



Embedding Diversity in Research Design

Diversity and inclusion in the design of research
involving human participants

Background Report & Recommendations

July 2022

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Executive Summary

Integrating diversity into the design and conduct of research is essential to achieving high quality scientific outputs and ensuring that research findings are reproducible, relevant and address the needs of different communities. Funders have a responsibility to encourage inclusive research practices in order to promote scientific excellence and support the fair distribution of research outputs to all those in society who have the potential to benefit. When diversity is not considered, there is a risk that research will be invalid and the ensuing mistakes and biases can be costly.

A rapid review of funder policies, consultation with researchers and evaluation of funding applications submitted to the MRC was undertaken in 2021-2022 to understand current research practice and the views of the research community with regard to diversity and inclusiveness in the design and conduct of health and biomedical research. The review identified 15 international funder policies and one UK 'framework' (NIHR-INCLUDE) on integrating sex and gender into research design and analyses; five of these extended beyond sex and gender to include broader concepts of diversity, such as ethnicity, socio-economic status or 'underserved' groups. A key expectation of these policies was that diversity should be considered at all stages of research, from recruitment to analysis and dissemination of findings. Several funders had developed tools to support researchers in designing and conducting inclusive research and to help peer reviewers assess whether diversity was appropriately addressed in a research proposal.

The MRC survey and evaluation of grant applications found that only around half of researchers consistently consider diversity when designing and conducting research, and only half explain their approach to diversity in their funding proposals. Importantly, researchers expected funders to show leadership in the area of inclusive research.

At a workshop held in May 2022, MRC Board and Panel members also recommended that the MRC take a leadership role in facilitating cultural change to embed diversity into research design. They further recommended changes to the MRC's current application processes and guidance for applicants and reviewers, to introduce a requirement for diversity to be considered in the design of all research proposals.

These recommendations will inform new policy and grant application requirements to support the integration of diversity into research design.

Introduction

Integrating diversity into the design and conduct of research is essential to achieving high quality scientific outputs and ensuring that research findings are reproducible, relevant and address the needs of different communities. Funders have a responsibility to encourage inclusive research practice in order to promote scientific excellence and support the fair distribution of research outputs to all those in society who have the potential to benefit.

MRC established a new project '*Embedding Diversity in Research Design*' in 2021 which sought to assess how the research funding process might promote principles of diversity and inclusion in the design and conduct of research, and to develop research policy and application processes to achieve more inclusive research design. The wider project includes preclinical and clinical research involving animals, cells and tissues, and human participants and has led to the implementation of the new *MRC expectations on the inclusion of both sexes in experimental design of animal research* that is being implemented in 2022. Key terms to describe diversity characteristics are explained in Appendix 1.

This report outlines the evidence review and subsequent workshop which have contributed to recommendations for a new policy on diversity and inclusion for MRC-funded research involving *human participants*. This developmental work included a review of funder policies, survey of researchers who involve human participants in their research, analysis of diversity in MRC grant applications submitted to the May 2020 Board rounds and a workshop with MRC Board and Panel members held in May 2022.

Background

Why is it important for funders to consider diversity in research?

It is now well-recognised by many research funders that a diverse workforce is critical to a healthy research culture; it improves the quality of science and can help ensure that the benefits of research are relevant and widely applicable across all population subgroups. Importantly research also gains added value from the explicit consideration of diversity in the design and conduct of studies, for example in the selection of human research participants, in the analysis of research data, and in exploring the impact that researchers have through their interaction with the individuals or communities that they are studying.

When diversity is not considered, there is a risk that research will have limited applicability and the ensuing mistakes and biases can be costly. There are multiple examples of bias in clinical and preclinical research when sex and gender are not taken into account:

- eight drugs were withdrawn from the US market in 2001 because the health risks in women were underestimated in pre-licensing trials¹;
- exclusion of pregnant women from drug trials means treatments are not licensed for them²;
- experiments lack reproducibility because the sex of cell line donors was not recorded.³

Avoiding such errors is vital to ensure the outputs from health and biomedical research are reproducible, high quality and do not marginalise specific groups in society.

¹ <http://www.gao.gov/products/GAO-01-286R>

² <https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-017-0419-x>

³ Shah K et al. Am J Physiol Cell Physiol 2014;;306:C3-C18

Evidence that diversity matters in health and biomedical research

The relevance of sex and gender differences in clinical research is reasonably well-recognised in relation to susceptibility to different diseases, however still often overlooked in terms of developing and implementing interventions and care, such as managing heart attacks in women⁴, osteoporosis in men⁵, or chronic pain.⁶ The COVID-19 pandemic has clearly demonstrated differences in the way the same virus affects men and women, highlighting the importance of evaluating disease risk and potential interventions by sex and gender.⁷

There are remarkable examples of women being excluded from research that is relevant to them, for example the first trial of oestrogen supplementation (hormone replacement therapy) to prevent heart disease, and an early study of the association between obesity and breast cancer, both involved men only. Other studies of heart disease and ageing, such as the Baltimore Longitudinal Study of Aging, the Physicians' Health Study, and the Multiple Risk Factor Intervention Trial (MRFIT) only recruited men.⁸

Until the 90s, many funders and regulators excluded women of childbearing age from early-stage drug trials in case the drug affected their fertility or an ongoing pregnancy; this meant all women were excluded from trials, regardless of their age, sexual orientation or desire to have children. And although women were excluded from trials due to their physiology, the results from trials involving men were still considered to apply to women despite these same physiological differences. For some groups, such as pregnant women or children, exclusion from clinical trials of new drugs also means exclusion from the licensing of these drugs so they do not have access to treatments that could be of benefit to them.⁹

Within a health research context, it is also essential to understand variations in the experience of health and illness, as well as health service use, so that the diverse needs of patients are addressed. This may mean evaluating research priorities against diversity criteria, and ensuring that study participants, partners in co-production or members of oversight bodies adequately represent diversity in the patient population. Importantly, it also means reporting the results by sex, gender and other diversity dimensions, so that data are accurately interpreted and the results generalisable and reproducible.

Physiological and pathophysiological processes in the bodies of humans and animals may be strongly sex-dependent, making it essential to include females and males in all types of basic research, and at all stages of drug development research, so that sex differences in efficacy, toxicity, safety and side-effects can inform sex-specific dosing and use.

Research involving stem cells has clearly demonstrated variations by chromosomal sex, such as human embryonic cell differentiation, that must be taken into account in the design and analysis. Understanding these sex differences is particularly relevant to clinical therapeutic uses, as better outcomes may result from matching the sex of donor and

⁴ Dey S, et al. Sex-related differences in the presentation, treatment and outcomes among patients with acute coronary syndromes: the Global Registry of Acute Coronary Events. *Heart* 2008;95(1):20-26.

