

# Evaluation of new guidance to support more meaningful involvement of patients and families in serious incident investigations

## Participant Information Sheet: Staff

### Invitation to take part

We are inviting you to take part in this research in the hope that it will improve the serious incident investigation process. The aim is to test new guidance that has been developed to more meaningfully involve patients and families after experiencing a serious incident. The guidance has been developed in partnership with patients, families and healthcare staff who have experienced a serious incident and the subsequent investigation process, as well as investigators, legal representatives, researchers and national policy makers. Before you decide if you would like to take part, please read this information sheet to understand why the research is being done and what it might mean for you. Don't hesitate to get in touch with any questions you might have (contact details can be found at the end of this sheet).

### What is the purpose of the study?

We know that greater involvement of patients and families in serious incident investigations can lead to better learning, meaning that incidents are less likely to occur in the future. However, until now, there has been very little guidance to support patient and family involvement. To develop our guidance, we interviewed 50 people with first-hand experience of serious incident investigations. This included patients and family members, as well as healthcare staff, investigators and legal representatives. We also brought people from each of these groups together in a series of workshops. They helped us to design the guidance by using their own experiences to think about what they would like to happen differently in future.

We understand that it can be difficult to decide whether to take part if you don't know how our new guidance might differ from what happens currently, and what this might mean for you. We have worked alongside the Trust throughout the development process to ensure our new guidance complements the Trust's existing serious incident investigation procedure. We have also worked with healthcare staff with experience of involvement in serious incident investigations to ensure that the new guidance will not cause additional harm or distress for any staff involved in the investigation. This means that, as a member of staff, you will still experience the same investigation process, but the investigator might involve patients and their families in the process in different ways. Examples of how patients and their families might be involved in the investigation are:

- More contact with the investigator with updates about the investigation;
- Talking to the investigator about their experience of the serious incident and the impact it has had on them;
- The opportunity to work with the Trust to help them make improvements.

This work is part of a 3-year research project running until 2023 which aims to develop, test and evaluate the new guidance. Data from this study will be used to refine the new guidance, and to share learning with those who will be using the new guidance in the future.

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

You have been invited to take part because you have been involved in a serious incident through your role as a member of staff working in, or linked to, one of our partner NHS Trusts, and the patient and/or their family member(s) have consented to the new guidance being used in the subsequent Trust level investigation. If you agree to take part in the research, your involvement in the serious incident investigation might be observed by a member of the research team if this involvement relates to implementation of the new guidance. We will also ask you about your experiences of the serious incident investigation process, and whether implementation of the new guidance and the more meaningful involvement of patients and their families has affected your experience in any way. This will help us to refine our guidance further.

### Do I have to take part?

No.

It is entirely up to you to decide whether or not to take part. If you agree to take part, you can change your mind and/or withdraw at any time without providing a reason. If you decide to take part, you may wish to keep this information sheet in a safe place for future reference.

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

If you agree to take part, we will ask you to sign a consent form in which you will be asked to agree to take part in the research study designed to test new guidance aimed at more meaningfully involve patients and families in serious incident investigations. You will also be asked to take part in one research interview at the end of the investigation. During this interview you will be asked about your experience of the investigation, your involvement in the investigation, and your experience of the new guidance used by the investigator. This interview is expected to last around 90 minutes.

The interview can be conducted face-to-face, over the telephone, or using video software such as Zoom or MS Teams. You will be able to choose how you would prefer to be interviewed, and the time and location of the interviews will be mutually agreed with the researcher. Face-to-face interviews will be carried out in accordance with local Covid-19 guidance. If you choose to be interviewed somewhere that you will need to travel to, your travel expenses will also be paid for. The researcher will verbally check that you still give consent for the interview before it begins, and you will be able to ask for the interview to be stopped or paused at any point, decline to comment on specific issues, or decline to answer specific questions without giving a reason.

Alongside this single interview, there are other ways you can share your thoughts and experiences with us. These are entirely optional and do not affect your participation in the research. You can also change your mind at any time. You will have the opportunity to discuss each element in more detail with a member of the research team, but a brief outline of all of the options is included here.

## Researcher Observations

The researcher following your investigation might ask if you are happy for them to observe any meetings or interactions you have with the investigator or anyone else involved in the investigation (for example the patient or family member, or another member of staff at the Trust). If everyone else in the meeting has also given consent, the researcher will communicate with you to decide whether you would prefer them to be present during the meeting, or whether the meeting will be recorded for the researcher to observe afterwards. If the researcher is present, whether the meeting is virtual or in person, they will not take any part in the meeting but may keep notes about how the new guidance is being implemented or experienced. If the meeting is recorded, the researcher will use the recording to take these notes. The researcher is the only person who will have access to this recording. They will keep the recordings secure, and will delete them as soon as they have made notes.

## Research Interviews

As part of the research, you have the option of taking part in two further interviews:

- An initial briefing interview before the investigation begins with the member of the research team who will be following your investigation. During this interview you might be asked questions about your expectations of the investigation process and how you might anticipate being involved.
- A follow up interview around 2 months after the investigation ends with the member of the research team that followed your investigation. During this interview you might be asked about the impact of the investigation and the outcomes of the investigation report.

Both interviews are expected to last around 60 minutes. The interviews will follow the same guidance as the post-investigation interview outlined above. The researcher following your investigation will discuss your preferences with you before each interview if you decide you would like to take part.

