Ethical health data sharing in public-private partnerships

Guidelines

1. Partners must define an aligned vision for the PPP and how they create public value.
2. Partners should determine and agree upon fair distribution of benefits among themselves as well as with the public.
3. Partners must clearly define IP rights on outcomes at the start of a PPP, and not seek to patent or claim IP rights on data sets generated through Swiss Personalized Health Network (SPHN) funding.
4. SPHN-funded grantees should not negotiate exclusive use of data with private sector entities.
5. Data subjects should be informed about PPPs which utilize their data.
6. Partners should define how they plan to engage data subjects in the research activities enabled by the PPP.
7. All partners should agree on criteria to ensure due credit to the parties who provide the data, as well as to SPHN for funding the research activities leading to data collection.
8. After the PPP, partners should make data available for further public value, via deposit in public repositories with appropriate access controls.

Swiss Personalized Health Network
Swiss Academy of Medical Sciences
Haus der Akademien I Laupenstrasse 7 I CH-3001 Bern
T +41 31 306 92 95 I info@sphn.ch I www.sphn.ch

Preamble

Purpose of this document

This document provides guidance for SPHN-funded grantees and private sector entities (*together*: the PPP partners) who intend to negotiate and establish public-private partnerships (PPPs), primarily for the purpose of accessing data generated, collected, or curated in the context of a SPHN-funded research project. This could include among others molecular / omics data, patient data from hospitals and clinics, or clinical research data. With these guidelines, SPHN aims to support the negotiation of ethically robust and fair conditions for such PPPs. The types of data referred to in this document are those generated or used within the context of SPHN-funded research, but not yet shared within a PPP. Finally, a reminder that clinical data generated in health contexts (e.g., medical history, treatment data) is governed by regulations beyond those specific to a research setting, that must also be taken into account.

This document seeks to support parties during the negotiation phase and is intended to supplement legal agreements. Templates for legal agreements which are suitable for PPPs can be found on the SPHN Website (https://sphn.ch/services/dtua/). SPHN-funded grantees must follow these guidelines when entering PPPs. Upon the completion of a PPP agreement involving SPHN data, the parties must report to the SPHN Management Office the specifics of how they met the guidelines. The term “data” in this document refers to data generated, collected, or curated in the context of an SPHN-funded research project.

SPHN’s mission and the need for private sector collaboration

SPHN’s objective is to advance personalized health research and innovation for the benefit of society. To leverage the potential of health-related data, SPHN is building a dynamic, scalable network of data providers who will establish a nationwide exchange of health-related data and oversee its effective use. As using and sharing data generates benefits for society, SPHN encourages its grantees to share data resulting from SPHN-funded initiatives with other organizations to further research and innovation in personalized health.

SPHN encourages collaboration between private and public entities, as these collaborations can lead to unique innovations and research, and thus further SPHN’s mission. Private and public entities have access to distinct, yet highly synergistic resources. Public parties have access to unique research data, bring scientific and medical expertise, and follow a public

mandate. Thus they enjoy public trust, and can function as custodians of the public's interests and data. Corporate entities understand market needs, have drug and product development capabilities, and are responsible for a considerable share of health product/service delivery.

SPHN considers data generated through its funds to be a common good, which is non-excludable and non-rivalrous (Malkin & Wildavsky, 1991), and which aims to ultimately benefit the public. Such data should be made broadly accessible to all eligible parties.

In order to share SPHN-funded data with private sector companies, several requirements must be met. SPHN is committed to a clear set of ethical principles which should be upheld (see below and Ethical Framework on Responsible Data Processing in Personalized Health Research issued by SPHN, 2018[1]). Furthermore, SPHN-funded grantees receive public funds, both from SPHN and other resources. Private entities, in addition to prioritizing knowledge, are motivated by their fiduciary responsibility to generate a profit. These priorities are not necessarily at odds, but rather can serve the interest of the community to deepen scientific knowledge and improve medical treatments. If the interest of the community is at the heart of the PPP, profit-making interests should not be an argument against collaboration with private entities.
However, the success of these PPP will depend on transparency, data fairness, and recognition of the contribution of those who made their data available for research.

