Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

# Participant Information Leaflet

**Name of Study:** Living with COPD in the community during the Covid-19 pandemic: an exploration of patients' perspectives.

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| Site | Trinity Centre for Practice and Healthcare Innovation, Trinity College Dublin and Community Healthcare Organisation 7, Health Service Executive |
| Principal Investigator(s) and Co-Investigator(s) | • Dr. Gobnait Byrne, Principal Investigator, School of Nursing and Midwifery, Trinity College Dublin, gobnait.byrne@tcd.ie<br>• Dr Éadaoin Butler, Co-investigator, School of Nursing and Midwifery, Trinity College Dublin, email: BUTLERAD@tcd.ie<br>• Dr Louise Daly, Co-investigator, School of Nursing and Midwifery, Trinity College Dublin, email: louise.daly@tcd.ie<br>• Ms Lynda Haran, Co-investigator, HSE Community Healthcare Dublin North, Dublin North Central, Dublin North West, email: lynda.haran@hse.ie<br>• Ms Fiona Murphy, Co-investigator, School of Nursing and Midwifery, Trinity College Dublin, email: fiona.murphy@tcd.ie<br>• Ms Fiona Kavanagh, Co-investigator, HSE Community Healthcare Dublin South, Kildare & West Wicklow, email: fiona.kavanagh1@hse.ie<br>• Ms Geraldine Cully, Co-investigator, HSE Community Healthcare Dublin South, Kildare & West Wicklow, email: geraldine.cully@hse.ie<br>• Ms Olivia Lee, Naas General Hospital, email: olivia.lee@hse.ie<br>• Mr. Stephen Shelly, St James' Hospital, email: Sshelly@STJAMES.ie<br>• Ms. Judith Maxwell, Tallaght University Hospital, email: judith.maxwell@TUH.ie<br>• Ms Teresa Madden, Patient Representative, email: teresam1@live.ie |
| Data Controllers | • Trinity College Dublin<br>• Health Service Executive<br>• St James' Hospital<br>• Tallaght University Hospital |
| Data Protection Officers | • Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2<br>• HSE Data Protection Officer, Consumer Affairs, HSE, Third Floor Scott Building, Midland Regional Hospital Campus, Arden Road, Tullamore, Co. Offaly |

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| | • St James' Hospital Data Protection Officer, Ground Floor, CEO Building, St James' Hospital, James Street, Dublin 8, Ireland, D08 NHY1<br>• Tallaght University Hospital Data Protection Officer, Tallaght University Hospital, Tallaght, Dublin 24, D24 NR07 |

*You are invited to take part in a research study to be carried out by a team of researchers from Trinity College Dublin, HSE Community Healthcare Dublin South, Kildare & West Wicklow, HSE Community Healthcare Dublin North, Dublin North Central, Dublin North West, St James's Hospital, Tallaght University Hospital, and Naas General Hospital. Before you decide whether or not you wish to take part, you should read the information provided on this page carefully. Ask Dr Éadaoin Butler (01 896 1775 or BUTLERAD@tcd.ie) any questions. Take time to read the information and don't feel rushed or under pressure to make a quick decision to participate or not. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your colleagues.*

*This leaflet has five main parts:*

*Part 1 – The Study*
*Part 2 – Data Protection*
*Part 3 – Costs, Funding and Approval*
*Part 4 – Future Research*
*Part 5 – Further Information*

# 1 – The Study

**Why is this study being done?**

The aim of this study is to understand the lived experience of people with Chronic Obstructive Pulmonary Disease (COPD) in the community during the COVID-19 pandemic.

**Why have I been invited to take part?**

You are invited to participate in this study as you were living at home in the community during the Covid-19 pandemic and have COPD for more than 18 months. You will need to be able to speak and understand English to participate in this study as it is not possible to facilitate a translator.

