CHRISPORTAL
eurac research

CHRIS Study sample and data access policy

Table of contents

Version 2 November 2022

CHRISPORTAL
eurac research

Overview

The Cooperative Health Research In South Tyrol (CHRIS) study is a population-based study that commenced in 2011 and involves more than 13,000 Val Venosta/Vinschgau inhabitants. The objective of the CHRIS study is to study the risk factors for common diseases within the South Tyrolean population.

Through the CHRIS portal, local, national, and international research institutes and companies that have a research purpose can apply for access to the samples and data.

This policy sets out the rules and procedures to be followed in accessing data and samples associated with the CHRIS study. In particular:

- Section 1 provides the definitions used for the purposes of this regulation.
- Section 2 describes the governance structure.
- Section 3 describes the type of data included.
- Section 4 describes the different types of access.
- Section 5 describes the rules and procedures for seeking access to samples and data.
- Section 6 and section 7 discuss the provisions on consent, notification, and withdrawal that apply to any application, irrespective of affiliation, seeking access.

1. Definitions

Access Committee shall mean the committee to review and make a decision as to whether to approve all applications for access to the Data and Samples of the CHRIS study.

Biological sample (also referred to as "Sample") shall mean any sample of biological material.

CHRIS study (also referred to as "CHRIS") shall mean the population-based study that aims to investigate the determinants of common diseases and health within the South Tyrolean population. Reference to the CHRIS study also includes all CHRIS sub-studies, any studies applied to CHRIS, and all waves of data collection.

Data shall mean raw data concerning participating individuals, aggregate data and research results as described in the Ethical Protocol for the CHRIS study

Data exploration is a preliminary analysis of data, including manual descriptive analyses and automated data-mining, with the aim of generating hypotheses and serving the purpose of conceiving a scientific research project.

Anonymous data shall mean data where the data subject is not or no longer identifiable and the process is irreversible, based on the current state of the knowledge. To ascertain whether means are reasonably likely to be used to identify the individual, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments.[1]

Genetic data shall mean personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained.[2]

Identifying data shall mean personal Data or combination of data that allows the identification of a specific natural person (i.e., a living human being) directly (e.g., name, surname, email, or other characteristics unique that make identification easy).[3]

Personal data shall mean any information relating to an identified or identifiable natural person (data subject). An identifiable natural person is a living person who can be identified, directly or indirectly, in particular, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Eurac staff are staff that have a Deed of Appointment with Eurac.

[1] As defined in the GDPR.
[2] As defined in the GDPR
[3] Cass. civ., sez. II, ord. n. 17665/2018.

IfB staff are staff that have a Deed of Appointment with the Institute for Biomedicine (IfB).

Joint project shall mean any research project in which the IfB is collaborating with a third party for research. This requires the IfB to be actively involved in the research, deciding the research questions and/or how that research question shall be addressed. The mere sharing of Biological samples, Data, or Research results will not constitute a Joint project. This collaboration must be formalised e.g., through a contract, consortium agreement, or a partnership agreement.

Third parties shall mean any individual or entity external to Eurac.

2. Governance structure

2.1 Access Committee membership structure

The AC is composed for the following voting members with one designated representative from each of the following categories:

1. Principal Investigators of the CHRIS study
2. ELSI
3. Data management, including statistics and epidemiology
4. IT and data security
5. Responsible for the Biobank

The AC also consists of the following non-voting members:

1. Legal expert
2. The AC Coordinator

From time to time, the Access Committee may need to seek advice and input from external experts in a non-voting capacity where a particular expertise is needed. They will be identified based on their expertise and after approval by the AC, they will be engaged for their expertise. The expert must declare themselves free from a conflict of interest and be bound by the principle of confidentiality.

AC members are reminded of their obligation of confidentiality included in their contract of employment. Should any AC members consult with members of their Group for discussion on aspects of an access request, they should remind those members that this information should be kept confidential.

2.1.1 Voting and delegates

All decisions must be unanimous. Members can submit their views and votes in advance of a meeting when they cannot attend.