## Optional Reflective Diary

You will also be given the option to capture your experience of the investigation and the new guidance in a diary. This is not a compulsory part of the research, but the researcher will offer you the option of filling out a reflective diary. The diaries can be completed online or as a hard copy, and will include prompts about your thoughts on, and experiences of, the investigation and the new guidance. There will also be space for you to capture your own personal reflections, or any other reflections you think may be beneficial for the research team to know. If you do choose to fill out a diary, you will be asked to return this to the researcher at the end of the investigation. If you use an online diary, you can email this to the researcher. If you use a paper diary you will be able to return the hard copy in person or in a pre-paid envelope (these copies can be returned to you at your request once they have been scanned by the researcher), or take pictures of the diary and send them electronically. If you start to use a diary, you are able to pause or stop using it at any time without being asked to give a reason.

## How will I benefit from being involved in this study?

We hope that more meaningful involvement of patients and families during the investigation process will lead to better learning from incidents and mean that they happen less frequently. The information you provide might also help us to understand the impact on healthcare staff, and further refine the guidance with the aim of implementing it more widely across the NHS.



## What are the possible disadvantages and risks of taking part?

You may find that talking about your experience of the serious incident investigation is upsetting. If this is the case, we will ensure you are provided with the relevant sources of support. You may want to talk to friends or family members, or access support through the Trust Occupational Health Department. We will support you in seeking alternative sources of support through your GP or other organisations where appropriate.



### Will taking part in the study be kept confidential?

Yes, any information you provide will be kept confidential. All personal information about you and the investigation will be handled in confidence. Data collection is strictly limited to the process of implementation of the new guidance. Specific details about the serious incident will not be collected. Data will be kept in secure locked cabinets and/or stored on encrypted, password-protected computers at the Bradford Institute for Health Research. We will keep these files for up to ten years after the end of the study in line with research protocols, but after that, they will be destroyed.

### What will happen to the data generated by the study?

The data will consist of audio and/or digital recordings of interviews and observation activity, researcher notes and/or reflective diaries. Data will be directly transcribed by experienced in-house administrators at Bradford Institute for Health Research where possible, or securely sent to a trusted transcription company who have a contract with the Bradford Institute for Research. Following transcription, original recordings will be immediately deleted. During transcription, any identifying details (e.g. names and places) will be removed. Each transcript will be given an anonymous code number and transcripts will be stored in encrypted, password-protected files on computers at the Bradford Institute for Health Research for up to ten years after the end of the study. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. However, if you wish to obtain an anonymised transcript of data you provided during an interview, the research team will provide you with a copy on request.



## How will we use information about you?

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor for this study. We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. All information about you will be stored in line with data storage protocols at the sponsor site. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

## What are your choices about how your information is used?

You can withdraw from the study at any time, without giving a reason. If you choose to withdraw, we will keep any anonymised data you have provided up to that point, unless you request otherwise. This request can be made up until the point the data has been analysed (expected to be October 2022 but may be sooner). If you wish to make this request, we advise that you do so as soon as possible.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information

- at [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team or,
- by sending an email to [dataprotectionofficer@bthft.nhs.uk](mailto:dataprotectionofficer@bthft.nhs.uk)

## What will happen to the results of the research study?

We will share the findings with those people who helped us design this guidance during the workshops outlined above via a final sharing event. We will publish the results as academic papers and these will be used to develop more research which aims to continue to improve healthcare services for patients and families. We will share the findings in a plain English summary alongside academic publications. We may also make a series of short film clips to summarise the findings from the research and these will be available on a public website that will be developed during the project. When we write up the results, all personal details will be removed so that no-one will know who you are. We may quote what you have said but real names or other identifying details will not be used. You will have the option of receiving a final summary document about the research, as well as links to any publicly available guidance material we develop.

## What will happen if I reveal information that indicates a risk of harm to myself or others while participating in the interview?

If you share any information during the study which reveals that you or somebody else is at risk of harm, or has been harmed, in such a way that would be reduced if the information you provided was disclosed, the research team may be required to act on this information. We would not do this without your involvement. This may include the decision to disclose the information that you have provided, your identity, and the identity of any individuals you have named, to an appropriate person who may decide to take further action. You will also be encouraged to discuss the disclosure with a trusted individual.

### Who is organising and funding the research?

The research team comprises experienced health services researchers at the Bradford Institute for Health Research. The Chief Investigator is Jane O'Hara, Professor in Patient Safety & Improvement Science. The research is funded by the National Institute for Health Research.

### Who has reviewed this study?

This study has been reviewed and given a favourable opinion by the NHS Ethics REC Committee (Wales REC 6; REC Reference: 21/WA/0287) and the NHS Health Research Authority.

## What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Please contact the study Chief Investigator: Professor Jane O'Hara on (01274) 383692 or email [Jane.O'Hara@bthft.nhs.uk](mailto:Jane.O'Hara@bthft.nhs.uk)

## What do I do now?

If you have decided that you are interested in taking part, and you have given consent for your contact details to be passed to the research team, one of the following research team members will have been in touch with you. Alternatively, you might have been contacted one of the research team from the contact details on our flyer. If you would like to discuss any aspect of your participation, please contact the research team on the contact details below:

Dr. Ruth Simms-Ellis (Programme Manager)  
[R.Simms-Ellis@leeds.ac.uk](mailto:R.Simms-Ellis@leeds.ac.uk)

## What do I have to do if I want to take part?

If you decide that you would like to take part, you can contact Ruth directly on the contact details provided above.

**Thank you very much for taking the time to read this information.**