⁵ <http://genderedinnovations.stanford.edu/case-studies/osteoporosis.html>

⁶ <http://genderedinnovations.stanford.edu/case-studies/pain.html>

⁷ Wenham C, et al. COVID-19: the gendered impacts of the outbreak. *The Lancet* 2020;395(10227):846-8. [https://doi.org/10.1016/S0140-6736\(20\)30526-2](https://doi.org/10.1016/S0140-6736(20)30526-2)

⁸ Dusenberry M. *Doing Harm: The Truth About How Bad Medicine and Lazy Science Leave Women Dismissed, Misdiagnosed and Sick*. Harper Collins, 2018.

⁹ <https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-017-0419-x>

recipient in stem cell transplantation or preferring female stem cells over male to treat specific diseases.¹⁰

Review of different funder approaches to diversity in research

A rapid review of UK and international funder policy on inclusive research design was undertaken by MRC to identify current approaches to integrating sex, gender and diversity into the design and conduct of research involving human participants. The review included policies on integrating sex, gender and broader diversity characteristics into research, and included all scientific disciplines. Equality, diversity and inclusion (EDI) policies that focused only on increasing diversity in the research workforce were excluded from the review. Additional evidence was also sought directly from funding bodies to supplement information available in policy documents.

The review addressed two questions:

1. What policies exist to improve the diversity of research participants and inclusion of underserved groups?
2. What changes have been made to research application and review processes to increase diversity?

Summary of funder policies

A summary of the funder policies identified by this review is provided in Appendix 2, Table 1. Fifteen international funder policies and one UK 'framework' (INCLUDE) were identified from funder websites and a review paper.¹¹ Five wider initiatives to promote diversity in research design and conduct were also identified (Appendix 2, Table 2). No UKRI Research Councils had a written policy.

All funder policies included sex and gender. Five policies also included ethnicity and/or race, or a broad range of individual characteristics variously described as race/ethnicity, intersectionality, 'groups underserved by research', and the 'diversity dimension'.

Six policies were from health and biomedical research funders and several of these included preclinical research. Nine policies were from cross-disciplinary funding organisations; these all included sex and gender but only one funder (Deutsche Forschungsgemeinschaft [DFG]) extended beyond sex and gender to broader dimensions of diversity.¹² The only UK policy, the NIHR-INCLUDE framework, focused solely on clinical research involving human participants. This framework was unique in considering the participation of underserved groups in research-related public involvement activities as well as in research projects.

A key expectation of funder policies was for diversity to be considered at all stages of research, from design, recruitment and analysis to dissemination of findings.

Policies on sex and gender specifically emphasised the need to specifically report sex and gender, and to investigate their impact as part of the study analyses; they often referenced the resources produced by the Canadian Institutes for Health Research (CIHR) and US National Institutes of Health (NIH). Policies from the CIHR and NIH had extended over time

¹⁰ Gendered Innovations. Stem Cells: Analyzing Sex. http://genderedinnovations.stanford.edu/case-studies/stem_cells.html#tabs-2

¹¹ Tannenbaum C, et al. Sex and gender analysis improves science and engineering. *Nature* 2019;575:137-146.

¹² Deutsche Forschungsgemeinschaft (DFG; German Research Agency)

from an initial focus on sex and gender to include race and ethnicity, minority groups and intersectionality. Funders, such as the DFG (Germany) and ZonMW (Netherlands), had taken a broad approach from the outset and required all aspects of diversity to be taken into account in any research.

The INCLUDE framework is not a funder policy but has been endorsed by the NIHR therefore is included in this review. The framework was developed for clinical trials to ensure these reflected the populations for which interventions were being developed.¹³ The framework defines groups that might be considered ‘underserved’¹⁴ by research and highlights the need to include members of these groups not only as research participants, but also as partners in the co-production of research.

Training and checklists to support implementation

Several funders had developed tools, including checklists, online training modules or case studies, to support researchers in designing inclusive research and to help peer reviewers assess whether diversity was appropriately addressed in a study protocol (Appendix 2).

Monitoring and evaluation of policies

There were few evaluations of funder policies. The percentage of research that addresses sex or gender considerations is reviewed annually by CIHR who report a steady rise since 2015-16, meeting the target (56%) in 2017-2018 for the first time.¹⁵ The NIH also releases data on the representativeness of research participants by gender and ethnicity for each research area or disease category.¹⁶ Arnegard *et al* published a ‘Progress Report’ on the impact of NIH initiatives related to the policy on sex and gender based analysis in research that described progress and lessons learned.¹⁷ Most NIH panel members believed the policy was important and that the focus on diversity would improve reproducibility and rigor, although they also expressed concerns about scoring grants appropriately.¹⁸

MRC survey of researcher views on inclusive research design

In July/August 2021, MRC conducted a survey to find out whether considerations about diversity are currently part of the design and conduct of research, what the perceived benefits and challenges are, and understand what expectation researchers have of funders in leading cultural change in this area. The survey was distributed via MRC-funded researchers and establishments, as well shared via other funders and research organisations. It included questions on human, animal and *in vitro* research; 415 researchers responded to the questions about research involving human participants and around 600 to questions about the role of funders and diversity in public involvement.

¹³ Trial Forge. The INCLUDE Ethnicity Framework. <https://www.trialforge.org/trial-forge-centre/include/>

¹⁴ https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435#Examples_of_under-served_groups

¹⁵ <https://cihr-irsc.gc.ca/e/51283.html>

¹⁶ <https://report.nih.gov/riscr/#/>

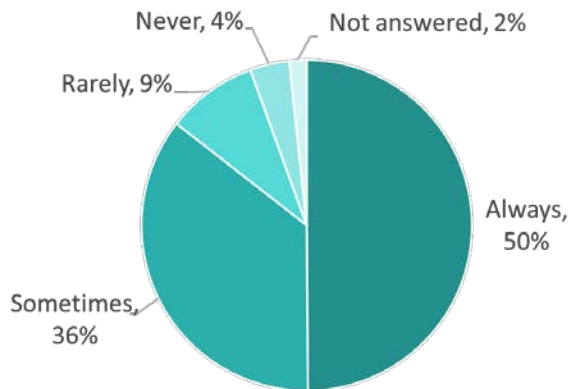
¹⁷ Arnegard M, et al. Sex as a Biological Variable: A 5-Year Progress Report and Call to Action. *J Women’s Health* 2020;29(6):858-864 <https://www.liebertpub.com/doi/pdf/10.1089/jwh.2019.8247>

