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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,



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

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

55

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

59

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

63

64 What benefits and risks are associated with participation?

65 **Benefits**

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

69 **Risks and burdens**

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

77

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

80

81 **Detailed information**

82

83 **Glossary**

84

Biological samples

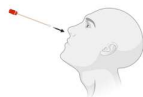
One or more of the following:



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



85 **1. Objective and selection**

86

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

90

91 All private households in the Canton of Bern are eligible to take part in the research project
92 provided that at least one person over the age of 18 years agrees to take part. Participants over
93 11 years must be able to understand, speak, read, and write German, French and/or English.
94 Participants over 14 years must have access to the internet. Participants under 14 years can take
95 part provided that at least one adult is taking part who understands German, French and/or English
96 and has access to the internet. Pets can be included as long as they live in a household that is
97 taking part.

98

99 **2. General information**

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

104

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

115

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

118

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

122

123 **3. Procedure**

124 The research project will follow the following procedure:

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

130

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




133 First visit (Month 0)

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

138

139 The study staff member () will do the following:


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

149


150 For pets, the first visit will take place at the Vetsuisse veterinary clinic for small animals
151 (Länggassstrasse 128, 3012 Bern, Switzerland) or at another veterinary clinic and will take about
152 45 minutes per pet.

153


154 The study staff member () will do the following:

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


161

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

165


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


168

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



174

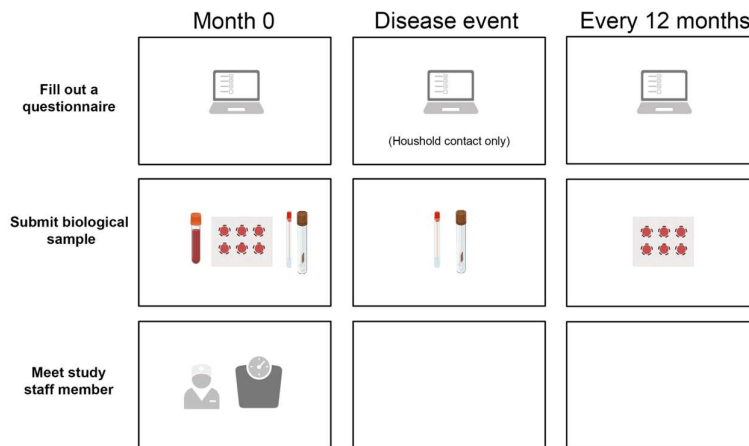
175 Assessment around every 12 months

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

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

184
 185 Disease event

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



197
 198 Figure 1. Procedure for the research project.

199
 200 Substudies

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

205
 206
 207 Early withdrawal or exclusion from the study

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

209
 210 It may also be the case that we have to exclude participants prematurely from the research project.

211 For example, this can happen

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

214
 215 The research project can also be terminated early by the Sponsor.

216
 217

218 **4. Benefits**

219 The results of the research project may be important to help people in the Canton of Bern be better
220 prepared for the next pandemic. However, participation may also lead to no direct benefit.

221 Participants will derive no personal benefit by taking part.

222

223 **5. Voluntary nature and obligations**

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

226

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

229

230 **6. Risks and burdens**

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

234

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

241

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

244

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

249

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

252

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

256

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

260

261 **7. Results**

262 There are

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



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

273
274 Re 2: Incidental findings are a sort of "side result", in other words results that have not been
275 explicitly sought but that have been found accidentally. In the case of incidental findings,
276 participants will be informed if they are relevant for their health. This means that they will be
277 informed of such findings if a previously unknown disease is discovered by chance in them, their
278 children or pets, or if a disease that has not yet occurred can be prevented through prevention.

279
280 Re 3: The project leader will provide participants with a summary of the overall results at regular
281 intervals, e.g., in the form of a newsletter.

282

283 **8. Confidentiality of data and samples**

284 8.1 Data processing and encryption

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

304

305 8.2 Data protection and protection of samples

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

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

312



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

319

320 8.3 Data protection in case of further use

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

331

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

339

340 8.4 Data protection for genetic investigations and internet-based research

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

349

350 8.5 Rights of inspection during controls

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

355

356 9. Withdrawal

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



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

364

365 **10. Compensation**

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

371

372 **11. Liability**

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

377

378 **12. Finanzierung**

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

381

382 **13. Kontaktperson(en)**

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

386

387 Project management:

388 BEready

389 University of Bern

390 Institute of Social and Preventive Medicine (ISPM)

391 Mittelstrasse 43

392 3012 Bern

393 Switzerland

394 Phone: **+41 79 804 00 68** (Monday to Friday, 8 a.m. to 5 p.m. CET)

395 E-Mail: **BEready.mcid@unibe.ch**

396

397 Project leader:

398 Prof. Dr. med. Nicola Low

399 University of Bern

400 Institute of Social and Preventive Medicine (ISPM)

401 Mittelstrasse 43

402 3012 Bern

403 Switzerland



404 **Informed consent form**

405

406 **Written informed consent form for participation in a research project**

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

409

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
Pet: Name (printed): Date of birth:	

410

411 **Informed consent form.** I hereby confirm that I have understood the structure of the project and
412 that, through my signature, I agree to my pet taking part in the above-mentioned project.

413

Place, date	Last name and first name of the pet owner (printed)
	Signature

414

415

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

416



417 **Informed consent form for the further use of data and biological material in encrypted form**
 418
 419

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.
Pet: Name (printed): Date of birth:

420
 421 **Informed consent form.** I hereby give my consent for my pet's encrypted (genetic) data and
 422 samples from this research project to be used for further medical research. The samples will be
 423 stored in a biobank and used for an unlimited period of time in future research projects that have
 424 not yet been defined in more detail.
 425

Place, date	Last name and first name of the pet owner (printed)
	Signature

426
 427

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

428
 429
 430
 431
 432