Request for participation in medical research:

Bern, get ready (BEready) population-based cohort study for pandemic preparedness: main study

Dear Prospective Participant,

We have created this study information sheet to ask people in the Canton of Bern whether they would be willing to take part in our research project.

Participation is voluntary. All data collected as part of this research project are subject to strict data protection requirements.

This research project was commissioned by the University of Bern. Prof. Dr. med. Nicola Low from the Institute of Social and Preventive Medicine (ISPM) is responsible for its concrete conduct.

As the research project progresses, we would be happy to give participants regular updates of ongoing results, if this interests them.

The first half of this information sheet presents the most important information about the study in a summarised format. The second part then provides more detailed information. This will be followed by a conversation during which perspective participants will be told once again about the most important points and their questions will be answered.

Summary

Why are we conducting this research project?

- The BEready project aims to find out how people in the Canton of Bern can be helped to be more prepared for the next pandemic.
- We want to understand how infections spread among people as well as between people and animals.
- We want to find out how social and environmental factors can influence the transmission or catching of infectious diseases.
- We want to better understand how households and their pets in the Canton of Bern were and continue to be affected by COVID-19.

What do I need to do if I take part? – What will happen to me if I take part?

People who decide to take part will be asked to do the following:

- fill out an online questionnaire at the start and then at yearly intervals,
- have a brief physical exam at the start of the study, either at the study site in Bern, at their home, or at a location close to their home, and provide a single blood sample from their elbow,

- take a sample of a few drops of blood from their fingertips by themselves at home once a year,
- and take nasal swabs and send them to us any time they have signs of a respiratory infection.

For children under 14, an adult from the same household must fill out the questionnaires on their behalf. Every time a person in the household shows signs of a respiratory infection, or if a dog or a cat has diarrhoea, an adult in the same household will have to fill out a short online questionnaire on behalf of the entire household.

All **pets** must have a brief physical exam at the Bern Animal Hospital or in another veterinary clinic, and their owners must fill out an online questionnaire about their pet at the start of the study and then at yearly intervals.

For **cats and dogs**, in addition to the poo sample collected at the start of the study, a single blood sample from the foreleg will be taken. Whenever a dog or cat shows signs of diarrhoea, the owners will be asked to collect a poo sample and send it to us.

What benefits and risks are associated with participation?

Benefits

- By taking part, participants will help us better understand infectious diseases and their effects. They will also help people in the Canton of Bern to be better prepared for future pandemics. Participants will derive no personal benefit by taking part.

Risks and burdens

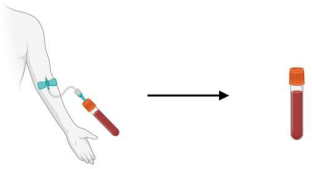
- The physical risks of the blood samples and swabs are very small, but the procedures can be felt as uncomfortable.
- The time required for study participation each year is low, but this can increase somewhat depending on the number of respiratory infections and the number of members in the household.
- Pet owners are at risk of injuries (e.g., scratches, bites) due to the swabs they have to take from their pets.

By signing the informed consent form, participants declare that they are taking part voluntarily and that they have understood all the information in this document.

Detailed information

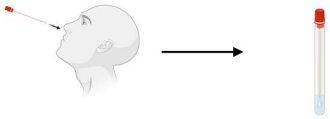
Glossary

Biological samples	One or more of the following:



Blood from the elbow (for people) or the foreleg (for pets)

Blood from the fingertip (for people only) dripped onto a sort of blotting paper



A swab taken with a sort of cotton bud (from the inside of the nose for people and dogs, or through the mouth into the throat for cats, or an anal swab for pets)

Poo samples (for pets only)

Substudy	A test or analysis that is embedded into the main study and is a specific aspect or question within the broader scope of the main study
Research project	The research project ('BEready') described in this information sheet
Household contact	The person in a household who is our main contact person
Disease event	Each time a member of the household show signs of respiratory infection (e.g., cough, sneezing, middle ear infection) or a dog or cat in the household has diarrhoea during the project
Participants	People taking part in our research project

1. Objective and selection

We are a group of researchers from the University of Bern. Our research project is called BEready ('Bern, get ready'). It was developed in response to the COVID-19 pandemic. BEready aims to find out how people in the Canton of Bern can be helped to be more prepared for the next pandemic.

