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Citizen-centred EU-EHR exchange for personalised health



WP1: Citizen- and Professional-User participation: user requirements and performance criteria

D1.4: 1st Citizen/User Consent Language Report

Deliverable Leader: UNIVIE

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Short Abstract

Deliverable D1.4 outlines a first set of insights concerning citizen/ user consent language in the framework of the Smart4Health project. It embeds this work into wider debates on the challenges of informed consent and describes the way a first version of the Informed Consent form for the use of the 4HealthPlatform was developed. It then reports the outcomes of co-creation workshops with citizens engaging with the informed consent form as well as the vetting by ethical and legal experts.

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D0.1	First draft version written by UNIVIE and sent out to HPI with requests for input.
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R0.1	Feedback from partners (EFN, HPI, ISMMS, ITTM, I-VLab); a subchapter on the vetting by legal experts was produced by HPI; a new version was prepared by UNIVIE, integrating the subchapter on legal experts as well as revising and extending parts of the report
F1.0	Final version ready for submission, of the report prepared by UNIVIE after feedback from internal reviewers

Contributors	Description
UNIVIE	Collect informed consent (IC) documents and procedures from partners; large cohort studies and the EC; review of the collected documents; extending a comparison of IC forms; conduct workshops and interviews with CUC partners, citizens and an ethics expert; analyse the transcripts of workshops; revise the S4H IC form; produce the report and integrate the partner feedback and contributions.
ISMMS, SHD, UKA, ZS-UG	Provision of IC documents and procedures.
HPI	Systematic comparison of collected IC forms and documents, Development of a first draft of the S4H IC (for the CHDP)

EFN, D4L, ISMMS, UNINOVA, UNIVIE	Provision of feedback on the first S4H IC draft.
HPI, UNIVIE	Redrafting of the S4H IC form.
EFN, D4L, ELIXIR-LU, HPI, HM, ISMMS, ITTM, I-VLab, KBZ, OSR, SHD, UKA, UMC+, UNINOVA, GovMad, UNIVIE, ZS-UG	Participation in monthly remote meetings of the Ethics Work Group (EWG) to discuss the IC form and proceedings in S4H.
HPI	Vetting of the S4H IC by a legal expert.
UNIVIE	Vetting of the S4H IC by an ethics expert and citizen group, and reformulation of the consent language in the IC form.
EFN, HPI, ISMMS, ITTM, I- VLab	Provision of feedback on the report, version D0.2

Further Information

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Executive Summary

The objective of Deliverable D1.4 is to outline a first set of insights concerning citizen/user consent language in the framework of the Smart4Health project. The central aim of Smart4Health is to develop a health-data infrastructure aiming at supporting citizens as future users to manage their own health (data). In doing so, the project puts European citizens centre stage – conceptually and methodologically. Designing and implementing informed consent procedures with and suitable for citizen-users are therefore central to the project. We do so in consideration of the GDPR and EU policy as well as of previous experiences made with informed consent processes.

Proposing a co-creation approach to building the health data platform and its services testifies to the consortium’s awareness that the final prototype must meet the needs and concerns of future users, both citizen- and professional users. Therefore, it is essential to ensure that also the informed consent processes meet this key objective. To achieve this objective, we studied existing informed consent forms and processes, analysed input from citizens partaking in co-creation workshops and had the first version of the informed consent form also vetted by experts on ethical and legal issues. This report marks a first step in this process which will continue all along the Smart4Health project, engaging with a diverse set of users in different contexts in order to better understand and refine the informed consent process.

The deliverable inscribes itself in the framework outlined in Deliverable D1.1 and to the co-creation process outlined in D1.2. Therefore, it is attentive to the four core values of inclusiveness, anticipation, reflexivity and responsiveness, which are seen as core to our work. Concretely, this meant for the deliverable (1) to **anticipate** issues that might emerge in offering citizens a space for uploading, storing and making accessible their health data and that must be addressed in an informed consent, (2) to be as **inclusive** as possible at this stage in developing and vetting this first version of an informed consent for the health-data platform prototype (chapter 3), (3) to **reflect** how the first version of the IC was produced (chapter 4), and (4) how potential future users perceive both the consent form and the process (chapter 5.1), and to ensure that the IC process and the supporting forms will be revised when new situations and/or regulations come up (**responsiveness**) (see Deliverables D8.1 and D8.2, which also address questions of informed consent, as well as D1.9, the follow-up report to this deliverable).

The report starts with a short introduction (chapter 2) to informed consent as a debate in the medical realm. It uses the recent report of the German Ethics Council on “Big Data and Health – Data Sovereignty as the Shaping of Informational Freedom” as a starting point, which clearly spells out what the advantages of data collection practices are, but also what ethical concerns should be considered. This is essential to sensitize readers and the consortium members to the fact that data collection always needs to be probed in terms of/for its ethical implications.

Chapter 3 presents five lines of general considerations in how to address informed consent in health-data related domains. They contain important context information for the next chapters which will describe the process as well as the outcomes. These considerations embraced in 3.1 reflect on the question of autonomy of data subjects and agency, which will be essential to consider when inviting citizens to engage with the Smart4Health platform. We then move on to 3.2, discussing the notion of

information in “informed consent.” This subchapter covers questions of informational obligation, it highlights the context dependency of any information provided as well as addresses issues of trust and data literacy. In the third part of this chapter (3.3) we touch on questions where data are located, and move in 3.4 to the question addressing if ‘donation’ would be regarded as the appropriate notion given the specificity of data. Finally, section 3.5 addresses a specific element of Smart4Health, namely the e-consent. While this is not yet relevant given the early development of the project, it will be important to start reflecting on it, as it will offer new ways to deliver informed consent.

Chapter 4 lays out in detail the process of producing the first informed consent form for the 4HealthPlatform. In the first subchapter (4.1) we describe in detail the production process. It is important to reflect on the considerations that went into the development, and to learn what we had overlooked in the early phase when it comes to the specificities of Smart4Health. In the second part (4.2) we describe the methodologies applied in order to elicit assessments of the form by potential users.

The core outcomes of the report are then captured in chapter 5, where we engage in detail with the co-creation workshops with citizens as well as with the vetting of the informed consent form by ethical and legal experts. In the co-creation workshops with citizens feedback was collected by going step by step through the informed consent form, discussing the information contained, what was missing (or what was too much) and the language used. However, they also reflected on the overall process of informed consent and how it was foreseen that future users could get answers to some of their concerns/questions. Their rich and valuable comments were summarised in 15 takeaways, many of which will flow into the reformulation of parts of the informed consent form. However, they will also need to be addressed in building the information environment of the platform (e.g. help desk etc.). At the same time, it is essential to see these comments as a first step in a longer process. All along the co-creation process we will collect further input by users and work on refining the process and contents of information given to users.

Furthermore, the ethical and legal experts gave us valuable advice. Part of it touches on user/citizens consent language, which is the core of this deliverable. The legal experts opened up further questions which the consortium will need to explore in the coming weeks.

Overall, the engagement with citizens as potential users showed the importance of the co-creation process. We obtained quite detailed reflections which transmit citizens’ concerns and attract our attention to sensitive issues that we need to be attentive to when developing the platform prototype. Hence, also the context of this report, in which we express the information needed by citizens to make an informed decision of whether or not to use the health-data platform Smart4Health, is developing. The report, however, also points to further work needed. More specifically, Smart4Health will have to engage with informed consent procedures in different national contexts and environments where Smart4Health is used (e.g. at work, in the hospital or from home) and thus also respond to different language environments and health care cultures.

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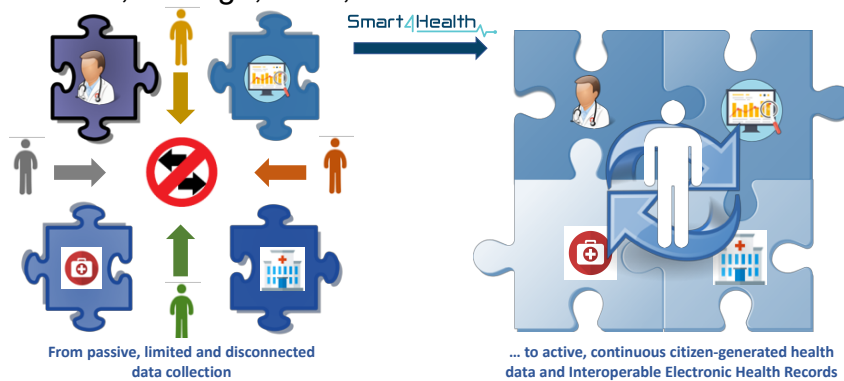
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1 Document Summary

1.1 Smart4Health Project Overview

Smart4Health: Building today a healthier tomorrow

Smart4Health aims at empowering EU Citizens with an interoperable and exchangeable European Electronic Health Record (EHR) that will allow EU citizens to be active participants in managing their own health. The key objective of Smart4Health is to place **the citizen** in the centre of the decision of citizen health care. The citizen will be empowered with the possibility of sharing health data with different clinicians, medical centres, local and international societal and for research activities as well as to cooperate directly with health care providers. The 4HealthPlatform will allow citizens to collect, manage, store, access and share own health and health care data, through



an easy-to-use, secure, constantly accessible and portable health data and services prototype within the EU and beyond. The 4HealthPlatform data layer connects with the 4HealthNavigator

portal for services and applications to provide advanced personalised health services accessible whenever and wherever. Citizens will be able to upload data (from EHR, over self-collected data, to work-health related data) through the interfaces MyHealthView, MyTime and MyWork.

Also, they will be able to share data with persons of trust as well as with health care professionals in situations when reliable health information is essential to assure efficient health care (MyTrusted, Mob.E.Health). Finally, citizens willing to support research, can donate their data to the scientific community (MyScience).



The technological elements will be developed in a co-creation process using eight Citizen Use Cases. These cases cover all aspects of citizens' active role in using the 4HealthNavigator to access the 4HealthPlatform and to increase positive user experience and system usability. Citizens from different national, cultural and institutional health-related contexts will be able to interact with and test the different steps of health data management at home, at work, while traveling, or during leisure and sport activities. Smart4Health is based on a truly multidisciplinary approach with a project team constituted by eighteen beneficiaries from eight different European Union member states and the United States of America, including ICT developers, hospitals, social sciences researchers, physiotherapists, nurses, informal caregivers, regional government, research centres, universities and SMEs.

Smart4Health will contribute for a positive impact on EU citizens health and wellbeing, for building today a healthier tomorrow.

1.2 Deliverable Purpose and scope

The objective of D1.4 is to deliver first insights to the development of a citizen/user consent language for different settings (e.g. at the work place, in the hospital, etc.), in consideration of the GDPR and EU policy as well as of previous experiences made with informed consent (IC) processes. This process will continue all along the Smart4Health project, engaging with a diverse set of users in different contexts in order to better understand and refine the IC process. To achieve this objective, we studied existing IC forms and processes, analysed input from citizens partaking in co-creation workshops and had the first version of IC also vetted by experts on ethical and legal issues.

1.3 Impact and target audiences

This deliverable is meant for both project internal as well as external audiences. For a project like Smart4Health, which puts citizens and their empowerment at its core, providing thorough and transparent information about what participating in the project means is essential. While having an IC process which meets the expectations of future users is essential for them to decide whether or not to register to the platform, it is also an important means of building trust. Therefore, a good IC process is key for making the prototype in a manner that is sustainable. For those working within the project this report highlights some of the challenges to have an IC process in place that meets not only the basic ethical and legal requirements, but also citizens' requirements. For societal actors this report also reflects the care that is taken to organise the development process in Smart4Health when it comes to refining the IC form and its language in an inclusive manner.

