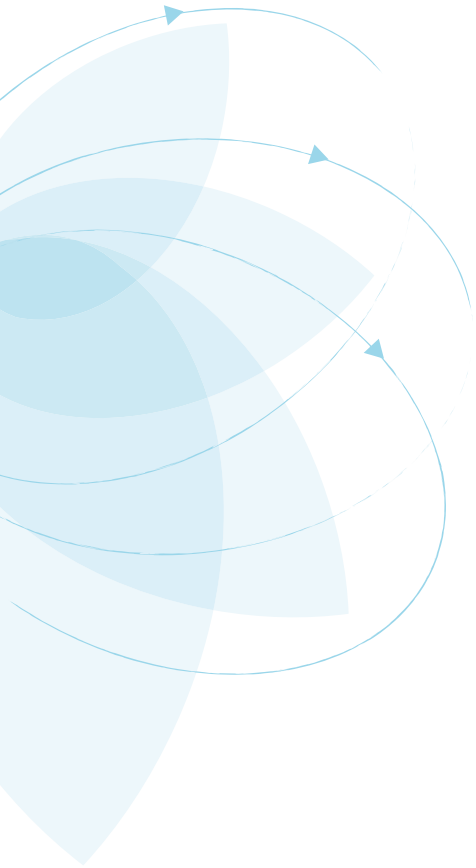

EVALUATION REPORT V1 / 2017 NATIONAL CONSENT

MANDATE SWISS ACADEMY OF MEDICAL SCIENCES

SWISS BIOBANKING PLATFORM
Avenue d'Echallens 9, 1004 Lausanne - Switzerland
+41 21 314 52 84 - info@swissbiobanking.ch - www.swissbiobanking.ch

1) INTRODUCTION AND CONTEXT

Swiss Biobanking Platform (SBP) is the national coordination platform for Swiss biobanks, initiated by the Swiss National Science Foundation. As an independent body, SBP supports Swiss institutions in their quality efforts for research excellence in compliance with legal requirements and professional/ethical standards.

SBP has been appointed by the Swiss Academy of Medical Sciences to evaluate the v1 / 2017 version of the national consent. For this task, SBP has consulted several stakeholders whose opinions have been considered essential for a comprehensive and relevant evaluation. Among the consulted parties there were:

— Expressing the Swiss institutional position, the five University Hospitals (Inselspital represented by Danielle Krebs, CHUV represented by Cindy Roth, University Hospitals of Geneva represented by Dr Caroline Samer, Universitätspital Zürich represented by Francisca Jörger, and Universitätspital Basel represented by Julia Maurer) and Kantonsspital Aarau (refer as Institutions)

— Expressing the ethical and societal position, the Interface science-société (ISS) - UNIL, Lausanne led by Alain Kaufmann, sociologist and biologist, and his team members, including Nolwenn Bühler, medical anthropologist; Gaia Barazzetti, researcher philosopher and ethicist; Séverine Trouilloud and Delphine Ducoulombier, scientific mediators at l'Eprouvette (refer as ISS)

— Expressing the patient/consumer position, Swiss Patient Organization (SPO/OSP represented by Franziska Sprecher and Margrit Kessler), Fédération suisse des patients (FSP represented by Rebecca Ruiz and Brigitte Kohler), and Fédération Romande des Consommateurs (FRC represented by Sophie Michaud Gigon and Joy Demeulemeester) (refer as POs)

— Expressing the point of view of the research community working with biological resources at the European level, BBMRI, the supporting infrastructure for European biobanks and in particular the Common Service ELSI which provided its expertise regarding ethical, legal and societal aspects (refer as BBMRI)

— To guarantee compliance with the Swiss data protection system, the Federal Data Protection and Information Commissioner (FDPIC)

The positions received were submitted for further assessment to the SBP Advisory Board (list of members in Appendix 1), which consists of multidisciplinary Swiss experts from the research and health communities including professionals with legal and ethical expertise.

2) SUMMARY OF KEY POINTS RAISED BY CONSULTED STAKEHOLDERS

As per of March 20, 2018, four stakeholders out of the five mentioned above have taken positions. Of note, the FDPIC gave up taking a stand.
Comments made by consulted parties have been summarized below into 9 key points. The parties which have raised the concern are listed under each statement.

1. LACK OF CLARITY IN THE TERMS AND FORMULATIONS USED

The version v1/2017 of the national consent, as well as the previous version submitted to consultation, is considered complex for the understanding of the participants.

