

Inclusivity Checklist for Clinical Research

	Checklist item	Yes	No	NA
Setting research priority and research question				
1	Describe the diversity of the target population.			
2	Engage with under-represented communities relevant to the target condition.			
3	Include members of the community as research partners.			
4	Evidence activities that raise awareness of and promote interest in the study amongst under-represented communities.			
Research Inclusion considerations				
5	Describe the Research Inclusion Plan in the study protocol.			
6	Budget for the Research Inclusion Plan in the funding application.			
7	Designate individual(s) responsible for delivering the Research Inclusion Plan.			
8	Document diversity of the research team.			
9	Embed an evaluation of the Research Inclusion Plan in the study. <i>(optional)</i>			
Study design				
10	Describe how inclusion and exclusion criteria mitigate discriminatory bias.			
11	Document how protocol flexibility accommodates the needs of under-represented groups.			
12	Pre-specify representative recruitment targets, ensuring these are reviewed throughout the research.			
13	Document the use of decentralised trial methods (move research delivery into communities) or non-traditional trial designs. <i>(optional)</i>			
14	Include options for partial participation, assent, and permission for future study contact in the consent form. <i>(optional)</i>			
Study delivery				
<i>Recruitment and retention strategies</i>				
15	Document how recruitment strategies are multiple, diverse, and flexible to address inclusivity.			

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16	Specify mechanisms of feedback about recruitment and retention with recruiting sites and under-represented groups.			
17	Document plan for inclusion of research sites from geographically under-represented areas.			
18	Document that research staff have received training in cultural competence, implicit bias, and inclusive communication.			
19	Document how people with lived experience of the target condition, clinicians, and healthcare professionals have helped with recruitment of under-represented groups.			
20	Document strategies used to increase accessibility for participants from under-represented communities (e.g. compensation, logistics, and travel arrangements).			
<i>Communication Strategy</i>				
21	Document steps to ensure study materials such as Patient Information Leaflets and Consent Forms are short, simple, and written in easy-to-read language.			
22	Document the strategies available throughout all stages of the research for people with communication difficulties (e.g. do not speak English, sight or hearing impairments).			
23	Document how communication strategies reflect participant preference.			
Data Collection and Reporting				
24	Collect comprehensive demographic data on participants.			
25	Report results stratified by under-represented characteristics or sub-groups.			
Impact, dissemination and engagement				
26	Document dissemination of research results to participants and wider relevant communities.			

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