¹⁸ Woitowich NC, Woodruff TK. Sex-Inclusion Policy: Attitudes and opinions of Study Section Members. *J Women’s Health* 2019; 28(1):9-16. <https://www.liebertpub.com/doi/abs/10.1089/jwh.2018.7396>

Research involving human participants

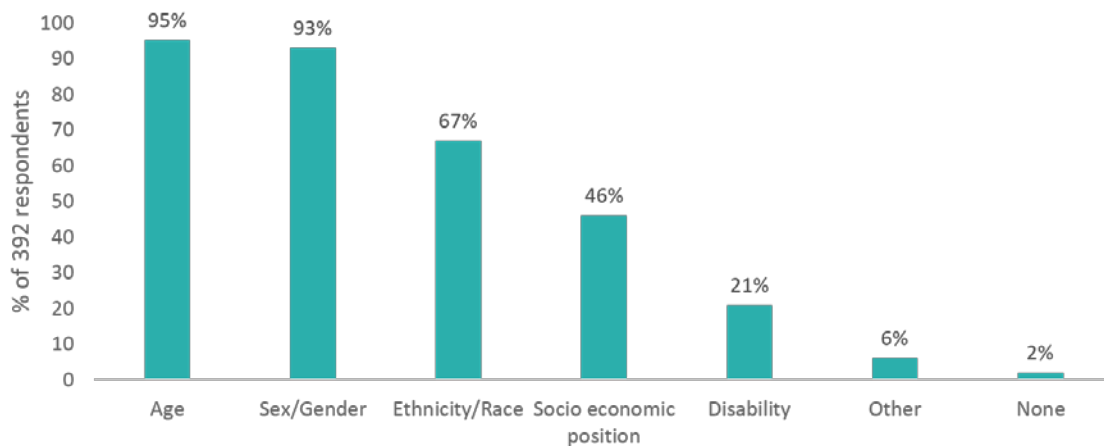
- 86% of researchers working with human participants reported that they considered diversity when designing or conducting research (50% *always* did so and 36% *sometimes* did so).

Figure 1: Percentage of researchers who considered diversity



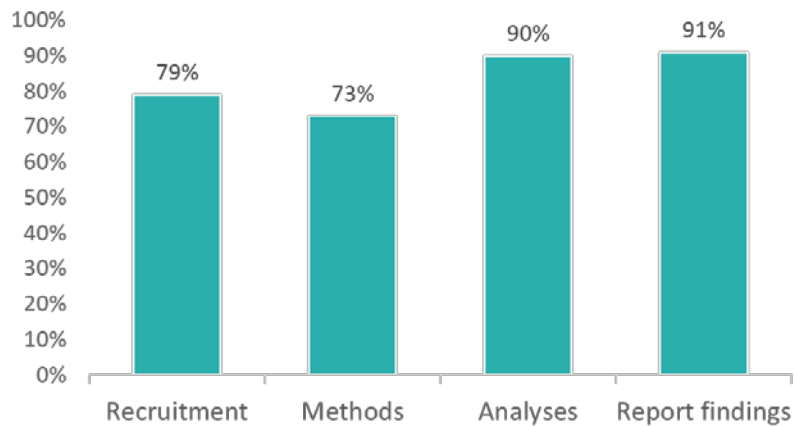
- Researchers considered age most often (95%), followed by sex/gender (93%), race/ethnicity (67%), socio-economic position (46%) and disability (21%).
- 95% of these researchers considered more than 1 characteristic (intersectionality).

Figure 2: Diversity characteristics considered by researchers



- 79% considered diversity during recruitment of participants; 72% adapted their research methods to investigate or take account of diversity; 90% conducted separate analyses for sex, gender or other diversity characteristics; and 91% reported findings in relation to diversity.

Figure 3: Stages of research when diversity is considered



Survey results: Role of funders

- 70% of researchers thought that funders should set out expectations for inclusive research



- 95% of researchers said it was important for funders to consider whether research proposals take account of diversity when awarding funding.



Survey results: Public involvement

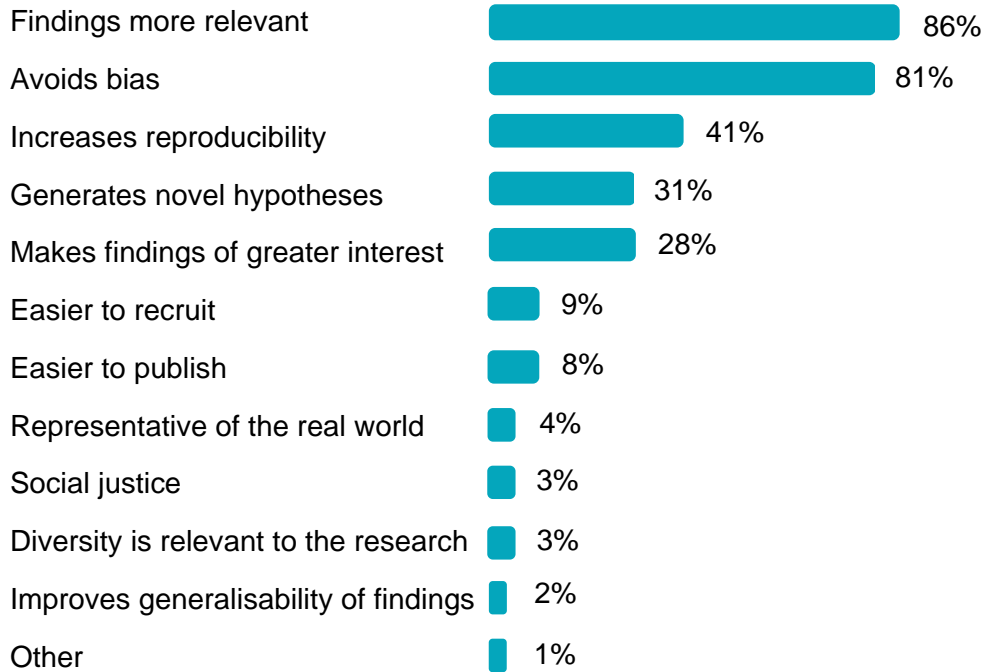
- 71% of researchers considered diversity in their public involvement activities



