NIHR's Inclusive Research Plans (new NIHR conditions Oct'24)

Inclusive Research Methods Team

November 2024

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Section 1: Overview

To fulfil NIHR's mission to improve the health and wealth of the nation through research, the NIHR has inclusion as part of their operating principle. NIHR is changing to ensure that research inclusion is properly costed and executed. NIHR produced the below release on how inclusive research will become a condition of funding.

"As of autumn 2024, the NIHR will require all applicants for domestic programme awards to detail how they will ensure inclusion is considered and built into the whole research lifecycle. This will formalise previous good practice expectations with respect to inclusion. Reasonable and justified costs will be provided by NIHR to enable researchers to conduct inclusive research.

Inclusion is an NIHR operating principle. Good research must include people from the diverse populations of the UK and include more women, children and older people. Research inclusion is an important key to improve health and care for everyone and reduce health and care inequalities". (NIHR July 2024).

Inclusive research contributes to scientific rigour, patient safety and health outcomes, human rights and ethics in a legal context.
- Research is often not covering those with greatest need, especially those under-served by health and care research. Research is often not covering those with greatest need.
- Including inclusive ways of thinking throughout the research cycle will result in improvements of outputs at both individual and population levels.

"Research that is intentionally designed, conducted and communicated inclusively, produces rigorous, generalisable, impactful science that benefits the entire population" (NIHR 2024).

NIHR has developed the EDI Toolkit "*to support researchers and research advisers to better understand how to embed equality, diversity and inclusion (EDI) in research design and to meet the National Institute for Health and Care Research (NIHR) Research Inclusion criteria. It is also a useful resource for researchers developing inclusive research applications for other funders*".

The EDI Toolkit states that NIHR aims to fund research that:
- "*tackles long-standing structural barriers that hinder certain groups from contributing to, participating in, and delivering research,*
- *reduces health and care inequalities,*
- *is inclusively designed and analysed, with methods suited to the target participants,*
- *addresses the needs of diverse, under-served, under-represented groups, or those with the highest needs."*

(RSS EDI Toolkit)

Applicants will be required to demonstrate how inclusion is being built into all stages of the research lifecycle including, but not limited to:
- the research question and design,
- the participants recruited,
- the research methods,
- data collections,
- analysis,
- and dissemination of findings.

The new application process will formalise previous good practice expectations relating to inclusion and will require applicants to detail how they will ensure inclusion is built into their research design. Stage 1 will require early consideration and articulation, with more detail required at Stage 2 applications including specifying the costs associated with conducting the research inclusively.

Note: this must be woven into the application (no new section) with no extra word allocation. These new conditions won't apply to global health and NIHR infrastructure awards until later (2025 onwards) at this time and is not a retrospective condition of funding.

Ten steps to embed inclusion into research and new NIHR grant applications (NIHR seminar 16/10/24):

1. **Substantiate your research inclusion statements** (good intentions not enough, is research team skilled in IR?)
2. **Ensure you know which inequalities are relevant to your field** (e.g. by conducting a literature review to make the invisible visible).
3. **Include under-served areas in research** (Where is the problem the greatest but research activity sparse? Look for alternative sites than the usual).
4. **Justify your research sample** (exclusion criteria, capture EDI data of samples, think about age, language etc.).
5. **Specify which demographic data you will collect and how you plan to use it?**
6. **Budget for inclusion** (clearly specify all costs, value for money).
7. **Consider how methodological innovation could overcome exclusionary aspects of conventional methods** (e.g. different participatory methods, community-based training and recruitment etc.) and limitations to traditional methods (e.g. Qualitative interviews and focus groups can be challenging for some participants who struggle with expressing themselves confidently)
8. **Demonstrate how research can be shaped by diverse and inclusive Patient and Public Involvement and Engagement (PPIE)** e.g. diversity of PPIE, work with communities, identify barriers to involvement (e.g. geography, socio-economic status, language), importance of 'lived experience'.
9. **Plan inclusive and impactful approaches to knowledge mobilisation** (knowledge mobilisation and impact plans, plan with diverse groups, key messages, who to share with etc.)
10. **Use resources available** (e.g. RSS EDI toolkit)

NIHR recognises that:
- There will be a learning curve for most researchers.
- There will initially be a need for a proportional approach to review.
- There will always be compromises (e.g. time, resources, feasibility)
- Design choices will need to be justified and approved for target population of the research (Evidence based and PPIE activities).