PPPs are defined as "collaborative models based on a contractual agreement between (a) at least one not-for-profit organization and (b) at least one for-profit organization" (Stevens et al., 2013). PPPs combine the assets and strengths of for-profit and not-for-profit organizations. Examples of not-for-profit organizations include public-sector institutions, (inter)governmental agencies or civil society bodies, non-governmental organizations, and academia. For-profit organizations in the SPHN domain include pharmaceutical, medical device, biotechnology, and other technology-related companies.

In the context of the SPHN, PPPs must jointly define issues regarding access to resources, accountability, transparency, conflicts of interest, and intellectual property. PPPs can be

[1] https://sphn.ch/network/projects/elsi-projects/

established as collaborations for specific projects or as long-term partnerships, both bi-lateral and multi-lateral.

Challenges in public-private collaboration

Data sharing between public and private entities presents challenges that must be balanced against expected benefits and opportunities. These challenges relate to aligning the objectives of the PPP and addressing priorities which may diverge (e.g., applicability vs. basic research), distributing benefits fairly, minimizing and acknowledging conflicts of interest, making data widely accessible, giving credit to data providers, maintaining and fostering public trust, obtaining informed consent about data use, and engaging those whose data are used, as well as acting transparently and accountably.

When these challenges are tackled accordingly, PPPs can promote ethical data sharing in line with SPHN's mission. The eight guidelines of this document set out how these challenges should be addressed.

Foundational SPHN principles

The following guidelines seek to ensure that PPPs which involve SPHN trustees or SPHN-sponsored projects comply with the principles outlined in the Ethical Framework for Responsible Data Processing (SPHN, 2018). This Ethical Framework provides guidance on issues relating to collecting, storing, analyzing, and sharing data for SPHN-funded research, and is built on four principles:

- Respect for persons: The rights and dignity of individuals, families, and communities contributing personal data and/or human biological material in the context of research and clinical care, as well as any other type of data that can be useful for biomedical research, must be respected, protected, and promoted.
- Privacy: The privacy of data subjects and the confidentiality of their personal information must be safeguarded.
- Data fairness: Research data and results should be made available for further research use, to advance the common good of scientific knowledge.
- Accountability: Accountability mechanisms should ensure fair, lawful, and transparent processing of personal data and handling of human biological material.

Recommendations

Based on these four principles and informed by the outcomes of stakeholder engagement sessions, the ELSI advisory group has developed eight ethical recommendations for SPHN-funded grantees entering PPPs. A list of meeting attendees and workshop objectives are provided in the Appendix.

1) Partners must define an aligned vision for the PPP and how it creates public value.

a. What does it mean?

Before commencing a partnership, parties must align on a vision of how they will create public value, with clear benefit for society and citizens at large. Throughout the partnership, the aligned vision should be the guiding priority for diverse entities with oftentimes complex and diverse interests.

In the context of the SPHN, PPPs' visions should consist of improving health knowledge, treatment, and health care, with reference to public health priorities when possible, e.g., the Swiss Federal Council's *Health2030* strategy (FOPH, 2019).

b. Why does it matter?

Research has shown that PPPs are more successful when a clear vision is identified and followed (Carol & Sang, 2008). This promotes accountability and data fairness as well. The need for aligned vision arises from the differing incentives of public and private institutions. Public entities' mandate to further the common good may take various forms (e.g., advance scientific knowledge, improve public health, uphold laws and regulations), while private entities are responsible to their investors and must generate a profit. To ensure successful collaboration, these misaligned incentives require resolution.

Resolving diverging interests is particularly complicated in the context of contemporary healthcare, where a multi-stakeholder landscape requires wide collaboration (Vayena, 2021). This is especially true in the case of health innovation involving big data. Digital health promises significant improvements in public health and life quality, while requiring wide access to compartmentalized and siloed data, deepening the need for collaboration.

