Inclusive Research with Participants: Considerations & Useful Resources

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This toolkit is not an exhaustive list and is based largely on the following guidance:

- The INCLUDE Ethnicity Framework—Trial Forge
- HRA and MHRA draft inclusion and diversity guidance—Health Research Authority
- Inclusive research funding application guidance—NIHR
- INCLUDE Socioeconomic Disadvantage Framework—Trial Forge

If you have any comments of questions, please contact: kirsty.roberts@bristol.ac.uk

1) Who should be Included in your Study?

- Who is affected by the disease/condition you are testing? Are there any relevant inequalities in your area of research?
- Is there data available on disease or condition prevalence and is it reliable? (note, should also consider researching data on detection, prognosis, priorities, outcomes, service accessibility if applicable especially if different between groups).
- Often this data cannot be found but you should aim to gather as much data as possible before discussing who should be involved in your study. Also speak to the groups with lived experiences to gain perspective on this data.
- Selecting which groups are needed in your research and at what proportion can be difficult.
- Following STRIDE guidance (How should trial teams make decisions about the proportions and diversity of the ethnic groups in their trial?) is advised. STRIDE guidance is based on ethnic minority groups but can be applied to other underserved groups.

Further reading:

- How to decide which ethnic groups your trial needs—Trial Forge
- Treweek et al. (2024), How should trial teams make decisions about the proportions and diversity of the ethnic groups in their trial?

2)Where should your research take place?

- Consider geographical areas underserved by research but where the problem is the greatest.
- If you can't include these areas, you need to have good justification as to why they haven't been included.
- Consider there will need to be more time and resources to set up the less research-ready sites- have you costed this into your budget?
- Do you need to consider Community-based or remote recruitment?

Further reading:

- Swanton et al. (2025), NHS-Galleri trial: Enriched enrolment approaches and sociodemographic characteristics of enrolled participants

3)How has your research sample been justified?

- Eligibility criteria- are all your exclusion criteria justifiable?
- Does your research team need training, will they require any specific skills or access to services to make the research inclusive?
- How will you capture Protected Characteristics and other EDI data of your sample throughout your study? Extra considerations: Informing people why you are collecting this data and how it will be used; Subgroup analyses; Caution with anonymity.

Further Reading:

- How to collect Ethnicity data (INCLUDED project)
- Using the correct EDI terminology by drawing on diverse PPI and resources—EDIS' Daisy guidance
- Wallace et al. (2023), Under recording and under reporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalisability
- Cunningham et al. (2025), Lack of data collection in clinical trials prevents us from evaluating inclusion of people with disabilities
- dos Santos et al. (2024), Most UK cardiovascular disease trial protocols feature criteria that exclude ethnic minority participants: a systematic review
- Cultural Competency Training Course—Centre for Ethnic Health Research

4) How has Diverse and Inclusive Patient and Public involvement (PPI) affected your research?

- Your research team should work with relevant members of the public and communities to embed research inclusion at EVERY stage of your project.
- Do you have a diverse PPI group and is it representative?
- Mistrust, Power dynamics, Cultural safety need to be carefully considered when working with communities.

Further reading:

- Jameson et al. (2023), Inclusive approaches to involvement of community groups in health research: the co-produced CHICO guidance
- Dawson et al. (2022), Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice
- Bodicoat et al. (2021), Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action

5) How accessible is your study?

- Will the people identified in 'Who should I include in my study' respond differently to the treatment?
- Will the intervention itself make it hard for some people to be involved?
- Will the study design make it hard for some people to be involved?

Strategies to improve the accessibility of your study design:

- Communication
  - Language considerations (translation, delivery)
  - Format of study documentation (easy-read, layered- approach, paper, videos, braille, BSL, animation)
  - Tailoring communication needs to particular groups
- Flexibility
  - Consider flexible recruitment, data collection methods
  - Consider alternative incentives
  - Could parts of the study be delivered more locally to the participant, such as in community venues or local GPs?

Further Reading:

- The INCLUDE Ethnicity Framework—Trial Forge
- Dawson et al. (2022), Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups—practical guidance to support better practice

- Bodicoat et al. (2021), Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action
- How to calculate the costs of involving interpreters and translators in health and social care research—National Institute for Health and Care Research Applied Research Collaboration North East and North Cumbria
- How to conduct research involving interpreters and translators—National Institute for Health and Care Research Applied Research Collaboration North East and North Cumbria
- Translation & Cultural Adaptation—Centre for Ethnic Health Research Services
- Resources to support researchers conducting research with adults who have impaired capacity to consent—Capacity and Consent to Research
- NIHR INCLUDE Impaired Capacity to Consent Framework—Capacity and Consent to Research
- Accessible Images—Learning Disability Service, Leeds and York NHS Foundation Trust
- Making Meetings Accessible—NHS England
- Wylde et al. (2024), Recommendations for developing accessible patient information leaflets for clinical trials to address English language literacy as a barrier to research participation
- Isaacs et al. (2016), The Inclusion of Ethnic Minority Patients and the Role of Language in Telehealth Trials for Type 2 Diabetes: A Systematic Review
- Willis, Isaacs, & Khunti (2021), Improving diversity in research and trial participation: the challenges of language

6) Are your plans for Dissemination, Knowledge Mobilisation inclusive and Impactful?

- Make your findings accessible
- Holding events for dissemination
- Including PPI in dissemination KM plans.
- Develop mechanisms to measure the impact of your findings on inequalities.

Further Reading:

- Dissemination, Implementation and Impact—NIHR Research Support Service

7) Have you budgeted appropriately for Inclusion in your research?

- In your research design costs for inclusive research should be considered and justified

- NIHR funding- it is now a requirement that Inclusion is incorporated and correctly costed in all grant applications
- Don't underestimate the costs involved

Further Reading:

- Budgeting for Inclusion—NIHR Research Support Service
- Biggs et al. (2024), Time to STEP UP: methods and findings from the development of guidance to help researchers design inclusive clinical trials
- EDI Toolkits and Checklists below which may help with budgeting:
  - NIHR EDI Toolkit
  - Inclusion Checklist for Clinical Research—Department of Cardiovascular Sciences, University of Leicester
  - EDI Toolkit for Researchers—Newcastle University