Stated by: BBMRI, Institutions, ISS and POs

2. LACK OF TRANSPARENCY AND TRUST

Along this line, the lack of transparency in the information provided to the participant is another key point highlighted by the consulted parties. Indeed, transparency is an essential element for gaining people trust who are likely to donate

their data and/or biological samples for research. In particular, the present version does not detail enough sensitive points which could potentially worry the participants (e.g. public/private partnership or risks related to access). Additionally, it does not describe enough the procedures affecting their rights directly (e.g. participant withdrawal and return of results procedures).

Stated by: BBMRI, Institutions, ISS and POs

3. OPT OUT

The issue of non-opposition has led to several discussions during the February-March 2017 consultation and remains one of the most debated issues. All the consulted parties have questioned the procedures for exercising the non-opposition right as proposed in version v1/2017. Many of them have raised doubts about the legality of the implementation of this right, stating in particular that the "no" answer should mean an absolute refusal to consent and should not be understood as a tacit agreement for potential use.

Stated by: BBMRI, Institutions, ISS and POs

4. SCOPE OF CONSENT

Limiting the scope to medical research and future research projects only is considered too restrictive. Other types of research as well as already existing research projects should also be allowed under general consent.

Stated by: BBMRI, Institutions and ISS

5. TRANSFER ABROAD

The transfer of data and/or biological samples abroad has raised comments on its practical aspects. Conditions under which transfer abroad is allowed have to be clearly established (i.e. security level, type of consent, type of biological resources).

Stated by: BBMRI, Institutions and POs

6. ALIGNMENT WITH THE DECLARATION OF TAIPEI

Another important point highlighted is the need for the consent form to be compliant with the requirements of the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks of the World Medical Association. Consent can only be used when the appropriate governance structures and rules (in particular §21 Declaration of Taipei) are in place and explained to the participants.

Stated by: BBMRI, Institutions and POs

7. ADDITIONAL SAMPLING

The consulted stakeholders have also raised an issue concerning the additional blood sampling. Indeed, the framework conditions, such as the purpose of the blood test and the application of this procedure (frequency, the extent of validity of the consent), are considered imprecise. Besides, the difference between further use of biological samples and additional sampling is considered confusing for participants and requires additional explanation.

Stated by: Institutions and ISS

8. GENERAL CONSENT FOR MINORS AND ADULTS INCAPABLE OF JUDGEMENT

The issue of separate forms for minors and adults without capacity of judgement is an example of divergent positions. While hospitals report difficulties in implementing three distinct forms for the three groups (adults, adults incapable of discernment, and minors), patient organizations welcome this initiative to have a different consent form for persons without capacity of judgement.

Stated by: Institutions and POs

9. ALIGNMENT WITH THE GENERAL DATA PROTECTION REGULATION (GDPR)

European experts have questioned the compatibility of this consent form with the upcoming General Data Protection Regulation (GDPR), which will enter into force on May 25, 2018. In particular, they have stressed the difference in terminology used (e.g., "coded" vs "pseudonymised") and have raised the incompatibility of the implementation of the right of opposition with the European regulation (Recital (32)).

Stated by: BBMRI

3) CONCLUSIONS

To date, the v1 version of the national consent published in July 2017 has not been used by any of the University Hospitals. Patient organizations have also requested the withdrawal of this version, particularly given the legal issues it raises. For this reason, the cantonal research ethics committee in Tessin and cantonal authorities together with the dean office in Vaud have recommended not to use this version in their respective cantons until a version addressing these points will have been agreed upon. Furthermore, the Federal Data Protection and Information Commissioner (FDPIC) gave up in taking position, but explicitly mentioned that this should not be interpreted as a tacit agreement of the form, preventing to raise any conclusion regarding the compatibility of the form with the data protection legislation. In addition, the Data Protection and Information Commissioner from Neuchâtel and Jura has published on February 2018 an opinion concerning research with health data and biological material that questions the validity of the SAMS General Consent Form (https://www.ppdt-june.ch). Finally, BBMRI has also expressed some concerns about fundamental issues, including the right of opposition and its compatibility with the upcoming GDPR. Such situation is problematic as the Swiss research community lacks a practical tool necessary for collaborations and exchange of data and biological material within Switzerland and at the European and international level.

In conclusion, we would like to remind the interest that parties have expressed by participating in the February-March 2017 consultation. Indeed, 67 positions were received, the vast majority of which supported the process of developing a unique consent form for the whole Switzerland. Despite a large number of comments and divergent opinions on certain aspects, the version available for consultation has been considered as a working document. Therefore, it is unfortunate that version v1 of the national consent, which should have taken into account the comments and remarks raised during the consultation, is considered to be less suitable than the previous version and remains unused. Finally, many consulted parties have complained about the lack of transparency and of a participatory approach during the development process.