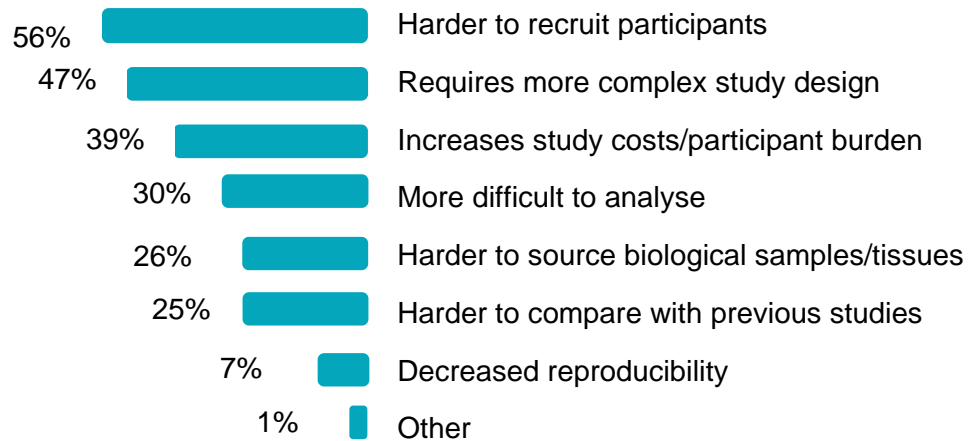
Survey results: Benefits and challenges

- Researchers identified a range of benefits and challenges to taking account of diversity in their research

BENEFITS



CHALLENGES



Evaluation of MRC grant applications

All 377 funding proposals involving human participant research that were submitted to MRC Boards and Panels in May 2020 were evaluated to assess how diversity was addressed by applicants. The current MRC application form asks all applicants whether equal numbers of male and female participants will be included in the study; any other descriptions of how diversity will be managed are included in the research proposal at the discretion of the applicant.

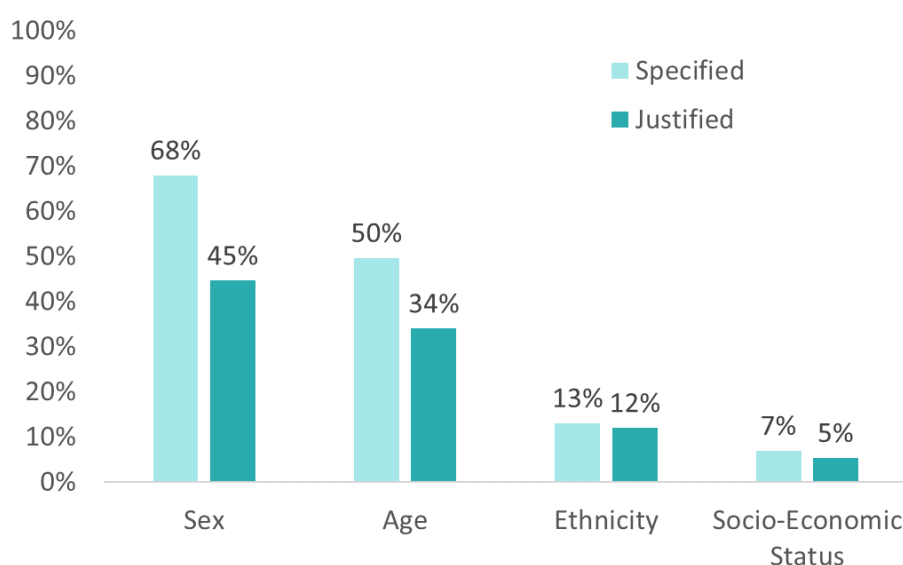
Grant applications either **specified** (made a statement about the characteristics of participants, in terms of sex/gender, age, ethnicity or other diversity characteristic) or **justified** (specified they would take diversity into account *and* explained their inclusion of at least one diversity characteristic). Therefore justification of diversity provided a better indication of whether an applicant had considered their approach to diversity when designing the research proposal.

In this evaluation, four diversity characteristics were specifically looked for in all applications: sex (or gender), age, ethnicity (or race) and socio-economic position.

Specifying and justifying diversity characteristics

- 284 (75%) of applications specified a diversity characteristic of participants.
- 194 (51%) of applications justified the inclusion of at least one diversity characteristic, 33% justified two characteristics and 9% justified three characteristics.
- Applications were most likely to specify and justify sex/gender or age than ethnicity or socio-economic position.

Figure 4: Percentage of applications that specified or justified diversity characteristics

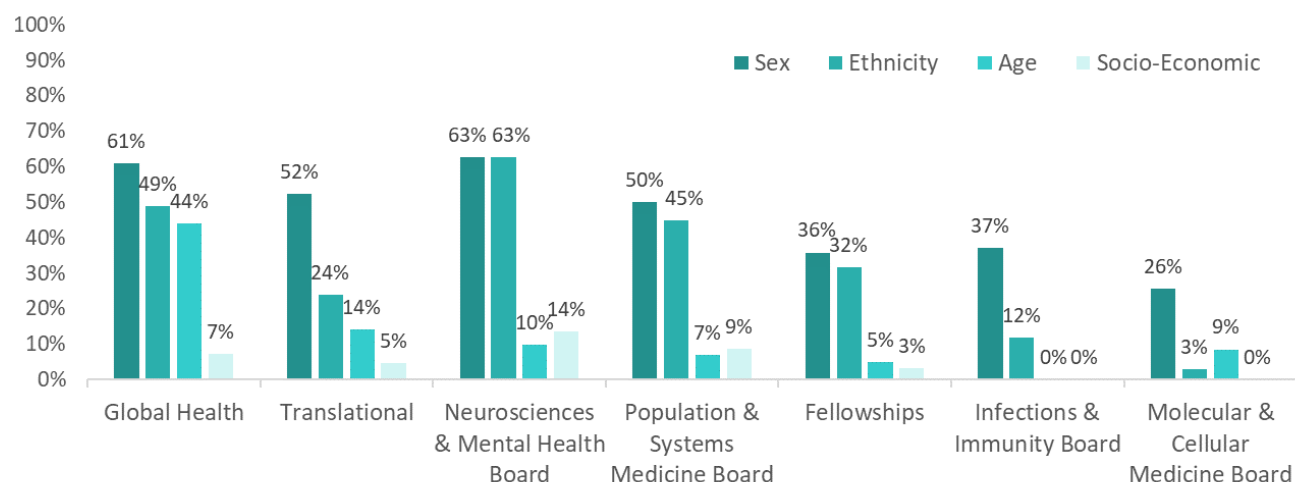


Research Board differences in the justification of diversity characteristics

There was variation between Boards in the percentage of applications that justified diversity.

