Participant Information Sheet

Involving patients and the public In sTatistIcal Analysis pLans (INITIAL)
You are invited to take part in a study to help us decide the most important statistical analysis items that patients and the public should be involved in defining.

Before you decide whether to participate, it is important you understand why the research is being conducted and what it will involve. Thank you for taking the time to read this information sheet. Discuss it with others if you wish and do ask if you have questions or would like more information.

About the research

- **Who will conduct the research?**

The INITIAL study is led by Dr Beatriz Goulao (University of Aberdeen). Co-investigators include Dr Katie Gillies and Prof Craig Ramsay (University of Aberdeen), Dr Tim Morris (University College London), Prof Jane Blazeby (University of Bristol), Prof Carrol Gamble (University of Liverpool), Nikki Totton (University of Sheffield), Derek Stewart (Public Partner), Lynn Laidlaw (Public Partner), Irene Soulsby (Public Partner). Thank you for your interest in our study. You can find out more here: https://www.abdn.ac.uk/hsru/what-we-do/research/projects/initial-1056.php

- **What is the purpose of the research?**

Improving relationships and communication between professionals working in trials and public partners is essential in patient and public involvement (PPI), which aims to enhance trials by improving relevance, increasing transparency and public trust. Statistical analysis plans contain many important analytical choices, but patients are rarely involved in these, which may undermine the relevance of the results of trials. Failing to actively communicate with and involve patients or the public in these decisions can ultimately lead to research waste, for example by answering non-relevant (to patients) research questions.

The current project proposes a first step to address this gap by identifying the most important items of statistical analysis plans to involve patients and the public.

- **Will the results of the research be published?**

The final results will be made publicly available at the end of the study. Participants interested in being notified of the publication should contact the Principal Investigator, Dr Beatriz Goulao (beatriz.goulao@abdn.ac.uk).

- **Who has reviewed the research project?**

The School of Medicine, Medical Sciences and Nutrition Ethics Review Board at the University of Aberdeen has reviewed and approved the study (Approval Number SERB 2022/1/2244).

- **Who is funding the research project?**

It is funded by the Medical Research Council-National Institute for Health Research.

What would be my involvement?

- **What would I be asked to do if I took part?**

You would complete two parts of an online survey, in which you would rate the importance of involving patients and the public in several statistical analysis items. There are no right or wrong answers - we are interested in your opinion.
In part 1, you will be asked to rate each potential measure using a scale 1-9. In round 2, you will be shown your scores from round 1 and you will be asked to reconsider each of them in the light of the anonymised results from across all participants in your group. If you change any of your scores, you will be invited to share reasons for your change.
Each round of the survey will take around 20 minutes and you will have two weeks from receiving each survey by email in which to complete them. There will be space of around two weeks between receiving the first and second parts of the survey.
To enable us to send the online survey to you, and to share the results with you at the end of the study, you will need to share your name and email address with us. We will also request basic demographic information that will be used to describe the participants in a summary format (anonymised). Information you provide will be used only for the purposes of the study and will not be shared with others or stored beyond the end of the study.

- **Will I be compensated for taking part?**

There will be no payments for participating in this project.

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

It is up to you to decide whether to take part. By completing the online survey form during each round of the on-line survey, you are giving your consent to participate.

If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. If you decide not to take part, you do not need to do anything further.

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research study, we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Your name
- Your email address

No audio or video recordings will be made during this study.

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

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. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research.

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Aberdeen is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:
Only the study team at The University of Aberdeen will have access to your personal information, and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. Only the research team will have access to the key that links this ID number to your personal information. Your consent form and contact details will be retained for 10 years in the University of Aberdeen secure data storage system.

The information will only be used for the purpose of identifying the statistical analysis items considered important to involve patients and the public. Unless you explicit give consent, this information cannot be used to contact you regarding any other matter.

Please also note that individuals from The University of Aberdeen or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

- **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact: **Dr Beatriz Goulao** on beatriz.goulao@abdn.ac.uk**.**

We do not expect any harm to come to you by taking part in this study. However, if you believe that you have been harmed, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen. Sponsor contact details are available through the research team.

Contact Details

If you have any queries about the study or if you are interested in taking part, please contact the researcher(s)**: Dr Beatriz Goulao –** beatriz.goulao@abdn.ac.uk