Special issue

# The dynamic consent of the Cooperative Health Research in South Tyrol (CHRIS) study: broad aim within specific oversight and communication

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ABSTRACT: In biobanking and genomics research, data and samples are stored for long time and used in further studies, which may not be sufficiently specified or foreseen at the time of the initial consent. The dynamic consent of the CHRIS study integrates broad research aims, specific oversight and governance mechanisms, and continuous communication with participants, and allows nuanced choices to be changed over time. With this paper, we describe the CHRIS dynamic consent, and illustrate, by discussing data sharing and ongoing consent in the CHRIS study, how dynamic consent can actualize an informed consent model that is suitable for biobanking and genomic research.

KEYWORDS: Dynamic consent; biobanking research; oversight; communication

SUMMARY: 1. Which informed consent for biobanking and genomics research? – 2. Dynamic consent in practice: the case of the CHRIS study – 2.1. The CHRIS study – 2.2. Ten years of dynamic consent in the CHRIS study – 2.2.1. Dynamic informed consent for participation in the follow-up phase of the CHRIS study – 2.2.2. Information for an informed decision on participation in research – 3. Data sharing and ongoing consent in the CHRIS dynamic consent: broad consent within strong governance, oversight mechanisms, and ongoing information – 4. Conclusions.

## 1. Which informed consent for biobanking and genomics research?

Genomics and biobanking research have been generating considerable amounts of data and biological samples, which are invaluable dynamic resources for health research conducted through large size and long-term research projects. In biobanking, collected data and samples are stored and can be used for future studies, and can be shared in wider international and global research networks. This type of research poses ethical challenges: for example, given the long-term dimension of the research project and the rapid development of technology, the future uses of data and samples may not be defined nor foreseen at the time of initial consent, therefore

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providing an actual informed consent for the future uses of data and samples might result problematic. A debate on what kind of informed consent would better address the challenges posed by genomics research and biobanking is ongoing. Different consent procedures have been discussed, besides specific or broad consent, as possible approaches to meet the researchers' need for flexibility on the use of data and samples, and, at the same time, to protect participant autonomy and privacy, to protect against risks of harm, and to inform participants about the aims of the research and the risks and benefits of participation (e.g., solutions that envision broad consent coupled with governance and oversight mechanisms and provision of information, meta-consent, tiered consent, dynamic consent).[1]

Dynamic consent[2] has been proposed as a solution that allows both to meet the needs of the most recent biomedical research, and to comply with the ethical and legal requirements for participation in research. Dynamic consent is an interactive informed consent model. It is implemented through an online platform that allows a flowing communication between researchers and participants, and also a timely revision of the choices made regarding participation in research by participants. Dynamic consent is meant as a participant-centered[3] informed consent model which promotes participant autonomy, in particular in the case of long-term genomics projects, longitudinal studies, and biobanking research, where uses of data and samples may not be defined and explicitly foreseen at the time of recruitment. The flow of information will allow participants to be updated about further research developments and to make autonomous choices according to the changing circumstances in life and their values.

In the present paper, we describe the dynamic consent of the Cooperative Health Research in South Tyrol (CHRIS) study,[4] and we focus on two specific aspects of the CHRIS dynamic consent: data shar-

[1] E. Vayena, A. Blasimme, *Health research with big data: Time for systemic oversight,* in *The Journal of Law, Medicine & Ethics*, 46, 1, 2018, 119-129; C. Grady, L. Eckstein, B. Berkman, D. Brock, R. Cook-Deegan, S. M. Fullerton, H. Greely, M. G. Hansson, S. Hull, S. Kim, B. Lo, R. Pentz, L. Rodriguez, C. Weil, B. S. Wilfond, D. Wendler, *Broad consent for research with biological samples: Workshop conclusions*, in *The American Journal of Bioethics*, 15, 9, 2015, 34-42; D. Mascalzoni, A. Hicks, P. Pramstaller, M. Wjst, *Informed consent in the genomics era*, in *PLoS Medicine*, 5/9, 2008, 1302-1305. R.B. Mikkelsen, M. Gjerris, G. Waldemar, P. Sandøe, *Broad consent for biobanks is best - provided it is also deep*, in *BMC Medical Ethics*, 20, 71, 2019, 1-12; M. Sheehan, R. Thompson, J. Fistein, J. Davies, M. Dunn, M. Parker, J. Savulescu, K. Woods, *Authority and the future of consent in population-level biomedical research*, in *Public Health Ethics*, 12, 3, 2019, 225-236; T. Ploug, S. Holm, *Meta consent: a flexible and autonomous way of obtaining informed consent for secondary research*, in *BMJ*, 350, h2146, 2015, 1-4; H.J. Teare, M. Prictor, J. Kaye, *Reflections on dynamic consent in biomedical research: the story so far,* in *European Journal of Human Genetics*, Nov 28, 2020, 1-8.