- **Sex** was included and justified by around
 - 60% of applications to the Neurosciences and Mental Health Board (NMHB) or for global health research,
 - 50% of applications to the Populations and Systems Medicine Board (PSMB) or for translational research, and
 - <40% of applications to the other Boards and Panels (Fellowships, Infections and Immunity [IIB] and Molecular and Cellular Medicine Boards [MCMB]).
- **Ethnicity** was included and justified by 60% of NMHB, 40-50% of PSMB and global health research applications, 20-30% of translational and fellowship applications and <15% of IIB or MCMB applications.
- **Age** was included and justified in 40% of global health research applications but in <15% of applications to all other Boards.
- **Socio-economic position** was included and justified in <15% of applications to any Board.

Figure 5: Percentage of applications justifying each diversity characteristic by Research Board



Applicant characteristics

Women were statistically significantly more likely to justify the consideration of diversity characteristics than men (58% compared with 47%) and senior researchers appeared more likely to justify diversity characteristics than early career researcher (55% compared with 46%; not statistically significant). Applications were evaluated by gender of the principal investigator (PI) to compare justification rates. Of 154 applications in which the lead applicant (Principal Investigator; PI) identified as a woman, 89 (58%) justified at least one diversity characteristic; this was significantly higher than for applications led by a PI who identified as a man (103 [47%] of 219 applications; difference 11%; 95% confidence intervals [CI] for difference 0.5%, 21%).

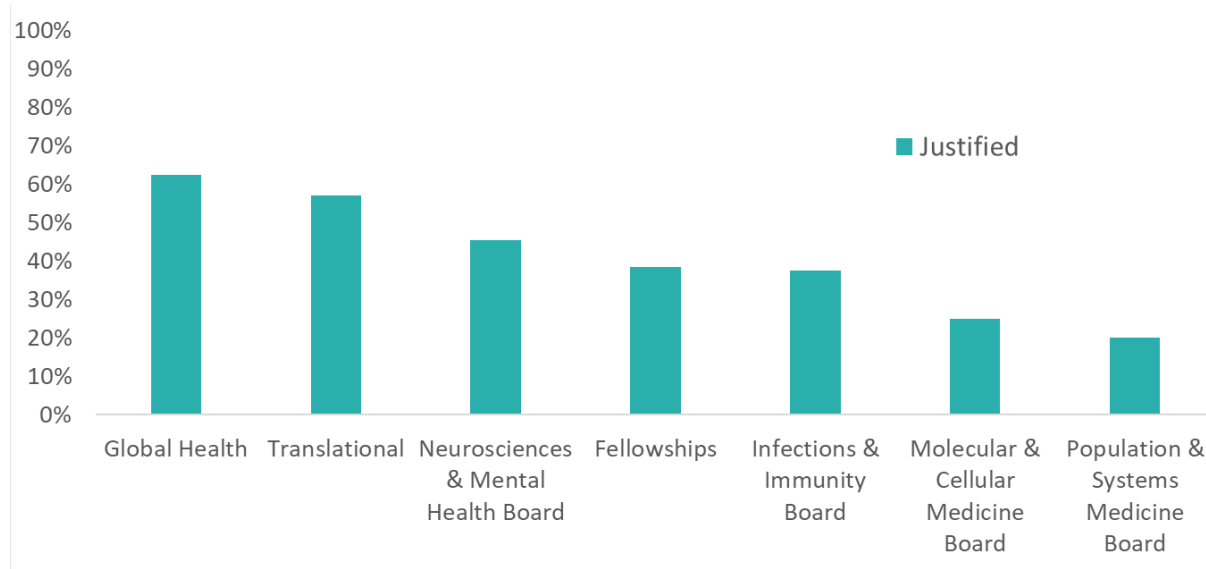
Senior researchers appeared slightly more likely to justify the inclusion of diversity characteristics than Early Career Researchers but the difference was not significant. There was insufficient data on other applicant characteristics, such as ethnicity, to explore these.

Awarded applications

Of the 377 total applications, 56 were awarded funding.

- A similar percentage of *awarded* applications (76%) *specified* at least one diversity characteristic compared to *all* applications.
- However only 43% of awarded applications *justified* the inclusion of diversity characteristics; this varied across the Boards from 20% (PSMB) to 63% (Global Health).

Figure 6: Percentage of awarded grants justifying each diversity characteristic by Research Board



Workshop with MRC Board and Panel members

On 27 May 2022, Professor Jill Pell chaired a workshop with MRC Council, Board and Panel members to discuss the importance of diversity and inclusion in the design of research involving human participants and to make recommendations for future MRC policy and actions to embed diversity in research design (Appendix 3 for agenda and papers).

Specific objectives of the workshop were:

- To share information about MRC activities to inform future policy and guidance on diversity in research design (inclusive research design), including
 - Research and innovation community perceptions (findings from the researcher survey)
 - Current practice in MRC peer review and funding decision-making processes
 - Development of policy on consideration of biological sex in experimental design for animal research
- To explore the benefits and challenges of embedding diversity in research design and conduct
- To consider how MRC might support the research community to embed considerations of diversity more widely in research design and conduct
- To consider how MRC's funding process might be developed to promote and facilitate inclusive research design
- To explore methods for monitoring diversity in research design and conduct for studies funded by the MRC.

Key conclusions and recommendations from the workshop are provided in the next sections.

Benefits and Challenges of embedding diversity in research design

Workshop attendees agreed that embedding diversity and inclusion in the design of research is fundamental to good research practice and high quality science.

The following benefits were identified:	The following challenges were identified:
<ul style="list-style-type: none"> • Better science • Better health and care • Meets journal requirements • Research results more generalisable • Increases fairness and equity • Social justice • Reduces discrimination • Improves the broader legitimacy of research • Value for money • Offers new opportunities 	<ul style="list-style-type: none"> • Requires more resources and time • Higher cost so more funding needed • More difficult to recruit participants • Particularly difficult to engage under-represented groups • Needs improved community networks • Requires a culture change • Lack of knowledge and skills, and requirement for training • Not feasible for every study

Potential role and actions for MRC

Three overarching themes emerged from the workshop discussions: changing culture, changing funding application processes, and evaluating and monitoring impact. Within each of these themes, are potential actions for MRC that workshop members identified would support and encourage diversity in research design.

Changing culture

Workshop attendees identified the need for a culture change among the research community, including funders, researchers and peer reviewers of funding applications, with clearer expectations that research should be inclusive as well as guidance and incentives to achieve this.