1.4 Deliverable methodology

The first citizen/user consent language report was produced as a first draft by UNIVIE, which includes partner input by HPI regarding the comparison of IC procedures and the vetting by an expert on legal issues, and by other partners as follows. (1) UNIVIE collected IC documents and procedures from partners (SHD, ZS-UG, ISMMS, and UKA), large cohort studies, and the European Commission (EC) (e.g. guidance notes), in order to review them, outline issues and identify the components to be included in the IC for Smart4Health. (2) Partner HPI started with the comparison of the collected IC documents, while (3) UNIVIE explored in workshops and interviews with Citizen Use Case (CUC) partners the storylines of the CUCs as well as platform scenarios in order to identify IC needs for different settings. The next step (4) was about developing a draft IC for the citizen health data platform (CHDP) provided by HPI with feedback from the consortium (D4L, EFN, ISMMS, UNINOVA, UNIVIE), which was (5) further developed by UNIVIE and circulated back to the ethics working group. (6) The first four citizen co-creation workshops organized by UNIVIE provided input regarding the IC situation and questions surrounding it. The first stabilized draft of the IC was vetted regarding social acceptability in the citizen group specifically dedicated to informed consent (UNIVIE), as well as by two experts, one on ethical issues (UNIVIE) and another on legal issues (HPI). The final report contains feedback from consortium members.

1.5 Document Structure

The document is structured in five chapters, starting after this chapter with an introduction (chapter 2) that frames and underlines IC as a core issue in health and research ethics. In chapter 3 the report reflects on past and present debates around IC and consent language in order to address four key notions to consider in consent

language related to using a health data platform. Chapter 4 covers the methodology of the report as outlined above in chapter 1.4, with the results of the threefold vetting by multiple citizen groups and two experts being presented thereafter (chapter 5). Finally, chapter 6 wraps up the report with a summary and final considerations.

1.6 Document status

After having received and integrated the feedback from our reviewers, this is the final version of D1.4. Further input from citizens/users on the IC form and procedures will be collected throughout the course of the project. Upcoming results will be included in the second and final report of this task (T1.5) in D1.9, due in M46.

1.7 Ethics

The report is closely related to ethics by being focused on citizen/user consent language and by unfolding the process of how a first stabilized IC of the project was developed. Thus, ethical considerations are central to this report and present in every chapter, in underlining that IC is at the core of health and research ethics, overviewing debates around IC and consent language, reporting about the applied methods and in the results that further refine the IC through formulated takeaway points by citizen and expert input.

1.8 Dependencies and supporting documents

This document refers to earlier deliverables by UNIVIE – D1.1 in which essential topics such as privacy have been addressed, and D1.2 that details the methods and procedures of user engagements and feedback loops with the consortium, structured in four waves throughout the course of the project. It also refers to D1.3 being handed in together with this report in M12. D1.3 delivers the first specification of user requirements and performance criteria, and thereby also addresses the situation of consenting to the platform and related questions (e.g. data sharing, deleting, unsubscribing, etc.) that have been discussed with citizen groups in the first round of workshops. Furthermore, this report is also connected to D8.1 when it comes to developing and testing the IC documents.

1.9 Main results

The main result of this report is the vetting of the first stabilized IC draft for the use of the 4HealthPlatform (4HP) of Smart4Health by citizens as well as by two experts on ethical and legal issues. Through analysing the feedback from citizens, a number of valuable takeaway points could be formulated. On the basis of these and the expert feedback the IC draft for using the 4HP could be further reworked and its language refined, in order to increase its social acceptability and the trust of future users in the project developing the platform prototype.

1.10 Future Work

This first report on citizen/user consent language will substantially shape the further work done in Task 1.5, which includes user engagements in the different CUC environments. Thereby, the diversity of users and use contexts can be addressed more in-depth, as the IC and its adaptations to the various environments can be tested with actual yet different users of the platform. Whereas these user engagements will take place over the course of the four waves of empirical work, the results concerning user/consent language will be reported in the second and final report of this task in D1.9 due in M46. Further citizen/user input collected about situations of consenting and interacting with the platform and its interface will also be part of user requirements in the respective and upcoming deliverables of Task 1.3 (D1.5-D1.7).

1.11 Remarks and considerations

If updates/changes to citizen/user consent language presented in this deliverable are made, they will be reported in the project periodic reports as well as in the future deliverables related to these issues.

2 Introduction

Informed consent has become a, if not THE core issue in medical and research ethics. IC procedures are by now an integral part of research and treatment in biomedicine and beyond, and countries have put in place numerous legislative and regulatory regimes that govern the use of personal data and health information. It was seen as essential, as “freely given consent legitimates action that would otherwise be unacceptable” (Manson & O’Neill 2007).

While these procedures have become deeply entrenched into practices and are hardly questioned, the discussions around IC began in new ways with the appearance of strongly data-driven health-related practices, such as producing health records or asking citizens/patients to collect, produce and manage their own health-related data or provide data for research.

Putting health data centre-stage while simultaneously aiming to empower citizens, raises new challenges. In a recent report by the German Ethics Council (2018) on “Big Data and Health – Data Sovereignty as the Shaping of Informational Freedom”, the complexity of data and health was addressed as follows:

“Because all data, regardless of the form in which it is generated, could be construed as being somehow related to personal health, it is in principle possible to classify all such data as health-relevant. As a result of this development, it is often no longer possible to determine at the time of their collection whether certain data should be considered sensitive or health-relevant. Rather, this depends primarily on the context in which the data is used. This context may change over time.”

This quote clearly points to the fact that, indeed, many sets of data that initially were not regarded as health-related can be considered as health-relevant data later on. Therefore, the challenges lie in the fact that at the time when collecting data, we might not even be able to know their relation to health yet. This in turn broadens the scope of data which should be regarded as sensitive and poses new challenges to classical IC procedures.

The report continues to reflect on the role of insurers and employers in case data can show traces to risky behaviour which might generate major costs (e.g. back-pain through lifting patients). As Smart4Health looks into backpain which is discussed in policy circles as a major cost factor from a health economic perspective, it will be important to consider the following statement also taken from the report of the German Ethics Council:

*“The monitoring of patient or employee behaviour allows for the introduction of incentives to encourage a healthy lifestyle, or sanctions to discourage an unhealthy one. Insofar as such programs result in the reduction of illness, they offer attractive prospects for everyone involved. However, the **risks cannot be ignored**. Neither the adjustment of one’s insurance premiums, **nor disciplinary warnings received for behaviour detrimental to one’s health, are in the interest of those who share their health data.**” (ibid., highlighted by the authors)*

Therefore, it will be essential to not only reflect the aspect of being informed about one's health status through access to health-related data which might empower citizens to act accordingly and of getting the better treatment through making health data available. We also have to closely reflect on uneven power relations and the fragility of labour conditions, to mention but two aspects, when collecting and potentially sharing data.

Finally, the report addresses ethical issues related to self-tracking. We find a clear warning that while generating data might support a health-conscious behaviour, “an excessive regime of self-control aided by such services and devices can contribute to an exaggerated drive for optimization detrimental to personal health, as well as the medicalisation of ‘natural’ life processes” (ibid.). As the report focuses on data sovereignty of citizens, the question is posed whether or not self-tracking has the **“potential for discrimination against persons unable or unwilling to subject themselves to such measurements.** The fact that many of the self-tracking apps and devices presently available are oriented towards the economic interests of their manufacturers, alongside an inadequate user-friendliness, transparency and privacy protection that many exhibit, has also been cause for criticism.” (ibid.)

Given these examples it becomes clear how important the diverse IC processes will be in the case of Smart4Health (see 4.1.4 and Figure 2). It will be essential – as argued below – to understand IC as a process well beyond a simple nexus of “good information-rational decision”. Rather it is a space in which citizens' own health status, health-related data and citizens' identity are negotiated. In this context it is also relevant to consider ongoing discussions on “data ethics”, as visible in the report by the German Data ethics commission (Datenethikkommission, 2019). These discussions raise awareness that many questions of the use and circulation of data are under negotiation and the years to come will for sure bring about new developments in this area. It will be essential for Smart4Health to closely follow these developments and gain an understanding of how these debates might take slightly different directions in different national contexts.

To reflect this understanding of IC, we will proceed in the deliverable in three steps. In chapter 3, we will elaborate important elements of the international debate around IC and reflect what this means in the context of Smart4Health. We will then, in chapter 4.1, describe in detail how in the framework of the project we elaborated the IC form for the use of the platform (CHDP consent). We have chosen to deliver a fine-grained description to show the many steps that needed to be taken to create some shared understanding of the process and the language to use. This is important as in the course of the project we will engage with IC in many different places and contexts of the CUCs (e.g. work environments, in therapy, leisure, etc.) and will need to reflect on the practices with health-relevant data. The aim is to develop all along the technical development of the 4HP also a robust IC process and the supporting documents. Documenting the process is thus part of our learning. In chapter 4.2 we also describe in detail the citizen discussion groups and their settings. Finally, in chapter 5 we look into the vetting process of this first version of an IC and its outcomes. This was done by citizen groups, by an expert on ethical issues in the health domain as well as by a legal expert.

The summary and final considerations chapter will then draw together the main lines of this report and point to the work that still needs to be done in order to learn more

about the IC process and the corresponding forms in the different contexts of application.

Before entering into the details of the report one further clarification is needed:

This report focuses on citizen/user consent language. So far, as will be described below, we did develop a printed version of an IC form which was then vetted by citizens as well as ethical and legal experts. However, in its final form, the IC process as well as the documents will be presented as an **e-consent** and therefore the documents and the information contained will be presented in ways different to a linear printed document. We will shortly touch on some of these issues related to e-consent in chapter 3, but will not discuss it in detail in this deliverable. This will be done at greater length when we report on the development of e-consent and how we engaged with users in the co-creation processes.

3 General Considerations: How to address Informed Consent in health-data related domains

In what follows, we will present some of the past and present debates around IC and reflect on user consent language. We organise it around some of the key-notions which are central and discuss what they mean for developing a consent related to the use of the health-data platform. While much of the past debates on IC in biomedicine were addressing questions outside the context of digital health, they are nevertheless of relevance as they allow us to reflect the two key assumptions underlying the very idea of IC as process and practice – autonomy (and agency) as well as information; both of which we explicate below. Then we will reflect debates on data related issues such as data sovereignty and finally, we will use “data donation” as an example to reflect the specific role of data in the health (research) context. Some of the essential topics, such as privacy, have already been addressed in Deliverable D1.1.

Before entering these reflections, however, it is important to stress that both “ethicists and policymakers continuously debate the most basic aspects of informed consent within the very agencies promoting its use as a mandatory requirement. Who should consent, and to what, when, and why? What counts as ‘adequately understood’? What counts as “coercion” or “undue influence”?” It is also essential to consider that “there are also profound differences in the type of ethical challenges informed consent is expected to address in different settings” (Hoyer and Hogle, 2014, p. 348). This underlines the importance to, on the one hand, engage in pre-existing discussions on IC, but, on the other hand, also **carefully reflect on the specificities of the environment where IC will be requested** in the context of Smart4Health (for broader debates on consent see e.g. Candilis & Lidz, 2010; Müller & Schaber, 2018).

3.1 Autonomy and agency

With the rise of bioethics, ‘autonomy’ has been a key term in the field of medicine with IC being the means to ensure this autonomy of patients and in our case of citizens using a health-data platform. While this has remained largely unchallenged, during the last two decades we could witness numerous studies which shed light on IC in diverse contexts.