**Do I have to take part? Can I withdraw?**

You do not have to take part in this study. It is entirely voluntary. You do not have to give a reason for not taking part or for opting out. Opting out will have no adverse consequences for you. If you wish to

opt out, please phone the researcher Dr Éadaoin Butler at 01 896 1775 or email BUTLERAD@tcd.ie who will be able to organise this for you.

Please be aware that you can change your mind about taking part in this study and withdraw from the study **up to the point of data analysis**. This will take approximately two weeks from the time of your interview. After this time your name and personal details will be removed from the interview so we will no longer be able to identify your data to remove or amend it. It will not be possible at any stage after the interview to amend or delete your responses to a brief survey you will also answer that collects basic anonymous information about you, your living arrangements and your condition. This is because this information will be stored entirely anonymously.

## How will the study be carried out?

This study involves a one-to-one interview with a member of the research team and a brief survey that will be completed just before your interview. The interview will take place on the telephone or on Microsoft Teams (your choice) and focus on your experience of living at home in the community with COPD during the Covid-19 pandemic. The brief survey will collect basic anonymous information about you, your living arrangements and your condition. We plan to conduct between 12 and 15 interviews. If more people volunteer to take part than is required to complete the study, the researcher will thank you for your willingness to participate but they will not conduct the interview with you. A member of the research team will contact you no earlier than seven days after you have been sent this information to ask if you would like to participate. If you decline, or do not respond to two attempted contacts from the researcher, you will not hear from the research team again.

## What will happen if I decide to take part?

If after reading this Participant Information Leaflet, you decide to take part in this study, it will involve the following:

**Telephone call.** Dr Éadaoin Butler will contact you to check your interest in participating in the study. If you inform Dr Butler that you would like to participate, will answer any questions that you have about the study, discuss the study and consent form with you, ask you to complete the consent form (sent to you after the telephone call) and arrange a suitable time you to complete the interview. She will also check what format you would prefer for the interview (telephone or Microsoft Teams).

**Online consent form.** After your phone call, Dr Butler will send you a link to an online consent form for you to complete. If you have chosen to use Microsoft Teams for the interview, Dr Butler will also send you a link for this.

**Interview.** Your interview will take place on the telephone or Microsoft Teams, depending on which you have chosen. If it is on the telephone, Dr Butler will call you at the time you agreed. If it is on Microsoft Teams, you will need to click the link the email she sent you at your agreed interview time.

At the beginning of the interview, Dr Butler will review the purpose of the study, offer to answer any questions you may have and ensure that you understand the study. You will be asked to give your consent again verbally. You will be informed of the inclusion/exclusion criteria, confidentiality, how the information collected will be stored and your right to withdraw or have your data corrected up to the point of data analysis, when your data is anonymised.

The interview will be audio recorded, with your permission, and subsequently typed out for analysis. Before you will be asked the interview questions, the researcher will go through a very brief survey with you about your living situation and your condition. This will take less than 5 minutes to complete. The interview itself will take approximately 30-45 minutes. During the interview you will be asked about your experiences and perceptions of living with COPD during the Covid-19 pandemic. All data will be collected according to EU General Data Protection Regulations.

**What will happen to my data?**

Your data includes your contact details, consent form, survey responses and interview data. A record of your contact details will be kept in a Microsoft Excel file on the password protected TCD School of Nursing and Midwifery secure server and will only be accessible to TCD members of the research team. This file will be permanently deleted transcripts have been anonymised.

Your consent will be collected via online software called Qualtrics. The only people who will have access to this information will be the TCD research team. The consent forms will be downloaded from Qualtrics and stored electronically on a secure server within the School of Nursing & Midwifery, TCD for seven years. Once they have been saved to the secure server, they will be deleted from Qualtrics.

Your survey responses will be entered into an Excel sheet at the time of your interview and transferred to another program (SPSS) for analysis. This Excel sheet and SPSS file will be stored electronically on a secure server within the School of Nursing & Midwifery and will remain there for seven years.

The recordings of the interviews will be sent securely to Audiotrans Ltd. to be typed into a transcript.

