

Equality, Diversity and Inclusion Strategy for the TIGERS platform trial - DRAFT

1. SCOPE

This strategy applies to Equality, Diversity and Inclusion (EDI, Research Inclusion) approach within the TIGERS Platform Trial.

2. PURPOSE

The purpose of this document is to describe the strategy for equality, diversity and inclusion within the TIGERS Platform, its objectives and how approaches will be operationalised to ensure equity of access to all aspects of this trial.

3. STRATEGY

The TIGERS Platform aims to ensure that all communities can access research opportunities in an equitable way. This strategy has been underpinned by the NIHR Equality Impact Assessment (EqIA) Toolkit and by the Medical Research Futures Fund 'Principles for Consumer Involvement in Research' document, which have been used to produce an action plan to identify and mitigate against barriers to research participation.

4. ROLES AND RESPONSIBILITIES

This policy applies to the TIGERS Platform, to its members and its committees where relevant, particularly the PPI/consumer engagement and EDI working groups, who are responsible for its application.

5. EQUALITY, DIVERSITY AND INCLUSION

Individuals of all backgrounds regardless of demographic, social or economic factors are diagnosed with sepsis and should have the opportunity to participate in research. However, many groups are under-represented in research with lower inclusion, which are often due to factors which are not considered but may affect participation. Such under-represented groups may include those identified by the NIHR-INCLUDE guidance or defined as having 'protected characteristics' (UK), or as 'priority populations' or 'underrepresented groups' (Australia). Characteristics include age (younger and older), gender reassignment, married or in a civil partnership, women of child-bearing age, pregnant or on maternity leave, disability, race including colour, nationality, ethnic or national extraction or origin, religion or belief, sex, sexual orientation. Other groups include individuals from areas of socioeconomic deprivation, people in alternative residential circumstances (for example, remote, rural and coastal communities), those with language barriers, mental health conditions, and those with impaired capacity. It is important to recognise that TIGERS is an international platform; these examples are not exhaustive and will differ depending on the local context.

The TIGERS Platform aims to be as inclusive and strives for representative involvement, engagement and trial participation.

6. TIGER PARTICIPATING SITES

Training will be provided to participating site teams on enhancing research and cultural competence and sensitivity within the Site Initiation Visit and at investigator and research coordinator meetings, with additional materials provided for further learning. During Site Initiation Visits, there will be a focus on research inclusion, with a particular emphasis on the local context and potential facilitators to recruiting diverse populations

in a culturally concordant manner. Diversity and inclusion data will be collected within the trial case report form (CRF) using the UK standardised CRF for protected characteristics where possible based on site and country norms. Protected characteristics will be monitored at regular intervals (6-monthly) and using the 'Screened, Eligible, Approached, Randomised' (SEAR) framework² with proactive site engagement, training and TIGERS meetings/events. Importantly, we will report on these characteristics in platform results publications and presentations. EDI data review will form part of the trial management group agenda.

7. TRIAL PARTICIPATION

Platform and domain inclusion and exclusion criteria will promote inclusion with patients excluded only if they are unlikely to benefit from or are at risk of an adverse event related to the study intervention(s). Participants will be enrolled across a large network of sites, enhancing diversity and geographic reach.

The NIHR INCLUDE framework will be used to support the recruitment of a diverse population during the trial. Patient characteristics will be monitored in relation to recruitment, and if these fall below representative thresholds (based on critical care unit data from the Intensive Care National Audit Centre and the Scottish Intensive Care Audit Group), the trial team will proactively work with sites to preferentially recruit patients with these protected characteristics if possible. This data will be fed into TIGERS governance meetings to ensure proactive strategies are taken to ensure equitable access to the research across diverse groups. This might include further training for staff, or improvement in patient facing information.

Patient-facing documents including consent forms and videos, will be co-designed with our patient and public involvement (PPI)/consumer partners to ensure accessibility of information provided. These materials will be reviewed for accessibility with additional versions created as required with our PPI/consumer partners, for example low visibility or literacy, translations and cultural contexts. Participant encounters such as consent and follow-up interviews will provide options for substitute decision maker (SDM) attendance and/or completion, translators and consider cultural sensitivity.

8. INVOLVEMENT AND ENGAGEMENT

PPI/consumer engagement within the TIGERS platform has been designed by critical care survivors and their families. We will continue to engage with patient and public groups to ensure that our approaches to research inclusion are meaningful and effective. We will work with relevant charities such as Sepsis Research (FEAT) and Sepsis Australia. Particular attention will be paid to diversity, with representation in terms of socio-economic background, geography (including rural, coastal and inner city), ethnicity and different illness trajectories. Anonymised equality monitoring will help understand diversity (or lack of) to enable the team to proactively provide opportunities for under-represented communities in our PPI/consumer engagement activities. Appropriate training for our PPI representatives will be provided, for example utilising the wider NIHR training hub, the NIHR Imperial BRC PPIE team and the Monash University Short Course: “Consumer and Community Involvement: A Beginner’s Guide”. Public participants can access 1:1 support from the research team, including debriefs following discussion of sensitive topics, such as those related to research inclusion.

We will work with participants (if requested) before these PPI/consumer engagement meetings, to ensure that they feel confident in participating. We anticipate offering a hybrid meeting approach (and have experience of this), to ensure participation is accessible to all communities, including those that might face barriers with digital access to participation.

We will continue to garner wider opinions and understand participation barriers of patients, trial participants and the public through engagement activities, which may include public presentations/conferences, systematic reviews, focus groups, surveys

We will host a community outreach event to discuss sepsis, intensive care medicine, clinical trials, platform trials, personalised medicine and trial participation in order to identify barriers and potential solutions to participation of under-represented groups.

9. DISSEMINATION

Dissemination activities will be co-designed with our PPI/consumer partners to ensure accessibility, with the use of animations, podcasts and translated outputs.

Clinical trials and their results are often not effectively communicated to patients and the public. We wish to develop targeted multimedia dissemination to improve patient and public understanding of acute care medicine and sepsis clinical trials, in particular platform trials and personalised medicine including video, lay summaries and infographics with PPI/consumer members and dissemination through social media, a dedicated section of our website and PPI/consumer engagement organisations/groups. We will aim to provide summaries for diverse participants to

enhance inclusivity, guided by our PPI members and community organisations e.g. additional languages and cultural contexts, communication preferences, low literacy or vision. We will host patient and public conference(s) with our collaborating organisations (translated in multiple languages) and shared with diverse groups. We will engage with organisations working with underserved communities for advice on producing these documents and their appropriate dissemination means.

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