Some point to the fact that the context in which IC is given needs careful consideration. Power relations between medical practitioners (e.g. doctors) and citizens potentially lead to rather unequal encounters. This in turn means that the ideal of personal autonomy cannot be realized in the way it is predominantly imagined as bioethical ideal (e.g. Corrigan, 2003). Some even call it an “illusory goal” (Dixon-Woods et al. 2006, p. 2750), pointing to the fact that in practice “the ideal of informed consent as the outcome of rational choices exercised by autonomous agents was far from being achieved”.

This can be linked to a further critique of autonomy, which mainly points to the weakness of conceptualising the citizen giving consent as an isolated, rational subject that is able to exercise autonomy through IC (Berg et al., 2001). If we were to embrace a more relational approach to autonomy, it would become **important to consider the situation and the social context in which an individual is asked to give consent**. More emphasis is placed on the individual’s social contexts. Then a citizen’s choice in the context of an IC process has to be understood as a process closely intertwined with the specific social location of the consenting person rather than as an exclusive

act of rational reasoning. The very idea of the “autonomy of the subject” can thus not be conceptualised as intrinsic to human nature and can therefore not be taken as the starting point for ethical considerations. Seen from this perspective, both the form and the process of IC bring a specific kind of autonomy into being.

Informed choice is thus not simply a selection between different kinds of ready-made options, but needs to take into account the cultural, social and historical contexts that shape the ways in which citizens (can) deal with to health-related encounters (e.g. Mackenzie and Stoljar, 2000). Debates have often looked into treatment or clinical trials (e.g. Krieger et al., 2017 investigate strategies for improving IC in clinical trials with a focus on low health-literary patients) and situations of donation in medicine (e.g. Felt et al., 2009). Other studies using quantitative readability scores (e.g. Villafranca et al., 2017) have, for example, pointed to the fact that templates of IC provided by Research Ethics Boards (REBs) in different national contexts proved being difficult to understand by those having to sign them. It becomes even more challenging when citizen have to find a new relation between data and their health status – a challenge that is at the core of Smart4Health.

This invites us to think more closely about the correlation between provision of information, on the one hand, and citizens acting autonomously and in a way that is regarded as “rational”, on the other.

3.2 Information

“The original meaning of ‘inform’ is to give form to something: to give it determinate shape, to arrange it, or modify it”. This is how Manson and O’Neill (2007, p. 34) start their reflection on *Rethinking Informed Consent in Bioethics*. The authors then invite the reader to carefully reflect on the many dimensions and expectations we have towards information being the basis on which we can make an ethically sound decision.

Very often, in debates around IC, the question of **informational obligations** emerges. This means starting with a close reflection of what information is needed and what not in order to make a decision in the framework of IC ethically sound (Manson & O’Neill 2007). Furthermore, we would need to clearly state which information is seen as in need of protection and how this is achieved. At the same time other kinds of information need disclosure. Institutional information, for example (in our case who is the consortium behind the Smart4Health project) is seen “as information that everybody else has a right to know, which should be disclosed in the name of transparency, accountability and freedom of information” (Manson & O’Neill 2007). However, the authors argue that such a straightforward classification of kinds of information might not fit well with the complexities of IC. Instead they suggest understanding what should happen during IC more in terms of a “communicative transactions, rather than as requirements that certain types of information be kept inaccessible” (ibid.) or be made accessible. This would mean that we have to go beyond thinking that communication through an IC sheet is mainly about the conveyance or disclosure of the right kind of information, but to reflect on the “rich set of background commitments and competencies that are essentially involved in the activity of communication” (ibid.).

Accordingly, we have to see that **informing strongly depends on the context** “and, more importantly, upon what participants take the context to be” (ibid.). In a study on IC procedures in a general hospital it has been shown that patients take into consideration the institutional context of the hospital they are in, when taking their

decision of how to engage in informed decision making (Felt et al., 2009). It was shown “that the ideal behind informed consent – namely, that a ‘qualified’ decision has to be built on predefined information – is countervailed by the patients’ practice with informed consent. Patients redefine the meaning of being informed by disregarding offered formal information in their decision making and drawing on different resources instead” (ibid., p. 100).

This is closely linked to **questions of trust** when it comes to IC. Indeed, studies (Felt et al., 2009; Manson & O’Neill 2007) show that it might not be the content of what is disclosed that is the most important element on the basis of which people trust medical professionals (e.g. doctors) and the system they are part of. For example, “the trustworthiness of institutions (a university hospital) [or] the patients’ rather positive progress-oriented image of the biomedical research built on solidarity” (Felt et al., 2009) could become the basis for the decision. Therefore, even if citizens might “not understand what is disclosed, or understands it poorly, [they] may (reasonably) infer that the [medical professional] is trustworthy simply because ‘she is not trying to hide anything’” (Manson & O’Neill 2007, p. 32).

Finally, we will need to consider insights into the IC process, reflecting the relation of **health literacy** to the degree in which patients/citizens might understand what they consent to. In a review study on “*The effectiveness of health literacy interventions on the informed consent process of health care users,*” Perrenoud and co-authors (2015) argue that citizens with low health-literacy are limited in their capacity to provide fully IC and thus also to participate in making decisions concerning their health care.

This means that user consent language is an important element in the process of communication and Smart4Health will thus focus attention on that. In the case of this project, it is not a hospital or similar health care institution, but a project consortium developing a prototype of an EU-EHR exchange for citizens, which requires their trust in order to operate sustainably. However, as we will outline in chapter 4.1, the IC process goes well beyond simply grasping on a knowledge-level what is at stake when using a data platform.

3.3 Locating data

“Where are my data?” is a question that comes to matter when agreeing to engage with a health-data infrastructure that is transnational such as the prototype of a health-data platform that Smart4Health builds. While this question popped up only in limited form in the debates with citizens so far, it will in the longer run become an important question also when it comes to IC. So far, we have not really addressed this question in the IC process.

Indeed, the consent of the data subject links the processing of personal data to the free decision of the data subject and is so far the key vehicle for ensuring his/her right to the protection of personal data. However, this also demands from the data subject to simply trust that data are lawfully handled and that the respective authorities act responsibly to ensure data protection.

Indeed, when starting to use a health data infrastructure, digitally literate citizens might ask:

1. Where are my health data created, where processed and what might that mean for me?
2. Where are my health data physically stored, and who owns the data centre?

3. What are your procedures for back-up? Where is my data backed-up to? What local stipulations exist for the security or encryption of my health data?
4. And the cloud partner(s), what evidence do I have how they understand the current and future data privacy regulations?

These are all important **data sovereignty** questions. It will be essential to also communicate these elements in an IC in order to create a trust relationship with users of the 4HP.

3.4 Data provision for research

While we are discussing in the report mainly the IC to the 4HP, “data donation” (providing health-related data for research purposes) has also been presented in the IC as an option for users of the platform. And, as we will show, citizens have started to debate this facet and functionality of the health-data platform prototype to be built in Smart4Health.

In a recent book with the title “The Ethics of Medical Data Donation”, Krutzinna and Floridi (2018, p. 1) start by stressing that

“[d]iscussions on the ethics of using medical data tend to take a system-centric perspective and focus on what researchers and the health service may or may not do with data that are placed within their trust. Rarely, if ever, is the question of the data subjects preferences addressed beyond practical matters of obtaining valid consent”.

As data donation is seen as one of the innovative features of the Smart4Health project, it will be important to address this issue in detail. This will particularly be essential when developing and negotiating the IC for what we called until this point “data donation”.

So far key-challenges identified range from trust issues, over social values that can limit the willingness to share data, to concerns about justice and inclusion. While it is often stressed how important it is to have health data for the advancement of research, there are so far relatively few widely publicly shared success stories of using and re-using data available – even though we currently have a lot of promises that the use of Artificial Intelligence and machine learning will profoundly change this in the long run.

Simultaneously, what citizens learn about the use of “their data” does not necessarily create the relation that builds on trust and incentivizes the provision of data for research. We learn about Facebook, Google or Amazon which have used their users’ data in often not quite transparent manners. As Prainsack (2019, p. 9) formulates it: they have “become a new Leviathan: a monster for which people give up freedoms in exchange for other goods that they consider essential”. While this would go beyond this report (and project), she suggests to understand data donation as “a specific type of transaction, [that] has three distinctive characteristics: relationality, indirect reciprocity and multiplicity”. This in turn invites us to think whether donation is actually the right term, suggesting to think of this act more in terms of provision of data, an issue that was also brought up by the legal expert when vetting the IC document prepared by Smart4Health.

Current debates also point to the need to more carefully reflect “harms arising from digital data use in the big data context [which] are often systemic and cannot always be captured by linear cause and effect. Individual data subjects and third parties can

bear the main downstream costs arising from increasingly complex forms of data uses—without being able to trace the exact data flows” (McMahon et al., 2019, p. 1). The authors also call for a “recalibration of data governance” (p. 3) and point to the fact that while the GDPR has taken positive steps to protect data subjects it has “remained too narrow to provide effective harm mitigation for all data subjects” (p. 4). The authors point to the fact that, “traditional distinctions drawn by data governance frameworks, such as the distinctions between identified (or identifiable) and anonymous data, and between sensitive and non-sensitive data, are increasingly difficult to operationalise in the big data era given the increased sharing, copying, and linking of data and datasets, and because of the [...] multiplicity of digital data—the fact that they can be in more than one place at the same time” (ibid., p. 5-6). This means that in the context of Smart4Health we will essentially have to reflect how to assure those engaging in the project how their data are handled, in particular as we invited citizen users to also discuss uploading data collected in private contexts (e.g. fitbits), which might be seen as “non-sensitive” health-related data. This reflection process will be particularly important once data provision will be possible in the context of Smart4Health, however will not be addressed in detail by this report.

During the co-creation process, which includes a number of social scientific methods (e.g. discussion groups, interviews), it will therefore be essential to explore citizens’ understanding of providing their data for research purposes, the values involved and why they would or would not provide their data for research. This will also help to find the adequate consent language for citizens in order to inform about what providing data for research actually means.

3.5 e-Consent – Granting consent digitally

Smart4Health will ask volunteers and potential users for IC before subscribing to and using the 4HP. This means that the project is complying not only to legal norms, but wants to respect the ethical standards and fundamental rights to autonomy and self-determination of individuals whose sensitive health data will be uploaded, stored and potentially shared or even provided for research. While we have so far been thinking of the IC sheet in terms of a paper version, it is important to state that once the platform is up and functioning as a prototype, we plan to use electronic informed consent – e-consent. This is even more important as citizen users will often join the platform from home rather than in a medical or health-related environment.

While e-consent is already in use, there are not very many studies that have investigated the impact of the e-consent on users and their understanding of the issues at stake **before consenting across several national/health-related environments**, as will be the case for Smart4Health. Those who did study them, often did so in the context of clinical studies and not for subscribing/registering to a health-data platform (e.g. Wilbanks, 2018).

The advantages of e-consent are numerous. It will allow an interactive presentation of the IC with visual materials, embedded comments that give more information on any part of the consent, to click on terms to get additional information on them, refer to podcasts or videos explaining the project and many more. Paper consent documents are linear and often quite long documents, which ask the reader to follow the information from the start to the end – even if not all seems relevant to the reader. The electronic presentation of IC does not have to follow this linear logic nor stay on the same level of depth throughout. Instead, reading can be more self-directed, have different degrees of depth and, in the end, allow for a better comprehension of what is

consented to. Furthermore, it would enable, for example, to create a function that allows to highlight and tag a specific, unclear section and transform it into a question to be asked to a helpdesk.

As outlined earlier, the environment in which users receive information matters. In an e-version of the IC, information can be presented to the user in a more digestible and therefore user-friendly manner. Hence, the situation of decision making can be improved for the individual user allowing him/her to better grasp what he/she is consenting to. Finally, this will allow Smart4Health to experiment with different levels of comprehension in the explanations used and offer various levels of information from which future users can choose depending on their health/data literacy and on how much information they want to get in order to make an informed choice.

