National Centre
for the Replacement
Refinement & Reduction
of Animals in Research

PARTICIPANT INFORMATION SHEET

Attitudes to ICH S7 Survey

Dr Sam Jackson on behalf of the NC3Rs

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part and remember that your participation is voluntary.

What is the purpose of the study?

The purpose of this study is to gather information on the opinions of researchers on the ICH S7 guidance covering the safety pharmacology testing of new pharmaceuticals.

Why have I been invited?

You have been invited because you have been identified as a as a researcher who uses or has operational knowledge of the ICH S7 guidance and therefore are qualified to provide information and/or opinion on the guidance.

Do I have to take part?

It is up to you to decide whether to take part. If you do decide to take part you will be asked to confirm your consent prior to beginning the survey. If you decide to take part you are still free to withdraw at any time and without giving a reason.

Am I eligible to take part?

You are eligible to take part in this survey if you carry out (or have operational knowledge of) the ICH S7 guidance for drug development.

Expenses and reimbursement

There is no financial incentive to take part in this study.

How much time will the study take?

The study asks you to provide information on your informed opinion of the ICH S7 guidance, and will take around 7 minutes to complete.

What will I have to do?

You will answer a series of questions asking about your opinion of the ICH S7 Guidance.

What are the possible disadvantages and risks of taking part?

There are no anticipated risks to you if you take part in the study, nor are there likely to be any adverse effects.

What are the possible benefits of taking part?

There are no direct benefits to you taking part; however your involvement will help us learn more about the experimental practices during safety testing, and will also help us to find out whether these tests can be improved.

What if there is a problem?

If you have any problems during the survey, please contact the primary researcher.

Will my taking part in this study be kept confidential?

Yes. This survey can be completed anonymously and personal information that could identify you (e.g. name, email address) will not be collected. It will not be possible for us to link your answers back to you.

What would happen to the results of the research study?

When the study has been completed, we will analyse the study data we have collected and report the findings. These will be reported in an appropriate scientific journal and/or presented at a scientific meeting. As your study data are anonymous, it will not be possible to identify you by name from any aspect of documentation or reporting for this research study.

At the end of the study your data will become “open data”. This means that it will be stored in an online database so that it is publicly available.

- What is open data?

Open data means that study data are made available, free of charge, to anyone interested in the research, or who wishes to conduct their own analysis of the data. We therefore have no control over how these data are used. However, all data are anonymous and therefore there is no way to identify you from the study data.

- Why open data?

Sharing research data and findings is considered best scientific practice and is a requirement of many funding bodies and scientific journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of investment through wider use, and encourages new avenues of research.

Can I withdraw my study data after I have participated in the study?

No. There will be no links between your identity and your anonymous data set, and therefore we are unable withdraw an individual’s data as we are unable to identity which data set is yours.

Who is organising and funding the research?

This study is organised and funded by the NC3Rs.

Who has reviewed the study?

Ethics approval has been given by the Social Science Research Ethical Review Board at the Royal Veterinary College (Ref: URN SR2019-0293).

Who can I contact for further information?

If you have any questions, then please contact the primary researcher:

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