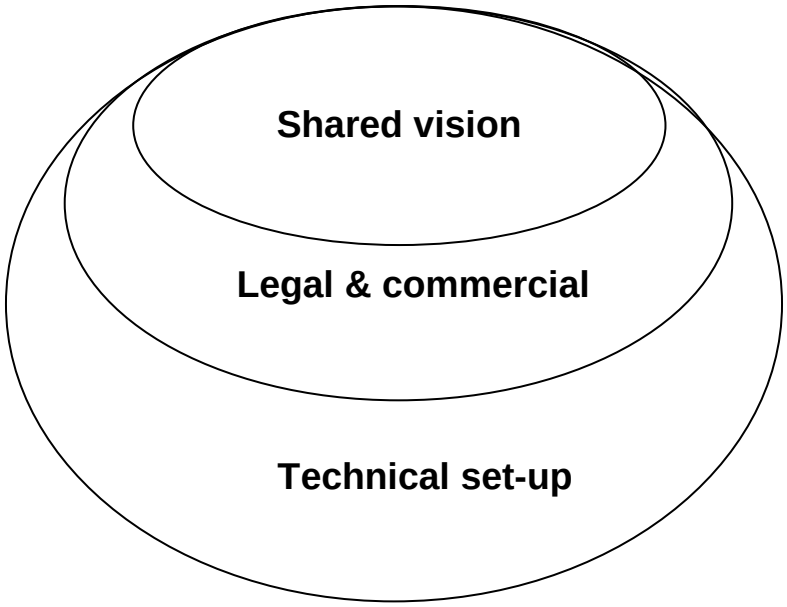
Advancing a jointly identified common good builds trust among PPP partners, reduces the risk for conflict, and ensures that partners focus and work in the same direction. Generating public

utility also lends PPPs legitimacy, which is necessary for the profits of private entities, that serve as a reward for their involvement and risk taking. Partners must also clarify how they will jointly approach moral and social trade-offs. When conflicts arise, an aligned vision that promotes accountability and data fairness offers a clear path to reconciliation.

c. How to achieve it?

Early in a PPP, partners should clearly identify which problems or opportunities in public health and healthcare the PPP will address. The aligned vision should help define the technical, legal, and commercial aspects of the PPP. Parties should agree on the types and amount of data, availability of metadata, data curation principles, and security measures and time limits on data access. It is helpful to create use-cases that are clearly limited to the aligned vision. Any further or additional use would require revision of the aligned vision and the PPP agreement.

When finalizing PPP negotiations, entities must agree on clear, meaningful, and measurable key performance indicators (KPIs) for consistently tracking how their aligned vision is advanced, during and after sharing data. Specific use-cases should be reviewed periodically, and partners should evaluate whether the data exchange has furthered the identified vision.



2) Partners should determine and agree upon fair distribution of benefits among themselves as well as the public.

a. What does it mean?

Data sharing partnerships must be based on mutual benefit and fairness. In the context of SPHN, overall benefits are envisaged as responsible innovation in the field of personalized health and improved health care for the public. This may take the form of innovative treatments and new knowledge in health and medicine. In this way, benefits derived from the data will be of utility to the data subjects.

b. Why does it matter?

PPPs require a clear definition of fair distribution of benefits, with clarity about the outcomes for various stakeholders. The principles of data fairness and accountability provide the ethical rationale for defining these benefits. Since data are derived from data subjects and collected by public entities with a public mandate, a fair distribution of benefits is morally required. Such fair distribution is here not understood in an egalitarian sense, with each party receiving the "same bundle" of material goods (Lamont & Favor, 2017), but in a utilitarian sense, which assigns value to maximizing welfare. Material goods and services have no intrinsic value except insofar as they increase benefit for society. In this spirit, data subjects should not expect compensation, and institutions should not expect a financial surplus beyond covering expenses, when contributing data for research. Their voluntary sharing of data, however, underscores the moral necessity of distributing benefits fairly.

Through the fair distribution of benefits to all stakeholders, trust can be increased between PPP parties and the public. This requires high standards in curating data, enhancing data accessibility, and sharing results open access.

c. How to achieve it?

The value of data varies depending on the type of data used and the purpose of use, and may vary over time. Different stakeholders might have different views on the value of the same data set. It is therefore advisable to focus on the outcomes and expected benefits of data use.