Audiotrans Ltd. is a professional transcribing company with whom the School of Nursing & Midwifery have an official contract. When the transcripts have been checked for accuracy, the recordings will be deleted. All transcripts will be stored in a restricted a secure electronic folder within the School of Nursing & Midwifery, TCD. Any identifying information on the interview transcripts will be removed. Following data analysis, the linkage between each interview participant and their interview transcript will be deleted.

All consent forms, survey responses, transcripts and data analysis will be destroyed after seven years under the supervision of the TCD Principal Investigator (Dr Gobnait Byrne).

**Are there any benefits to taking part in this research?**

There will be no direct benefit for you taking part in this research study. However, this research will help us to better understand the experiences and perceptions of individuals living with COPD in the community amid COVID-19 and hopefully will enhance service care delivery in this area.

The dissemination of findings from this research (for example via conferences and publications) will also help increase the understanding of the experiences of individuals living with COPD which may result in recommendations for changes in healthcare practice.

**Are there any risks to me or others if I take part?**

This is a low-risk study. It is anticipated that there will be no potential harm. However, during research interviews, there is the potential for upset. If this occurs, you may stop the interview at any point and withdraw from the study. You can also contact the COPD Adviceline free phone 1800 83 21 46.

If you have any concerns about this study, you are welcome to contact a member of the research team at any stage. The contact details are provided at the end of this document.

**Will I be told the outcome of the study?**

The results of the study will be reported in relevant peer reviewed journals and presented locally and at national conferences. There will be no disclosure of information which reveals your identity.

If you would like to receive a copy of your interview transcript, you can do so up to the point of data analysis (two weeks after your interview) by contacting the researcher, Dr Éadaoin Butler at BUTLERAD@tcd.ie.

After this time your data will be anonymised, and we will no longer be able to identify your data.

## Part 2 – Data Protection

**What information about me (personal data) will be used as part of this study?**

The personal data that will be collected in relation to you in this study will be your name and contact details (telephone number and email address). It is necessary for us to retain this information so that we can communicate with you during the recruitment for the study (e.g., we will need to access your telephone number so that we can call you to discuss the study). The demographic and health data collected at the beginning of the interview will be recorded anonymously. This will include age, gender, marital status, length of time diagnosed with COPD, whether you are living alone, and if you require oxygen. There will be no medical records accessed.

Personal data routinely collected will be limited to your name, email address, and telephone number. If you share identifying information during the interview, this will be anonymised.

**What will happen to my personal data?**

The personal data will be processed only as is necessary to achieve the objective of the research study. The personal data will not be processed in any way that will cause damage or distress to you as a participant. Your contact details will be deleted after the interview transcripts have been anonymised. The consent forms and data will be stored for a period of seven years. The interview data will be anonymised during the transcription process and only these transcriptions of the interviews will be retained. The Principal Investigator Dr Gobnait Byrne will be responsible for destroying all data from the project. All data will be stored in a restricted access project folder on a secure encrypted server located within the School of Nursing & Midwifery, Trinity College Dublin. This will be accessible only to the research team. None of your personal data will ever leave the State. No third parties will ever have access to this data.

**Who will access and use my personal data as part of this study?**

Only members of the research team from the School of Nursing and Midwifery Trinity College Dublin will have access to your personal data (Dr Gobnait Byrne, Dr Louise Daly, Ms Fiona Murphy, Dr Éadaoin Butler). It will be stored in a restricted access project folder on a secure encrypted server located within the School of Nursing & Midwifery, Trinity College Dublin. This will be accessed via Trinity College Dublin approved computers.

The anonymised interview data and anonymous survey responses will be accessed by all members of the research team.