In the case of a long-term absence, the AC can appoint a replacement with the relevant expertise.

2.1.2 Sub-committees

To assist with workload, the AC may see fit to appoint a sub-committee for specific tasks. The terms of reference and membership of any sub-committee is to be decided by the AC. The sub-committees must report any decisions made to the AC. Responsibility for any sub-committees lies with the AC.

2.1.3 Revocation of a decision

The AC has in its power to revoke an approval if it finds that the terms of access approval are not met.

3. Data and/or Sample access

Data and / or Samples can be accessed for:

1. Technical purposes (see below, 4.1).
2. Exploratory purposes (see below, 4.2).
3. Research purposes (see below, 4.3).

3.1 Data and/or Sample access for technical purposes

Technical data access is any kind of Sample and Data access that is necessary:

- To guarantee the CHRIS study setup, conduction, administration, and expansion of the study (new phases, sub-studies).
- For project evaluation by the CHRIS Access Committee.
- To process raw data files into CHRIS data sets (e.g., pre-processing of raw mass spectrometry data files to generate metabolomics or proteomics data sets, raw genotype data, raw spiralography data, raw ECG data, raw biochemical parameter data, raw questionnaire data, etc.).
- To ensure and assess the data quality, including monitoring of ongoing data measurement procedures, data cleaning, standardization and normalization, preparatory tasks to ensure the usability of the database, generation of datasets that are necessary for the study conduction (e.g.: genotype imputation).
- To guarantee the quality of samples stored in the biobank, including analysis of collection-related data pre- and post-conservation.
- For study maintenance (IT operations).
- To guarantee participant's health (e.g., emergency situations).

Technical access is only provided to IfB staff. Prior consent of the respective Group Leader must be obtained, who will then contact the Principal Investigators of the CHRIS study. The Principal Investigator will authorize the person Responsible for IT and IT Privacy of the CHRIS study to enable access to data.

Data access for technical purposes **does not** require the Access Committee's approval.

3.2 Data access for exploratory purposes without Access Committee approval

Data exploration without Access Committee approval is limited to IfB staff only who must follow this process to obtain access:

1. IfB staff member must submit a title, synopsis, and justification for seeking access to the required data for exploratory purposes to the respective Group Leader. If a Group Leader requests access for exploratory purposes, they must submit a request to the Principal Investigators.
2. Group leader makes the decision and communicates it to the requestor.

3. Access Committee to be notified of all approved applications for exploratory purposes in advance of the next Access Committee meeting.
4. The Access Committee keeps a record of all approved requests.

For all other exploratory requests, Access Committee approval is required.

3.3 Data and/or Sample access for research

Access to CHRIS Samples and/or Data may be requested for Research purposes only by submitting an application to the Access Committee through the CHRIS portal.

4. Data and Sample access for research

The following procedure is to be followed for all Data and Sample access requests for research purposes

4.1 Online registration

To be allowed to submit an access request, the Principal Investigator(s) must register an account at the CHRIS portal.

To this end, the applicant must provide the following information:

1. Personal information and contact details.
2. Organisation of affiliation.
3. *Curriculum vitae* to demonstrate that they are a bona fide researcher.
4. Confirmation that the applicant's organisation of affiliation has a Research purpose aimed at protecting the health of data subjects, third parties, or the community in the medical, biomedical, or genetic area. If the organisation of affiliation does not have such a Research purpose, the Data or Samples cannot be shared under Italian law. This assessment of Research purpose is subject to the following:
    a. All Italian public universities and research centres have research in their mission and are automatically considered to fulfil this requirement.
    b. For private Italian entities, that includes companies and other for-profit institutions, the IfB will assess the Chamber of Commerce certificate of the organization of the applicant.
    c. For public and private entities outside of Italy, the application can submit their statute, or national chamber of commerce registration (or the equivalent), or any other evidence according to their domestic law.
    d. For all other entities who do not have the documentation described above, a decision will be made on a case-by-case basis to determine whether the entity has a research purpose.