All private households in the Canton of Bern are eligible to take part in the research project provided that at least one person over the age of 18 years agrees to take part. Participants over 11 years must be able to understand, speak, read, and write German, French and/or English. Participants over 14 years must have access to the internet. Participants under 14 years can take part provided that at least one adult is taking part who understands German, French and/or English and has access to the internet. Pets can be included as long as they live in a household that is taking part.

2. General information

All of us in the Canton of Bern lived through the first year of the COVID-19 pandemic together and were affected by it. One conclusion that we can draw from the pandemic is that we will be able to react to future pandemics more quickly and better protect our people if we as a society are better prepared.

BEready is what is called a cohort study, which means that health data and biological samples are repeatedly collected over a long time from the general population. This means that, in future pandemics, we would be able to more quickly identify the pathogen causing the pandemic and therefore react better and more quickly as a result. The BEready cohort is probably the first cohort of its kind in the world. Participants will make an important contribution to this research project by helping us to investigate existing infectious diseases and their transmission among people and between people and animals, and therefore possibly helping to make society more prepared for new health threats. They will also help us to understand how social and environmental factors can influence the transmission or catching of infectious diseases, as well as how households and their pets in the Canton of Bern were and continue to be affected by COVID-19.

This study will include 1500 households in the Canton of Bern and currently has no planned end date.

We are conducting this research project according to the laws of Switzerland. In addition, we follow all international and recognised guidelines. The responsible Ethics Committee and competent veterinary authority have reviewed and approved the research project.

3. Procedure

The research project will follow the following procedure:

- First visit in Month 0,
- Self-taken swab for respiratory infections in people or for diarrhoea in dogs and cats (the exact number depends on the infection. The diagram below gives an example of one time during the entire study),
- An assessment every 12 months.

The procedure of the research project will be explained in more detail below. Figure 1 shows the procedure for the research project in graphic form.

First visit (Month 0)

The first visit at the start of the research project will take place at the Swiss Institute for Translational and Entrepreneurial Medicine (SITEM, Freiburgstrasse 3, 3010 Bern, Switzerland), at participants' homes, or at a location near participants' homes, and will take about 60 minutes per person.

The study staff member ( ) will do the following:

- Explain the study and answer questions
- Discuss the inclusion and exclusion criteria with participants
- Obtain written informed consent
- Measure participants' weight, height, hip/waist size, and blood pressure ( )
- Take 50 mL of blood (about three tablespoons) from a vein in participants' elbows
- Show participants how to sample 5-10 drops of blood from their own fingertips, and if applicable, from their children
- Show participants how to take a swab from the inside of their own nose, and if applicable, from their children

For pets, the first visit will take place at the Vetsuisse veterinary clinic for small animals (Länggassstrasse 128, 3012 Bern, Switzerland) or at another veterinary clinic and will take about 45 minutes per pet.

The study staff member ( ) will do the following:

- A quick health check for the pet ( )
- For dogs and cats: Take 3-10 mL of blood (around 1-2 teaspoons, depending on the size of the pet) from a vein in a foreleg
- Show participants how to take a swab from the inside of their pet's nose (for dogs) or through the mouth from the throat (for cats)
- Show participants how to take a swab from their pet's anus and how to collect a poo sample

People with cats or dogs must collect a poo sample ( ) from their pet every day from two days before the visit until the day of the visit, and then bring these to the first visit with them. They will be tested for parasites in a lab.

The samples ( ) collected from participants and pets will be stored permanently in the Bern biobank (Freiburgstrasse 10, 3010 Bern, Switzerland) and may be analysed later.

