** ~~**and decide on the *type of consent necessary***~~, taking into consideration risks and benefits of the activity. --- *No specific proposal* --- Include possibility of sanctions being enforced.
22. Special considera-	Should the issue of sharing biobank tissue among	Need to address Articles 15 and 18 first, so the donors are aware of who has

tions should be given to the possible exploitation of intellectual property. Protections for ownership of materials, rights and privileges must be considered before collecting and sharing the material.	research communities be made explicit? This deals with researchers' rights – depends on local legislation which will vary from one country to another regarding IP. --- We cannot always speak of "ownership" about human material, instead the word "guardianship, custodianship or stewardship" should be used. There is also here a risk of confusion between intellectual property rights and the other prerogatives on the resources.	rights on the donated material. --- Switch the two sentences of the article for better clarity: "Protections for **guardianship/custodianship/stewardship of human biological resources**, rights and privileges must be considered before collecting and sharing the material. Special considerations should be given to the possible exploitation of intellectual property **rights**".
25. An appropriately qualified physician should be appointed to safeguard Health Databases or Biobanks with responsibility for ensuring compliance with this declaration.	See previous comments on individualistic framing of the obligations involved in the Declaration. --- It is not clear why should the appointed person be a physician? As an example, has every biobank to have a physician to be the responsible person? Prefer "qualified person" as it may be much more relevant to not have a physician appointed for doing that task! We suggest that this person can be any appropriately qualified person, not necessarily a physician. Replace "physician" by "qualified person" --- What is being considered here? Legal sanctions? Fines? Black listing? How enforceable will this be? This will prove difficult for one person unless there is robust legal backup.	An appropriately qualified ~~**physician**~~ **person and governance arrangement applying to any individual working with the Databases/Biobanks** should be ~~**appointed**~~ **in place** to safeguard Health Databases or Biobanks with responsibility for ensuring compliance with this declaration. ---
26. Governance arrangements must	No mention is made of feedback of (clinically relevant) findings. Consensus seems to have	Add clause to 26: **Governance arrangements must include:**

include: …	emerged over the need to at least establish policies for dealing with sufficiently grave clinically relevant findings (i.e. 'the rule of rescue'). --- Principles for governance arrangements now do not include any mention of reciprocity, involvement, engagement and accountability. --- It refers only to data collection and it should include also biological samples collection.	- **How and if incidental findings relevant to contributing individuals' health will be identified and fed back to them;** - **Arrangements for ensuring transparency and accountability;** - **Arrangements for patient, public and/or community engagement wherever appropriate; education and training** - **Contingency plans, discontinuation plans, review, standard operating procedures (e.g. for recruitment, collection, processing, storage/registration, removal/ destruction, QA/QC, audits)** --- "…obtaining appropriate consent or other legal basis for data **and/or biological samples** collection".
General comments	The Declaration does not contain articles dealing specifically with children and incapacitated persons. --- The policies – again- should include health education for people (professionals and participants), in the last years only individuality have been protected. --- Concern that the Declaration deals only with data collected by health professionals for caring for their patients. In fact epidemiologists are using more and more administrative data which are generated for administrative and financial purposes (reimbursement for example) and in this case consent is usually not asked to patients and their recording is compulsory. In most of the practical situations it's very difficult and often impossible to contact the individuals for asking a formal consent for using their data. --- Provisions for linking, sharing and pooling data	Include a new article or reference to relevant texts covering this issue. --- Insert an article 27 dealing with education of participants to biobanks and databases and training on best practices for professionals involved. --- Insert an article which deal with the data of patients used by the epidemiologists. --- Add an article similar to the article 22 about special considerations for intellectual

	and material from different databases and biobanks are entirely absent. Health databases and biobanks should not just be regarded as stand-alone entities in their own right, but rather as embedded in healthcare organizations as well as part and parcel of and feeding data and samples into research networks.[10] In order to bring ethical guidance to the burgeoning field of data- and sample-driven research, the ethical obligations involved should be framed in a more layered, distributed and process-oriented fashion as well.	property rights?

[10] Kaye J. From single biobanks to international networks: developing e-governance. *Hum Genet*. 2011;130(3):377-382. doi:10.1007/s00439-011-1063-0; Knoppers BM, Harris JR, Tassé AM, et al. Towards a data sharing Code of Conduct for international genomic research. *Genome Medicine*. 2011;3(7):46. doi:10.1186/gm262; Kosseim P, Dove ES, Baggaley C, et al. Building a data sharing model for global genomic research. *Genome Biology*. 2014;15(8):430. doi:10.1186/s13059-014-0430-2.