Being able to take time and selectively navigate the IC form and reach a satisfactory level of information is also an advantage in tackling a serious problem of IC processes in the health domain and beyond: (the feeling of) being under time pressure when studying the IC sheet and taking a decision.

However, e-consent has also draw-backs. The process of giving consent electronically might not be embedded in a human interaction process and thus have no immediate possibility to ask questions. Furthermore, some format of authentication will be needed in order to ensure the subscriber's identity. Other details will have to be considered when preparing such an electronic IC solution (e.g. not pre-ticking boxed to impose that people have to opt-out instead of opt-in).

As with the paper consent, also in the case of an e-consent we will consider potentially different national solutions, with the GDPR only being the minimum requirement.

4 Process/Methodology

4.1 Development of platform consent

In what follows the process of producing the “platform consent” is described in detail. This has two main reasons: (1) it shows the engagement of the consortium that went into this process and documents the struggle for understanding what kind of IC documents and processes will be needed for a European health data platform; (2) it points to the struggles over language and formulations that led to the first agreed draft. To document this process is important as a tool to reflect the assumptions that went into the IC process and in further steps along the process to be able to adapt it to new input from citizen users in diverse contexts signing and testing the platform. These reflections will also be important when producing the second and last Citizen/User Consent Language Report towards the end of the project. Thereby, we will be able to reflect the learning process and deliver input to other data intensive projects in the health domain.

4.1.1 Collection and review of informed consent documents and procedures

UNIVIE collected (generic) IC documents and procedures

- (1) (generic) informed consent documents and procedures from consortium partners (SHD, ZS-UG, ISMMS, UKA);
- (2) templates used for large cohort studies (German Medizininitiative, UK Biobank, BioMe Biobank Program);
- (3) European Commission documents/guidance on informed consent (Article 29 Data Protection WP Guidelines on Consent under Regulation 2016/679¹; Guidance for applicants on informed consent in FP7²; EC guidance note on data protection for H2020 that included statements on IC³)

and reviewed them, outlining issues of concern with regard to IC in Smart4Health.

As outlined by the Article 29 Data Protection Working Party Guidelines valid consent comprises a number of elements⁴. For consent to be valid, it has to be **freely given**, i.e. research participants must have a real choice as well as control over their participation. This is specifically complex in the employment context, in particular when it comes to health and medicine related issues, due to the imbalance of power between employers and employees. Employees must not (explicitly or tacitly) be coerced into participation and it needs to be ensured that they do not face any adverse consequences if they decide not to consent to participating and/or data collecting in the context of Smart4Health. Also, consent has to be **specific**, which shall ensure user control and transparency. As outlined in Recital 32 of the GDPR, consent requires “a clear affirmative act establishing a freely given, specific, informed and **unambiguous** indication of the data subject’s agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement” (our emphasis). Furthermore, those giving consent have a right to

¹ https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051 (last accessed 29/10/2019)

² http://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf (last accessed 29/10/2019)

³ http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf (last accessed 29/10/2019)

⁴ https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051 (last accessed 29/10/2019)

withdrawal, which has to be as easy and straightforward as giving consent. And, crucially for consent to be valid, it has to be **informed**.

Based on the reviewed documents mentioned above, the following points can be summarized. The person giving consent has to be **informed** of the project they are supposed to participate in, their intended role of participation and the reason for recruitment as well as the name and contact of the principal investigator and the funding body. They need to be informed of the mode of participation, i.e. what will be expected of them, what will be the duration/frequency of participation, that their participation is voluntary and they have the right to ask questions and to withdraw their participation. Also, participants need to be informed about what data is being collected, processed and stored (where and for how long), how the data are protected, who has access, with whom will they be shared and, ultimately, what happens with the data after the project is over. Furthermore, individual benefits and risks need to be clarified, as well as a potential reimbursement procedure where this is a valid perspective. When it comes to the specific use of data for research or in any medical treatment context, additionally, it needs to be clarified how incidental findings are handled and if/how participants can find out about them, and that non-participation/withdrawal from participation does not interfere with the provision of services or treatment. Moreover, for both the platform for personal health data storage and for the donation of health data for research, it needs to be clarified what will happen to the data that has been collected after the withdrawal of consent to data collection/participation.

For **consent** to be informed, the Article 29 Data Protection Working Party outlined minimum content requirements. The person giving IC has been made aware of the data controller's identity and contact details as well as of the Data Protection Officer, of the purpose of each of the processing operations for which consent is sought, what (type of) data will be collected and used, the existence of the right to withdraw consent, information about the use of the data for automated decision-making (if applicable), and possible risks of data transfers due to absence of an adequacy decision (in terms of data protection in third country) and of appropriate safeguards⁵ (p. 3).

UNIVIE presented this **review** in the 1st remote meeting of the Ethics Work Group (EWG) (TelCo, 27/02/2019). We agreed that before we can come to concrete decisions about IC, its requirements and technicalities, we need to have a more concrete understanding of **situated scenarios**, i.e. to clarify where, when and how the process of giving IC will happen. This is a prerequisite in order to be able to develop a sustainable data platform consent that can be vetted by ethical and legal experts (see chapter 5.2). This is in line with international debates around IC which highlight that “[w]hat is communicated in an act of informing – the information – will depend upon the context, and, more importantly, upon what participants take the context to be” (Manson & O’Neill 2007).

Thus, we agreed on and conducted a two-pronged approach, as explained in more detail in the sections below. In short:

- (1) HPI systematically compared first IC documents provided by the consortium partners, templates from large cohort studies and the EC guidance documents, and
- (2) UNIVIE continued the work on platform scenarios in workshops with technical and CUC partners focusing on the co-creation environment (T1.2), with the output also

⁵ https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051 (last accessed 29/10/2019)

feeding into the development of the platform consent; it also provided HPI with further collected IC documents and procedures for the comparative analysis of IC procedures in the CUCs.

4.1.2 Systematic comparison of IC procedures from the CUCs

As the CUCs play a central role in the 4HP development, HPI developed a **grid** to systematically compare the different IC procedures in the 8 CUCs, investigating if they contained the following type of information (based on the EC Guidance for applicants on informed consent in FP7):

- Title, purpose and explanation of project;
- Expected duration;
- Description of procedure;
- Statement participation on voluntary basis;
- Organization and funding of project;
- Description of any reasonably foreseeable risk, discomfort/disadvantages;
- Description of benefits to subject or to others;
- Disclosure of appropriate alternative procedures for treatment/diagnosis;
- Data protection/confidentiality/privacy;
- Description how incidental findings are handled;
- Any planned genetic tests?
- Any compensation if injury occurs?
- Insurance coverage;
- Contact person, address;
- Statement about opportunity to ask questions and withdraw at any times;
- What will happen with data/samples at the end of the project;
- What will happen to the results of the research.

UNIVIE added **specifications and reformulations for some of the comparative categories** (e.g. on statement about opportunity to ask questions and withdraw consent for participation or access to their data at any times without any negative consequences; on procedures for doing so; on right to lodge a complaint) to be considered when formulating the IC. Furthermore, the following types of information were added to this grid, based on the EC *Ethics and data protection guidance* document of November 2018:

- Data transfer to non-EU countries;
- Collection of personal data outside the EU and transfer to EU;
- Procedures of pseudonymization, anonymization, de-identification, risk of re-identification.

HPI gave an update of the procedures and the developed grid in the 2nd remote EWG meeting (TelCo, 20/03/2019) and presented the results from the comparison in the 3rd remote EWG meeting (TelCo, 08/04/2019).

Based on this work, the consortium agreed to establish a **general IC framework for the CHDP**, that then can be **adapted** to the specific situated requirements in the respective **CUCs**. The IC framework for the **research data platform (RP)** would be developed separately and would only be needed once the research data platform was ready to be used.

Also, standard ethical and legal prerequisites such as the GDPR, Declaration of Helsinki⁶ and the Declaration of Taipei⁷ were considered in the development process.

4.1.3 Development of a draft informed consent for the CHDP and initial revisions

Based on this, HPI developed a **first draft** of an IC for the CHDP as a basis for CUC-specific consents and starting point for a series of discussions within the consortium on ethical and legal issues to consider when asking citizens to use the 4HP (Figure 1). The status of the development and its evolving structure was discussed in the 4th and 5th remote EWG meeting (TelCo, 29/04/2019 and 13/05/2019) and the first draft was circulated to the consortium by HPI on 10/06/2019 with the request for feedback and revision. HPI collected the feedback from the consortium (EFN, ISMMS, UNINOVA, UNIVIE, D4L), conducted a detailed review and implemented the changes. In the 6th remote EWG meeting (TelCo, 24/06/2019), open points were raised and discussed. Following up on this, HPI redrafted the consent and circulated it to UNIVIE (15/07/2019).

Concurrently, two main decisions regarding ethical aspects resulted from these meetings. We decided that

- 1) minors would be excluded from participating in the prototype phase and
- 2) EU-residency is an eligibility criterium for using the 4HP.

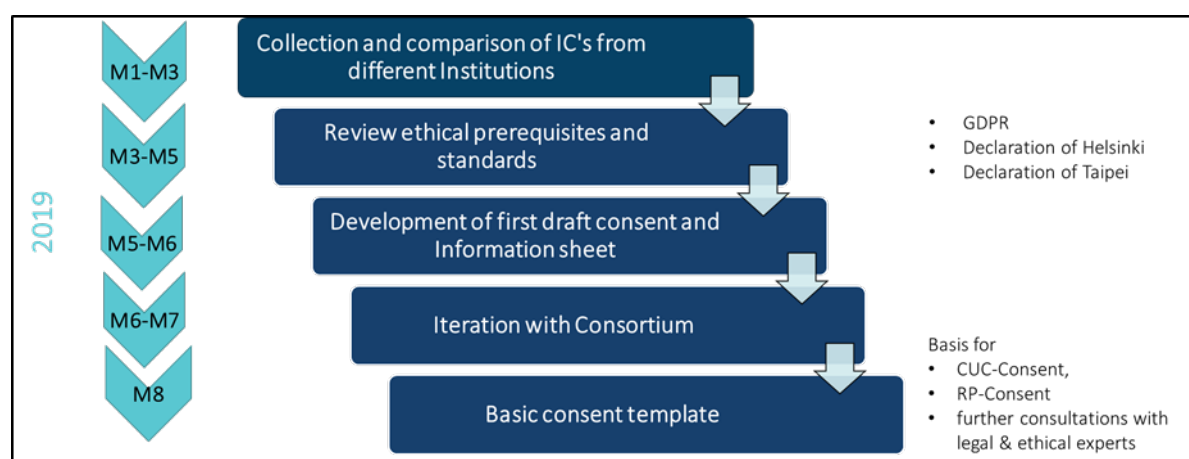


Figure 1 – Development process of first consent draft (graphic prepared by HPI)

4.1.4 Two phases and respective informed consent requirements

In parallel to this and providing input to these processes, engagement with the development of the **platform scenario** and related specific **IC requirements** started. Smart4Health aims at establishing a citizen-centred health data infrastructure, which is not only a technical project but much more a socio-technical one with citizens not only being addressed but actively engaged. Therefore, it is crucial to bring together both perspectives – the social and the technical – all along the development

⁶ World Medical Association: Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (2008). (last accessed 14/04/2019) <https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2008.pdf>

⁷ World Medical Association: Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. 2016 (last accessed 14/04/2019). <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>

procedure. Triggered by debates on IC requirements for Smart4Health at different points in time, UNIVIE underlined that we need to conceptualize **two phases** relevant for this project. Both need to be addressed specifically as they demand different considerations for developing IC forms and the related processes.