After the visit, participants will fill out an online questionnaire ( ) (about 45 minutes per person and 15 minutes per pet). For children under 14 years and for pets, an adult from the household must do this on their behalf. The questions cover the current state of health and the risk and protection factors that make people and animals more prone to infections or protect them from them.

Assessment around every 12 months

Every 12 months, participants will fill out an online questionnaire ( ) (about 45 minutes per person and 15 minutes per pet). For children under 14 years and for pets, an adult from the household must do this on their behalf. The questions ask about health aspects that have changed since the first visit. The household contact will also fill out a 5-minute online questionnaire on changes in the household (new members, pets, change in address, etc.).

All participants will sample 5-10 drops of blood from their fingertips ( ) at home. For children, an adult in the same household must sample the blood from their fingertips for them. The household contact must then send these samples by post to the biobank for storage.

Disease event

- In the event of an illness, the household contact must fill out an online questionnaire at home on the signs of the disease (around 5 minutes per member of the household).
- If participants experience cold symptoms, they must take a swab from the inside of their nose themselves at home ( ). For children, an adult in the same household must take the swab for them.
- If cats or dogs have diarrhoea, an adult in the household must take a poo sample from the pet in question ( ).
- The household contact must then send these samples by post to the laboratory where they will be investigated for viruses that could have caused the respiratory infection and/or for parasites that could have caused the diarrhoea. Any residual material is stored permanently and may be analysed later.

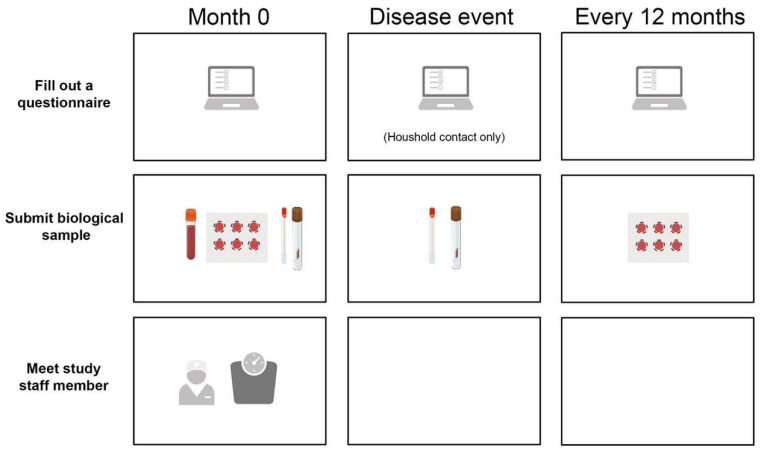


Figure 1. Procedure for the research project.

Substudies

An important aspect of BEready is the ability to create substudies on research questions that have not yet been precisely defined. These will allow researchers to react to scientific questions that will be asked in the future. Participants will be approached separately for these substudies and can decide on a case-by-case basis whether they want to take part or not.

Early withdrawal or exclusion from the study

If participants want to stop taking part, they may do so at any time without giving reasons.

It may also be the case that we have to exclude participants prematurely from the research project. For example, this can happen

- if they move away from the Canton of Bern, or
- if they do not comply with the instructions and requirements of the research project.

The research project can also be terminated early by the Sponsor.

4. Benefits

The results of the research project may be important to help people in the Canton of Bern be better prepared for the next pandemic. However, participation may also lead to no direct benefit. Participants will derive no personal benefit by taking part.

5. Voluntary nature and obligations

Participants take part voluntarily. If they do not participate in this research project or if they want to withdraw their participation at a later date, they will not have to justify this.

If people take part in this research project, they will be asked to adhere to the guidelines and requirements imposed on the research project by the protocol.

6. Risks and burdens

We will ask participants personal questions about their health and living situation. Most questions are quite general, but some specific questions (e.g., on mental health) may make them feel slightly uncomfortable.