4.2 Access outside of the EU and European Economic Area

Any access request that involves any individuals and/or organisations getting access to the Personal Data and Samples that will be involved in the research who are not based in the EU or the EEA must, in addition to meeting the other requirements set forth in this document, meet one of the following requirements:

1. If that country is subject to an adequacy decision, the access (if approved) will be based on this adequacy decision and no further action is required. A list of all countries that are subject to an adequacy decision can be found **here**.
2. If that country is outside of the EU or EEA and is not subject to an adequacy decision, the IfB and the applicant must identify a suitable legal basis provided for in the GDPR on which that transfer may take place.

4.3 Applicant access request submission

Once the Access Committee Administration has checked and approved the registration, the applicant can submit one or more access requests through the CHRIS portal.

4.4 Access Committee assessment

All access requests must be in line with all principles of data protection, including the principle of data minimisation (i.e., only the minimal amount of Data and/or Samples required to meet to the objective of the research can be accessed) and purpose limitation (i.e., the data can only be used for the purpose for which it was collected).

In Italy, the lawful basis for the use of Samples and/or data in research is consent. As a result, Samples and/or data can only be used for research purposes set out in the consent form, including anonymisation of Samples and/or data. Samples and/or data accessed for research also cannot be anonymised without the express approval of the AC.

The Access Committee approves the access request provided that all the following conditions are met:

4.4.1 Access for research in Joint project with IfB

If the applicant is in a Joint project with the IfB, the Principal Investigator at the IfB must be indicated.

4.4.2 Research proposal

The project proposal meets all the following conditions:

1. The research is in line with the objectives of the CHRIS study and the CHRIS participants consent. For research outside of these objectives, the Access Committee will consider applications on a case-by-case basis.
2. The proposed aims, objectives, and methodology of the research are sound.
3. The Samples and/or Data requested is the minimal amount necessary to meet the objectives of the research.

Should the applicant not meet any of these requirements, the Access Committee may communicate a request for clarification, a request for more information, a request to amend the application, or reject the application.

4.4.3 Ethics review

Ethics review is necessary for:

1. Research that does not fall under the approved Ethical Protocol of the CHRIS study
2. Research scope that is not sufficiently described in the CHRIS consent
3. All non-joint projects

The following may require ethics review:

1. Joint-projects where the third party/parties are not in Italy and are accessing the Samples and/or Data as part of the research may require ethics review.
2. The Access Committee may also decide on a case-by-case basis that a project needs ethics review e.g., any research that uses new technology not foreseen at the time of collection that has ethical implications may require ethics review.

4.4.4 Security

The applicant must have in place all security measures required by Italian law, EU law, and the applicant's domestic law (when stricter), including measures prescribed or recommended by the competent data protection authorities. These include measures to guard against unlawful access to the data, security standards to guard against loss, unauthorised access, modification, and destruction of personal data.

If the applicant requests access to Genetic data and/or Samples, the following specific measures are also required:

1. Access to where the Samples and Genetic data are held follows a documented procedure.
2. Samples must be stored, used, and transported in ways that ensure their quality, integrity, availability, and traceability.
3. Genetic data can only be transmitted through dedicated encryption channels.
4. Protected communication channels will be used in accordance with the state of the art. To this end, the applicant must secure all Data and Samples and use encryption standards in accordance with current best practices.
5. The use of "web application" communication channels is allowed, which envisage the use of protected transmission channels, taking into account the state of the art of technology, and guarantee, after verification, the digital identity of the server that supplies the service and the client station from which the data is accessed, using digital certificates issued in compliance with the law by a certification authority.
6. Applicant has a two-factor authentication system in place so that only authorised personnel can get access to Genetic data by electronic means. The two-factor authentication is based on the combined use of knowledge (something the user knows) and possession (something the use has).