- **Phase I** is the phase during the **building of the prototype** of the Smart4Health citizen health data platform, i.e. for the duration of the project.
- **Phase II** on the other side is the phase in which the **prototype is finalized** and a “product” as outcome of the project is established.

During Phase I, using the prototype needs to be considered as a study/experiment. This means that the platform is in development and testing, that the consortium – committed to a citizen-centred co-creation approach (see D1.1 and D1.2) – engages with different user groups, integrating their perceptions of the functionalities and their input in order to develop and validate the prototype with citizens/users. The exact use features and with it also the kind of IC needed, which would come to matter in Phase II (i.e. when the platform is no longer just a prototype), will also be elaborated during the project (D1.9 will address the consent issues as well as the consent language more generally speaking; M46).

Following these considerations, UNIVIE outlined the relationship between the different ICs that are relevant during the work in the project. Given that we have the two phases, we need to make an important differentiation:

- **ICp: Informed consent(s) during the project process** of designing, developing and implementing the prototype of the 4HealthPlatform/4Health Navigator; ICps come in different version (see Figure 2) depending where they are used in the process of developing and testing the platform prototype;
- **ICpf: Informed consent as foreseen in the final “product”** (i.e. the finished prototype), including a detailed reflection of the user consent language.

The exact formulation of these ICs (ICp and ICpf alike) will differ in some parts. For instance, citizens need to understand what happens to their data once the project ends at month 50 of Smart4Health, wherefore we need such a specification in the ICp. ICpf, however, will not need to address a fixed end date, but should communicate what happens to personal data if the platform should cease to exist. Hence, ICp and ICpf will need to address different concerns and find context specific formulations. Furthermore, we will have to develop ICs adapted for the specific empirical settings of the CUCs, e.g. work and leisure or hospital contexts (see Figure 2), i.e. for the different engagement exercises in the framework of the co-creation process.

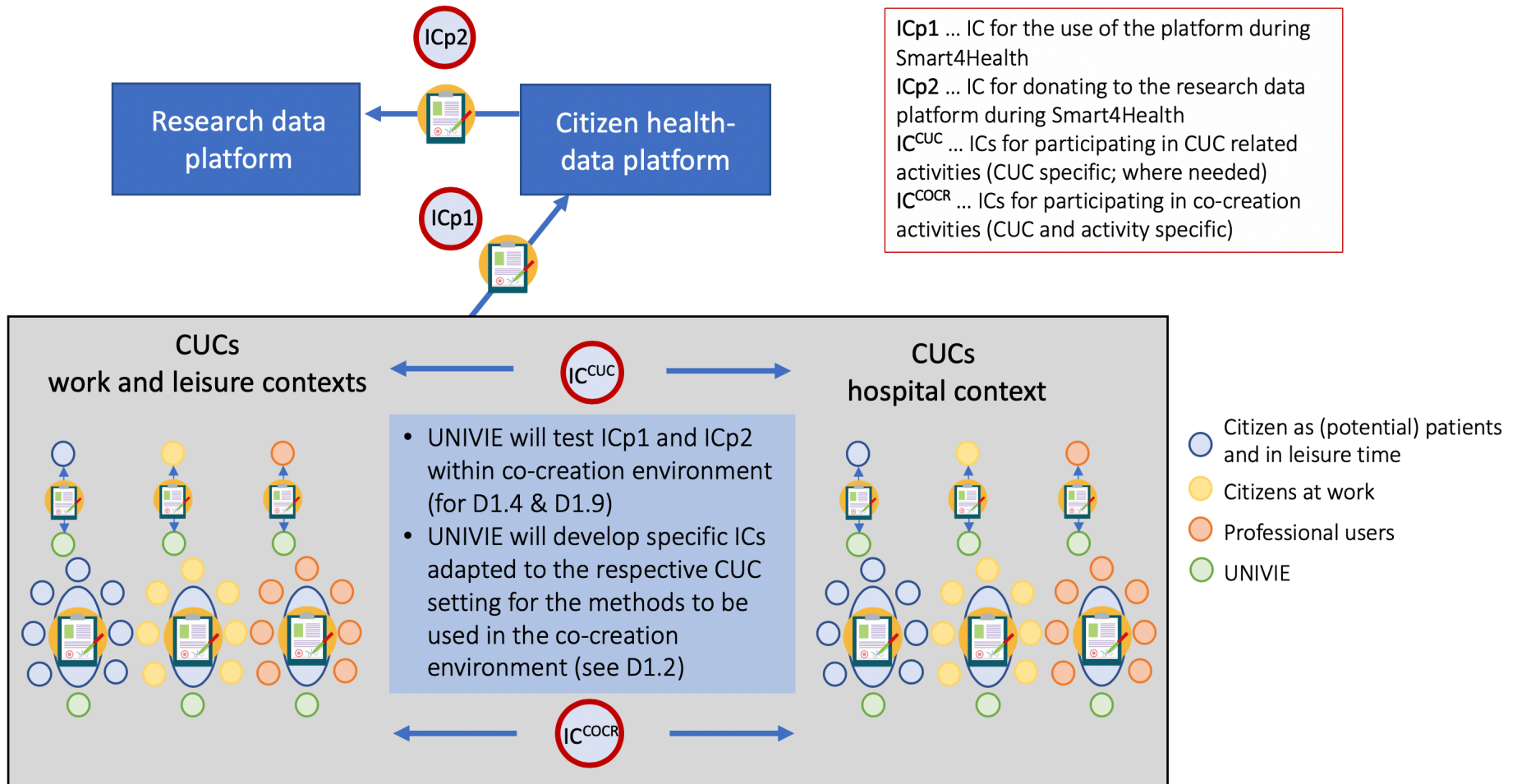


Figure 2 – Informed Consent procedures in Smart4Health

Still, while the project IC (**ICp**) for the use of the platform needs to be prepared in the first year of the project and must be **in place for the empirical work to begin**, the **ICpf will be part of the results of the project itself**. The “final product” IC (ICpf) will be based on the initial work for the ICp and the stabilization of the consent procedures in the platform consent. It will be tested, validated and further developed in the course of T1.5 (i.e. the development of the Citizen/User Consent Language), always in consideration of the GDPR, specific national and institutional regulatory contexts and EU policy. This process will gradually lead to **an ICpf that has been substantially vetted by experts on ethical and legal issues as well as by citizens** with regard to its structure, language and social acceptability (D1.9; M46).

In Figure 2 we have outlined the different situations in which IC will be needed:

- ICp1 refers to the citizen health data platform consent that has been under development in the first year of the project. This IC is for the use of the platform during Smart4Health. As most of the CUCs will only be fully functional early next year, ICp1 has been tested with citizens independent of CUCs (see chapter 5). Testing will continue with users in the CUCs starting in year 2.
- ICp2 refers to the research data platform consent that will be under development as of the second year of the project (and will thus feed into D1.9). This IC is for donating to the research data platform during Smart4Health.
- In addition to the two platform-specific ICps, during Smart4Health there will be specific ICs for the engagement exercises that will take place in the co-creation environment (IC^{COCR}). These specific ICs will be adapted to the respective CUC setting. This comprises the CUCs in work and leisure contexts, as well as the CUCs in the hospital context, where we will engage different user groups (e.g. citizens as (potential) patients and citizens in leisure, citizens at work as well as professional users of Smart4Health).
- The CUC partners will provide the CUC participants with an IC for participating in CUC-related activities (IC^{CUC}).

For the co-creation environment this means that the IC procedures in Phase I of Smart4Health (i.e. the **IC procedures during the project phase**) comprise **three elements**. While not all three elements will be relevant in all phases of the development of the Smart4Health platform prototype, **all three need to be in place for the co-creation environment to be performed in an ethically sound way** (as mentioned above the CUC partners will use their specific IC^{CUC} forms).

1. The IC^{COCR} regarding the citizen/professional users' participation in the co-creation workshops (CCWs) and user engagement exercises (USEEs) in WP1 applies to all waves of the co-creation environment (see D1.2 for details). It was also used in year 1 when citizens have provided highly valuable feedback on ICp1, even without the platform or the CUCs running yet.
2. As soon as the 4HP is operative, citizens will be able to register, upload, access and share health and health-related data. If the use, testing and validation of 4HP functionalities is part of the USEE and citizens engage directly with the platform, ICp1 also has to be signed.
3. As soon as the research data platform is operative, citizens will be able to donate their data to research. If the use, testing and validation of research data platform functionalities is part of the USEE, ICp2 has to be signed as well.

Language matters strongly for the process of being able to give IC. In general, all ICs will be **translated into the respective national languages with particular attention**

to formulations specific to the context. ICs need to be formulated in a way that participants easily understand what their participation entails, and we need to carefully consider the situations in which consent is given. Smart4Health follows a citizen-centred approach, and in that sense, it is crucial to involve citizens recruited from the different CUCs also in the development of the user consent language and IC processes they see as acceptable and supportive to them. Given that different national contexts have different approaches to health-related data, we not only need the ICps in different languages but need to test them in different countries and contexts in order to produce a robust result.

4.1.5 Further development of the informed consent for the CHDP (UNIVIE)

Drawing on these considerations and building on a review of debates concerning the consent processes (e.g. Manson & O'Neill 2007; Felt et al. 2009; Krutzinna & Floridi, 2018) UNIVIE substantially developed the draft version further. We reworked the information sheet and the way citizens were addressed and introduced to Smart4Health, added a number of additional points and questions and reformulated parts of the IC, ensuring that it followed certain conventions and mapped onto the requirements for the two different phases (during and after the project ended) outlined in section 4.1.4. In general, we also unified the terminology and adapted part of the language of the draft IC for the CHDP to potential user groups as envisaged at this point in time – discussions in the Ethics Working Group of Smart4Health, experiences of UNIVIE with IC processes in medical contexts and pre-existing consent forms were important input here. The reworked version was circulated back to HPI and the EWG (22/07/2019). HPI incorporated the changes and in the 8th remote meeting of the EWG a stable version was agreed on (29/08/2019).

4.1.6 Stabilization and vetting by citizens, ethics and legal experts (HPI, UNIVIE)

By the end of M8, **the final draft version of ICp** was released to be vetted, i.e. to go through **a process of careful examination and critical appraisal** performed by three sets of actors (explained in more detail in 4.2 and 5.2):

- (1) via the means of citizen discussion groups specifically devoted to informed consent procedures and user consent language (UNIVIE, M11).
- (2) by an ethics expert (UNIVIE, M11) and
- (3) by a legal expert (HPI, M10)

The outcomes of these processes will be presented in chapter 5.

4.2 Citizen groups

This section describes the method and process of conducting citizen co-creation groups in general and specifically devoted to the IC. This comprises in total 5 co-creation workshops (CCWs) held by UNIVIE with citizens of Vienna. IC was one of many situations to be discussed in the first 4 groups (4.2.1), while a further CCW was specifically devoted to IC procedures regarding the structure and social acceptability of the IC form and processes (4.2.2). The method applied is outlined in D1.2. The following therefore mainly addresses the specifics of these groups.

4.2.1 Co-creation workshops with citizens (M9-10)

As outlined in D1.2, the co-creation process of Smart4Health is organized in four waves, each comprising multiple forms of engagement with different user groups (see our methods tools box in D1.2, e.g. card-based focus groups, qualitative interviews, etc.). In the first wave spanning the first year of Smart4Health we conducted four

co-creation workshops with citizens who are not involved in the CUCs. Participants were recruited from the general public in the Austrian context by an open call sent out by bulk mail. These four groups were carried out from September to October 2019 (Sept 13/14/21, Oct 5), with each lasting four hours at the premises of WP1 lead UNIVIE, the Department for Science and Technology Studies, University of Vienna. We assembled each group as diverse as possible regarding the following categories: gender, age, educational background, current job, and having opted out of the Austrian national electronic health record (ELGA) or not. As there has been a debate about electronic health records in the Austrian context, of its (potential) pros and cons, we identified this as ideal to explore visions of citizens towards the making of a citizen-centred health data platform. We applied a card-based discussion method (Felt et al., 2018), which supports citizens in defining and expressing their positions in a fine-grained manner.