The physical risks of the blood samples are very small, but the procedures can be felt as uncomfortable. Sometimes, a bruise may form at the blood sampling site in the elbow (for people), foreleg (for pets) and/or fingertip (for people), which may be painful for a few days. If required, the study staff member can give participants, especially children, a plaster or cream for the elbow that temporarily numbs the place where the blood is to be taken from a vein. No blood samples will be taken from people at risk of bleeding.

Anal swabs in pets are basically the same as taking their temperature. They should not be painful but can be felt as uncomfortable.

Depending on the number of cases of disease in a given household, the number of swabs required can vary. Swabs from people and dogs are taken only from the front of the inside of the nose, and for cats through the mouth from the throat (unlike the swabs for some COVID-19 PCR tests that go through the nose into the throat). They should not be painful but can be felt as uncomfortable.

Pet owners are at risk of injuries (e.g., scratches, bites) due to the swabs they have to take from their pets.

For the purposes of the research project, personal data and biological samples will be collected from participants and pets. These will be encrypted and stored securely. The risk of unauthorised people gaining access to them is very low (see also Section 8 below).

The time required for study participation each year is low and spread out over the year, but this can increase somewhat depending on the number of infections and the number of members in the household.

7. Results

There are

1. individual results from the research project that relate directly to participants
2. individual results from the research project that occur by chance (called incidental findings)
3. objective final results of the entire research project

Re 1: If participants so desire, we can give them information on specific personal results, such as blood pressure, directly during the examination. Participants have a general right to receive information about their results. However, most results from the research project relate to a group of people and pets rather than individuals. Participants will be informed of all new results and knowledge (for example, the analysis of viruses in the swabs or parasites in poo samples) that are personally important for them. Depending on the analysis, they will be informed either over the phone by a healthcare professional or via a password-protected e-mail.

Re 2: Incidental findings are a sort of "side result", in other words results that have not been explicitly sought but that have been found accidentally. In the case of incidental findings, participants will be informed if they are relevant for their health. This means that they will be informed of such findings if a previously unknown disease is discovered by chance in them, their children or pets, or if a disease that has not yet occurred can be prevented through prevention.

Re 3: The project leader will provide participants with a summary of the overall results at regular intervals, e.g., in the form of a newsletter.

8. Confidentiality of data and samples

8.1 Data processing and encryption

For this research project, data about participants and pets and their health will be collected and processed, to some extent in automated form. The data will be entered in the database in encrypted form, so that third parties cannot draw any conclusions on individuals. Encryption means that all reference data that could be used to directly identify participants and pets (name, date of birth, address) will be stored separately and can only be linked with the data and samples by using a randomly generated identification number. An exception to this is the e-mail address that participants give to us which may contain their name (or parts thereof). This must be stored in the database so that the requests to fill out questionnaires can be sent to them automatically. We recommend the use of an e-mail address that does not contain any parts of a name. However, the e-mail address is generally only visible to the people who enter it into the database and the technical staff responsible for the database. At the end of the study, the e-mail address will be deleted from the database. Accordingly, the data can be linked with participants and pets only with the use of the key list which is stored separately from the database. The key list will remain secure at the University of Bern at all times, under the responsibility of the project leader. People who do not have access to the keys therefore cannot draw conclusions on participants and pets. Only very few professionals will see the unencrypted data and only to fulfil tasks as part of the research project. These persons are bound by professional secrecy. Participants have the right to access their data. The data from participants and pets will be stored for at least 10 years after the end of the study.

8.2 Data protection and protection of samples

All data protection specifications are strictly adhered to. It is possible that data from participants and pets may need to be transmitted in encrypted form, for example for publication, and may be made available to other researchers.

If health-related data/samples are stored on site, a database/biobank for research purposes will be used. If participants agree to possible further use of the data and samples (see Section 8.3 below), these will be stored for an unlimited time period.

As part of this project, these data and samples may be sent in encrypted form to another database/biobank. If the data and samples are transferred outside of Switzerland, the Sponsor is responsible for ensuring that the same data protection standards are adhered to abroad as in Switzerland. If the local legal situation does not allow data protection to Swiss standards to be ensured, the data and samples can be transferred only if the recipient has explicitly committed in contracts to appropriately protecting participants' rights.