**Will my personal data be kept confidential? How will my data be kept safe?**

It is important to us that your privacy is maintained. We take many steps to make sure that we protect your confidentiality and keep your data safe. All electronic data collected will be held on a password protected designated project folder held on a secure research drive in the School of Nursing and Midwifery. This data will have access restricted to only the named members of the

research team. Your electronic consent form will be retained in a designated folder in the secured research project folder. The data from your interview will be anonymised and kept strictly confidential. The audio recording of your interview will be downloaded and stored to the secured project folder immediately after each interview. The audio recordings will be deleted from this folder once transcription has been completed. The final research report will not contain information about your identity so it will not be possible to identify you in the results. A Data Protection Impact Assessment was carried out and indicated a low level of risk. All members of the team with access to the data have completed training in data protection law and practice.

## What is the lawful basis to use my personal data?

By law,[1] we can use your personal information for scientific research[2] (in the public interest[3]). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations. We are carrying out this research in the public interest and will process personal data for scientific research purposes under Articles 6(1)(e) and 9(2)(j) of the General Data Protection Regulations (2018). This means that we will only use your data in the ways needed to conduct the research study.

## What are my rights?

As a participant of this research study, you have a number of rights under data protection (GDPR) regulations:

1. The right to access to your data and receive a copy of it.
2. The right to restrict or object to processing of your data.
3. The right to object to any further processing of the information we hold about you (except where it is de-identified).
4. The right to have inaccurate information about you corrected or deleted. This applies up the point of data anonymisation.
5. The right to receive your data in a portable format and to have it transferred to another data controller.
6. The right to request deletion of your data.

[1] The European General Data Protection Regulation ( GDPR)
[2] *Article 9(2) (j))*
[3] *(Article 6(1)(e)*

The study will not involve any profiling or decision making about individuals by automated means.

By law you can exercise the above rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise any of these rights by contacting:

1. Dr Gobnait Byrne - gobnait.byrne@tcd.ie
2. Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you have the right to lodge a complaint with the Data Protection Commissioner at: https://www.dataprotection.ie/.

## Part 3 – Costs, Funding and Approval

**Has this study been approved by a research ethics committee?**

Ethical approval for this study has been given by the Trinity College Dublin Faculty of Health Sciences Research Ethics Committee on 09th June 2022. Any amendments to the study will be submitted to the Committee prior to being implemented.

**Who is organising and funding this study? Will the results be used for commercial purposes?**

The HSE has provided funding for the research collaboration between the Trinity Centre for Healthcare Practice and Innovation and HSE Community Healthcare Dublin South, Kildare & West Wicklow Public Health Nursing Services. This study is being conducted as a result of this collaboration. The results will not be used for any commercial purposes. The project is not being conducted for the purpose of obtaining an academic qualification.

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

No, you will not receive payment for taking part in this study and it will not cost you anything to take part.

## Part 4 – Future Research

**Will my personal data be used in future studies?**

As your personal data will be irreversibly deleted once the interview transcripts have been checked and anonymised, it will not be possible for us to use them in future studies.

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# Part 5 – Further Information

**Who should I contact for information or complaints?**

If you need any further information now or at any time in the future, please contact

- Dr Gobnait Byrne, email: gobnait.byrne@tcd.ie
- Dr Éadaoin Butler, email: BUTLERAD@tcd.ie or telephone: 01 896 1775

**Joint Data Controller's Identity and contact details**

- TCD Data Protection Officer: Data Protection Officer Secretary's Office, Trinity College Dublin, Dublin 2, email dataprotection@tcd.ie
- HSE Deputy Data Protection Officer – Consumer Affairs, HSE, Third Floor Scott Building, Midland Regional Hospital Campus, Arden Road, Tullamore, Co. Offaly, Ireland email ddpo.dml@hse.ie, phone 057-9357876
- St James' Hospital Data Protection Officer - Ground Floor, CEO Building, St James' Hospital, James Street, Dublin 8, Ireland, D08 NHY1, email dataprotection@stjames.ie, phone (01) 410 3021
- Tallaght University Hospital Data Protection Officer – Data Protection Officer, Tallaght University Hospital, Tallaght, Dublin 24, D24 NR07, email dpo@tuh.ie, phone (01) 414 2000

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

**Will I be contacted again?**

As we are not retaining any of your personal data (including contact details), you will not hear from us again after the interview.