**Participant Information Sheet (PIS)**

**Workshop**

**Project Title:** Benefit-Risk Assessment to Inform Non-Inferiority and Superiority study design (BRAINS)

You are being invited to take part in a research study related to the use of benefit-risk methodologies within clinical trials. Below we will outline the purpose of the study and the participation you can have, should you choose to. Please do not hesitate to contact us if you have any further information on the details below.

**Background to the project:** Often in practice a selection of either a standard superiority or non-inferiority trial design is taken within clinical trials, however it is felt there is the potential to utilise a benefit-risk (B-R) methodology to inform the interpretation and implementation of trial results by ascertaining the overall clinical benefit of treatments.

The majority of B-R work to date has been done in a regulatory setting and this project aims to provide guidance on appropriate methodologies within publicly-funded HTA trials.

All information and updates on the project can be found on the webpage: <https://www.sheffield.ac.uk/scharr/sections/dts/ctru/brains>

**Project’s Purpose:** The purpose of this project is to produce a consensus driven guidance document which will assist researchers to include B-R within their trial design.

**Inclusion in the project:** You have been contacted as we believe you may have some experience or knowledge in the area of B-R. We would like to get a wide range of opinions from different stakeholders within clinical trials so any experience and thoughts are appreciated.

**Taking Part:** It is completely your choice if you would like to take part in the project. If you decide to take part, you will be asked to give written informed consent by signing a form that explains what is involved in the study. This information sheet will be given to you at the time, as well as being available on the project’s webpage, to keep along with the consent form. You are able to withdraw your participation at any time and do not have to give a reason. If you wish to withdraw please use the contact details below. Once aggregated data has been published you will no longer be able to remove your responses from this, however this will not be identifiable in any way.

**Project methods:** A workshop is being held to gain expert consensus on the use of B-R methodologies in clinical trials and how this can inform trial design in the future. Elements of the workshop will be:

1. A briefing document which summarised the findings of the survey and literature review (containing all B-R approaches identified) will be sent to workshop participants in advance;
2. Brainstorming round – panel members will be asked to record their individual preferences for the different B-R methodologies. Then a ‘round robin’ sharing of ideas will be completed to allow identification of all potential approaches, followed by a structured whole group discussion;
3. A preliminary rating round will be completed to gain preferences of each B-R methodologies, the results of which will be considered within a second structured group discussion;
4. A second, final round of rating will be completed to elicit final preferences of approaches.

The workshop will be audio recorded and some written notes taken. Audio files will be transcribed by the ScHARR Transcribing Service and subsequently pseudo-anonymised so responses are not identifiable. The original unanonymised recording will be securely deleted from the device using DiskWipe.

**Benefits and risks of taking part:** There are no risks of taking part in the workshop but the benefits would be to improve the guidance provided to other researchers in this area for future use.

**Expenses/Payments:** There are no payments for taking part in this study but expenses for travel, accommodation and subsistence will be paid for attending the workshop. **Data Confidentiality:** All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be identified in any reports of publication (aside from acknowledgements where specifically requested). All information we collect from you will be stored in a folder that is only accessible to members of the research team.

The University of Sheffield is the sponsor for this study based in the UK. We will using information from you in order to undertake this study and will act as the data controller of this study. This means that we are responsible for looking after your information and using it properly. The University of Sheffield will keep identifiable information about you for one year after the study has finished, no later than February 2021.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The University of Sheffield will collect information from you for this research study in accordance with our instructions. The University of Sheffield will use your contact details to contact you about the research study, and will oversee the quality of the research. Individuals from the University of Sheffield may look at your research records to check the accuracy of the research study. The only people in the University of Sheffield who will have access to information that identifies you will be people who need to contact you about the study, audit or data collection process (i.e. members of the research team). The University of Sheffield will keep identifiable information about you from this study for one year after the study has finished (no later than February 2021).

**Legal Basis for Data Processing:** The legal basis we are applying in order to process your personal data is that ‘processing is necessary for the performance of a task carried out in the public interest’ (Article 6(1)(e)). Further information can be found in the Privacy Notice of the University: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general> (date accessed 4 March 2019). The data controller is the University of Sheffield.

**Results:** The results from the workshop will inform a guidance document on the best approaches of using B-R methodology within clinical trials submitted to the MRC. Additionally, the guidance will aim to be published in an academic paper that will be available to the public. All results will provide aggregated data, we may use direct quotations from you to help write reports and publications but this will be anonymous to ensure it is not possible to identify individuals. A copy of the final guidance document will be made available to you if you indicate you would like this. You can also indicate you would like to be acknowledged for your contribution to the workshop on the final guidance document and in publications but your responses will not be identifiable to you. You will be able to indicate these requests when you provide informed consent. We hope to publish within a year of the workshop (October 2021).

**Organisation and Funding:** The project is being ran by a team at The University of Sheffield with input from other key experts from other institutions. This project was funded by the MRC and National Institute for Health Research (NIHR). They are holding a series of Methodology State-of-the-Art Workshops (M-SAW) which are designed to achieve clarity around best practice in methodology, and to provide guidance to the community.

**Ethics:** This research has been ethically reviewed by the University of Sheffield’s School of Health and Related Research’s independent Ethics Committee.

**Complaints:** If you have any issues you wish to raise which are of concern to you at any point during the project, please contact the Chief Investigator in the first instance. If the complaint relates to your personal data and how this has been handled, information on complaints can be found in the University’s Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>. If you have a problem with data management within the study, you can contact Anne Cutler (Tel: 0114 222 1117; email: dataprotection@sheffield.ac.uk). Should you feel the research team has not handled your complain properly, you can contact Professor John Brazier, Dean of the School of Health and Related Research (Tel: 0114 222 0726; email: j.e.brazier@sheffield.ac.uk).

**Contact:** For further information about the project, please contact either:

Prof Steven Julious (Chief Investigator) Nikki Totton (Researcher)

Email - s.a.julious@sheffield.ac.uk Email - n.v.totton@sheffield.ac.uk

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Thank you in advance for your input to this project, it is an essential first step for us to understand the current practice and future guidance requirements for this important methodological area.