4.4.5 Discrimination and stigmatisation

The proposed research project does not discriminate or stigmatise the CHRIS population. This includes physical, psychological, health, or psychiatric conditions in a manner that can stigmatise:

1. CHRIS study participants (that is, the CHRIS study sample).
2. The population to which the CHRIS study refers to.

Presence of a stigmatisation aspect result in the rejection of the project proposal. The applicant can amend it and resubmit at their earliest convenience.

4.5 Changes by the Access Committee

The Access Committee may request changes to be made to the access application before approval is granted.

4.6 Material transfer agreement/data transfer agreement

The Access Committee will determine projects that require a Data Transfer Agreement or a Material Transfer Agreement. Where required, transfer cannot take place until such an agreement has been agreed and signed by both Parties' duly authorised legal representatives and is mandatory to ensure the compliance with the applicable laws and regulations concerning the protection of personal data,

workplace safety and safety in the laboratory and the protection of intellectual property and confidential information.

5. Consent and notification to the CHRIS participants

As per the CHRIS consent, it may be necessary to notify CHRIS participants about approved projects that will use their Samples and/or Data in research. For other approved projects, their re-consent may be necessary.

Notification and re-consent will be done in line with the communication preferences indicated at the time of consent.

The Access Committee will determine when notification is necessary and when re-consent is necessary.

The lay summary of all approved research will be available on MyCHRIS.

5.1 Projects within the CHRIS consent

All projects already described in the CHRIS original consent will be available in MyCHRIS and a periodic newsletter. No further specific informed consent is required.

5.2 Projects insufficiently described in CHRIS consent but in line with the research areas

Projects that are not sufficiently detailed in the CHRIS original consent are notified to the participant via e-mail, SMS, mail, or telephone (at the choice of the participant). This notification requests the participant to actively opt-out, otherwise, as per the consent, they are deemed to opt-in.

5.3 Projects not described in the CHRIS consent

Projects not described in the CHRIS consent must be approved by the Ethics Committee and there must be an active re-consent. Adequate information will be provided to the potential participant, and they will be provided with the opportunity to ask questions. To be included in the study, the participant must actively opt-in.

Projects involving third parties where re-consent is necessary can only proceed on the basis of a Joint project with the IfB.

6. Withdrawal of consent

CHRIS participants have the right to withdraw their consent to the use of their Samples and/or Data at any time. Once the IfB has been notified of a withdrawal of consent, they will initiate the process of withdrawal immediately in accordance with the participants' withdrawal preference.

All third parties must respect and honour any withdrawal once they are notified and have in place a process to withdraw the Sample and/or Data should they be notified of a withdrawal by the IfB. This withdrawal applies to the future processing of the data and not for analyses already completed.

6.1 Death and withdrawal of consent

In case of death or supervening incapacity of the participant, the consent is considered to be withdrawn if the participant stated so when giving their consent.

All third parties must respect and honour any withdrawal and have in place a process to withdraw the Sample and/or Data should they be notified of a withdrawal by the IfB.

7. Non-profit use

All applicants must commit to a non-profit use of any samples and data collected or generated through the CHRIS study data or samples.

In case of possible revenues from the results for the IfB, these revenues shall be reinvested in local research and public health projects as set out in section 13 of the Ethical Protocol of the CHRIS study.

8. Dissemination of research

The applicant commits to notifying any proposed publications, such as in journals, pre-prints, book chapters, theses, abstracts, and conference posters, related to the access request (hereinafter, proposed publication) to the Access Committee for prior approval.

The Access Committee, or a relevant sub-committee
is tasked with approving the following:

- Abstracts for conferences / workshops
- Poster presentations
- Manuscript submissions
- BSc, MSc, PhD theses or similar types of research products

9. Return of Samples and Data

Any Samples left-over at the end of the research must be returned to the IfB or destroyed if they cannot be re-used. All copies of the Data shall be deleted by the Recipient according to the timing and procedures set out in the DTA. Written confirmation of deletion of the Data or samples is required.

11. Review

This policy must be reviewed every 3 years, or sooner if there are any changes in the law that directly impact the use of samples and data in research.