[2] I. Budin-Ljosne, H.J. Teare, J. Kaye, S. Beck, H.B. Bentzen, L. Caenazzo, C. Collett, F. D'Abramo, H. Felzmann, T. Finlay, M. K. Javaid, E. Jones, V. Katić, A. Simpson, D. Mascalzoni. *Dynamic consent: a potential solution to some of the challenges of modern biomedical research*, in *BMC Medical Ethics*, 18, 4, 2017; J. Kaye, E. A. Whitley, D. Lund, M. Morrison, H. Teare, K. Melham, *Dynamic consent: a patient interface for twenty-first century research networks* in *European Journal of Human Genetics*, 23, 2, 2015, 141-146.

[3] J. Kaye, L. Curren, N. Anderson, K. Edwards, S. M. Fullerton, N. Kanellopoulou, D. Lund, D. G. MacArthur, D. Mascalzoni, J. Shepherd, P. L. Taylor, S. F. Terry, S. F. Winter, *From patients to partners: participant-centric initiatives in biomedical research*, in *Nature Reviews Genetics*, 13, 5, 2012, 371-376.

[4] The study protocol of the CHRIS study was described in C. Pattaro, M. Gögele, D. Mascalzoni, R. Melotti, C. Schwienbacher, A. De Grandi, L. Foco, Y. D'Elia, B. Linder, C. Fuchsberger, C. Minelli, C. Egger, L. S. Kofink, S. Zanigni, T. Schäfer, M. F. Facheris, S. V. Smárason, A. Rossini, A. A. Hicks, H. Weiss, P. P. Pramstaller, *The Cooperative*


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ing and ongoing consent. With these two cases, we illustrate how the dynamic consent of the CHRIS study actualizes a model in which broad and specific coexist, meaning that the broad aim of research is framed within strong governance and oversight mechanisms, and an ongoing specific communication, which allow participants to be informed and to make autonomous choices on participation in research through time.

## 2. Dynamic consent in practice: the case of the CHRIS study

The CHRIS dynamic consent was developed as a solution to meet the researchers' needs of conducting a long-term longitudinal biobank-based project, and the ethical and legal requirements for research in Italy, such as transparency and specific consent. In this section, we briefly describe the CHRIS study, and the dynamic consent as developed and implemented in the frame of the CHRIS study.

### 2.1. The CHRIS study

The CHRIS study is an ongoing longitudinal study, whose aim is to analyse the interplay among the genetic mechanisms, environmental factors, and human behaviour, which results in chronic conditions associated with human ageing in the general population of South Tyrol, Italy. The focus of the study is twofold: besides aiming to understand the etiological role of genetic and environmental risk factors on the onset and course of cardiovascular, neurological, metabolic, and oncologic diseases, the CHRIS study intends to promote awareness on the themes of health promotion and disease prevention.[5]

The CHRIS study started in 2011. The cohort was recruited in the middle and upper Val Venosta in South Tyrol, by inviting all the residents registered in the electoral list of 13 municipalities of the valley. The recruitment phase proceeded until December 2018, while the first follow-up phase begun in October 2019.[6] CHRIS researchers have been collecting biological samples (e.g., blood, urine) and data (anthropometric data and data on family history, lifestyle, and health, obtained through clinical

*Health Research in South Tyrol (CHRIS) study: rationale, objectives, and preliminary results,* in *Journal of Translational Medicine,* 13, 2015, 1-16. Further information on the CHRIS study can be found in the Eurac website (http://www.eurac.edu/en/research/health/biomed/projects/Pages/CHRIS.aspx last visited 16/01/2021) and in the dedicated CHRIS website (https://it.chris.eurac.edu/ last visited 16/01/2021).