Workshop attendees proposed several ways in which funders could promote culture change:

- Encouraging a broad view of diversity characteristics, not limited to sex and gender, or to protected characteristics, but also including concepts such as ‘underserved’ groups or defined by culture or behavioural characteristics
- Encouraging collection and reporting of diversity characteristics in all studies
- Encouraging testing of statistical interactions with diversity characteristics and reporting of sub-group analyses where these are significant (noting that these may be used in future meta-analyses to increase power for smaller sub-groups)
- Developing case studies to share best practice in inclusive research design
- Investing in and/or providing training and education for researchers and peer reviewers
- Providing leadership (including developing the role of institutional champions)
- Establishing diversity and inclusion criteria for funding
- Creating targeted funding calls and investment to support diversity in research design
- Developing incentives for embedding diversity in research design
- Involving the public and wider stakeholder networks in research
- Developing and implementing metrics for diversity.

Changing funding application processes

Workshop attendees were in favour of changes to MRC application processes, including:

- Introducing an expectation that diversity will be embedded in research design as the default position with justification required if it is not
- Requiring applicants to outline the relevance of diversity in their research proposal and explain how they have addressed this, including specifying who is the target group for their research and how they will ensure this group benefits in the shorter and longer term
- Ensuring that any questions about diversity in application forms support researchers to outline approaches that promote high quality research, while acknowledging that researchers should be able to justify an approach that does not include all diversity characteristics or subgroups
- Changes to applicant and peer reviewer guidance to ensure consistency of approach.

Evaluation and monitoring

With regard to evaluating and monitoring the impact of embedding diversity in research design, and more specifically of changes to application processes, workshop attendees suggested:

- It is important to focus not only on individual projects but to also capture diversity and inclusion across the entire funding portfolio
- Collection of metrics to evaluate diversity and inclusion in grant proposals should be embedded throughout the whole application process
- Researchfish® could be used to collect relevant metrics on an annual basis
- Measures of long-term impact could be difficult to capture.

Key Workshop Recommendations

In summary, the key recommendations for MRC from the workshop were:

1. To establish diversity and inclusion principles and criteria for funding.
2. To take a broad view of diversity, not limited to sex and gender or to protected characteristics, but also including concepts such as 'under-served' groups or those defined by culture or behavioural characteristics.
3. To revise funding application processes and make it a requirement to consider diversity in all applications by default. Researchers should be allowed to define and justify the approach taken to diversity in their proposal on the basis of the population affected and likely to benefit from the research outputs.
4. To develop guidance and/or training to offer to applicants and peer reviewers, as well as more broadly to the research community, to promote best practice.
5. To develop incentives for embedding diversity in research design.
6. To provide leadership and support the development of a culture of inclusive research design. This could involve initiatives aimed at the research community, wider stakeholders and the public.
7. To support the development of improved methods for embedding diversity in research design by supporting grants on research methodology and initiating targeted funding calls that would address various aspects of diversity.
8. To establish and implement relevant metrics to evaluate diversity in research proposals and the benefits of increased diversity on research outputs in the short- and longer-term. Annual Researchfish® returns could be a source of metrics for evaluation.

It was acknowledged that, where appropriate, these recommendations might be pursued in partnership across UKRI Councils.

Conclusions

Recent years have seen an increasing focus on diversity and inclusion in the design of research with several international funders introducing requirements in their application processes and guidance for diversity to be considered in research proposals.

The MRC survey of researchers demonstrated that only 50% of researchers consistently considered diversity when designing and conducting research, while an analysis of funding applications submitted to the MRC found that only 51% of applicants explain their approach

to diversity in their research proposals. There is clearly significant scope for improvement to ensure that research is inclusive and offers fair and equitable benefits to a diverse population.

In May 2022, a workshop with MRC Board and Panel members discussed potential changes to MRC policy and applicant guidance to improve recognition of diversity in research design. They recommended that the MRC develop new requirements for diversity to be considered in funding applications, support this change with new training and guidance for applicants and peer reviewers, and implement measures to monitor and evaluate the impact of these changes. In common with survey respondents, workshop attendees strongly recommended that the MRC should demonstrate leadership in supporting wider cultural change and recognition of the fundamental importance of embedding diversity in research design.

Next Steps

In the light of these recommendations, the MRC will develop and implement new policy, guidance and training, to support diversity and inclusion in research design, with the overarching aim of ensuring that the research funded by MRC offers fair benefits for all across our society. Consultation on policy and guidance changes will take place in 2022 with a view to implementing these in 2023.

Appendix 1: Describing Diversity

The key diversity dimensions that are described in funder policies on the conduct of scientific research are described below:

- **Sex** refers to the biological attributes of humans and animals that differentiate male, female and intersex, including chromosomes, gene expression, hormone levels and function, and reproductive organs. The categories of sex are usually male and female but there is variation in the presentation of different biological components of sex.
- **Gender** is distinct from sex and refers to the attribution of behaviours, expectations and roles to different sexes, therefore varies over time and by social and cultural context. Gender is often regarded as binary, however there is diversity in how individuals and groups experience and express gender.
- **Race and ethnicity** are often used interchangeably. Race has sometimes been considered to be a biological attribute in contrast to ethnicity which is considered a socio-cultural attribute, however races are not clearly distinct at a genetic level and the genetic differences within a racial group are often greater than the differences between them. Race is therefore now often considered a social category similar to ethnicity. Ethnic groups are usually defined by a common language, identity, culture, beliefs and customs, and migration histories. Distinct ethnic groups that do not represent the majority in a population may be referred to as minority ethnic groups.
- **Other dimensions of diversity** include age, religion, sexual identity, educational level, disability, health status, language, geography, social and economic status, and many others.
- **Intersectionality** describes how overlapping forms of discrimination or difference, which may be related to gender, sex, ethnicity, age, religion, socioeconomic status, sexuality, geographic location, migration history or other characteristics, can affect an individual or group.
- **Underserved** is a term increasingly used to describe under-represented groups in clinical and health research. The INCLUDE guidance describes this group as individuals who have lower inclusion in health research than would be expected, a high healthcare burden that is not matched by the volume of research designed for them, and who have important differences in how they respond to or engage with interventions.

