Infectieradar.be

Study sponsor:

- Hasselt University, Martelarenlaan 42, 3500 Hasselt
- University of Antwerp, Prinsstraat 13, 2000 Antwerp

Who can I contact if I have any questions?

Name	**Position**	**For**	**Contact details**
Pierre Van Damme Niel Hens	Study leaders	Information, problems, concerns	infectieradar@uhasselt.be
	Study personnel	Information, problems, concerns	infectieradar@uhasselt.be
	Belgian Data Protection Authority	Complaints about the confidentiality of your data	Email: contact@apd-gba.be

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Contents

Note to the ethics committee: The 'Study at a glance' section is shown to potential participants in an initial online window. After seeing this, the visitor can look at the more detailed description in another online window before giving informed consent.

THE STUDY AT A GLANCE

In this 'Study at a glance' window we provide a brief description of the study. You can find more detailed information by clicking here. We recommend that you read the more detailed information, even though it will take around ten minutes of your time.

It is important for you to read and understand everything. Before you agree to participate in this study, we want to inform you fully. This will mean that you can make an informed decision about your participation, known as giving 'informed consent'.

Why Infectieradar.be?

We know that many people who become infected with the new SARS-CoV-2 virus ('coronavirus' as it is popularly known) have mild or few symptoms and do not go to the doctor. Also, not everyone is tested. This make it difficult to track how the new coronavirus is spreading in Belgium. It is important to monitor symptoms that are not reported to a doctor.

Who can take part?

Anyone who lives in Belgium and is 18 years or older can participate in the study on a voluntary basis. To ensure that information about the spread of infectious diseases is also obtained for children and young people, the parents or guardians of a minor can also complete the questionnaires on behalf of their child. This is not mandatory, but it will contribute to the research.

How does Infectieradar.be work?

Participants receive an initial registration form with questions about their background, age and existing diseases and conditions. Following this they receive an email every week with a link to a questionnaire asking what symptoms they have had in the past week: a runny nose, coughing, sneezing, a high temperature and so on. The questionnaire must be completed even if the participant has no symptoms. It takes about 30 seconds to complete the questionnaire if the participant has no symptoms, and about 3 to 5 minutes if he or she has symptoms.

The completion of the questionnaire enables us to monitor how certain symptoms are distributed across Belgium and changes in this pattern over time. These data will be used for scientific research into the spread of the new coronavirus. In the future, that research will also be useful for other viruses and infectious diseases.

Data

The data are collected and processed in the context of scientific research, and exclusively for the following purposes:

- Carrying out scientific research and statistical analyses on the spread of infectious diseases in Belgium and Europe;
- Publishing statistical analyses, including graphical representations of the results;
- Providing you, the user, with information about the survey results (for example: how many registered users in your region have flu or other infectious diseases);

The personal data that we may process for these purposes are:

- Year of birth, month of birth, postcode, gender, family composition;
- Background data relevant to the risk of infection, i.e. data about whether you belong to a risk group recommended for flu vaccination, occupation and lifestyle;
- Data about symptoms provided in the symptoms questionnaire;

The data obtained in this study will be processed by Hasselt University and the University of Antwerp for the stated purposes. We would also like to inform you that we will process your data in accordance with the applicable laws and regulations and with full respect for your rights and in particular your privacy.

Taking part

After registration, you will be sent an email every week inviting you to complete a questionnaire. Your participation in this study is voluntary and you can withdraw from the study at any time without giving a reason.

You can also choose to skip questions at any point when completing the questionnaires.

The study is funded by the European Union and has been evaluated by an ethics committee. The fact that it has been funded and approved does not mean that you should feel obliged to participate.

CHAPTER I - DESCRIPTION OF THE STUDY AND YOUR RIGHTS AS A PARTICIPANT

1. Why are we carrying out this study?

The aim of this study is to learn about the spread of infectious diseases in Belgium and Europe. The study is part of a larger research project entitled 'EpiPose', which refers to our efforts to 'pause' the COVID-19 epidemic and is an acronym for: Epidemic intelligence to minimise 2019-nCoV's public health, economic and social impact in Europe. This project is funded by the research and innovation arm of the European Union in the context of work programme H2020 (grant agreement ID: 101003688). More information about the EpiPose project can be found here.

We know that many people who become infected with the new coronavirus have mild or few symptoms and do not go to the doctor. Also, not everyone is tested. This make it difficult to track how the new coronavirus is developing in Belgium. It is important also to monitor symptoms that are not reported to a doctor.

Your reporting of symptoms enables Infectieradar.be to keep an eye on the spread of infectious diseases, including the new coronavirus. Infectieradar.be tries to establish the number of people with symptoms that may indicate an infection.

Participants report once a week whether they have had any symptoms in the past week. Even if they have no symptoms, they report this fact. Using these data we can detect any increase or decrease in infections sooner, including infections with SARS-Cov-2 (coronavirus).