When establishing a PPP, each party determines what they consider to be a fair distribution of benefits. The following criteria should be used:

- What is the value of the expected outcome for the partners in the PPP and the public, both short- and long-term?
- Are the expected benefits distributed fairly – do parties feel that the benefits are shared in a manner proportional to respective contributions and risks?
  - If not, why? How is this justified?
  - Are there long-term benefits that may outlive the PPP?

Based on these considerations, PPP partners determine a value exchange model to define how benefits will be shared. While a fair distribution of benefits typically indicates the balance of interests between the PPP partners, a further key focus in SPHN-funded PPPs is to generate benefit for society. The following describes four potential models of value exchange:

- Equal contribution models: Exchange of data based on equal contributions of each partner (in terms of time and effort)
- System-wide models: Exchange of data with the aim to create system-related value, e.g., additional expertise, tidied data, or improved healthcare processes
- Future potential models: Exchange of data for a stake in a product, company, or share of profits from a product or service developed
- Monetary models: Exchange of data for a fee/one-off payment or discount on a product (for more detailed information see Harwich & Lasko-Skinner, 2018.)

While each of these models can be designed to incorporate a fair distribution of benefits, equal contribution models, system-wide models, and future potential models are favored for SPHN-funded grantees. The monetary model describes a rather outdated value exchange model that, in the context of SPHN, should be limited to receiving payments to cover the costs of data generation only. For-profit selling of data is not allowed in any circumstances.

The models above provide an overview of existing approaches. Partners of a PPP are encouraged to think beyond these models and to advance other ways to trade data that consider the interests of all parties, including data subjects. Examples include returning general (or, where possible, individual) research results to data subjects, or engaging the public as an active stakeholder in data sharing activities.

3) Partners must clearly define intellectual property (IP) rights on outcomes at the start of a PPP, and must not seek to patent or claim IP rights on data sets generated through SPHN funding.

a. What does it mean?

Establishing successful PPPs requires a clear definition of how IP rights will be handled, for data sets or other "research products" (such as drugs or algorithms) generated through SPHN funding. However, core differences exist between data sets and other outcomes.

Data sets

PPP partners must not place IP on the data sets with which products or algorithms are developed, rather only on the outcomes of data use (e.g., developed products or algorithms).

Research products

For products that are developed through a PPP, IP rights must be handled as defined in the SPHN legal agreement templates (see https://sphn.ch/document/template-consortium-agreement-dtua-dtpa-multiple-nodes/). The templates suggest two alternatives: 1) The IP is jointly owned by the parties, or 2) the IP is jointly owned by the parties for common works, and is otherwise solely owned by the party generating it.

b. Why does it matter?

IP is placed on the outcome of the data use rather than the data set itself; any data set alone is of limited value. Under Swiss law, it is not possible to assert IP rights on the data concerned in our case. In algorithm development, using several data sets to build and test the algorithm is essential. For data to take on value, data sets must come from different sources. Isolated data sets usually have lower value than data sets which can be linked. Placing IP on a data set restricts its value, contravening the goal of public benefit.

c. How to achieve it?

PPP partners should define IP rights in the legal agreement. In addition, they should attach a statement on *IP and data* to the legal agreement, specifying that data are excluded from any IP.

4) SPHN-funded grantees should not negotiate exclusive use of data with private sector entities.

a. What does it mean?

Data access is essential to advances in disease prevention, medical practice, and treatment innovation. Data collected or generated from SPHN funding should, to the extent possible, be considered a public good and should therefore be made available for use by as many research groups as possible, to maximize its potential scientific outcome. Allowing exclusive rights over data sets would favor certain entities and prevent the wider scientific community from accessing valuable data, perpetuating the creation of data silos.

Therefore, exclusive access rights to data collected or made available in the context of SPHN-funded project shall not be granted.

b. Why does it matter?

In line with SPHN's mission to promote responsible innovation in personalized health, broad data access is needed to harness its full value. The ethical rationale for refraining from exclusive access rights is SPHN's commitment to data fairness. To obtain as much potential scientific knowledge from each data set as possible, all eligible researchers should be allowed access to a data set.

c. How to achieve it?