[5] C. Pattaro, M. Gögele, D. Mascalzoni, R. Melotti, C. Schwienbacher, A. De Grandi, L. Foco, Y. D'Elia, B. Linder, C. Fuchsberger, C. Minelli, C. Egger, L.S. Kofink, S. Zanigni, T. Schäfer, M. F. Facheris, S. V. Smárason, A. Rossini, A. A. Hicks, H. Weiss, P.P. Pramstaller, *The Cooperative Health Research in South Tyrol (CHRIS) study: rationale, objectives, and preliminary results,* cit., 1-2.

[6] Since March 2020, when the COVID-19 emergency hit Italy, the CHRIS follow-up has been suspended. However, CHRIS researchers, in collaboration with Azienda Sanitaria dell'Alto Adige, developed and implemented the CHRIS-Covid-19 study, which started in July 2020. The study aims to understand the determinants of the infection and of viral transmission, and to study the immunity development and the long-term effects on health of SARS-CoV-2 infection (https://it.chris.eurac.edu/_startpage/chris-covid-19/, last visited 07/01/2021). The CHRIS follow-up is envisioned to re-start later this year when conditions for safety will allow.

examinations and questionnaires) from a closed cohort of more than 13000 adult participants.[7] All the data and samples are safely stored in the CHRIS biobank.

### 2.2. Ten years of dynamic consent in the CHRIS study

The dynamic consent of the CHRIS study can be defined as broad, for the broad description of aims of research and the broad time frame, but also specific, as regards the security of information, the data handling, the governance mechanisms, and the continuous information. The dynamic consent of the CHRIS study consists of two integrated components, the informed consent with dynamic options and the information material delivered through an ongoing multimedia, multilevel and culturally sensitive communication strategy.[8] The informed consent is an online interface, accessed for the first time and filled in at the study centre in Silandro, when prospective participants decide to enrol and participate in the CHRIS study. Through the online dynamic informed consent, participants express their preferences for each item of the consent. At any time afterwards, they can access their informed consent and visualize and change, if they wish so, their choices by entering MyCHRIS, a password-protected personal area of the website, which contains informed consent forms, clinical results, and further information on participation and data and samples use.

Prospective participants are invited through an invitation letter, which is sent at home. At the time of the initial consent (during the baseline), participants received all the relevant information through the brochure, which is integral part of the informed consent and whose aim is to explain all the aspects of the study. In order to participate in the first follow-up phase, invited participants receive a brochure about the follow-up study and sign a new dynamic informed consent at the study centre. Two brochures were issued so far: the first one, for the informed consent for participation in the CHRIS baseline, during the recruitment phase 2011-2018; the second one, for the informed consent of the first follow-up phase (from 2019). At the study centre, participants go through visual information material (videos, presentations), which explains the study and all the issues related to participation, and may ask the CHRIS study team questions and clarifications, if they wish so. The communication with study participants continues through the website, newsletters, emails, letters, text

[7] C. Pattaro, M. Gögele, D. Mascalzoni, R. Melotti, C. Schwienbacher, A. De Grandi, L. Foco, Y. D'Elia, B. Linder, C. Fuchsberger, C. Minelli, C. Egger, L. S. Kofink, S. Zanigni, T. Schäfer, M. F. Facheris, S. V. Smárason, A. Rossini, A. A. Hicks, H. Weiss, P.P. Pramstaller, *The Cooperative Health Research in South Tyrol (CHRIS) study: rationale, objectives, and preliminary results,* cit., 5-11; D. Noce, M. Gögele, C. Schwienbacher, G. Caprioli, A. De Grandi, L. Foco, S. Platzgummer, P.P. Pramstaller, C. Pattaro, *Sequential recruitment of study participants may inflate genetic heritability estimates*, in *Human Genetics*, 136, 6, 2017, 743-757; F. Murgia, R. Melotti, L. Foco, M. Gögele, V. Meraviglia, B. Motta, A. Steger, M. Toifl, D. Sinnecker, A. Müller, G. Merati, G. Schmidt, A. Rossini, P.P. Pramstaller, C. Pattaro, *Effects of smoking status, history and intensity on heart rate variability in the general population: The CHRIS study*, in *PLoS One*, 14, 4, 2019, 1-17; R. Melotti, R. Ruscheweyh, P.P. Pramstaller, A.A. Hicks, C. Pattaro, *Structural consistency of the pain sensitivity questionnaire in the Cooperative Health Research In South Tyrol (CHRIS) population-based study*, in *The Journal of Pain*, 19, 12, 2018, 1424-1434.