Appendix 2 – Review of policies to support inclusive research developed by funders and other organisations

Table 1: Funder policies

FUNDER	COUNTRY	DIMENSIONS	EXPECTATIONS	TOOLS
Agence nationale de la recherche (French National Research Agency)¹⁹	France	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Researchers should systematically consider sex and/or gender aspects in all research disciplines and in review processes 	<ul style="list-style-type: none"> • Guidance and training for peer reviewers
CIHR (Canadian Institutes of Health Research)²⁰	Canada	<ul style="list-style-type: none"> • Sex and gender • Intersectionality • Tri-Agency EDI initiative with the Natural Sciences and Engineering Research Council and Social Sciences and Humanities Research Council 	<ul style="list-style-type: none"> • Grant applicants should integrate sex and gender-based analysis into their research or justify exclusion • 	<ul style="list-style-type: none"> • Guidance on distinguishing between sex and gender • Guidance on identifying sex/gender differences in the mechanism, disease or treatment • Guidance on methods for integrating sex/gender • <i>Guidance video for structured assessment by peer reviewers</i> • Online training modules
Deutsche Forschungsgemeinschaft (DFG); German Research Foundation²¹	Germany	<ul style="list-style-type: none"> • Sex and gender • Diversity – dimensions in which people differ • Cross-disciplinary 	<ul style="list-style-type: none"> • Grant applicants should state whether the sex/gender and diversity of researchers, research participants, animals, samples is relevant • Taking diversity into account in research design, recruitment and analysis 	<ul style="list-style-type: none"> • <i>Application checklist</i> (3 questions) • Principles document • Webpages with guidance and examples

¹⁹ <https://anr.fr/fr/lanr-et-la-recherche/engagements-et-valeurs/le-genre/>

²⁰ <https://cihr-irsc.gc.ca/e/50837.html>

²¹ https://www.dfg.de/en/research_funding/principles_dfg_funding/diversity_dimensions/index.html

European Commission Directorate-General for Research and Innovation²²	Europe	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Horizon 2020 promotes the inclusion of gender/sex analysis in research and innovation (R&I) to improve the scientific quality and social relevance of R&I outputs 	<ul style="list-style-type: none"> • Applicants are asked: Where relevant, describe how sex and/or gender analysis is taken into account in the project
Forschungsförderungsgesellschaft (FFG); Austrian Research Promotion Agency²³	Austria	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Grant applicants are expected to demonstrate that gender has been considered in analyses, outputs and that the team is gender-balanced 	<ul style="list-style-type: none"> • Guidelines - Applicants and reviewers are asked: Has gender been considered? (p12, section 1.4) Are research teams gender-balance? (p13, s2.3) Will outputs provide gender-equal benefits to users? (p14, s3.3)
Fonds zur Förderung der wissenschaftlichen Forschung (FWF); Austrian Science Fund²⁴	Austria	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • FIX the Knowledge: Gender-related analyses are mandatory in the Special Research Programmes (SFBs) and Doctoral Programmes (DKs) 	<ul style="list-style-type: none"> • <u>Checklist for Gender in Research</u>
Health Research Board²⁵	Ireland	<ul style="list-style-type: none"> • Sex and gender 	<ul style="list-style-type: none"> • Integration of sex and gender based analysis into research 	
Irish Research Council (IRC)²⁶	Ireland	<ul style="list-style-type: none"> • Sex and gender 	<ul style="list-style-type: none"> • Consider if sex/gender dimension is relevant to a proposal • Integration of sex and gender based analysis into research • More equal gender representation in the research population • Gender-blind review 	<ul style="list-style-type: none"> • Gender-blind assessment/review process • Requirement to indicate if sex/gender dimension is present and how it will be addressed in the research • Training workshops/materials

²² https://ec.europa.eu/research/swafs/pdf/pub_gender_equality/2016-03-21-Vademecum_Gender%20in%20H2020-clean-rev.pdf (pages 12-14)

²³ https://www.ffg.at/sites/default/files/dok/il_kooperativueprojekte_v31.pdf

²⁴ <https://www.fwf.ac.at/en/about-the-fwf/gender-issues/fix-the-knowledge>

²⁵ <https://www.hrb.ie/funding/research-policies-and-practices/research-practices/gender/>

²⁶ https://research.ie/assets/uploads/2013/01/irish_research_council_gender_action_plan_2013_-2020.pdf

Ministerio de Ciencia, Innovacion y Universidades (Ministry of Science, Innovation and Universities) ²⁷	Spain	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Policy includes mainstreaming of gender, the participation of women in all scientific fields and the incorporation of gender issues in research content and methodology 	
National Institutes of Health (NIH) ²⁸	US	<ul style="list-style-type: none"> • Sex/gender • Racial/ethnic minority groups • Other biological variables (age, socioeconomic status, BMI, comorbidities) 	<ul style="list-style-type: none"> • Mandated by law to include women and minority groups in all NIH-funded research • Clinical trials must report differences by sex/gender, race and ethnicity • Sex as a biological variable must be included in all research designs and analyses for human and animal studies • Must justify not undertaking sex and gender based analysis 	<ul style="list-style-type: none"> • Guidelines for reviewing • Decision tree for reporting sex/gender, race and ethnicity in annual reports • Instructions for applicants to explain approach to sex (as a biological variable) • Workshop on preclinical research
National Institute for Health Research (NIHR) ²⁹	UK	<ul style="list-style-type: none"> • Underserved groups: groups under-represented in research who also have a high healthcare burden 	<ul style="list-style-type: none"> • INCLUDE project: Inclusion of underserved important for generalisability of research outputs; to understand different impacts of intervention; to ensure all groups get offered treatment and that delivery is successful at reaching all 	<ul style="list-style-type: none"> • List of underserved groups • List of potential barriers to inclusion • Framework to guide researchers in designing inclusive research; for reviewers to assess inclusive research; for those delivering research
Norges forskningsråd (Research Council of Norway) ³⁰	Norway	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Applicants should describe the relevance of gender perspectives 	

²⁷ <https://www.ciencia.gob.es/portal/site/MICINN/menuitem.7eeac5cd345b4f34f09dfd1001432ea0/?vgnnextoid=f1c443ce850c6610VgnVCM1000001d04140aRCRD>

²⁸ <https://orwh.od.nih.gov/sex-gender>

²⁹ <https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435>

³⁰ Gender equality and gender perspectives in research: <https://www.forskningsradet.no/en/Adviser-research-policy/strategies-and-plans/>

Vetenskapsrådet (Swedish Research Council)	Sweden	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Grant applicants required to describe whether sex and gender perspectives are relevant, how they will be included (or justify exclusion) • Assessment of quality includes management of sex and gender 	<ul style="list-style-type: none"> • Applicant guidance includes instructions on reporting sex and gender perspectives
Vinnova	Sweden	<ul style="list-style-type: none"> • Sex and gender • Cross-disciplinary 	<ul style="list-style-type: none"> • Expects integration of a sex and gender perspective in research and innovation 	
World Health Organization (WHO)³¹		<ul style="list-style-type: none"> • Sex and gender 	<ul style="list-style-type: none"> • Health research, policies and programmes should give due attention to gender considerations and promote equity and equality between women and men • Include gender analysis 	
ZonMW (Organisation for Health Research and Development)³²	Netherlands	<ul style="list-style-type: none"> • Sex and gender • Diversity – e.g. sex, age, socio-economic situation, education level, sexual orientation, migration and cultural background 	<ul style="list-style-type: none"> • Gender and Health Program funds research explicitly linked to sex and gender analysis to reduce the knowledge gap about gender differences • Overarching 'Diversity' theme includes exploring sex and gender, ethnicity and youth policy • Sex and gender based analysis must be considered but may be excluded if not relevant to the project 	<ul style="list-style-type: none"> • <u>FAQs</u> (based on Gendered Innovations and CIHR): <ul style="list-style-type: none"> ○ Taking sex/gender into account at different stages of research ○ Relevance of sex/gender to a specific research question ○ When sex/gender is not relevant • Guidance on making research multicultural

Source: Individual funder websites and Tannenbaum C *et al.* Sex and gender analysis improves science and engineering. *Nature* 2019;575:137-146.