8.3 Data protection in case of further use

Data and samples from participants and pets could be important at a later time for answering other questions and/or could be sent later to another database/biobank in Switzerland or abroad and used for investigations (further use) yet to be defined in more detail. This other database/biobank has to maintain the same standards as the database/biobank for this project. If the local legal situation does not allow data protection to Swiss standards to be ensured, the data and samples can be transferred only if the recipient has explicitly committed in contracts to appropriately protecting participants' rights. For this further use, we ask participants to sign an additional informed consent form at the end of this document. This second consent is independent of participation in this project. All participants who exceed the age of 18 during or after study participation will be asked again to give their consent for further use.

To better understand the body's response to infections, further use may also involve examining the genetic information contained in the blood of participants and pets, for example. This means that all or part of their genome could be investigated, as could the mechanisms that influence the activity of their genes (epigenetics). The genetic information from participants and pets will be encrypted and stored securely. We will take strict security precautions to ensure that no unauthorised persons gain access to this. However, a risk of illegal, unauthorised access cannot be fully ruled out.

8.4 Data protection for genetic investigations and internet-based research

Whenever data from samples are collected, saved and shared as part of genetic research and internet-based research, there are risks regarding confidentiality (e.g., the possibility that you will be identified), in particular regarding information about genetic make-up These risks cannot be completely ruled out and increase the more data can be linked with each other, especially if participants have published genetic data about themselves on the internet (e.g., for genealogical research). Information about genetic make-up may also be of importance for relatives or family planning. The project leader will take all measures to minimise these confidentiality risks for participants and pets.

8.5 Rights of inspection during controls

This research project can be inspected by the competent Ethics Committee, the veterinary authority, and the project leader and Sponsor that commissioned the study. The project leader must then disclose the data from participants and pets for such inspections. All entities must maintain absolute confidentiality.

9. Withdrawal

Participants can withdraw at any time from the research project. In this case, however, the data and samples collected up to that point in time will continue to be assessed in encrypted format. In addition, the data and samples collected up to that point will also continue be available in encrypted form for further use, if the participants agreed to this.

If they did not agree to further use, the biological samples will be destroyed after their assessment. However, the data will remain in the project files in encrypted form. Participants should therefore check whether they agree to this before they take part in the project.

10. Compensation

If participants and pets take part in this project, you will not receive compensation for this. They will be reimbursed for expenses such as travel costs due to participation. There will be no costs for them or their medical insurance if they take part. Under certain circumstances, the results of this research project may contribute to the development of commercial products. Participants and pets will not have any right to claim commercial developments (e.g., patents) due to their participation.

11. Liability

If participants or pets suffer any damage due to the research project, the University of Bern, which commissioned the research project and is responsible for its conduct, is liable for this damage. The requirements and the procedure are governed by law. If participants and/or pets do suffer damage, the participants should contact the project leader (see Section 13).

12. Finanzierung

The research project is being fully paid for by the University of Bern. However, substudies may also be paid for by as yet undetermined third parties.

13. Kontaktperson(en)

Participants may ask questions about participation in the project at any time. Even in case of uncertainties that arise during or after the research project, they can contact the following contact point(s):

Project management:
BEready
University of Bern
Institute of Social and Preventive Medicine (ISPM)
Mittelstrasse 43
3012 Bern
Switzerland
Phone: **+41 79 804 00 68** (Monday to Friday, 8 a.m. to 5 p.m. CET)
E-Mail: **BEready.mcid@unibe.ch**

Project leader:
Prof. Dr. med. Nicola Low
University of Bern
Institute of Social and Preventive Medicine (ISPM)
Mittelstrasse 43
3012 Bern
Switzerland

Informed consent form

Written informed consent form for participation in a research project

Please read this form carefully. Please ask if there is something you do not understand or if there is something you would like to know. Your written consent is required for participation.

