







Participant Information Leaflet

Study Title	An exploration of New-Graduate Nurses transition experiences
	to adult critical care
Site	Trinity College Dublin, Dublin 2.
TCD Principal and Co- investigators Trinity Centre for Practice and Healthcare Innovation (TCPHI), School of Nursing and Midwifery, Trinity College Dublin	 Dr. Gobnait Byrne, Principal Investigator, gobnait.byrne@tcd.ie Dr. Catherine Mc Cabe, Ms. Geraldine Prizeman,
Co-Investigators St James's Hospital ICU, James Street, Dublin 8.	 Ms. Beatriz Tejada Rios, Clinical Facilitator ICU Ms. Ciara Mc Hale, Clinical Facilitator, ICU Ms. Deborah Gaffney, Clinical Facilitator, ICU
Co-Investigators Tallaght University Hospital ICU, Dublin 24	 Ms. Bernie Garvin, Clinical Facilitator, ICU Ms. Shauna Delaney, Clinical Facilitator, ICU Ms. Sinead Gill, Clinical Facilitator, ICU Ms Lisa Dunne CMN3 ICU
Data Controllers	Trinity College DublinSt James HospitalTallaght University Hospital
Data Protection Officer	Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie . Website: www.tcd.ie/privacy Data Protection Officer of St James Hospital, Ground Floor, CEO building, St James Hospital, James Street, Dublin 8, Ireland, D08 NHYI, email dataprotection@stjames.ie , Phone 014103021. Tallaght University Hospital Data Protection Officer – Data Protection Officer, Tallaght University Hospital, Tallaght, Dublin 24, D24 NR07, email dpo@tuh.ie , phone 014142000.

You are Invited to take part in a research study to be carried out by a team of researchers from Trinity College Dublin, Intensive Care Unit St James Hospital Dublin and Intensive Care Unit Tallaght University Hospital, Dublin. Before you decide whether or not you wish to take part, you should read the

information provided in this booklet carefully. Ask nominated person of contact any questions. Take time to read the information and don't feel rushed or any pressure to make a decision to participate. You should understand the risks and benefits of taking part in this study so you can make a decision that's right for you.

Part 1 – The Study

Why is this study being done?

The experiences of new graduate nurses transitioning into critical care environments is a concept that has been well researched international, however, little is known of this phenomenon from an Irish perspective, as the recruitment of new graduate nurses into critical care nationally has not been an established practice. The aim of this study is to understand the experiences of new graduate nurses transition from new graduate nurse to ICU nurse.

Why have I been invited to take part?

You are invited to participate in this study because you are a newly graduated nurse who within the last 18 months began working in an Intensive Care Unit in the Republic of Ireland.

Do I have to take part? Can I withdraw?

Participating in this study is completely 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 contact Dr Gobnait Byrne at gobyrne@tcd.ie or (01)8963105 and we 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 <u>up to the point that we make your data anonymous</u>. 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.

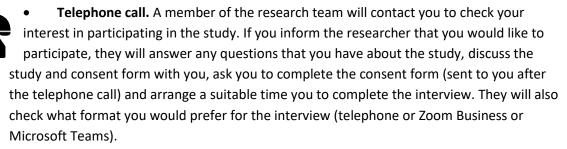
How will the study be carried out?

This study involves a one-to-one interview facilitated by a School of Nursing, Trinity College Dublin (TCD) member of the research team. The interview will take place via Zoom Business, Microsoft Teams or phone call whichever is your preference. We plan to conduct at least 10- 15 interviews. If more people volunteer to take part in this study, the researcher will thank you for your willingness to

participate but they will not conduct an interview with you. A TCD member of the research team will contact you no earlier than seven days after you have been sent information about the study 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 be contacted by the research team again.

What will happen to me 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:





- Online consent form. After your phone call, the researcher will send you a link to an online consent form for you to complete. If you have chosen to use Zoom/Teams for the interview, the researcher will also send you a link for this.
- Interview. Your interview will take place over the telephone or Zoom/Teams, depending on which you have chosen. If it is over the telephone, a researcher will call you at the time you agreed. If it is on Zoom/Teams, you will need to click the link which will have been sent to you by email, at your agreed interview time.
- At the beginning of the interview, the researcher 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.

There are no right or wrong answers. You are invited to answer the questions based on your personal experiences during the interview. However, you are free to refuse to answer any of the questions and you can pause or stop the interview at any time.