³¹ <https://www.who.int/gender/mainstreaming/ENGwhole.pdf>

³² Gender and Health Program (funded by Ministry of Health, Welfare and Sport): <https://www.zonmw.nl/nl/over-zonmw/diversiteit/programmas/programma-detail/gender-en-gezondheid/>

Table 2: Wider initiatives

FUNDER	COUNTRY	DIMENSIONS	SCOPE AND PURPOSE	TOOLS
Gendered Innovations³³	US (Stanford University)	Gender and Sex	<ul style="list-style-type: none"> • Avoiding doing research wrongly – add value • Integrating sex, gender and intersectional analysis 	<ul style="list-style-type: none"> • Provides practical methods for sex and gender analysis • Case studies – animals/human, cross disciplines
GENDER-NET Plus³⁴	European Union	Gender and Sex	<ul style="list-style-type: none"> • A policy initiative, funded by the European Commission with partners from 13 countries in Europe and North America, to promote gender equality in research institutions and improve the integration of the gender dimension in research 	<ul style="list-style-type: none"> • Supporting 16 transnational projects
Kifinfo³⁵	Norway	Gender and Diversity	<ul style="list-style-type: none"> • Committee for Gender Balance and Diversity in Research 	<ul style="list-style-type: none"> • Various publications, evidence and action plans to inform and support diversity in research
Libra³⁶	Europe	Gender and Sex	<ul style="list-style-type: none"> • Raise awareness of sex/gender • Policies for experimental design • Deliver training/teaching • Engage funders/industry to ensure integration of sex/gender dimension 	<ul style="list-style-type: none"> • Workshop on experimental design • Case studies on basic science research
Trial Forge³⁷	UK (Methodology Hubs/NIHR)	Ethnicity and Underserved	<ul style="list-style-type: none"> • INCLUDE Ethnicity Framework • Policy on inclusion in trials 	<ul style="list-style-type: none"> • Framework with 4 key questions

³³ <https://genderedinnovations.stanford.edu/>

³⁴ <http://www.gender-net.eu/>

³⁵ <http://kifinfo.no/en/content/committee-gender-balance-and-diversity-research-kif-0>

³⁶ <https://www.eu-libra.eu/>

³⁷ <https://www.trialforge.org/trial-forge-centre/include/>

Appendix 3 - Workshop Agenda & Papers

Embedding Diversity in Research Design

- inclusive research with human participants -

Online Workshop - Friday 27 May 10:00h – 13:00h

Purpose of the Workshop

Key aims of this workshop are:

- To share information about MRC activities to inform future policy and guidance on diversity in research design (inclusive research design), including
 - Community perceptions
 - Current practice in funding applications
 - Experience with developing a new policy on sex in experimental design for animal research
- To explore the benefits and challenges of embedding diversity in research design and conduct
- To consider how MRC might support the research community to embed considerations of diversity more widely in research design and conduct
- To consider how MRC's funding process might be developed to promote and facilitate inclusive research design
- To explore methods for monitoring diversity in research design and conduct for studies funded by the MRC.

The outputs from this workshop will inform the further development of MRC policy and guidance on inclusive research design, including guidance for applicants and peer reviewers.

Workshop Attendees

		MRC committee membership (current or former)
Professor Jill Pell	University of Glasgow	MRC Council
Professor Tom Gaunt	University of Bristol	PSMB, BMBR
Professor Catherine Williamson	Kings College London	PSMB
Professor Linda Bauld	University of Edinburgh	PSMB
Professor John Wain	Quadram Institute, Norwich	IIB
Professor Faith Osier	Imperial College London	IIB
Professor Adam Cunningham	University of Birmingham	IIB
Professor Ann John	Swansea University	NMHB
Professor Trevor Sharp	University of Oxford	NMHB
Professor Christopher Yau	University of Oxford	MCMB
Professor Ann Morgan	University of Leeds	DPFS
Professor Robin Choudhury	University of Oxford	CARP
Professor Paramjit Gill	University of Warwick	Clinical Training
Professor Monica Busse	Cardiff University	Clinical Training
Professor Lynne Corner	Newcastle University	Multimorbidity Panel
Professor Shaun Treweek	University of Aberdeen	
Professor Nyovani Madise	African Institute for Development Policy	AGHRB
Professor Ruth Keogh	London School of Hygiene and Tropical Medicine	BMBR
<i>Unable to attend but submitted written comments</i>		
Professor Alastair Denniston	University of Birmingham	Data Science

Key: *PSMB Population and Systems Medicine Board*
IIB Infections and Immunity Board
NMHB Neurosciences and Mental Health Board
DPFS Developmental Pathway Funding Scheme
BMBR Better Methods Better Research Panel
CARP Clinical Academic Research Partnerships Panel
AGHRB Applied Global Health Research Board

MRC Head Office Staff

Rachel Knowles
Ivan Pavlov
Stella Child
Christina Mulligan

WORKSHOP AGENDA

Session 1 – Developing an inclusive research process

- 10:00 Welcome
- 10:05 Introduction to the workshop (Chair)
- 10:20 *Key findings from MRC consultation and grants analysis* – MRC Policy Ethics and Governance team
- 10:40 Breakout groups 1
- 11:00 Feedback from breakout groups 1
- 11:20 BREAK (10 mins)

Session 2 – Changing the funding process

- 11:30 *Funder approaches to diversity in research design* – Lilian Hunt, Head of Equality Diversity and Inclusiveness in Science and Health (EDIS)
- 11:45 *The INCLUDE Project* – Gary Nestor, Head of CRN Cluster E & NIHR-INCLUDE Deputy Lead
- 12:00 Breakout groups 2
- 12:20 Feedback from breakout groups 2
- 12:40 Mentimeter – How could we encourage change?
- 12:50 Thank you (Chair)
- 13:00 CLOSE