**Participation Information Sheet: Questionnaire and interviews: Version 3, 12.09.2018**

**IRAS ID:** 247835

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| **Scoping the integration of Simulation Based Education in the delivery of** **healthcare education programmes** |

# Participant Information Sheet

You are being invited to take part in a study. Before you decide if you want to take part it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for reading this.

# Who will conduct the research?

A team of researchers being led by Prof Ellen Schafheutle, Senior Lecturer in Law & Professionalism at the Centre for Pharmacy Workforce Studies, Division of Pharmacy and Optometry, University of Manchester. Data collection for the study is being conducted by Dr Jane Ferguson, Research Associate, Division of Pharmacy and Optometry.

# What is the purpose of the research?

Simulation Based Education has been recognised as a valuable way to prepare healthcare workers for practice. Simulation Based Education includes the use of tools, devices, and/or an environment that mimics an aspect of clinical care to improve health care provider performance, health care processes, and ultimately patient outcomes.

Health Education England, who have commissioned this research, recognise that the appropriate application and use of Simulation Based Education can be potentially increased as part of the delivery of healthcare pre-registration programmes, aiding the development of clinical knowledge, skills and practice, whilst also contributing to clinical placement capacity management approaches, this research will consider the current state of simulation education integration by healthcare education providers and an assessment of the potential for its further development.

# Why have I been chosen?

You have been invited to take part because of your involvement in Simulation Based Education.

# What would I be asked to do if I took part?

There are two parts to the study.

**Part 1:** An online **self-completion questionnaire**. This will ask about your experiences of the Simulation Based Education and seek information about the current state of development and integration of Simulation Based Education. If you would like a paper copy of the questionnaire, please get in touch with Jane Ferguson on the contact details at the end of this sheet. Please return the questionnaire using the FREEPOST address on the questionnaire (you will not need a stamp).

**Part 2:** If you complete the questionnaire then we will ask if you are willing to take part in a short **telephone interview** about your experiences of Simulation Based Education relating to the following areas:

1. Current state of development and integration

2. Plans and readiness for incremental increases

3. Potential for collaboration

4. Development of infrastructure

5. Examples of national and international best practice

If you are happy to provide an interview then the study team may then contact you to arrange a convenient time and date to take part in a short audio recorded interview. Please note that not all participants who agree to be contacted to take part in an interview will be contacted as we will select a sample from the responses we receive. If you are not contacted and you wish to discuss your participation, please contact Jane Ferguson on the details below.

# TUOM_4COLWhat is the duration of the research?

The questionnaire is likely to take about 15-20 minutes to complete. Interviews are likely to take approximately 30 minutes.

# Where will the research be conducted?

Part 1: Questionnaires will be online at a time and place convenient to you.

Part 2: Interviews will take place over the telephone at a time and place convenient to you.

# Will I be paid for participating in the research?

You will not be paid for completing the questionnaire or taking part in an interview.

# What happens to the information collected?

In order to undertake the research project we will need to collect the following personal information/data about you:

* Name of the organisation where you work
* Your role within the organisation

Only the research team, and the study funders - Health Education England, will have access to this information.

With your consent, information you provide will be shared with Health Education England. Health Education England has requested that this research questions the current state of integration of Simulation Based Education by healthcare education providers and assesses the potential for its further development. In order to do this we will share identifiable information about your organisation and your responses to the questionnaire and interview schedule. This will provide information that will allow for strategic planning for the future delivery of Simulation Based Education. You will also be given the opportunity to provide anonymous answers that will remain confidential and we will be clear with you which responses will be shared and which will be anonymous and confidential.

Responses to the questionnaires will be combined with responses from other participants into a database. Interview recordings will be transcribed and answer you wish to remain confidential will be anonymised. This information will then be analysed by the researcher to look for any common themes and differences. These findings may be published in a report to the Health Education England, journal papers and/or conference presentations.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is “public interest task” and “for research purposes” if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our [Privacy Notice for Research Participants](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

The study team at the University of Manchester and Health Education England will have access to your personal identifiable information, that is data which could identify you, but they will anonymise it as soon as the objectives of the project allow. However your consent form and contact details will be securely stored at the University of Manchester for 5 years, after which it will be deleted. All computers used for storing data will be are firewall and pass-word protected and personal information will be stored and kept securely in a locked drawer (accessed only by the researcher) and separate from any data collected. Study data and materials may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information.

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our [privacy notice for research](http://documents.manchester.ac.uk/display.aspx?DocID=37095) and if you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns), Tel 0303 123 1113

# What are the potential benefits and risks to me in taking part?

You may benefit from the satisfaction of knowing that you have contributed to the development of Simulation Based Education in your area and your input into the strategic direction may potentially benefit delivery of Simulation Based Education across the region. It is extremely unlikely that you will experience any dangers, discomfort or inconvenience.

# How is confidentiality maintained?

Your participation in the study will be kept confidential within the study team and those with access to your personal information as listed above. However, there is a professional obligation to report misconduct/poor practice to inform employers/professional body should you disclose any misconduct or poor practice which has not been dealt with through the appropriate channels. Recordings will be used only to facilitate transcription and transferred securely on encrypted computers to a University approved transcriber based in the United Kingdom. All electronic information, including digital audio files and their transcripts will be password protected and stored on encrypted university computers. Digital audio files will be destroyed at the end of the project. All paper documentation will be stored for 5 years, will be kept in accordance with the University of Manchester retention schedule, on university encrypted computers/locked filing cabinet in a locked office.

# What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised and forms part of the dataset as we will not be able to identify your specific data. This does not affect your data protection rights.

Audio recording is not essential to participants in an interview, and you are free to decline recording and the researcher will take notes if you prefer. You are free to stop the recording at any time should you feel at all uncomfortable.

# Will my data be used for future research?

No. The information you provide will be used solely for this study.

# Who has reviewed the research project?

This study has been reviewed and commissioned by Health Education England, funded by NHS England and has been reviewed received ethical approval from the University of Manchester Proportionate Research Ethics Committee (XXX).

# Will the outcomes of the research be published?

Outcomes of the research will be published in open access journals, conference presentations, and via a report to the funders. We are planning to run a stakeholder event, to which we will invite stakeholders from Higher Education Institutes offering healthcare professional education programmes, including partner organisations (such as NHS Trusts); the invitation will further be extended to healthcare regulators, who also recognise the importance of simulation, and indeed student representatives studying on these programmmes. Stakeholders will include those where simulation is established/ integrated, and those which would likely benefit from introducing or expanding simulation. We will also invite representatives from partner organisations such as NHS trusts, where much simulation learning may take place. If you would like to be involved in this half day event, please contact Jane Ferguson on the details at the end of this document.

# What if something goes wrong?

**Minor complaints**

If you have a minor complaint then you need to contact the researcher(s) in the first instance **please contact Prof Ellen Schafheutle on the details below.**

**Formal Complaints**

**If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact**

TheResearch Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk  or by telephoning 0161 275 2674.

# What Do I Do Now?

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

**Dr Jane Ferguson|** **jane.ferguson@manchester.ac.uk**

**Prof Ellen Schafheutle | 0161 275 7493|** **ellen.schafheutle@manchester.acuk**

**This Project Has Been Approved by the University of Manchester Proportionate Research Ethics Committee** [2018-4282-7004].