The citizen responses allowed us to assemble diverse groups regarding the above categories and reach the aimed group size of 4 to 6 participants in each – the duration of discussion of each group being 4 hours. This allows for in-depth discussions between participants and to follow the discussion dynamics, instead of running risk to collect many brief statements.

The overall **composition of the four citizen CCW groups** regarding the categories in the recruiting survey is as follows:

- Gender: Two of the groups were gender balanced; the other were either mainly female or male participants. There is not a clear difference in the discussion dynamics due to gender to be noted.
- Age: In three of the groups all four age categories (18-30, 31-45, 46-60, >61) were present, whereas group 4 was equally split between two age ranges (18-30 and 46-60).
- Educational background: From the five possible options, we had not managed to attract participants who only had compulsory schooling (until 15/16 years); participants who had finished an apprenticeship were present twice (group 1 and 3). Hence, the majority had at least a high-school level of education. Those remaining on that level (including students, employees as well as retirees) were present in each group and amounted with those having a professional education to about the half of the cohort. Participants with professional education were present in all but one group (group 4). Meaning, the other half of the cohort had a college degree or similar.
- Current job: With this category having an open answer field, the responses reflect the achieved diversity ranging from retired, jobs in various fields (gastronomy, marketing, office in general, as well as two nurses), to housewife, student, and unemployed. Missing, however, for example, were self-employed citizens, doctors, civil servants, or workers in physically demanding areas (e.g. industry).
- National EHR opt-out: From all respondents two citizens had opted-out of the Austrian EHR, about a third did not know, and the majority responded with not having opted out.

All in all, we have quite detailed and engaged accounts from a broad variety of citizens. While some of them were missing from our groups, such as physical workers, we will be able to engage with representatives from that group in the framework of the CUCs, as they facilitate access to them.

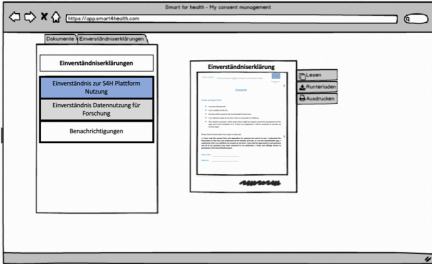
We started the workshop with a short video, briefly explaining Smart4Health and delineating the scope of the discussion. We began the discussion with a broader exercise asking people for their more general position towards eHealth and in particular digital health data infrastructures (such as national EHRs). To get this discussion started and to allow participants to reflect on their position we offered them so-called “position cards”, i.e. a set of 9 cards containing short statements as expressed by different actors with regard to e-health/electronic patient data records; they are meant to stand for the spectrum of existing positions towards the issue. We asked them to choose two cards: one position which they found appropriate and could more or less align with and one position that they did largely disagree with. This choosing exercise helps participants to develop a starting point for their own position. After having come to a choice, we invited them to share their choice with the others and explain the reasons behind it. The cards and the discussion process support participants’ efforts to express their position towards questions of electronic health data records, they invite each person to first reflect on their own and then to open up a debate in the group. This enables a round of first exchanges of opinions, positions and experiences with electronic health records.

After this first stage had been concluded, we then walked them through the whole process of using the 4HP step by step. For this purpose, we structured the process in “**situations**”, i.e. moments **when users would have to act or take a decision** – such as registering to the future 4HP, giving IC, collecting health data, sharing data with the doctor/a loved one, providing data for research, being re-contacted after data-provision, or assembling an emergency information kit to be shared in case of e.g. an accident, to name but a few of the “situations”. These situation cards contained some mock-ups or other visuals to stimulate a clearer imagination of potential future interfaces (Figure 3).

They also gave us first insights into how participants reflected on the role of IC in the context of registering to use the 4HP.

Situation 2: Informed Consent

I am in the process of registration and I have entered my basic information. Now I get a declaration of consent displayed. This is a quite detailed document describing what I can do on this platform and how my data will be protected. I have to read it and then give my consent. I can also later retrieve and view the declaration of consent.



- What information is important to me so that I can give my consent to the use of the platform?
- In how much detail should I read the document, or can I trust the site anyway?
- What if I do not understand everything? Who would I want to talk to?
- What choices should be available for me?

Figure 3 – “Situation card” Informed Consent in Smart4Health (translation from the German language card; mock-up provided by D4L)

We ended with a discussion on the key-values that are essential in the citizens' views when developing and implementing the 4HP. Again, we offered them a set of cards to choose from (e.g. data protection, justice, solidarity, transparency, trust, burden, right to not know, privacy,), but also made empty cards available if they did not find the cards expressing their value choices. We asked them to choose three cards that they wanted us to specifically pay attention to in the further course of the project and of developing the prototype. This allowed us to extract specific scenarios of use, to identify major concerns citizens voice more generally and in specific situations, to learn what would be essential to them, but also more broadly speaking the values they would want to see respected.

4.2.2 CCW solely focusing on the Informed Consent (M11)

After having conducted four co-creation workshops with citizens, UNIVIE organized one co-creation workshop that was specifically **focussed on IC procedures** regarding the structure and social acceptability of IC forms, language and processes. Having received citizens' permission for re-contacting them for the purpose of further engagement exercises in the course of the project, **we recruited this group from participants of the previous four co-creation workshops**. This had the advantage that they already knew about the project and did not need a further introduction. Furthermore, as all of them had been participants in previous CCWs we could best identify a diverse group of people (regarding the above categories) for discussing IC issues.

This workshop started with a brief presentation in order to remind them of the purpose and approach of Smart4Health and the scope of the engagement. We then offered them a set of cards with each dealing with one part of the stabilized citizen-centred health data platform consent (ICp1). This allowed citizens to focus on each section of the consent form and then in a second step to reflect on both the information within each subsection of the IC as well as on the overall process. The cards covered the following aspects in the order they appear on the consent form (1-3 are visible in Figure 4:

- (1) the information cover letter,
- (2) the set of cards outlining
 - ✓ Smart4Health itself,
 - ✓ the scope of participation,
 - ✓ benefits, risks and costs,
 - ✓ data protection and security,
 - ✓ data donation (we had used this term on the cards as well as in the first version of the IC citizens) and
 - ✓ duration of data storage,
- (3) the declaration of consent and
- (4) the appendices.

We led them through each of the sections, inviting them to voice concerns that they have and issues that they want to raise. The outcome and analysis of which are presented in the following chapter.

Informationsblatt: Handlungsanweisung

1. Was ist Smart4Health?

2. Was ist der Zweck des Smart4Health Projekts?

3. Was beinhaltet meine Teilnahme am Smart4Health Projekt?

4. Zu welchem Zweck kann ich die Smart4Health Apps nutzen?

5. Welche Vorteile habe ich durch die Nutzung der Smart4Health Apps?

6. Welche Risiken habe ich durch die Teilnahme an Smart4Health?

7. Kann ich meine Gesundheitsdaten über Smart4Health der Forschung spenden?

8. Wie schützt Smart4Health meine Privatsphäre?

9. Wie speichert und schützt Smart4Health meine Daten?

10. Was passiert mit meinen Daten nach Abschluss des Projekts?

11. Fallen für mich Kosten durch die Nutzung der Apps an?

12. Muss ich an Smart4Health teilnehmen?

Einwilligungserklärung

Ich weiß und stimme zu:

- Ich bin über 18 Jahre alt.
- Ich bin in der Europäischen Union wohnhaft.
- Meine Daten werden in meinem Smart4Health Privatbereich gespeichert.
- Ich kann jederzeit zurücktreten (kündigen). Es gibt keine Strafe, wenn ich aussteige.
- Diese Zustimmung ist dynamisch, d.h. es kann zu Änderungen bei der Entwicklung der Apps und bei der Auswertung kommen. Wenn es Anpassungen gibt, werde ich kontaktiert, um meine Zustimmung erneut zu erteilen.

Bitte kreuzen Sie das untenstehende Kästchen an, wenn Sie mit der Teilnahme einverstanden sind:

Ich habe diese Einwilligungserklärung und die Anhänge gelesen (oder jemand hat sie mir vorgelesen). Ich verstehe die Informationen, die im Informationsblatt enthalten sind, und verstehe alle Vorteile und Risiken, die durch die Verwendung der Smart4Health-Apps entstehen. Ich verstehe, dass ich meine Einwilligung jederzeit widerrufen kann. Ich hatte Gelegenheit, Fragen zu stellen, und alle meine Fragen wurden zu meiner Zufriedenheit beantwortet. Ich habe mich frei und willens für die Teilnahme am Smart4Health-Projekt entschieden.

Die Teilnahme an Smart4Health ist völlig freiwillig. Sie können wählen, ob sie beitreten möchten oder nicht. Egal, was Sie jetzt oder in Zukunft entscheiden, es wird Ihre Gesundheitsversorgung nicht beeinträchtigen.

Sie können Ihre Meinung über Ihre Teilnahme auch ändern. Wenn Sie sich für die Smart4Health-Apps registrieren, Ihre Meinung aber später ändern, können Sie jederzeit gehen. Sie können Ihre Teilnahme über die Apps auf Ihrem mobilen Gerät und auf der Website oder über die Kontaktinformationen auf der ersten Seite schriftlich widerrufen.

Wenn Sie einen Austritt vornehmen, werden Ihr Smart4Health-Konto und Ihre hochgeladenen Daten gelöscht.

Figure 4 – Steps in the Platform IC for citizen co-creation workshops on user consent language

5 First observations concerning consent language

5.1 Citizens' concerns with consent language

In this chapter we present preliminary analytical observations on values and concerns with regard to IC processes and the language used. We draw on material from our first four CCWs regarding the IC situation and questions surrounding it, and in particular from the first discussion group specifically dedicated to the current IC form. Accordingly, the structure follows the IC form for reasons of readability and traceability of changes made to it. The IC form with adaptations based on input from citizens and experts will be presented in Deliverable 8.1.

Disclaimer: this is a first approach and has to be seen as a qualitative effort to identify key-concerns raised; the number of participants is relatively small; the platform is not yet up and working (so it is more a projection on a platform to come); and the discussion is held in a specific place (we aim to use the IC across many different national/local contexts). However, it was still very important to see the concerns that were raised, the situated understanding of the information delivered, the difficulty to grasp some of the jargon used (e.g. see debate below of what is meant by “apps”) and the places where more explanation is needed.

5.1.1 The information sheet as part of the Informed Consent

The information given for the project was perceived by the group as being too long, detailed and in part repetitive. Starting from this information sheet but also coming up as question throughout the following sections was in which context they would encounter this IC sheet, i.e. is it on the platform and they read it on their own or with a health care professional who introduces them to the platform.

Regarding the files mentioned (from health care practitioners or wearables), **a differentiation in the IC form between patient records and electronic health record was in citizens' view not drawn clearly enough**. Thus, it was unclear what data uploading will include: only those data meant for the patient or also those going to the health service provider (e.g. “Kassenteil und der Patiententeil”?). The purpose and benefit of being able to also upload data from fitness apps on mobile devices was questioned, as it was associated with potential yet undefined/unclear risks of collecting too much data.

The notion “file” used in the text also sparked questions about who should do the uploading. One participant constructed the example of an older user persona (83-year-old woman) to underline the importance of knowing early on who will be doing the work of uploading and managing health data once a person can no longer do so. In his/her thinking, which was backed by the others too, the persona would refrain from signing up and using the health data platform if it were solely her duty to do all the uploading, and not also her doctor's.

