Promoting Equality, Diversity and Inclusion in Health-Related Research Studies

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1 INTRODUCTION

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 The human response to medicines and interventions can be affected by a variety of factors, including age, sex, gender, race, ethnic origin and geographical location, as well as differences in physiology or disease state.

1.3 It is important to perform health and care research studies with the inclusion of a broad range of participants to ensure that the design of research studies are relevant to a broad population, and to optimise the safety and efficacy of medicines and interventions under investigation.

1.4 The UoE and NHSL are committed to maintaining the highest standards of research integrity, including equality, diversity and inclusion and to providing patients with a better experience of NHS services, regardless of their age, disability, ethnicity, religion, gender or sexuality.

1.5 ACCORD fully supports extending this commitment to equality and diversity in clinical research, from how it is designed, how it is carried out and who is involved, and expects all staff, students and researchers to uphold the highest standards. Promoting equality and diversity enhances public trust in the research process and subsequent results.

2 SCOPE

2.1 This policy is applicable to researchers working within NHSL and/or UoE, planning and conducting research involving healthy volunteers and NHS patients as research participants.

2.2 This policy is also applicable to ACCORD personnel who review research studies involving healthy volunteers and NHS patients as research participants e.g. Sponsor Representatives.

3 POLICY

3.1 The following points outline considerations that researchers and Sponsor Representatives should make when developing/reviewing a research study and the associated study documents. This is not an exhaustive list and researchers/Sponsor Representatives can make other considerations as appropriate.

3.2 Equality, Diversity and Inclusion Considerations

3.2.1 Consider and understand the participant population to be recruited, ensuring the recruitment strategy reflects the needs of the population you are asking to take part in the research study.

3.2.2 Engage with the Patient and Public Involvement (PPI) Team when designing a research study and ensure that PPI feedback is considered when deciding how best to serve the needs of the demographic to be involved in the research. Think about who the research study will benefit in the future.

3.2.3 Consider costs for PPI activities in funding applications. The PPI Team can help with this.

3.2.4 Look at broadening eligibility criteria to include a diverse range of participants e.g. age range, different ethnic minority groups.

3.2.5 If the study has sites in Scotland consider collecting information to populate the SIMD (Scottish Index of Multiple Deprivation) which is a tool for identifying areas with high levels of deprivation. This would assist researchers in analysing, understanding and reporting how the outcomes of research affect the population of Scotland, including those in the most deprived areas.

3.2.6 Consider any barriers to recruitment that the target participant population may have and do this at an early stage to improve retention within the study e.g. physical disability, specific cultural barriers.

3.2.7 Consider where and how recruitment of potential research participants takes place e.g. can a broader population be reached by conducting outreach activities such as advertising on social media or building and sustaining trusting relationships through community engagement and working with community organisations.

3.2.8 Consider offering travel/childcare expenses to assist research participants with additional costs of attending research appointments.

3.2.9 Look at offering remote visits to ensure research participants can attend appointments either online, on the telephone or at the person's home.

3.2.10 Consider potential participants' communication needs for example:

- provide participant information sheets in larger font

- ensure that the participant information sheet is in lay language
- translate participant information sheets if required
- provide paper copies of electronically available participant facing documents

3.2.11 Consider how you will report your results e.g. can analysis include reports on ethnicity, age and sex/gender.

3.2.12 Publish a summary and the results of your research study to ensure full transparency and to build trust with participants. How results will be shared or made available to research participants should be detailed in the participant information sheet.

4 REFERENCES AND RELATED DOCUMENTS

- UKRI.org pages covering Equality, diversity and inclusion
- NIHR Include Guidance
- NHS Lothian Equality, Diversity and Human Rights Policy
- Patient and Public Involvement | The University of Edinburgh
- Scottish Index of Multiple Deprivation 2020

Version Number	Effective Date	Reason for Change
1.0	08 APR 2022	New Policy
2.0	03 MAY 2024	Consideration to collecting information to populate the SIMD (Scottish Index of Multiple Deprivation) added at section 3.2.5

5 APPROVALS

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