Recommended Summary Plans for Emergency Care and Treatment (ReSPECT) Evaluation Study

Information for Clinician Participants: Observation and Interview study

We are researchers at the University of Warwick, University Hospitals Birmingham NHS Foundation Trust, Cambridge University Hospitals NHS Foundation Trust, St Christopher's Hospice, London and the Intensive Care National Audit and Research Centre. We are carrying out a study to look at how doctors and senior nurses use the ReSPECT process to make a plan with a patient and/or their family for future emergency care and treatment in case of a serious deterioration in the person's health.

What is the study about?

The ReSPECT process records a summary of the discussion, relevant health information and the agreed recommendations about treatment. It will be used to guide clinicians and other healthcare professionals looking after a patient in a future emergency situation when the person cannot make decisions for themselves. It sets Do Not Attempt Cardiopulmonary Resuscitation Decisions in the context of overall care and treatment plans. The Resuscitation Council UK and Royal College of Nursing established a national working group, with membership drawn from many professional, health care and regulatory organisations, to work collaboratively to develop the ReSPECT process form to record anticipatory decisions about Cardio Pulmonary Resuscitation (CPR) and other life-sustaining treatment.

What is the purpose of the study?

This study is part of a larger evaluation study of the newly implemented national ReSPECT process. In this study we will explore how, when and why recommendations about emergency care and treatment are made in NHS Trusts using the ReSPECT process. We will do this through observation of discussions between clinicians and patients and interviews with clinicians, patients, and families about their experience of the ReSPECT process.

Why am I being asked to take part?

You have been asked to take part because you are a clinician who is involved in implementing the ReSPECT process. Your trust has agreed to be one of the study sites and we are now seeking consent of individual clinicians to participate.

What happens if I agree to take part?

If you agree to take part in this research the researcher will meet with you to agree an appropriate period when he/she can shadow you to observe any discussions you have with patients involving the ReSPECT process. A shadowing period will typically last 4-6 hours, and may be split into shorter periods with your agreement, whilst you conduct the ReSPECT process with up to eight patients. Observations will be timetabled as far in advance as possible for when you will be available over the subsequent 24 hours for interview. Session timetabling will be reviewed during the observation

period to ensure observation of admissions is spread across the week. If the patient, their family, or any other people present do not want the researcher to be present he/she will leave.

After the shadowing period the researcher will arrange to interview you at a time that you are free during the next 48 hours while the ReSPECT process is fresh in your memory. The researcher will ask you to describe your experience of the ReSPECT process including what you took into account when discussing treatment and care options with the patient. The researcher will also ask you to reflect on how the ReSPECT process could be improved. This interview will last for an estimated 20 minutes during which 1-3 observation cases will be discussed. The interview will be audio recorded or field notes can be taken if preferred.

Do I have to take part?
No you do not have to take part in the study and if you agree to be observed and interviewed you can change your mind at any time prior to data being analysed. If you change your mind after you have done the interview with the researcher, please contact the study coordinator using the contact details given at the end of the sheet.

If you withdraw from the study prior to data analysis, we will remove the information about you that we have already obtained. If you withdraw from the study after data analysis, we may not be able to remove the information about you. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What are the potential advantages of taking part?
Taking part in this study is unlikely to have any direct benefit for you or your unit. However taking part will help to evaluate the ReSPECT process to increase our understanding of how it works, or needs to be improved to support decision-making for emergency care and treatment in partnership with patients and relatives.

What are the potential disadvantages of taking part?
There may be occasions when the presence of a researcher places an extra burden on you during a busy period. The researcher will do his/her best to minimise any disruption caused, and will not interfere at times when emergency life-preserving treatment is being given.

Will my involvement in this study be confidential?
All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 2018. Only the researcher and members of the study team will have access to the information. Any audio recordings from the interviews may be transcribed by a third party transcription service or a member of the research team contracted to work on the research project. You will be identified by a study number and no personal details will be included in the analysis of the interview transcripts. We may use written quotations from the transcripts to illustrate academic presentations or publications based on this research. However, you will not be

identifiable in any published material. In exceptional circumstances the principal investigator may need to disclose information obtained in the study if there was a concern about a significant risk of serious harm to others. Study documentation and data will be archived for at least ten years after completion of the study.

What will happen to the results of the study?

We will seek to publish the study findings in peer reviewed journals and present them to health care professionals at national and international conferences. The findings will also be made available to the national working group who developed ReSPECT and to the hospitals taking part so they can make any necessary improvements. We will make any developments to the ReSPECT process available to all NHS Trusts. A summary of the research findings will be provided for all participating Trusts and to patients and the public.

Who is organising, funding and sponsoring the study?

The study is led by Professor Gavin Perkins, Consultant and Professor in Critical Care Medicine at University Hospitals Birmingham NHS Foundation Trust and at the University of Warwick. This project was funded by the National Institute for Health Research [Health Services and Delivery Research] (project number 15/15/09).

University Hospitals Birmingham NHS Foundation Trust and the University of Warwick are the sponsors for this study based in the United Kingdom. We will be using information provided by you in order to undertake this study. The University of Warwick will act as the data controller for this study, and are responsible for looking after your information and using it properly.

Further information on how your data will be used can be found in the ReSPECT Data Transparency Statement for Clinicians, Implementers and Ward Managers which you will receive from the study researcher in addition to this information sheet. This information can also be found on the study website www.warwick.ac.uk/respectevaluation.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people. This study has been reviewed and approved by the Coventry and Warwickshire Research Ethics Committee (REC reference: 17/WM/0134).

What if there is a problem?

If you have a question about any aspect of this study you should first speak to the study researcher from Warwick Clinical Trials Unit who will do their best to answers your questions. You can contact the researcher on (07384 231 325, Email: respect@warwick.ac.uk)

If you have a problem or concern about the conduct of this study, please contact the Head of Research governance from the University of Warwick who is the study co-sponsor - Email: researchgovernance@warwick.ac.uk.

Further information and contact details

If, at any time, you would like further general information about this study, please contact the study coordinator at Warwick Clinical Trials Unit - Claire Jacques; telephone 02476 575923; email respect@warwick.ac.uk.

General study information is also available on the study website:
www.warwick.ac.uk/fac/med/research/hscience/ctu/trials/respect/

Thank you for taking the time to read this information sheet.