



1. **Research Project Title:**

Responding to the increased genetic risk associated with customary consanguineous marriage: developing an expert consensus statement and principles for service design and delivery

2. **Invitation to participate**

You are invited to contribute to a project by answering an online survey, and, if you wish, by attending a face-to-face workshop in Sheffield on 3rd July 2018.

Before you decide it is important to understand why the project is being done and what it will involve. Please take time to read this information and ask us if anything is not clear.

3. **What is the project's purpose?**

In populations where it is common for people to marry close relatives there is a higher incidence of autosomal recessive genetic disorders than in those in which reproductive partners are usually unrelated. Research has shown that many affected individuals are poorly informed of these risks and that appropriate services are often not accessible. In recent years, a number of local level responses have developed across England but these are variable in form, content and longevity. A more coordinated, national response is needed to support more consistent practice and encourage the sharing of knowledge. This project has been initiated by a stakeholder group working across Sheffield, Manchester, Bradford and London, with the aim of developing an expert consensus statement and principles for service design and delivery in response to this area of unmet need.

We aim to:

- (1) explore the extent to which it is possible to establish common inter-professional principles for the design and delivery of service responses in the area of consanguinity (close relative marriage) and genetic risk.
- (2) identify a set of principles upon which there is sufficient consensus to warrant the production of a national guidance document.
- (3) highlight areas/issues where inter-professional differences of opinion warrant further debate and dialogue.

The project will last 7 months from May to December 2018.

4. **Why have I been chosen?**

You are being invited to contribute to the project because we believe you have important insights to share. We are inviting a range of people who will offer different and complementary perspectives on the issues.

5. **Do I have to take part?**

Taking part is entirely up to you.

If you do not want to take part, you need do nothing more. If you do decide to contribute you will be emailed further information about how to contribute to the project via the online survey and workshop. You will be free to withdraw at any time without giving a reason.

6. **What will happen to me if I take part?**

If you choose to take part, you should indicate this by following the link to the google form sent you by email to register your interest. You will then receive an email with further information and a link to the online survey.

The survey will involve 3 rounds and completion of each round should take between 15 and 45 minutes depending on how much information you wish to contribute.

In Round 1, you will be asked to provide suggestions in response to a series of open-ended questions. This round is designed to gather a wide range of statements on what the priorities are for the design and delivery of service responses to this issue.

In Round 2 and 3, you will be presented with the combined statements from the group and asked to score each of them according to how strongly you agree or disagree with them.

While we would like people to contribute to all 3 rounds if at all possible, this is not a requirement and you may decide to contribute to Round 1 but not to subsequent rounds, or to participate in Rounds 2 and 3, but not Round 1.

Following Round 3 of the online survey, we will convene a face-to-face workshop on July 3rd 2018. Participants who are able to will come together in Sheffield for a workshop in which we will discuss and debate the findings from the online survey and seek to produce a draft of a consensus statement and set of principles for this area of service design and delivery. The workshops will be structured and last 3 to 4 hours with refreshments.

Individuals who are unable to attend the workshop but would like to contribute to the production of the consensus document will be given the opportunity to comment on the draft as it is produced.

7. Will I be recorded and how will the recording be used?

We do not plan to use audio recording in this project. Detailed notes will be taken during the workshop.

8. What will happen to the data/information that I provide to the project?

The data you provide will be held by the University for the purposes of research which is legally deemed to be a task in the public interest. As we will be collecting some data that is defined in the legislation as more sensitive (ethnic identity), we also need to let you know that we are applying the following condition: 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (Article 9(2)(j)).

If you complete the online forms, we will hold the following personal information about you: name, professional role, organisational affiliation, age-group, ethnicity, gender, region of work and email address. This information will be stored together with your answers to the Delphi exercise for the duration of the study period (up to December 2018). We need to store this information together so that we can send you your personalised responses in Round 3.

All the data you provide will be stored on the University's secure network with access only available to the research team members via University login and password. Research team members will adhere to the data security procedures established by the University of Sheffield and all researchers who have access to your personal data will complete University of Sheffield data security training.

Beyond the end of the project period, we will detach your personally identifiable data (name, email address and organisational affiliation) from your responses and store these separately so that your answers can not be linked to you personally. The anonymised data will then be stored for at least 10 years within the University of Sheffield secure data archive – ORDA. The anonymised stored data will be available in an open and controlled manner for future research. Data storage will allow any data verification to take place should the need arise during the process of publishing the research findings.

Only aggregated data with no personally identifiable information, will be shared outside of the research team. Any data included in reports or publications from the project will not be identifiable as relating to you. However, if you wish, your name and organisational affiliation can be reported in project outputs to acknowledge your contribution. You will be given the opportunity to decide whether or not you wish to be acknowledged in this way.

In some exceptional circumstances it may be necessary for the researchers to break confidentiality, for example if we become aware of illegal activity or if we feel that you or another individual is at risk of harm. If this situation arises, we will always discuss it with you prior to disclosing any information to a third party.

The 'Data Controller' for this project is the University of Sheffield and the Data Protection Officer is Anne Cutler.

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

We have not identified any significant risks in taking part in this study, although we recognise that participation will involve a significant time commitment.

We will ask all participants in the face-to-face workshop not to pass any of the information shared during group discussions to anyone outside of the group. However, we cannot guarantee that people outside of the research team will maintain this confidentiality.

It is possible that some of the discussions may become heated or that participants may become upset. Researchers will do their best to ensure that a respectful and supportive environment is maintained at all times.

10. What are the possible benefits of taking part?

By participating in the consensus exercise you will be making an important contribution to the development of a national-level guidance document. If you wish, your name can be included as a contributor on any products that are developed through this process. There are no other immediate benefits for people participating in the project but it is hoped that the process will be interesting and informative.

11. What if I am not happy with things or have a question about my data?

If you have any concern about this research or any complaint you should first contact the Principal Investigator:

Professor Sarah Salway, Department of Sociological Studies
Elmfield, Northumberland Road, Sheffield, S10 2TU. s.salway@sheffield.ac.uk
0114 222 6438

If you are not satisfied with the response, then you should contact:

Professor James Wilsdon, Faculty of Social Sciences
Director Impact and Engagement
ICOSS, 219 Portobello, Sheffield, S1 4DP
j.wilsdon@sheffield.ac.uk
0114 222 8343
0771 076 0086

For any concern or query relating to the storage and use of your personal data, please contact the University's Data Protection Officer:

Anne Cutler

University's Secretary's Office

University of Sheffield

Western Bank

Sheffield S10 2TN

A.Cutler@sheffield.ac.uk

0114 22 21117

12. What will happen to the results of the research project?

Early findings will be shared at the workshop in July. This workshop will determine the form and content of the consensus statement or set of principles to be produced and disseminated. We hope to finalise this document/product by December 2018. We also anticipate producing an academic paper for publication in a journal.

13. Who is organising and funding the research?

This research is funded by the University of Sheffield and the NIHR CLAHRC for Yorkshire & Humber.

14. Who has ethically reviewed the project?

This project has been ethically approved via the ethics review procedure of the Department of Sociological Studies at the University of Sheffield.

15. Contact for further information

Principal Investigator:

Professor Sarah Salway, Department of Sociological Studies

Elmfield, Northumberland Road, Sheffield, S10 2TU. s.salway@sheffield.ac.uk

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Please keep a copy of this information sheet for your records.

Thank you for your interest in our project.