A recording of the **NIHR Introductory 1hr Webinar** held on **16/10/24** run by the NIHR Inclusion Team and the NIHR Research Support Service is available on 'transforming lives through research' (NIHR YouTube channel) - https://www.youtube.com/watch?v=g3IRujUSQj0

NIHR will expect researchers / PIs to report back (post award) on inclusion elements of the research undertaken and review this against the original proposals. This will help create a continuous learning approach and enable the sharing of best practice.

NIHR guidance on [Inclusive research funding application guidance | NIHR](#) is now available and from 27/11/24 applications need to show how the research aligns with: [NIHR mission to reduce inequalities in health, social care and public health](#) and [NIHR's aim to become a more inclusive health research funder](#).

Section 2: Support and guidance from the Inclusive Research Methods Infrastructure (for the Manchester BRC / CRF / HRC and HDRC) and other sources of help.

Below is a summary of papers, recommendations and advice presented to IROB previously to help with NIHR's implementation of their plans.

Inclusive Research

- Researchers / PIs are encouraged to come and speak to the **IR Methods Team** (through your designated IR Methods Team lead linked to Clusters) as soon as possible when thinking about projects. This includes methodological queries. It may be necessary to prioritise support for projects from the team depending on volume of requests and we may ask for Cluster leads to prioritise.
- Researchers / PIs are encouraged to speak to **VOCAL** (through your designated VOCAL leads linked to Clusters) about Public and Patient Involvement and Engagement (PPIE).
- Some Clusters are running joint (PPIE and IR Methods) first meetings with PIs (where possible) to gain an understanding of support required and timescales.
- Researchers / PIs are encouraged to speak to the **Equality, Diversity and Inclusion** (EDI) Team for queries about Workforce EDI.

If in doubt speak to a member of the relevant team (EDI, IR Methods, PPIE) so we can work out who is best suited to help and when.

- Training courses

To support and enhance your knowledge of **inclusive research** a free eLearning module has been produced for the Manchester BRC/CRF by Bella Starling and Vocal. The module draws on case studies and data from Greater Manchester and is relevant for everyone involved in clinical research, to help develop and apply an inclusive approach in your own environment. The module is open to all. The module can be completed within one to two hours - this can be done in one session, or in bite size chunks. It can be accessed via the University of Manchester's online platform, [Life Long Learning](#) (search for 'Inclusive Research'). In order to take the quiz and obtain a certificate of completion, **enrol** in the course (rather than completing it via Open Access).

The **Manchester Measuring Inequalities Toolkit** is designed to help public health professionals, policymakers, researchers, and others assess and identify inequalities. It was developed by the Manchester BRC (IR Methods Team) with input from the Public Health Team at Manchester City Council. It is freely available through the University of Manchester's Life Long Learning Platform, it offers flexibility, allowing users to engage with the content at their own pace. The toolkit includes quizzes to reinforce understanding and provides a certificate upon completion. By focusing on the accurate measurement and identification of inequalities, it supports users in making informed decisions that contribute to a deeper understanding of health disparities. Registration is required for full access. It can be accessed via the University of Manchester's online platform, [Life Long Learning](#) (search for 'Toolkit'). In order to obtain a certificate of completion, **enrol** in the course (rather than completing it via Open Access).

NIHR advise for staff and students to undertake training available on their portal (account required): https://learn.nihr.ac.uk

Inclusive Research Methods

- Each Cluster (BRC) has a member of the IR Methods Team to support activities. CRF/HRC and HDRC teams – please email arpana.verma@manchester.ac.uk with any requests.
- Start considering as early as possible how your chosen methods (sample selection, recruitment methods, inclusion / exclusion criteria, geographical coverage etc) may impact on the inclusivity of your research.
- Think about the whole research cycle including but not limited to: the research question and design; sampling frame; sampling strategy; the participants recruited; the research methods; data collection; analysis; and dissemination of findings.
- If you are looking for an inclusivity related literature review to inform research / prepare for a grant application, we sometimes have MPH/MRes Students seeking such opportunities. Tutors are encouraged to suggest a suitable methodology (e.g., systematic review) that aligns with MPH/MRes requirements. However, the student will work with you to further develop the topic and define the research objectives or questions. While we cannot guarantee that students will choose your project, last year about 10 students successfully completed similar reviews. Students are required to conduct a Critical Literature Review of 5,000 words, adhering to PRISMA guidelines, with a current completion date of September 2025. If you are interested in having a student conduct a review, please fill out the expression of interest form below (click link).