Data held by SPHN-funded grantees and shared in PPPs should be broadly accessible. Research groups may access data if their individual members are employed or associated with an institution that is a SPHN grantee or a contract party to a PPP. Data should be shared only as described in a research protocol approved by the competent ethics committee, according to the applicable law or the ethics review mechanism of the institutions involved.

5) Data subjects should be informed about PPPs which utilize their data.

a. What does it mean?

Those whose data are used should be made aware that their data will be used by private sector entities as part of a PPP. The following principles should apply:

- To the extent possible, timely and transparent communication about who will potentially use the data, the purpose of the data use, and value for the public good

- Broadly accessible communication on institutional websites
- Dissemination of results of the PPP to the data subjects' community (e.g., hospital-level communication)

If access and use of data by private sector entities is expected at the time of data collection, this should be made explicit in the informed consent. Informing subjects adequately before collecting data is the easiest way to be transparent about data use, and allows potential participants autonomy to make a decision. Despite public interest in biomedical research and a general willingness to provide data, studies have shown that people make a distinction between publicly funded and privately/corporate funded research, with concern about commercial entities using their data for profit (Ipsos MORI, 2016; Vayena et al., 2014; Brall et al., 2021; Ghafur et al., 2020). Acknowledging this distinction as meaningful, it is important to ensure that prospective data subjects are duly informed.

In the case of existing data, potential reuse depends on the type of data (identifiable, pseudonymized/coded, anonymized) and the specifics of the previously obtained consent. In the interest of transparency and public trust, if data is to become accessible to private sector entities, this should be ideally communicated to data subjects even when obtaining new consent is not required (at a minimum and to preserve anonymity, this could be done via announcement on the SPHN website).

b. Why does it matter?

The principles of respect for persons, truthfulness, accountability, and trust form the underlying ethical rationale for the requirement to inform data subjects about data use by PPPs. Potential or existing data subjects should have the autonomy to determine in what manner their data is used. By employing truthful communication and accountability in the consent and follow up process, PPP partners maintain the trust of both data subjects and the public.

In the case of preexisting data sets, for which data subjects were not informed about the potential of PPP use, respecting the right of participants to choose is more complicated. In the case of anonymized data, contacting the original data subject is not possible. Providing information about the possibility of sharing data with private sector entities before data collection can simplify the process of controlling data after original consent and improve the feasibility of managing large data sets.

c. How to achieve it?

Many of the relevant points are regulated by the Human Research Act, in particular Articles 7, 17, 18, and 32-35. However, these legal regulations should be seen as a minimal requirement, and we urge all PPPs to actively strive towards maximum transparency. Data subjects should be informed about the use of their data within PPPs as early as possible, and latest at the time of initial consent. In addition, data subjects should be educated about the benefits of data sharing by public and private entities (see guideline 2) and the potential value for the public good.

When it is not feasible to go back to data subjects directly, SPHN-funded grantees who share those types of data in PPPs must inform them on an institutional website before the start of the PPP, offering the possibility to revoke consent. These notifications must be published sufficiently in advance of the start of the PPP and minimally list the following:

- *With whom* data will be shared
- *Why* data is shared: The purpose and expected outcome of sharing the data
- *What* data is being shared: What type and volume of data are being shared and in which form (anonymized, pseudonymized/coded, identifiable)
- A contact point for any queries

SPHN grantees may continue to use data from data subjects who decline PPP use, but cannot share such data in the PPP.

6) Partners should define how they plan to engage data subjects in research activities enabled by the PPP.

a. What does it mean?

Data originates from individuals, and data subjects and members of the public are important (but often passive) stakeholders in data sharing activities. Inclusiveness of all stakeholders should be a central part of the planning and development of a PPP. PPPs should define how they will engage the public and data subject representatives (e.g., advocacy organization leaders, participant representatives) in their research. Thus the interests of data subjects are recognized, by promoting public dialogue about data sharing, involving patient advocacy groups or members of the public in PPP negotiation, and communicating research results.

b. Why does it matter?