2. Who can participate in this study?

Anyone who lives in Belgium and is 18 years or older can participate in this study on a voluntary basis. To ensure that information about the spread of infectious diseases is also obtained for children and young people, the parents or guardians of a minor can also complete the questionnaires on behalf of their child. This is not mandatory, but it will contribute to the research.

3. Do I have to participate in this study?

Your participation in the study is voluntary and should never take place under pressure. This means that you have the right not to participate in the study. You may also withdraw at any time without having to give a reason, even though you previously agreed to participate. Your decision will not affect your relationship with the researcher or your doctor, or the quality of your future medical care.

4. What will happen during the study?

After registration you will receive a questionnaire relating to your demographic data, medical history and vaccination data.

You will receive an email every week inviting you to click on a link to complete a questionnaire. In this questionnaire you will be asked about recent symptoms that you have experienced, the start date of these symptoms and whether you have sought medical help for them.

You can choose to skip questions at any point when completing the questionnaires.

5. Will I benefit from the study?

The information obtained during the study may contribute to a better understanding of the spread of infectious diseases in Belgium and Europe. These insights may support policymakers in making decisions about measures to contain the epidemic.

6. What are the possible risks and disadvantages of participating in the study?

We do not expect there to be any risks or disadvantages from participating in this study. However, any complaints about your participation or the confidentiality of your personal data can be submitted (see section 7).

7. What if something goes wrong during the study?

Even if no error has been committed, the sponsor is liable for any harm or damage you suffer that is directly or indirectly related to your participation in the study. The sponsor has arranged insurance to cover this liability ('NO FAULT' LIABILITY) (Ref. [1]). A copy of the insurance certificate may be obtained from the researcher or the study personnel.

Although we do not expect there to be any risks or disadvantages, you always have the option to contact the sponsor if you believe you have suffered any harm or damage. This can be done by sending an email to infectieradar@uhasselt.be. You should do so as soon as possible. More information can be found here.

If the sponsor believes that there may be a link between new or aggravated symptoms and the study, he or she will report this to the sponsor. The sponsor will then immediately submit a claim to its insurance company. If the insurance company considers it necessary, it will appoint an expert to determine whether there is a link between your reported symptoms and the study.

If you have any complaints about the confidentiality and processing of your personal data, you can contact the Belgian data protection authority by email at: contact@apd-gba.be.

8. Can my participation in the study be terminated early?

Your participation in the study can come to end early if:

- you decide to withdraw your consent,
- the researcher decides to discontinue your participation in the study, or
- other authorities interrupt or terminate the study.

The sponsor may keep and continue to use any data already collected before your participation ended, to avoid misinterpretation of the study results.

8.1. You decide to withdraw your consent

We wish to repeat that your participation in this study is voluntary and that you can pull out from the study and withdraw your consent at any time, without giving a reason; you can also ask for your email address to be deleted.

[1] This is in line with Article 29 of the Belgian Law of 7 May 2004 on experiments on humans and the applicable Royal Decrees.

You can also choose to skip questions at any point when completing the questionnaires.

8.2. The researcher decides to discontinue your participation in the study

The researchers may interrupt or terminate the study.

8.3. Other authorities may interrupt or terminate the study.

The sponsor and the competent Belgian health authorities may interrupt or terminate the study.

9. Will my participation in the study entail any additional costs for me?

No.

10. What data will be collected about me during the study and what will happen to them?

10.1. What data are collected and processed during the study?

The personal data that are collected and processed are data about your health and medical condition, including your medical history, some background information (e.g. your age, gender, etc.) and information about medical care you have sought.

10.2. How will the researcher treat my personal data?

The researchers who analyse your data will only have access to non-identifiable data. The data will be encrypted or coded by the following method:

The database administrator will never disclose your identity (email address), and he/she will encrypt your data (i.e. replace your identity in the study with an identification code) before the researchers analyse your data. Your identity will therefore not be used in a scientific publication or presentation.

This means that the database administrator, under the responsibility of the study leaders, will be the only person able to link your identity to the data communicated during the study, with the exceptions mentioned in section 10.6.

The data that the researchers analyse will not allow them to identify you.

10.3. What will happen to the information about me that is collected during the study?

Your participation in the study means that your personal data

- will be collected, and
- will be used in encrypted form by the researchers.

The researcher and the sponsor may only use the encrypted personal data for the specific research purposes described earlier.

In addition, the sponsor may grant external researchers (who are not involved in this study) access to the encrypted data. If an external researcher wishes to use the data in

research not yet described in this document, this research must be approved by an Ethics Committee.

10.4. How will my data be processed?

Your study data will be processed in accordance with the General Data Protection Regulation (GDPR) (Ref. [2]) and the Belgian data protection law of 30 July 2018 (Ref. [3]). The sponsor is the controller with responsibility for this.

The grounds on which we are allowed to process your personal data are that we are conducting scientific research and that you have given your consent.

10.5. Can I access and correct my data that have been collected and processed during the study?

You have the right to ask the researchers what data about you have been collected and what they are used for in this study.