[8] For an overview of the dynamic consent of the CHRIS study: C. Pattaro, M. Gögele, D. Mascalzoni, R. Melotti, C. Schwienbacher, A. De Grandi, L. Foco, Y. D'Elia, B. Linder, C. Fuchsberger, C. Minelli, C. Egger, L. S. Kofink, S. Zanigni, T. Schäfer, M. F. Facheris, S. V. Smárason, A. Rossini, A. A. Hicks, H. Weiss, P. P. Pramstaller, *The Cooperative Health Research in South Tyrol (CHRIS) study: rationale, objectives, and preliminary results,* cit., 3-5. . Additionally, a manuscript aon an overall assessment of the CHRIS dynamic consent, focused on participation, trust, and communication during the recruitment phase is currently under review.

messages, and public conferences and press releases for the general public as well. All these different communication tools are meant to keep participants informed and updated about the development of the study, the achievements and outcomes of the research, and are used also to promote engagement and participation, and a trust-based relationship with participants. In the dynamic consent, an ongoing and continuous communication plays a key role in the informed consent process, and for the consent to be meaningfully informed through time.

With the beginning of the first follow-up phase, changes in several aspects of the study were introduced and novel aspects were added in comparison with the baseline. For example, new types of data and additional clinical measurements are collected, and new strategies of data collection are employed (e.g., through smart devices and remote phenotyping). Furthermore, participants are asked to give the CHRIS study permission to access their medical records (exclusively for health data which are relevant for the aim of the CHRIS study), and to consent to the production and storage of immortalized cell lines for functional studies. The ongoing consent process, and the related communication to participants have been refined and clarified (see below in 3.). The information on the governance for the return of results has been furtherly improved with a nuanced model describing four genetic diseases: participants are provided with a description of four types of genetic results, which are associated with pathologies differing for severity, transmission, opportunities for therapy and prevention. This information is meant to clarify the meaning and the implications of getting to know own genetic results associated with pathologies, and to enable an informed decision on the return of result option in the informed consent. The CHRIS follow-up phase was approved by the ethics board of Azienda Sanitaria dell'Alto Adige, and the new aspects were addressed in the information material provided to participants, and, of course, in the dynamic consent of the follow-up phase. The use of dynamic consent allowed to address changes reflecting both the researchers' scientific needs, and participants' interests as well, with the result of facilitating the conduction of biomedical research in the long-run, and of adjusting and improving governance mechanisms and communication with participants.

In the following paragraphs, we describe the dynamic informed consent and the contents of the information material (mainly, the brochure, the presentation, and the videos) of the CHRIS follow-up phase,[9] in order to provide an overview of what participants are asked to consent to, and which information they receive for an informed decision about participation.

### 2.2.1. Dynamic informed consent for participation in the follow-up phase of the CHRIS study

The dynamic consent of the CHRIS follow-up phase includes three main sections: the consent for the participation in the CHRIS follow-up, the consent for the use of data and samples in research, and the consent to the use of the online platform MyCHRIS.

In the consent for participation, participants consent to the collection of biological samples, to go through a series of clinical and scientific examinations, to answers interviews and questionnaires on general health, lifestyle, medical history. Participants can choose the way they prefer to receive the

[9] Informed consent forms and brochures are available in the CHRIS study website at https://it.chris.eurac.edu/download/ (last visited 19/01/2021)

results of the clinical examinations[10] (at the CHRIS centre, sent at home, through MyCHRIS or the smartphone application).

In the consent for data and samples use, participants consent to long-term storage of data and samples in the biobank (codified, non-identifiable data and samples) for the research purposes of the CHRIS study. Then, participants can choose through different options for some questions where they can approve or refuse. These are data sharing, functional studies with immortalized cell lines, access to medical records, use of data and samples in case of incapacity and death, return of results, and re-contact for participation in further studies. The choices made are changeable by using MyCHRIS or through other authorized channels (see below). In this way, participants are enabled to choose and modify the extent of their participation in research over time. Participants can withdraw from the study by contacting the CHRIS centre by phone or email.