To maintain public trust and guide data sharing according to the interests and rights of data subjects, PPPs should actively engage data subjects and the public, based upon the underlying principles of accountability and respect for persons. This will result in greater acceptance of and support for data sharing activities, leading to more sustainable outcomes. Equally, representatives from PPPs can learn from public knowledge, which informs current practices.

c. How to achieve it?

SPHN will initiate such public dialogue in the 2021-2024 timeframe. All SPHN-funded grantees and their PPP partners should actively participate in these activities.

In addition, plans to engage data subjects should be created by a PPP. These may include:

- How and when to involve patient advocacy groups or members of the public (in the negotiation of the PPP, during its activities, and in subsequent evaluation)
- Topics on which engagement will take place (e.g., data access, return of results, communication to data subjects and the public). Individual data subjects should receive validated and medically relevant research findings (see Recommendation "Reporting Actionable Genetic Findings to Research Participants", SPHN, 2020).

7) All partners in a PPP should agree on criteria to ensure due credit to the parties who provide the data, as well as to SPHN for funding the research activities leading to data collection.

a. What does it mean?

All parties involved in a PPP benefit from shared data and should therefore agree on criteria to ensure acknowledgement of the parties that provided the data, as well as to SPHN.

b. Why does it matter?

The Swiss Academy of Arts and Sciences makes recommendations for authorship in scientific publications, stating that those involved in the research must be acknowledged for their "important scientific contribution to the planning, conduct, evaluation or control of the research work" (Swiss Academies of Arts and Sciences, 2013). Beyond analysis and publication, such acknowledgment should include data collection and sharing processes. Recognition of those parties providing the data (usually SPHN grantees) motivates and incentivizes data sharing in

general. Besides discouraging scientific misconduct and promoting scientific integrity, giving credit to those providing the data influences their reputation and research opportunities. The underlying ethical principles for giving credit are data fairness and accountability, specifically scientific integrity.

c. How to achieve it?

When negotiating the PPP, partners should specify in an attachment to the legal agreement the criteria for giving credit to those who provide data. These criteria should be defined for all outcomes of the PPP.

8) After the PPP, partners should make data available for further public value, via deposit in public repositories with appropriate access controls.

a. What does it mean?

Data resulting from a PPP should be made available in FAIR (findable, accessible, interoperable, and reusable) repositories; sensitive data should be made available upon reasonable request.

b. Why does it matter?

Making health data FAIR is a component of the mission of SPHN. Data used in PPPs should be made available in public repositories, to the extent reasonably possible. There is growing consensus that data sharing is an inseparable part of the research process (Blasimme et al., 2018; Gewin, 2016; Tenopir et al., 2015; Taichman et al., 2016; Krumholz, 2015). Sharing data not only improves the reproducibility and robustness of scientific insights (Editorial, 2018), but enables new discoveries. Since the future value of a data set cannot be predicted today, there is a strong argument for data sharing, and that not sharing would be an obstruction to scientists in the future (Editorial, 2018). Some even argue that investigators “implicitly agreed to a social contract, which includes the responsibility to make the raw data available” (Packer, 2018). Research data should therefore be treated as a knowledge commons. Given its objective to generate the greatest benefit for society, SPHN does not limit its data sharing activities to entities from the public sector, but aims to function as a hub for multiple stakeholders involved in data research.

It is important to note that open access research data does not disincentivize collaboration, as PPPs can often achieve results more efficiently than one party can alone.

c. How to achieve it?

All partners have a responsibility to ensure the data they gather and generate is properly managed and made accessible and usable by others. As SPHN grantees are handling sensitive human subject data, data be submitted to a public repository with appropriate access controls (e.g., Genotype-Phenotype repository).

Plans for data sharing should be considered from the earliest stages of negotiations and set out in a Data Management Plan, attached to the legal agreement.

Swiss Personalized Health Network
Swiss Academy of Medical Sciences
Haus der Akademien I Laupenstrasse 7 I CH-3001 Bern
T +41 31 306 92 95 I info@sphn.ch I www.sphn.ch

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