BASEC-Nummer:	2023-02290
Title of the research project (in scientific and lay language):	Bern, get ready (BEready) population-based cohort study for pandemic preparedness: main study
Responsible institution:	University of Bern Represented by Prof. Dr. med. Nicola Low Institute of Social and Preventive Medicine (ISPM) Mittelstrasse 43 3012 Bern Switzerland
Site for the project:	Canton of Bern
Leader of the research project	Prof. Dr. med. Nicola Low
Participant: Last name and first name (printed): Date of birth:	…….. ……..

- The study staff member whose signature appears below has informed me both verbally and in writing of the purpose and course of the research project with the possible benefits and disadvantages, and the possible risks.
- I am taking part in this research project of my own free will, and I accept the content of the written information on the above-mentioned research project that has been given to me. I have had sufficient time to make my decision.
- My questions about participation in this research project have been answered. I can keep the written information sheet, and I will receive a copy of my written informed consent form.
- I agree to competent specialists from the project leader and the Ethics Committee competent for this research project inspecting my unencrypted data for review and control purposes, albeit under strict conditions of confidentiality.
- In the event of results and/or incidental findings that directly affect my health, I will be informed.
- I know that my health-related and personal data and samples may be transmitted only in encrypted form for research purposes for this research project (including outside of Switzerland). The Sponsor ensures that data protection will be maintained according to Swiss standards. If the local legal situation does not allow data protection to Swiss standards to be ensured, the data and samples can be transferred only if the recipient has explicitly committed in contracts to appropriately protecting participants' rights.
- I agree to be contacted again for substudies.
- I can withdraw from participation at any time and without having to provide reasons. The data and samples collected up to that time will still be used for the evaluation of the research project.
- The University of Bern is liable for any damages that may be suffered.
- I am aware that the obligations listed in the information sheet are to be complied with. In the interests of my health, the project leader can remove me at any time.

Place, date	Signature of participant

Declaration by the study staff member: I hereby confirm that I have explained the nature, significance and scope of the research project to the participant who signed above. I affirm that I shall fulfil all of my obligations in connection with this research project in accordance with the laws applicable in Switzerland. If at any point during the conduct of the research project I learn of aspects that could influence the willingness of the participant who signed above to take part in the research project, I will inform him/her of this immediately.

Place, date	Last name and first name of the study staff member (printed) Signature of the study staff member

Informed consent form for the further use of data and biological material in encrypted form

BASEC-Nummer:	2023-02290
Title of the research project (in scientific and lay language):	Bern, get ready (BEready) population-based cohort study for pandemic preparedness: main study
Participant: Last name and first name (printed): Date of birth:	…….. ……..

- I give my consent for my encrypted (including genetic) data and samples from this research project to be used for further medical research. The samples will be stored in a biobank and used for an unlimited period of time in future research projects that have not yet been defined in more detail.
- I have understood that the samples are encrypted and that the key will be stored securely. The data and samples may be sent to other databases and biobanks within and outside of Switzerland for analysis, provided they observe the same standards as in Switzerland. All legal data protection requirements will be observed. If the local legal situation does not allow data protection to Swiss standards to be ensured, the data and samples can be transferred only if the recipient has explicitly committed in contracts to appropriately protecting participants' rights.
- I am making this decision of my own free will, and I can withdraw this decision at any time. If I withdraw, all of my (genetic) data will remain encrypted and stored in the database (for technical reasons) and my samples will be destroyed. I only have to inform the project leader, and I do not need to justify this decision.
- Normally, all data and samples will be assessed as a whole, and the results will be published as a summary. Should any result prove important for my health, it is possible that I will be contacted.
- If results from the data and samples are used for commercial purposes, I have no claim to a share of the commercial use.

Place, date	Signature of participant

Declaration by the study staff member: I hereby confirm that I have explained the nature, significance and scope of the further use of samples and/or genetic data to the participant who signed above.

Place, date	Last name and first name of the study staff member (printed) Signature of the study staff member