My CHRIS is the core of the control by patients. Participants are asked to consent to the use of the dynamic consent online platform MyCHRIS, where they can legally modify the choices made in the consent, consent to new studies, and withdraw the consent. Through MyCHRIS, it is also possible to receive information on the studies, to participate in sub-studies remotely by filling-in questionnaires, and to access own clinical results. By using username and password, MyCHRIS is accessible through the CHRIS website or through the relative smartphone application. A one-time password sent through email or text message is needed in addition, as a system of two-factor authentication, for all those actions that imply an active decision by the participant to exert own will and rights, and that will have an impact in participation, such as to consent to new sub-studies, to modify the consent already given, to modify the password, to download own clinical records, to request the modification of personal data and contact information.

Participants are kept updated and, for studies whose aim does not fall within the areas covered by the general consent, participants will receive a notification and/or a consent request (opt-in or opt-out, as decided by the ethics board). For this reason, it is very important that participants express their preference on the way of communication with the CHRIS team: they are asked to choose at least two ways of re-contact among email, text message, CHRIS application, and phone, or, if the none of the other options are feasible, mail. In the consent form, participants are informed that all the changes made through MyCHRIS have legal value. Participants can also decide not to accept to the use of MyCHRIS as tool for consent management. In this situation, all the changes can occur via letter, signed by the participant and accompanied by a copy of a valid identity document, and all the relevant information about further studies will be given via phone or mail.

### 2.2.2. Information for an informed decision on participation in research

After the end of the recruitment and before re-inviting participants to the follow-up, all CHRIS participants received a newsletter, which informed them about the outcomes achieved during the recruitment phase and about the upcoming first follow-up phase. Information on the CHRIS study and on the follow-up phase were made available also in the CHRIS webpage. Participants that were progressively re-called for the follow-up appointment received an invitation letter, which briefly describes

[10] Participants are informed and aware that only specific measurements with clinical value (listed in the informed consent and in the brochure) are returned.

the study. If the invited CHRIS participants agree to participate, they can fix an appointment at the study centre, where they will proceed with the visit and the data and samples collection, after consenting to participate. Before the appointment, the participant is sent a brochure (sent at home through mail, paper version), which provides the information about participation, including all the changes introduced in the follow-up phase, participant rights, and governance. Both the newsletter and the brochure are available also in electronic version.

Through the brochure for the follow-up phase, participants are informed on the CHRIS study and its aim, about the benefits and risks of participation in research, and the ways of re-contact and interaction with participants. The clinical measurements and the other types of data collected are described. Participants are informed on which clinical measurements will be returned (that is, those of clinical value) and which ones will not be returned. They are also informed that individual genetic research results will not be communicated, with the exception of those that have relevance for the health of the participant or for the participant's family, upon decision of the ethics board and involvement of genetic counsellors, according to the international guidelines on medically actionable genes, and according to the participant's right to know or not to know. Four conditions (malignant hyperthermia, Parkinson's disease, breast cancer, and Huntington's disease) are described as model for the typology of genetic research results, and the mechanisms in place for the return of results are explained. Participants are informed about their rights and about other legal aspects (dynamic consent, consent to sub-studies, flow of information supporting the consent and on the development of the study, use of the dynamic consent platform MyCHRIS, withdraw). Furthermore, participants receive all the information on data and samples treatment and storage (access to medical records, privacy and protection, governance for data sharing, storage in the biobank, dissemination of research results, oversight bodies).

The information material paired with the informed consent of the CHRIS study includes also a voice-over presentation, which summarizes the study in the same line as the brochure, and videos about the four genetic diseases.

## 3. Data sharing and ongoing consent in the CHRIS dynamic consent: broad consent within strong governance, oversight mechanisms, and ongoing information

Data Sharing and ongoing consent are good examples to show how the CHRIS dynamic consent works in practice. We decided to focus on these aspects in order to show how dynamic consent allows participants to exert their autonomy by making individual choices about the extent of their participation. This occurs within established mechanisms of oversight and governance. By consenting to participate in research within the broad aim of the CHRIS study, participants consent to a governance structure which they are made aware of through the information material and the informed consent. The information that participants receive about the development of the study, about the sub-studies, and the governance mechanisms for further participation in research frames the broad research aim within the defined boundaries of the specific information provided. Through the samples illustrated in this section, we want to clarify how the dynamic consent can be used in practice, and thus rectify some of the misconceptions and misunderstandings about its use and potentialities.

