

FACTS STUDY

Participant Information Sheet

Version 1.0 -13-Oct-2022

Ethics Project ID: FMHS 101-1022

1. You are invited to take part in our research study

- The FACTS (Flourishing As Clinical Trial Staff) study is looking at how we can best support clinical trial staff to flourish in their job.
- This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part.
- Please take time to read this information and ask us if there is anything that is not clear to you, or you would like more information
- It is entirely your decision whether to take part in this study. If you agree to take part, you are free to withdraw at any time without giving a reason.

2. A summary of the study

The aim of this study is to develop guidance for UK Clinical Trial Units (CTUs) to support their staff to flourish.

The study is comprised of three stages.

1. Online survey to assess flourishing and measures of job satisfaction in CTU staff
2. Focus group work to investigate the experiences and opinions of CTU staff on wellbeing policies and how these may be modified to best support staff to flourish
3. Development of the guidance through a short online survey and group discussions

3. What is the purpose of the study?

Through working with CTU staff we aim to produce freely available guidance that educates on the role of flourishing in CTU staff, as well as provide useful strategies to improve flourishing in the workplace. By educating organisations on how to best support their staff to realise their potential, we hope this will improve staff satisfaction, wellbeing, and efficiency in running clinical trials.

4. Why have I been invited to take part?

You have been invited to take part in this research because you work in a UK CTU. To take part you must meet the following inclusion criteria:

- Are currently employed by a [UKCRC](#) registered CTU
- Have been employed at your current CTU for at least 3 months
- Have availability to respond during the specified data collection period

5. Do I have to take part?

No. It is up to you to decide if you want to take part in this research. If you decide to take part in any stage of the study, you do not have to take part in any other stage. You are free to withdraw from the study at any time, without giving a reason and without any negative consequences, by letting the researcher, Jenny Riga, know.

6. What would taking part involve?

The study involves three stages. You can take part in some, all, or none of the stages.

Stage 1 – Survey: You will be invited to complete an online survey. This should take no longer 15 minutes to complete. The survey mainly involves tick box/rating scale questions. The questions ask about your wellbeing at work and your job satisfaction. We will not ask for your name and we will store any identifying information separately from your answers so they cannot be associated with you. The survey also includes some short open-ended questions where you can write as much or as little as you wish. We will ask if you would like to potentially be involved in a focus group discussion as part of the survey. We will not contact you to take part in any further stages if you do not wish to be involved in this.

Participants who complete the survey have the opportunity to be entered into a prize draw to receive one of four **£50 online** shopping vouchers.

Stage 2 – Focus groups: We are looking to speak to around 36 staff who are employed in a range of different roles in CTUs. We will organise groups of approx. 6 people to take part in online discussion groups, called focus groups. We expect to run approx. 5 focus groups. You can only participate in one focus group. The focus groups will be conducted and recorded via Microsoft Teams. The recordings will be transcribed with any reference to names, or other identifying information removed. The audio/visual recordings will be permanently destroyed after this process. As such, all information shared will remain anonymous outside of the focus group members and the study team. You will not be asked to share any sensitive information. We shall ask you to discuss topics relating to:

- how current models/policies map on to aspects of flourishing which are related to job satisfaction
- opportunities for developing/implementing new models/policies
- barriers and facilitators to implementing new models/policies

Prior to the focus group we may give you some information to help facilitate the discussions. We do not expect this to take longer than 20minutes to read. We approximate a focus group will last around 1 hour - 1hour 30 minutes. As a thank you for your time we can offer you a **£20** online shopping voucher.

Stage 3 - Survey: Using the information from Stage 1 and Stage 2 we shall develop a FACTS guidance document, which will be comprised of a number of statements. To make sure these statements are important and useful we will invite participants to complete another short survey. As part of the survey, you will be asked to read the statements and say whether you think it should be included in the final guidance or not, you can also suggest ways to improve the statements. Participants who complete the survey have the opportunity to be entered into a prize draw to receive one of two **£50 online** shopping vouchers.

7. What are the possible benefits of taking part?

We cannot promise there will be a direct benefit to you from taking part in this research, but your contribution will help a range of people interested in improving workplace wellbeing and clinical trial efficiency. Your CTU will be provided with free copies of the FACTS guidance.

Participants who complete the Stage 1 survey have the opportunity to be entered into a prize draw to receive one of four **£50 online** shopping vouchers. Participants who complete the Stage 3 survey have the opportunity to be entered into a prize draw to receive one of two **£50 online** shopping vouchers. Recipients will be selected using a random number generator. Recipients will be notified via email within 4-weeks of the survey closing. No cash alternative is available.

Participants who take part in the focus groups will be given **£20** of online shopping vouchers. This cannot be substituted for a cash alternative. The vouchers will be sent out within 2 weeks of participation in the focus group.

8. What are the possible disadvantages and risks of taking part?

There are no anticipated risks in taking part in the study. No potentially sensitive information will be collected, and data will be shared anonymously. All members of the focus group are required to maintain confidentiality of the discussions. In the unlikely event any information is shared which poses a significant risk to health/life the relevant authorities will be informed in collaboration with the individual in question.

9. What if there is a problem?

If you have a concern about any aspect of this project, please speak to the researcher, Jenny Riga or the Chief Investigator Dr Sophie Hall and co-leads Kirsty Sprange and Dr Eleanor Mitchell, who will do their best to answer your query. The research team will acknowledge your concern and give you an indication of how they intend to deal with it.

If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk.

Please quote ref no: FMHS 101-1022

10. What will happen if I don't want to carry on with the study?

Even after you have registered consent, you are free to withdraw from the study at any time without giving any reason. If you withdraw, we will no longer collect any information about you or from you, but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses.

11. How will information about me be used?

Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) will need to use information from you for this research project. This information will include your name and contact details. The researchers will use this information to do the research. 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. All information about you will be kept safe and secure.

Once the study has finished, some of the data will be kept so the results can be checked and you can be told what happened in the trial (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the study.

12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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. After a minimum of 7 years your data collected during the study will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research that you may be interested in taking part in. If you do not wish for your contact details to be kept for a copy of the study results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the study.

13. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by sending an email to sophie.hall@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit on 0115 823 1600

14. Who is organising and funding this study? How has it been approved?

The study is being organised and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the study is provided by the National Institute of Health Research (NIHR) Efficient Studies Funding. All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the School of Medicine Research Ethics Committee.

15. What will happen to the results of the study?

At the end of the study the results will be used to develop guidance and will be published in scientific medical journals and presented at conferences. The study will also be published on Open Science Framework <https://osf.io/>, to enable free and widely available sharing of the study. You will not be identified in any publication. We will send you a newsletter with a summary of the study findings unless you ask us not to.

16. How to contact us

Contact details of the study team:

- Study email: facts-flourishing@nottingham.ac.uk
- Dr Sophie Hall: sophie.hall@nottingham.ac.uk
- Kirsty Sprange: kirsty.sprange@nottingham.ac.uk
- Dr Eleanor Mitchell: elanor.mitchell@nottingham.ac.uk
- Jenny Riga: jenny.riga@nottingham.ac.uk