4) RECOMMENDATIONS

In view of the non-application of the current version of the general consent form based on the above-mentioned concerns of the main stakeholders, several recommendations have been formulated to develop a workable document:

1. The drafting process of the new workable version should be clarified in order to include all relevant stakeholders in a transparent and consistent manner and in particular to involve patients' and society representatives, legal and ethical experts, representatives of the 5 University hospitals as well as social scientists.
   Our consultation has indeed outlined divergent opinions on several points, stressing the need to open the discussion with interested parties on:
   - **risks**, especially those regarding the access to data (insurance, employer, third party, medical staff)
   - **opt-out** implementation (pros and cons, compatibility with the Federal Law on Data Protection and European GDPR)
   - **scope** of consent to be clarified (e.g. inclusion of 1) **additional sampling**, 2) use of **anonymized** material and/or data)
   - **transfer abroad** (need of a specific consent?, transfer rules)
   - **return of results** (incidental findings, procedure, what types of results are returned to participants?)
   - consent form for **minors and adults lacking capacity**

2. The current version should not be used as a basis for drafting a new workable version. In view of the above-mentioned concerns it raises, this form should be withdrawn from SAMS, Swissethics websites. The version submitted to consultation in February-March 2017 was identified as more suitable.

3. Implementation of essential Governance documents (i.e. Biobank regulation and Material Transfer Agreement, see SBP templates currently submitted to public consultation) is a pre-requisite to the development of a new version. It is indeed

necessary to set the framework conditions in order that each biobank operates in accordance with the legal, Swiss and European, requirements and the international standards as expressed in the Declaration of Taipei.

4. Consistently, the new version should be developed to comply with applicable ethical and legal requirements as specified in SBP Consent Checklist (document in preparation).

5. In order to improve the understanding of the consent form:
- The terms used throughout the text should be uniformed and defined at their first appearance. Additionally, giving concrete examples shall enhance understanding.
- A communication professional should provide feedback on the wording to avoid complicated and incomprehensible phrasing and to help structure the document logically and appealingly.
- Patients, not only patient organizations, should test for comprehensibility and reader-friendliness.
- Systematic efforts should be made to harmonize glossaries among national initiatives (e.g. SPHN/ SBP).

6. In order to improve the public trust, the information given in the consent form should be as precise as possible.
To enhance trust, some propositions emerging from our consultation have been listed below:
- the possible private-public partnership
- the possible use of biological resources for genetic analyses
- explicit the revocation procedure and its consequences
- who has access to the data

Involving main stakeholders in the drafting process is also part of enhancing trust (see point 1 and questions to be addressed to find a consensus among interested parties).

7. Decision has to be made to clearly define the scope of the general consent and specifically address whether additional sampling should be part of the consent or should be proposed in a separate form. If it is decided to include additional sampling in the scope of general consent, then the framework conditions should be clearly established.

8. An implementation process should be developed in parallel of the drafting procedure.
This process should include:
- an assessment group, involving wide expertise and led by patient's organizations, responsible to evaluate implementation issues at national level
- a communication strategy relying on SBP Consent checklist to define the framework conditions when seeking consent (training and qualified personnel, think time, etc) and to harmonize practice among Institutions
- participative research to evaluate national acceptance of general consent.

5)
APPENDIX 1
LIST OF SBP ADVISORY BOARD MEMBERS

- **DR. KARIM BOUBAKER**
  Médecin cantonal VD
  Department of Health and Social Services, Lausanne

- **PROF. BERNICE ELGER**
  Head of the Institute for Biomedical Ethics
  Institute for Biomedical Ethics, Basel

- **DANIELLE KREBS, PHD**
  Bereichsleiterin
  University hospitals representative
  Inselspital, Bern

- **PD DR. MED. TANJA KRONES**
  Leitende Ärztin Klinische Ethik
  Geschäftsführerin Klinisches Ethikkomitee Universitätsspital Zürich
  Universitätsspital, Zürich

- **DR. MARIO LAZZARO**
  Médecin cantonal adjoint TI
  Vice-président Commission d'éthique de la recherche TI
  Ufficio del medico cantonale, Bellinzona

- **DR. PHIL. SIMONE ROMAGNOLI**
  Collaborateur scientifique
  CNE/NEK, Bern

- **PROF. DR. FRANZISKA SPRECHER**
  Assistenzprofessorin für Staats- und Verwaltungsrecht mit besonderer Berücksichtigung des Gesundheitsrechts, Universität Bern
  Patients' organization representative
  SPO Patienschutz, Zürich

- **PROF. DOMINIQUE SPRUMONT**
  Professeur ordinaire
  Directeur-adjoint de l'Institut de droit de la santé
  Vice-directeur SSPH+
  Président de la Commission d'éthique de la recherche de l'Université de Neuchâtel
  Institut du droit de la santé - Université de Neuchâtel, Neuchâtel