CHRIS data and research results can be shared with other institutions and researchers, to be used for research purposes. Institutions and researchers interested in accessing the CHRIS repository must submit a formal request to the access committee, which oversees data and samples access.[11] The access committee is an internal body composed of multidisciplinary experts, which evaluates applications for data and samples access, by considering the scientific validity of the submitted project, its conformity to the scientific aims of the CHRIS study, and the compliance with ethical and legal regulations in place in the CHRIS study. Additionally, the projects that will make use of CHRIS data and samples must be approved by an ethics board. After approval of the access committee, access to data and samples occurs only after a contract (data/material transfer agreement, DTA/MTA) is signed. This contract establishes that the data are used according to the General Data Protection Regulation 2016/679 (GDPR).[12] As safety measure, only codified and non-identifiable data are shared. Furthermore, also the dissemination of results obtained by using the CHRIS data or samples must be approved by the access committee. How are the CHRIS participants given choices within the data sharing process? In the informed consent, they can agree or not to sharing, and they can express their preferences on the extent of it: they can specifically agree (or not) to sharing with partner institutions that are bound through a DTA/MTA, and/or with larger scientific institutions (such as databases and consortia) which allow maximization of data usage. Participants are informed that the legal regulations might differ if data sharing occurs with institutions which are not under the GDPR. In MyCHRIS, participants are informed about the projects that their data are being shared in, they are updated about the research development through the webpage, and/or other apt communication channels. The flow of information will allow them to be aware of what happens with their data and samples, and of how the governance works, and, therefore, to retain control of their data and samples by having the possibility of changing the degree of their participation regarding data sharing in the dynamic informed consent platform. In this way, they receive all the information that put their individual choice on participation within the research process and the oversight mechanisms in place, while making an autonomous decision on participation that reflects their values through time.

Dynamic consent has been criticized for the risk of impairing the governance of the biobank.[13] However, by describing how the data sharing is handled in the CHRIS study through dynamic consent, it is evident that the authority of deciding on scientific value of research, and compliance to ethical and legal standard stays in the hands of experts and oversight bodies, such as researchers, the access committee and the ethics board. Therefore, for the way in which dynamic consent is implemented in the CHRIS study, the authority of the governance and of the oversight bodies is neither weakened nor transferred to participants.[14]

[11] The form and guidelines for application for data and samples access in the CHRIS study are available in the Eurac website at http://www.eurac.edu/en/research/health/biomed/projects/Pages/CHRIS.aspx (last visited 12/01/2021).

[12] GDPR: https://eur-lex.europa.eu/eli/reg/2016/679/oj (last visited 18/01/2021).

[13] A. SOULIER, *Reconsidering dynamic consent in biobanking: Ethical and political consequences of transforming research participants into ICT users*, in *IEEE Technology and Society Magazine*, 38, 2, 2019, 62-70.

[14] We want to add further nuance on this issue, by suggesting that research participants can play an active role within the research process and the governance structure by providing inputs and insights on research from their perspective. In fact, CHRIS participants have been actually involved in policy design and recommendations

As the CHRIS study is designed as prospective and longitudinal, and the CHRIS biobank is meant as a dynamic resource for research, CHRIS participants' data and samples are foreseen to be used for several future studies. However, these possible future studies may not be explicitly described, defined or known at the time of the initial consent. Through dynamic consent, CHRIS participants agree to an initial broad consent for the collection and use of data and samples within the scientific areas of interest of the CHRIS study and the limits of the informed consent. In order to keep participants aware of the development of the study and of the use of their data and samples in sub-studies that were already described at the time of the initial consent and therefore within the CHRIS objectives, participants are informed through MyCHRIS and through the other communication channels of the CHRIS study (webpage, newsletter). However, in order to participate in other further studies, they may be asked to re-consent. For new studies within the main aim of the CHRIS study, but that were not enough described or defined at the time of initial consent, participants are asked to re-consent through opt-in or to opt-out, following an ad hoc communication through the tools preferred by the participant (email, text message, phone, mail). The opt-in strategy is for specific projects which were not foreseen in the description of the CHRIS study, while the opt-out strategy applies to specific projects within the aim of the CHRIS study and already described, but not detailed enough at the time of the initial consent. With the opt-in strategy, participants are asked to provide an "active" consent, while in the opt-out they are included in the study unless they actively refuse to participate ("passive" consent). In both the opt-in and the opt-out strategy, an ad hoc communication (information material through email and MyCHRIS, possibility to ask the CHRIS study team clarifications and questions) supports the active or passive consent request. The strategy for such studies is summarized in Table 1.[15]