Takeaway 1:

- The project description should be built in a way that allows people to select between basic info and different levels of extended information. This point was also brought up by the ethics expert vetting the IC form.
- The notions used in the project description should be clear (or a short explanation should be added).

5.1.2 Questions outlining Smart4Health

» *What is Smart4Health?*

This section was perceived as being too detailed, especially the list of countries where the partners come from, which can also be found in appendix A (of the IC form presented in D8.1). Yet, two details were regarded as missing here:

- (1) what kinds of private organisations are involved and
- (2) why is a US partner involved in an EU project.

Both points were discussed critically, as the former triggered associations with pharmaceutical industry (which was seen as only wanting to profit from patient data), and the second raised concerns about US access to EU data, what this means for data protection, and on which legal basis that partner acts. The role of the US partners thus needs to be clarified early in the document (it is done later in the document but needs to move up).

Takeaway 2:

- Re-formulate partner information in order to not trigger these kinds of questions.

» *What is the purpose of Smart4Health?*

In terms of the project's purpose, it was unclear who would be the one to do the managing of data.

Furthermore, the description was perceived as being, again, too detailed and already having been outlined on the first page (the information sheet).

A repeating theme was the lack of understanding of the notion “apps” and in particular why the plural was used.

Takeaway 3:

- It would be beneficial to (briefly) explain what “apps” refers to here (for citizens this notion is tied to other understandings, e.g. my banking app) and what kinds of apps are developed in the course of the project (e.g. apps to upload data from wearables or physio machines). These could then also be mentioned in appendix A where it is explained what each partner does in the project.
- Also, the issue of who will have to be active in managing data needs to be clear from the start.

» *What does my participation in Smart4Health involve?*

Regarding the list of bullet points in the IC form, it was not clear if it should be read as a sequence and how strict it was – for example, would it also be possible to install the app(s) first and only then register? While that question indicates a wish of having a sequential order, others read it in a non-linear fashion.

Following this point of discussion was the question if the first data upload already takes place when creating the profile, and if that includes health data? This led participants to pose further questions, such as what the profile creation entails concretely; i.e. the scope and type of information requested, if the profile is something that could be accessed by others (if given permission), and when the uploading begins in the process.

Interestingly, a participant being very positive about using EHRs and enthusiastic about what Smart4Health aims to achieve, got irritated and outright annoyed by the

last bullet point, because it mentioned again the data donation option (rephrased now as data provision). The inclusion of its optionality in the text and the reformulation to data provision might help therein (see more under the data donation question below).

Takeaway 4:

- Rethink what the bullet point list communicates;
- Data provision should not be mentioned too often in order to not create the impression that the platform is mainly about harvesting health data from citizens.

» *What else will you be asked to do?*

When reading about the option of giving feedback and partaking in user engagements, one of the participants only realised that this is an IC process for a prototype research and development project. Other participants found the information sufficiently clear.

The group agreed that the language used was at times overly simplistic, such as the repeated use of 'you can say yes or no'. This should be replaced according to their view.

Takeaway 5:

- It needs to be highlighted right from the start and very explicitly that this is a consent for participating in a **research project**.
- Consider the level of simplification

» *For what purpose can I use the Smart4Health apps?*

Here again, apps in plural confused the participants. They were concerned about having to download and use many different apps for the purpose of using the platform, without knowing how many and which kinds.

Concern was voiced regarding if and how one could upload results etc. from an 'analogue' source. After all, a participant said, many of such files are still on paper at home. The follow-up question thus addressed if and how such files could be uploaded, and who is supposed to do that, i.e. if others could do that for them or if they would need to.

When speaking about the functionality of sharing data, which is explained as "show and send" (in brackets), the notion 'send' caused confusion, as it was unclear what 'sending' implies and what exactly is being sent. Does one really send information or simply give access to information?

Takeaway 6:

- It will be important to have a place where notions such as uploading, sharing or giving access are explained in an unambiguous manner.

» *What benefits may I experience when using the Smart4Health apps?*

Some of the participants did not appreciate and were even appalled by the formulation "You may be able to better handle your own health data in the following ways", as this seemed to imply that they are incapable of doing this at the moment.

Takeaway 7:

- Delete this formulation as it is perceived as patronizing.

» *What are the risks of taking part in Smart4Health?*

This was a hot topic in the context of these discussions for two reasons:

The very limited scope and the way it is communicated. Given that the risks are not outlined in detail here – actually only one is mentioned – it seemed to them as if risks were downplayed and, therefore, something is being hidden. Hence, this seemed to put trust at risk.

The shortness of this section also triggered a surprised reaction as the information sheet promises that risks (in plural) will be addressed in the following paragraphs (just like the benefits), but then only a brief “minimal risk” is mentioned.

Takeaway 8:

- Data risks are widely debated in contemporary societies. Health data are seen as data to be strongly protected. Therefore, the question of risks should be spelled out more clearly.

» *How does Smart4Health protect my privacy?*

This point was similarly controversial as the one on risks. The way privacy protection is formulated was not seen as adequate by the citizens in the CCW. The participants expected to get a much more formal/legal description, even if this meant a longer explanation.

One particular phrase – “We will work very hard to protect ...” – caused irritation and some mockery. This was understood as a ‘we will try’ approach.

They also formulated the more complex question if data security, in this case, is not also a matter of how others, e.g. the health care practitioner, handle their data.

Also missing was in citizens’ view an explanation about the 72 hours timeframe of being contacted after a data breach; they wanted to know more about procedures such as: What will happen after being contacted? Is that timeframe mandatory? and Why can it not be shorter?

Takeaway 9:

- The part on privacy would need a more detailed explanation of how protection is implemented and how potential data breaches will be handled and communicated.

» *How does Smart4Health store and protect my data?*

This section did not receive any criticism. Instead, the information about the US partner and that no data transfer to the US takes place was highly appreciated and regarded as very important. (See the comment above about a reference to this section, when mentioning the US partner for the first time).

Takeaway 10:

- Transparency is highly appreciated and manages to quickly dissolve suspicions (e.g. why an US partner is involved in an EU project needs to be clearly spelled out).

» *Can I donate my health data to Smart4Health for research?*

As highlighted above (under What does my participation in Smart4Health involve?), the repeated presence of the donation element led to annoyance of a participant, who was actually very positive about EHR usage and the Smart4Health project (e.g. willing to sign-up very quickly). He perceived it as a constant reminder and would have preferred reading about it only once, or for instance briefly up front and then once in detail.

Although both we as moderators as well as other participants explained that the data donation is part of the project and thus needs appropriate mentioning, he thereby got the impression that it is actually more about the data donation than giving citizens something helpful to manage their own health data (despite being integral to it). For him it thus seemed to be a trust issue.

While the remaining group understood and accepted the mentioning of data donation, also they perceived it as being too pushy and too prominent. Collectively, the idea was born to subsume the data donation option under the phrase of ‘managing health data’ from the start, and only mention it here explicitly to not drop the donation notion entirely and put trust potentially at risk.

The participating citizens, however, also suggested to rephrase the notion of donation, as it was also associated with caritative purposes such as for church, and was thus deemed as being inappropriate. Suggestions revolved around the German notion ‘Datenfreigabe’ (data clearance, approval, authorization, provision), which also captures the voluntary decision and the one-way transfer of data. As both the experts, ethical and legal, proposed to reformulate the donation notion too, we see this also supported by the citizen group.

In regard to the receiving-end of the data donation/provision, the question was raised on which basis researchers are authorized, by which criteria, who exactly decides on this, and what makes a researcher qualified? As the latter point can be expected, it was dropped in the text. Thus, the regulatory board still needs explanation for citizens, which confirms its status as an open issue in the text, and could also refer to appendix C on legal aspects.

Takeaway 11:

- Change the use of “data donation” to “data provision for research” or similar wording.
- Clarify how access to data provided for research will be handled; this comes down to make the governance of the health data platform and its services more explicit and transparent.

» *What will happen to my data once the project ends?*

A collective comment was made that this question should come at the end of the IC. The wording of project completion caused irritation, as it was understood as being different to the clearly stated end-date.

An explanation was requested about the 6-month timeframe for the automatic deletion of the user’s data and account after the project ended. A participant thought that it is generally 3 months after not hearing from a user, and would have liked to get some background information on this (either here or in an appendix).

Takeaway 12:

- Move this section to the end of the IC.
- Clarify the wording of what “the end of the project” means.
- Explain the timelines given.

» *Are there any costs associated if I use the apps?*

While this one-sentence-section was slightly awkward to read for the participants, because of temporal differentiation between “now and then” within the same project, they understood it as a legally required terminology.

Takeaway 13:

- Be a bit more explicit about the why of the differentiation between now and then (prototype and product).

» *Do I have to take part in Smart4Health?*

In general, but in this section in particular, the participants felt not being taken seriously when things were explained in simple language and very short sentences (e.g. 'You can say yes or no'). They had expected a more legal language and felt that the language used was somewhat condescending in not considering that they would be able to understand it, given that one has to sign such forms regularly.

The participants, however, understood the necessity of formulating the IC in an easily approachable and thus inclusive way.

Takeaway 14:

- Adapt terminology slightly and avoid repetitions.
- This supports the approach of further testing the consent language in various environments to ensure a widely intelligible consent language, which, however, also meets general expectations on how wordy it is written.

5.1.3 Declaration of consent

Having had the possibility to ask questions is an important element of the IC. Yet, in the context of the consent within the application, participants wanted to know who will be responding to their questions. The formulation implies a relationship that supports the consent procedure, yet it is unclear, if this will be in place for everyone who signs the IC. Is it enough, to be able to get in contact with someone and pose questions?

Moreover, out of their experience of getting in touch with support electronically, a clear reservation against a generic 'service hotlines' or similar (e.g. preformulated Q&A) was stated. It was suggested though that this could be mitigated by having the option to select a sub-topic first before contacting any person further.

Finally, the question was raised if a checkbox alone will define the actual consenting, and why the box needs to be checked if there is no alternative box, e.g. 'I want to be contacted first' or similar? However, the current layout of the single checkbox was accepted in case that it appears in a digital format, i.e. e-consent, in which it might activate the signature field.

Takeaway 15:

- Reconsider the options offered at the moment of consenting.
- Clearly communicate the information infrastructure (who will respond to questions by users, ...).

5.1.4 Appendices

Appendix A:

The first of the above questions triggered the participants' desire to know more about each partner, e.g. if public or private and in which private sector (to make sure pharma is not onboard). The country of origin did not matter at all, except for the US partner, whose role in the EU project could also be explained here.

The current table thus would benefit from a public/private distinction and a brief description of the partners' roles in the project (e.g. developing XY, testing Y, or similar).

Appendix B:

This section went by rather unnoticed, as no questions were posed at this point in time. However, also the circumstance of not being able to actually use what is described here, might make it too abstract to reflect on.

Hence, it can be expected that this will change once users will be able to compare their use experience with the platform against the description of its functionalities here. The upcoming User Engagement Exercises in the context of the CUCs with first functional versions of the platform will be important in this regard.

Appendix C:

The participants were particularly curious about the Smart4Health regulatory board and wanted to have a point somewhere, where one could find out more about it (see above about data donation/provision). Furthermore, they emphasized the importance of having a general point of contact. This seemed to reflect a need for having a concrete counterpart who is responsible for user-related activities and thus facilitates trust towards the platform.