You have the right to

- access and check these data
- have all your data deleted
- request correction if they are incorrect
- restrict the processing of your data
- oppose the processing of your personal data
- withdraw your consent to the processing of personal data. Your personal data that have already been collected before your withdrawal of consent will be kept to prevent any misinterpretation of the study results.

10.6. Apart from the researcher and the researcher's personnel, who else has access to my personal data?

In order to check the quality of the study, your non-encrypted personal data or information relevant to this study may be inspected by people other than the study personnel. Any such inspection will take place under the researcher's supervision, and the people concerned will be bound by professional secrecy or by a confidentiality agreement. They may include:

- personnel designated by the sponsor (MONITORS and AUDITORS) and people or organisations providing services to or collaborating with the sponsor. However, they will never pass on your name and contact details to the sponsor.
- inspectors from competent health authorities from around the world
- an independent audit group

[2] Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC.

[3] The Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

- persons designated by the Ethics Committee

If required for the study, the encrypted study data may be sent to other countries within and outside the European Union (EU) and verified by:

- personnel (other than inspectors) of the competent health authorities of Belgium (the Federal Agency for Medicines and Health Products, FAMHP) or other countries within and outside the EU,
- the Belgian evaluating Ethics Committee(s),
- external researchers,
- the study's sponsor, personnel designated by the sponsor and people or organisations providing services to or collaborating with the sponsor, and/or
- companies from the sponsor's group in Belgium and in other countries within and outside the EU.

European regulations and Belgian data protection legislation impose restrictions on the transfer of data to non-EU countries. The sponsor must always ensure that your encrypted study data are equally protected when transferred to a non-EU country. If the sponsor concludes a data protection agreement for this purpose, a copy of this agreement may be obtained from the researcher.

10.7. What will happen to the results of the study?

After its completion, a description and the results of the study will be published in specialist medical journals. A copy of the scientific publication will be published on the website and will be available from the researcher or study personnel.

These websites or publications will not contain any information by which you can be identified.

10.8. Will my data be used for purposes other than the study in which I am participating?

The results of the study will only be used to answer the scientific questions in this study. Any additional or future research outside the study must always be approved by a recognised Belgian Ethics Committee.

10.9. For how long will my data be kept?

After the study, your encrypted data will be kept for at least 25 years (Ref. [4]) to ensure the validity of the study. This will be the case even if you withdraw from the study before its completion.

11. What biological samples will be collected from me during the study and what will happen to them?

No biological samples will be collected.

[4] In accordance with Article 58 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

12. Who has reviewed and approved the study documents?

The study documents have been reviewed by an independent Belgian ethics committee. The role of ethics committees is to protect participants in studies. The competent health authorities will ensure that the study is conducted in accordance with the applicable law.

You should not take their approval as a reason to participate in the study.

CHAPTER II - INFORMED CONSENT

PARTICIPANT

REQUIREMENTS FOR YOUR PARTICIPATION IN THE STUDY

- I declare that I have been informed of and understand the purpose of the study, its duration and consequences, any risks and inconveniences, and what is expected of me.
- I understand that I will be participating in this study voluntarily and without being compelled to do so, and that I may stop participating at any time.
- I understand that data about me will be collected and will be treated confidentially.
- I agree that my personal data will be processed as described in Chapter I.
- I understand that the sponsor of the study has arranged insurance in case I suffer harm in connection with my participation in this study.
- I understand that participating in this study will not cost me anything.
- I understand that my participation in the study may be terminated without my consent.
- I declare that I am 18 years of age or older and I am aware that infectieradar.be is not a medical website, and will always seek help from a doctor for any medical questions or complaints.
- For consent granted on behalf of a minor, the following applies in addition to the foregoing conditions:
    - If consent is granted on behalf of a minor under the age of 14, I declare that I am legally authorised to grant consent as a parent or guardian.
    - If consent is granted on behalf of a minor between the ages of 14 and 17, I declare that I am legally authorised to grant consent as a parent or guardian and have also discussed this with the child concerned.
    - For the sake of clarity, consent for anyone aged 18 or over must always be granted by the person concerned and not by anyone else.

I agree to participate in the study.

Date (DD/MMM/YYYY):

GLOSSARY

FAMHP: Federal Agency for Medicines and Health Products

DPA: The Belgian Data Protection Authority ensures that personal data are properly used and protected, and that your privacy is also safeguarded in the future.

‘NO FAULT’ LIABILITY INSURANCE:

The sponsor is liable for any harm or damage to a participant that is directly or indirectly related to the study. You do not need to demonstrate any error for this to apply.

MONITOR and AUDITOR:

Both the monitor and the auditor work for the sponsor.

The monitor ensures continuous quality control during the running of the study. The auditor conducts an audit at the end of the study. Together they check that the study is/was carried out according to the protocol, that the reported data are reliable and that the study complies with the applicable laws.

REFERENCES