    Qualtrics Form.

Collecting EDI characteristics of research sample for monitoring inclusivity

- In autumn 2023, the IR Methods Team / IROB recommended using the NIHR workforce questions for anonymised non-linked monitoring (this will need to be justified in both ethics applications and data management plans). NIHR modified their questionnaire, and this advice was updated in spring 2024.
- University ethical committee leads were consulted. Their advice was for PIs to include in their paperwork for monitoring data, an additional paragraph at the beginning of the **questionnaire** that reads – "*We would like to understand whether under-represented groups in our research are being reached to support the shaping of future research. To help us with this, please can you answer the following optional questions? Please note the data you are providing in these questions are anonymised (your name and other identifiers removed) and may be used for other educational and research purposes in the future.*"
- In addition you should also add a new tick box to your **consent form** – "*I consent to the use of combined anonymised data (excluding personal identifiers) derived from this study for future secondary analysis aimed at further research, education, training, and capacity building purposes*" and a paragraph into your **Participant Information Sheet** – "*The data collected during this research may, in future, be used for secondary analysis in combined anonymised form. This means that your data is gathered together with everyone else's, with all personal identifiers removed to ensure your privacy and confidentiality. This work could support further research projects or educational activities (including training and capacity building), conducted by our research team or by others who have received our permission to use the data for their projects*".

- The IR Methods Team can supply the NIHR Workforce questions to be asked on the characteristics (standardised format) as a word document, a Qualtrics template and in a QSF file (Qualtrics) to be used and adapted by research teams / PIs to use to monitor characteristics within their project.
- The QSF file can be used as a template (questions and wording) for researchers to convert themselves into a REDCap version if preferred.
- The IR Methods Team does not currently have capacity or the ethics permissions to store this data collected so it should be kept by the research team / PI to monitor within their Theme / Cluster unless the paragraphs above had been included.
- In updated guidance, NIHR made a few changes to the response texts with respect to 6 indicators (ethnicity, religion, gender, sexual orientation, marriage or civil partnership, parental leave, and caring responsibility). This is included in the recommendations and the QSF file (above).
- The literature review underpinning these recommendations are being reviewed in autumn 2024 (annual review of literature).
- IROB have been trying to get blanket ethical approval for monitoring inclusive research participant's data. This has not been possible. HRA have issued a consultation – IROB would like to recommend participation. HRA Now - Help shape our new inclusion and diversity guidance

NIHR Grant Applications
- Adequate funding for EDI, PPIE and IR Methods support will need to be costed into new NIHR research applications from autumn 2024. Please speak to us early.
- Justification of inclusivity will be required throughout the whole of the research cycle and needs to be woven through the application.
- The Research Support Service (RSS) is set up to help with specific queries about Inclusive Research in NIHR grant applications - Research Support Service | NIHR and more information can be found in the RSS EDI Toolkit.

Useful resources
NIHR Research Inclusion Toolkit Hub

NIHR (July 2024) Inclusive research design to become an NIHR condition of funding. https://www.nihr.ac.uk/inclusive-research-design-become-nihr-condition-funding

NIHR Research Support Service. https://www.nihr.ac.uk/support-and-services/research-support-service

NIHR Research Support Service. EDI Toolkit (updated July 2024) https://www.rssleicesterresources.org.uk/edi-toolkit

NIHR guidance on Inclusive research funding applications (from 27/11/24). https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/funding-application-guidance

NIHR mission to reduce inequalities in health, social care and public health (June 2021) https://www.nihr.ac.uk/best-research-best-health-next-chapter

NIHR Aim to become a more inclusive health research funder (Sept 2022) https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/strategy-2022-27

University of Manchester's online Life Long Learning platform