5.2 Vetting of the IC by expert on ethical and legal issues around informed consent under the GDPR

5.2.1 Vetting by expert on ethical issues

As expert on ethical issues in relation to medical and data related issues we contacted Prof. Barbara Prainsack. She knew the Smart4Health project as she was one of the experts also discussing D1.1 with us. She is a member of the European Group on Ethics advising the European Commission, of the National Bioethics Council advising the Federal government of Austria, and a member of the UK National DNA Database Ethics Group.

Overall, she assessed the IC form as containing all the essential parts and insisted on the importance of having an IC process for the use of the 4HP. She asked for a number of specifications to be made in the text, to clarify notions used and made suggestions, which were integrated into the current "final version" of the platform consent (ICp1) where possible (see D8.1).

Here are her main concerns raised:

- 1) The IC form as it stands is quite long and demands a lot of attention and time when reading through it. She suggested that over the course of the project and through doing more discussions of IC with citizens, to develop a model of an IC which is available online and offers different levels of detail which can be chosen by each person. In particular, as the IC process for the platform might be developed as an online/digital version, she suggested to build a basic short version of the IC, which can be expanded in each section if citizen users want to know more. An online IC would also allow to use visuals, short videos, etc. to make the information acquisition process as interactive as possible. In this way, each citizen can decide on the details he/she wants to know.

- 2) She pointed to the fact that instead of using the notion of “data donation” it would be better to use the notion of “providing data for research”, which ties into current debates around issues of using the notion of data donation. This is in line with a recommendation also made by the legal expert referred to below. The notion of data donation was also critically reflected by the citizens in the group dedicated to the IC.
- 3) At several occasions she underlined that it might be difficult for citizen users to imagine what was exactly meant by certain notions. Therefore, she suggested to insert examples at specific places throughout the document.
- 4) Finally, she noted some imprecisions in formulations and made suggestions for reformulation.

All this has been integrated into the version of the Informed Consent that can be found in the Annex to D8.1.

5.2.2 Vetting by expert on legal issues (HPI)

Due to its high relevance for the project, we had the consent developed by the consortium legally reviewed by Dierks+Company, a law firm specializing in European data protection law in health care and life sciences. Dierks+Company assessed the IC form for the use of the CHDP. They concluded that there is **information missing** on the privacy policy while the wording concerning the consent should be **more concrete** to be legally binding.

Therefore, Dierks+Company suggested to **separate the privacy policy** from the IC form and **shorten the IC**. In the privacy policy each processing needs to be explained. Also, information about the project itself is not required for the consent form. Rather, they advised against, for example, including the information on the constantly changing processing, as this could lack the certainty of the privacy policy and/or the consent.

A proposed draft of a new consent form in combination with a draft privacy policy are to be found in D8.1 to demonstrate how that could be realized. Note that these documents have not been adjusted to reflect the project so far. Dierks+Company’s assessment considers also the rather strict views of the German Data Protection Authorities. At the stage of writing this deliverable we are considering following their advice, especially since the data controller of the Smart4Health infrastructure Data4Life will be subject to the Brandenburg⁸ authorities’ scrutiny.

Dierks+Company also pointed out that **general terms of use are required** for legal aspects in order to establish rules for the use of the platform. Otherwise, the respective law of the country would apply, which may differ from country to country and be unfavourable for the consortium partners. This applies to Smart4Health in the following aspects:

- Declare that misuse of the platform by storing other than medical or health-related data is forbidden.
- Declare that we are not liable in case a user uploads data, which falls under copyright or author’s law.
- Restrictions on use due to server failures; force majeure
- Liability and accountability

⁸ Brandenburg is a region in Germany.

- Indemnity in case of any technical misuse, e.g. brute force attack
- Damages
- Copyright a.o.

Background Dierks+Company

As expert on legal advice in relation to medical and data related issues throughout Europe we contacted Prof. Dr. med. iur. Christian Dierks of Dierks+Company Rechtsanwaltsgesellschaft mbH. Prof. Dierks has been thoroughly informed about the Smart4Health project and knows HPI and Data4Life from former cooperation. He is one of the leading lawyers for medical law in Germany and Europe and has provided legal advice in many EU and national projects. He is a trained physician, expert in regulatory issues, reimbursement, digital health and member of or liaised with Charité Berlin, GVG, TMF and AWMF.

Dierks+Company has special experience in EU-wide consulting on data protection law. Due to the lawyer's duty of confidentiality, the projects cannot be explicitly named. Based on the information provided by D+C, we can describe some projects they advised as follows:

1. Comprehensive advice in data protection law on the issue of cross-border, shared use of servers by various physicians and service personnel;
2. Legal advice on special characteristic of consent in clinical trials for a European association;
3. Legal Opinion on data privacy regarding a comprehensive register for the Baltic Sea region in Sweden, Finland, Lithuania, Poland, Estonia and Germany with numerous locations in hospitals in these countries.

6 Summary and final considerations

The objective of Deliverable D1.4 was to outline a first set of observations concerning citizen/user consent language in the framework of the Smart4Health project. The central aim of Smart4Health is to develop a health-data infrastructure aiming at supporting citizens as future users to manage their own health (data). Therefore, the project puts European citizens centre-stage – conceptually and methodologically. Designing and implementing informed consent procedures with and suitable for citizen-users are therefore important to the development of the project. We do so in consideration of the GDPR and EU policy as well as of previous experiences made with informed consent processes.

Proposing a co-creation approach to building the health-data platform and its services testifies to the consortium’s awareness that the final prototype must meet the needs and concerns of future users, both citizen- and professional users. Therefore, it is essential to ensure that the informed consent processes also meet this key objective. To achieve this objective, we studied existing informed consent forms and processes, analysed input from citizens partaking in co-creation workshops and had the first version of informed consent form also vetted by experts on ethical and legal issues. This report marks a first step in this process which will continue all along the Smart4Health project, engaging with a diverse set of users in different contexts in order to better understand and refine the informed consent processes. For the time being, this report only focuses on the informed consent future users would need to sign before starting to use the health-data platform and engages with the consent language used in this context.

The deliverable inscribes itself in the framework outlined in Deliverable D1.1 and to the co-creation process outlined in D1.2. Therefore, it attended to the four core values of inclusiveness, anticipation, reflexivity and responsiveness, which are seen as core to our work. Concretely, this meant for the deliverable (1) to anticipate issues that might emerge in offering citizens a space for uploading, storing and making accessible of their health data and that must be addressed in an informed consent, (2) to be as inclusive as possible at this stage in developing and vetting this first version of an informed consent for the health-data platform prototype (chapter 3), (3) to reflect how the first version of the IC was produced (chapter 4), and (4) how potential future users perceive both the consent form and the process (chapter 5.1), and to ensure that the IC process and the supporting forms will be revised when new situations and/or regulations come up (responsiveness) (see Deliverables D8.1 and D8.2, which also address questions of informed consent, as well as D1.9 the follow-up report to this Deliverable).

After a short introduction to the report and its structure, chapter 3 presented five lines of considerations of how to address informed consent in health-data related domains. They contain important context information for the next chapters which described the process as well as the outcomes. These considerations embraced in 3.1 reflected on the question of autonomy of data subjects and agency, which will be essential to consider when inviting citizens to engage with the Smart4Health platform. In 3.2 we then discussed the notion of information in “informed consent.” This subchapter covered questions of informational obligation, highlighted the context dependency of any information provided as well as addressed issues of trust and data literacy. In the third part of this chapter (3.3) we shortly touched on questions where data are located, and moved in 3.4 on to address the question whether donation could be regarded as

the appropriate notion given the specificity of data. Finally, section 3.5 addressed a specific element of Smart4Health, namely the e-consent. While this is not yet relevant given the early development of the project, it will be important to start reflecting on it as it will offer new ways to deliver informed consent.

Chapter 4 laid out in detail the process of producing the first informed consent form for the 4Health platform. We described in the first subchapter in detail the production process, which is important to reflect on the considerations that went into the development and to learn what we had overlooked in the early phase when it comes to the specificities of Smart4Health. In the second part we described the methodologies applied to elicit assessments of the IC form by citizens as potential users.

The core outcomes of the report are then captured in chapter 5, where we engaged in detail with the co-creation workshops with citizens as well as with the vetting of the IC form by ethical and legal experts. In the co-creation workshops with citizens feedback was collected by going step by step through the IC form, discussing the information contained, what was missing (or too much) and the language used. However, they also reflected on the overall process of informed consent and how it was foreseen that future users could get answers to some of their concerns/questions. Their rich and valuable comments were summarised around 15 takeaways, many of which have flown into the reformulation of parts of the informed consent form. These, however, will also need to be addressed in building the information environment of the platform (e.g. help desk etc.). At the same time, it is essential to see these comments as a first step. All along the co-creation process we will collect further input by users and work on refining process and information given to users.

Furthermore, the ethical and legal experts gave us valuable advice. Part of it touches on user/citizen consent language, which is the core of this deliverable. The legal experts open up further questions, which the consortium will need to explore in the coming weeks.

Overall, the engagement with potential users showed the importance of the co-creation process. We obtained quite detailed reflections which transmit citizens' concerns and direct our attention to sensitive issues we need to be attentive to when developing the platform prototype. Hence, also the context of this report, in which we express the information needed by citizens to make an informed decision of whether or not to use the health-data platform Smart4Health, is developing. It also points to further work needed. More specifically, Smart4Health will have to engage with informed consent procedures in different national contexts and environments where Smart4Health is used (e.g. at work, in the hospital or from home) and thus also respond to different language environments and health care cultures.

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List of Acronyms/Abbreviations

Acronym/ Abbreviation	Description
4HP	4Health Platform
AWMF	Arbeitsgemeinschaft der Wissenschaftlich Medizinischen Fachgesellschaften e.V.
CCW	Co-creation workshop
CHDP	Citizen Health Data Platform
CUC	Citizen Use Case
D	Deliverable
D+C	Dierks+Company
D4L	Data4Life gGmbH
DNA	Deoxyribonucleic acid
EC	European Commission
EFN	European Federation of Nurses
EHR	Electronic Health Record
ELGA	Elektronische Gesundheitsakte (Austrian EHR)
ELIXIR-LU	European infrastructure for life science information – Luxembourg node
EU	European Union
EWG	Ethics Work Group
FP7	EU Research and Innovation funding programme 2007-2013
GDPR	General Data Protection Regulation
GVG	Gesellschaft für Versicherungswissenschaft und -gestaltung e.V.
H2020	EU Research and Innovation funding programme 2014-2020, Horizon 2020
HPI	Hasso-Plattner-Institute for Digital Engineering gGmbH
IC	Informed Consent
IC CUC	Informed Consent for partaking in CUC related activities
IC COCR	Informed Consent for partaking in co-creation activities
ICp	Informed Consent during project/prototype phase
ICp1	Informed Consent for using the CHDP
ICp2	Informed Consent for using the RP
ICpf	Informed Consent for final prototype/product
ICT	Information and Communication Technology

ITTM	Information Technology for Translational Medicine
ISMMS	Icahn School of Medicine at Mount Sinai
I-VLab	Laboratoire Virtuel Européen dans le Domaine de l'interopérabilité des Entreprises AISBL
KBZ	Knowledgebiz
M	Month
OSR	Ospedale San Raffaele
Q&A	Questions & answers
REB	Research ethics board
RP	Research Platform
SHD	Stiftung Hëllef Doheem
S4H	Smart4Health
SME	Small and medium enterprise
T	Task
TelCo	Telephone Conference
TMF	Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.
UK	United Kingdom
UKA	Universitätsklinikum Aachen
UMC+	University Medical Center Maastricht
UNINOVA	Instituto de Desenvolvimento de Novas Tecnologias
UNIVIE	University of Vienna
US	United States
USEE	User Engagement Exercise
WP	Work Package
ZS-UG	ZS Unternehmen Gesundheit

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