| Already described studies, whose aim is within the areas of the CHRIS study and the limit of the informed consent | Specific projects not foreseen in the description of the CHRIS study | Studies that were described but not detailed enough |
|---|---|---|
| Communication through MyCHRIS and the other CHRIS communication channels<br>No re-consent | Ad hoc communication with specific information<br>Opt-in ("active consent") through MyCHRIS | Ad hoc communication with specific information<br>Opt-out ("passive consent") through MyCHRIS |

**Table 1. Ongoing consent in the CHRIS study: consent and respective communication strategy**

development on recall-by-genotype and return of results. With this, we mean that their views on recall-by-genotype and on return of results were investigated and explored through empirical studies, and the results of these studies (one manuscript under review and one manuscript in preparation) will contribute to the understanding of participants' wishes on participation in genetic research and their views on the possible communication of genetic results, and to further develop and improve the policy on such issue. Therefore, CHRIS participants' contribution in the biobank policy and governance should be understood in the context of a dialogue with the researchers and the experts in charge of the governance.

[15] The table is an adaptation from the CHRIS follow-up brochure (p. 27), which is available at https://it.chris.eurac.edu/download/ (last visited 31/01/2021).

For new studies whose aim is beyond the one that participant consented to and where a new participation (e.g., new data and samples collection) is asked, a new specific informed consent, accompanied by specific informative material, is asked. The ethics board deliberates for each approved project which type of consent strategy is needed. Through these differential re-consent strategies and the ongoing consent process, the broad consent regarding the research scope is situated within specific and defined conditions.

The governance on communication, the oversight on the scientific aim and the ongoing consent process provide the level of specificity that is required as an ethical and legal requirement in research, and especially in broad research endeavours such as biobanking. As in the data-sharing situation, the flow of information allows participants to make informed decision on their participation in research through time and to exert their rights through the dynamic consent tools. So, it is a misconception that, when participating in research through dynamic consent, participants will be asked to re-consent all the time for every single new research project and that the ethical assessment will be weakened,[16] because as shown by the case of the CHRIS study, the ongoing consent process is held within a specific governance.

This includes the ethics board, which defines the approach to re-consent or notification that should be applied, and an ongoing information policy and communication structure, meant to notify and update participants about the research projects that are conducted within the biobank so that they receive all the information for the consent to be properly informed.

On a different note, even though dynamic consent relies on information technology and communication strategies broadly embedded within digital and electronic platform and devices, this does not exclude alternative ways of communication. More traditional communication tools (such as phone or paper-based material, e.g. mail, newsletter, etc.) are in place as an alternative to guarantee that participants are not excluded as a result of the digital divide.[17] In fact, in the CHRIS study, participants who decide that they prefer not to use MyCHRIS, the online platform of the dynamic consent, are offered other strategies to be informed and contacted about research studies, and to exert their rights as research participants.

## 4. Conclusion

With this paper we wanted to showcase how the dynamic consent model was implemented in the frame of the CHRIS study, a population study conducted in South Tyrol since 2011. The dynamic consent of the CHRIS study can be intended as a broad consent (as regards the aims of research and the long-term storage and use of data and samples) within strong oversight and governance mechanisms, paired with an ongoing communication with participants. By discussing the mechanisms of data sharing and ongoing consent in the CHRIS follow-up phase, we took the chance to address some of what we considered as misconceptions regarding dynamic consent and its actual implementation in

[16] K.S. Steinsbekk, B.K. Myskja, B. Solberg, *Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?*, in *European Journal of Human Genetics,* 21, 2013, 898-901.

[17] M. Prictor, H.J.A. Teare, J. Kaye, *Equitable Participation in Biobanks: The risks and benefits of a "Dynamic Consent" approach*, in *Frontiers in Public Health*, 6, 253, 2018, 4.

practical terms. Given this premise, our experience with the dynamic consent of the CHRIS study becomes even more relevant in the context of the current debate on informed consent in biobanking research. We believe that it is important to share our experience in the dynamic consent of the CHRIS study with the scientific community, because it can serve as an example of practical implementation of a model suitable for long-term genomics research and biobanking research.


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