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POLICY ON INCLUSIVE CLINICAL STUDY & TRIAL DESIGN AND RECRUITMENT

Equity, diversity and inclusion are fundamental to the advancement of clinical research and the improvement of health outcomes for all. This policy on inclusive clinical study and trial design aligns with the **Diabetes UK Research Equality, Diversity and Inclusion (EDI) Strategy,** reinforcing our commitment to fair and representative research practices. Please note, adherence to this policy forms a key component of the **grant terms and conditions, as well as other relevant policies** governing the application process for research funding.

1. Purpose

This policy sets out the expectations for all applicants seeking funding for clinical or translational research studies. Its aims are to ensure that research:

- Is designed and conducted inclusively.
- Recruits participants who reflect the diversity of populations affected by the health condition(s) under study.
- Reduces health inequities by enabling under-served groups to participate.

2. Scope

This policy applies to all applications involving **human participants**, including:

- Interventional clinical trials
- Observational clinical studies
- Feasibility and pilot studies
- Mixed methods or mechanistic research involving participants
- Studies involving recruitment through NHS, community, or digital pathways

3. Policy Requirements

3.1 Inclusive Research Design

Applicants must demonstrate how the study has been intentionally designed to include diverse populations. This includes:

a. Representation

Studies must recruit participants who:

- Reflect the demographics of the population affected by the condition being researched.
- Include groups historically under-represented in research, e.g.:
    - People from ethnic minority backgrounds
    - Older adults
        - Diabetes UK has signed up to the **NIHR Statement of Intent: Integrating older age into health and care research**, and we will challenge any unwarranted exclusion of older adults or those with multiple long-term conditions from research. These exclusions are rarely justified and fail to align with the principles of equity and scientific excellence.
    - Women and pregnant women (where appropriate)
    - Socioeconomically deprived populations
    - People with multiple long-term conditions
    - People with disabilities
    - Non-English speakers, where feasible

b. Barriers & Enablers

Applicants must identify potential barriers to participation and propose mitigation strategies (examples include):

- Travel, cost, and time burdens
- Cultural or language barriers
- Accessibility of study venues
- Digital exclusion
- Trust and community relationships
- Complex procedures or intimidating clinical environments

c. Flexible & Accessible Study Design

Examples include:

- Decentralised or hybrid trial designs
- Community based recruitment
- Home visits or remote participation
- Translation and interpretation support

- Adjusted visit schedules, childcare support, transport reimbursement

3.2 Recruitment Strategy Requirements

Applicants must submit a detailed **Recruitment Inclusivity Plan**, covering:

a. Target Populations & Justification

- Clear justification for chosen populations
- Explanation and mitigation where certain groups are excluded

b. Recruitment Channels

Use multiple channels that support reaching under-served groups, such as:

- Primary care, community pharmacies, or NHS Trusts in areas of deprivation
- Community organisations, faith groups, and Voluntary, Community, and Social Enterprise (VCSE) partners
- Social care, youth groups, or migrant health networks
- Local media or community specific platforms

c. Partnership with Communities

Applicants should describe plans for:

- Early engagement with communities
- Co-design of materials
- Support from community leaders or advisory panels
- Ongoing feedback loops during the study

3.3 Required Plan for Sex, Gender and Intersectional Analysis

Following **NIHR's Sex And Gender Policy (2025)**, applicants must:

- Consider sex and gender at every stage of design, analysis, and dissemination
- Provide justification when sex/gender analyses are not applicable
- Integrate intersectional considerations where relevant (e.g., ethnicity × gender interactions)

3.4 Data Collection & Monitoring Requirements

Applicants must collect and report:

- Standardised demographic data (age, gender, ethnicity, socioeconomic status, geography, disability)

- Recruitment progress disaggregated by relevant demographic variables
- Challenges encountered and response measures
- Evidence of meaningful engagement

3.5 Costs & Resourcing for Inclusive Research

Applicants should include justified costs to support inclusive involvement, such as:

- Translation, interpretation, or accessible formats
- Community outreach and engagement activities
- Additional recruitment staff or inclusive trial coordinators
- Transportation, childcare, digital access support

3.6 Reporting Requirements for Funded Studies

Funded researchers are required to:

- Provide regular progress reports with demographic breakdowns inline with the terms of the Award
- Explain divergences from recruitment plans and actions taken
- Share best practice and case studies
- Include inclusivity reflections in final study reports

4. Patient and Public Involvement (PPIE)

Researchers must demonstrate:

- Early and meaningful involvement of people with lived experience in study design
- Representation of under-served groups within PPIE activities
- Accessible, culturally appropriate involvement formats
- Evidence of how PPIE feedback has shaped study design and recruitment approaches

5. Ethical and Legal Compliance

Applicants must comply with:

- HRA ethics requirements, including inclusive approaches to consent
- Data protection and safeguarding responsibilities
- Good Clinical Practice guidelines