The interview will be audio recorded using a digital voice recorder, with your permission, and subsequently typed out for analysis. The interview itself will take approximately 30-45 minutes. During the interview you will be asked about your experiences of your transition from newly graduated nurse to ICU nurse. 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, 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 once 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.

The recordings of the interviews will be sent securely for transcription by Audiotrans Ltd. A service and data processing agreement in place between TCD and Audiotrans Ltd., including confidentiality clause, will underpin the transcription process. When the transcripts have been checked for accuracy, the recordings will be deleted. All transcripts will be stored in a secure electronic folder within the School of Nursing & Midwifery, TCD. Any identifying information in the interview transcripts will be removed. Following data analysis, the ID Number linking 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
 could help us to understand the experiences of newly graduated nurses transitioning to ICU
 nurse.
- The findings of this research will be disseminated via publications or via conferences and will also help increase the understanding of the transition of newly graduated nurse to ICU nurse.
- This in turn could benefit future generations of nurses starting their careers in ICU in recommendations for changes in healthcare practices.

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 the interviews there is the potential for emotional upset. If this occurs, you may stop the interview at any point and withdraw from the study if you wish.

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 Dr Gobnait Byrne at gobyrne@tcd.ie or (01) 8963105.

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? Will my medical records be accessed?

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 we can facilitate communicating with you during the recruitment for this study (e.g., we will need to access your telephone number so we can call you to discuss the study). The personal data routinely collected will be limited to your name, email address and telephone number. The demographic and health data collected at the beginning of the interview will be recorded anonymously. This will include, gender, age range, time since registration as an RGN, completion of a new-graduate programme and length of supernumerary status.

If you share any identifiable information during the interview, this will be anonymised. We will not keep your name or contact information once your interview has been transcribed. After this time, your personal information will be removed from the participant database.

What will happen to my personal data?

The personal data will be processed 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 and Midwifery, Trinity College Dublin. This will be accessible only by the Trinity members of 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 Catherine McCabe, Ms Geraldine Prizeman). 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 results of the data analysis 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 your privacy is maintained. We will take all necessary steps to ensure we protect your confidentiality and keep your data safe. All electronic data collected will be held on a secure research drive in the School of Nursing and Midwifery. There will be restricted access to the data to only named members of the research team from TCD.

Your electronic consent form will be retained in a designated folder is a 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.

Your data will be coded with a pseudonym. The re-identification key will be kept securely and separately to your data. As your data will be coded we do not envisage any situation where a data breach could cause harm.

What is the lawful basis to use my personal data?

By law, we can use your personal information for scientific research (in the public interest). 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 only under Articles 6(1)(a), 6(1)(e), 9(2)(a) 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, your rights under the data protection regulations are:

- The right to access your data and receive a copy of it.
- The right to restrict or object to the processing of your data.

- The right to have any inaccurate information about you corrected or deleted. This applies up to the point of data anonymization.
- The right to receive your data in a portable format and to have transferred to another data controller.
- The right to request deletion of your data.

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

By law you can exercise the following rights in relation to your personal data unless the request would make it impossible or very difficult to conduct the research.

You can exercise these rights by contacting Gobnait Byrne. Email: gobnait.byrne@tcd.ie or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

If you are unsatisfied with our response or believe we are processing your personal data in a way that is unlawful, you have the right to lodge a complaint with the Data Protection Commissioner @: https://www.dataprotection.ie/.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, Ethical approval for this study has been given by the Trinity College Dublin School of Nursing and Midwifery Research Ethics Committee on XXX. 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?

Trinity College Dublin is conducting this study. The research is being funded by XXXX. The study is not being conducted for the purpose of obtaining an academic qualification. The results will not be used for any commercial purposes.

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 and/or biological material be used in future studies? (May not apply)

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

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

• Principal Investigator: Dr Gobnait Byrne, email: gobnait.byrne@tcd.ie.

If you wish to make a complaint about this project to someone not directly connected with the study, relevant contact details are listed below.

• Dr. Sharon O'Donnell, Director of Research, School of Nursing and Midwifery, Trinity College Dublin **Tel:** 01-8963896 **E-mail:** snmresearch@tcd.ie

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.

Psychological support services contact details:

For participants currently employed by the HSE, the Employee Assist Programme is available for support details provided below: https://healthservice.hse.ie/staff/benefits-services/benefits/counselling.html