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An Audit of Socio-demographic and Economic Indicators Collection in [add database] for People with [add disease / condition / attribute] in [add place]: A Template

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Inclusive Research Oversight Board

An Audit Protocol: A Template[1]

[green text=instructions, blue text=standard wording/template, red text= add/change the content]

Please see the flow chart to help you decide if completing an audit is the most suitable choice, and read the instructions below before filling out this template:

A list of abbreviations:

BRC	Biomedical Research Centre
CRF	Clinical Research Facility
EPR	Electronic Patient Records
HDRC	Health Determinants Research Collaboration
HRC	HealthTech Research Centre
IRM	Inclusive Research Methods
IROB	Inclusive Research Oversight Board
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PPIEP	Patient and Public Involvement and Engagement and Participation
QIP	Quality Improvement Projects
UoM	University of Manchester
UREC	University Research Ethics Committee

[1] This template is adapted from AuditTempBSH73management-of-post-transplantation-lymphoproliferative-disorder-PTLD-in-adult-solid-organ-transplant-SOT-recipientsFinal. (Last Accessed 15/03/2025).

Key instructions:

1. This audit template has been developed for the University of Manchester and four National Institute for Health and Care Research (NIHR) infrastructures: Biomedical Research Centre (BRC), Clinical Research Facility (CRF), Health Determinants Research Collaboration (HDRC), and HealthTech Research Centre (HRC) and the relevant partners working with them.
2. Please see the flow chart below to decide if you need to use this template.
3. You can fill out the contact form here to get in touch with a member of the Inclusive Research Methods (IRM) team to gain more information and / or support.
4. It is the responsibility of the lead researcher to conduct the audit ethically. In relation to the purpose of the audit and the necessary number of indicators to be collected, consult the relevant local department (e.g. Clinical audit department within the Trust) about the indicator data collection and the local guidelines on consent. You should review the recommended number of core indicators data (highlighted in orange boxes below) as part of the audit to help with your plans for improving inclusivity in your research. In consultation with the IRM team, additional indicators can be added (highlighted in light blue boxes below) to the audit where appropriate to a specific study.
5. This template can be customised according to the needs of the specific research and research team.
6. Before starting the audit, the project team should also consider approaching the relevant Patient and Public Involvement, Engagement and Participation (PPIEP) team for their advice.
7. The terminologies used here (people, patients, service users) need to be adapted to the needs of the specific audit.
8. If the audit is carried out by NHS Trust colleagues via electronic patient record (EPR) or similar system, you can store data on encrypted and password-protected NHS Trust computers. If the audit is carried out via University colleagues, a research database can be used and stored as per the data protection policy of the University. For CRF, HDRC and HRC, similar data management and storage principles can be applied.
9. The individual who is leading the audit or their team member should have full access to the data. If the data is already grouped and anonymised, use high-level summary statistics to report findings.
10. Explain the data collection purpose of the audit (in the ethics application / data management plan etc.) as follows for a prospective study: “The data collected during this audit 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.” See the document here (see pages 5-6 under the ‘Collecting EDI characteristics of research sample for monitoring inclusivity’ section). The recommended standard paragraphs for UREC applications (patient information sheet / consent / online application / data management protocol) can be obtained from the IRM team. The audit team also need to include their dissemination plans (conference presentation, journal articles etc) if they want to publish the results in

anonymous format. Overall, the audit team should clearly state the purpose of the audit and explain how the results will be utilised (e.g. for future grant applications or to inform research). The lead researcher needs to decide whether to include this template as part of the original research application.

11. The person who leads the audit should decide whether to collect data prospectively or retrospectively. A prospective audit involves ongoing data collection from the start of the audit process, whereas a retrospective audit uses existing data collected before the start date of the audit process.[2] In relation to getting consent for a prospective audit, the research team can justify the purpose of the audit as part of the ethics application of the main research study or put in an amendment. The audit team need to consider this as part of local NHS projects too (e.g., health improvement projects/Quality Improvement Projects (QIP).
12. The data collection should be carried out by authorised personnel from the audit team who are trained in the safe and secure management of data. New staff and students joining the project must complete the relevant training on data security and management provided by the relevant trust, university, or organisation. Please check the relevant websites for training specific to your organisation or institution. The person who leads the audit should ensure safe and secure management of data.
13. The number of individuals/service users to be audited (all or a sample) can be determined based on the sample selection criteria in relation to the topic, the population of interest, and the nature of data collection. Based on the purpose of the audit, you can also consider power calculations and contacting a statistician.
14. The IRM team will pilot this template with selected projects and will review and update the template in the future as required. Please provide your feedback to IRM team to improve this template further using the contact form [see instruction 3].
15. At the end of the audit cycle, the project team can discuss the findings with IRM team to decide on the next steps in relation to embedding inclusive research methods in future research plans. The audit can also be used to inform future grant and ethics applications for monitoring anonymised non-linked indicator data.

[2] Please see https://cdn.southampton.ac.uk/assets/imported/transforms/content-block/UsefulDownloads_Download/6580710E495E4E69885C59E4AA2B12F0/NSAMR%20Audit.pdf (Last accessed 01/05/2025).

Decision chart for indicators audit* v1/24.07.2025 (adapted from the University of Manchester ethics decision tool)

This chart is developed for the staff at the University of Manchester, National Institute for Health and Care Research (NIHR) infrastructures: Biomedical Research Centre (BRC), Clinical Research Facility (CRF), Health Determinants Research Collaboration (HDRC), HealthTech Research Centre (HRC), and their collaborating NHS Foundation Trusts

Consider the following 4 circumstances to decide on doing an audit

1. Is the topic you are interested in part of the report titled 'Differences in prevalence of health conditions being identified in Primary Care across areas of Greater Manchester, Blackpool and Preston: hot and cold spot analysis'*, which discusses 19 health conditions, as well as patients with a learning disability or those receiving palliative care?

Yes

No

2. Are you interested in using anonymised non-linked monitoring of indicators in your research?

Yes

No

3. Is there a database or disease register for the topic you have in mind to collect the data from?

Yes

No

4. Is it possible for Inclusive Research Methods team to have access to your data?

Yes

No

Use the NIHR workforce questions, and the UREC-recommended standardised paragraphs for monitoring data* in the ethics application, and refer to 'A report on indicators in health research- An update'*

Speak to the inclusive Research Methods team

Use the audit template and work with Inclusive Research Methods team

*Please see the URL links to the following documents in the 'Useful Resources' section:

1. *Differences in Prevalence of Health Conditions Being Identified in Primary Care Across Areas of Greater Manchester, Blackpool and Preston: Hot and Cold Spot Analysis*
2. *NIHR's Inclusive Research Plans (New NIHR Conditions, Oct '24)* – for the UREC-recommended standardised paragraphs (see pages 5–6)
3. *A Report on Indicators of Inclusivity in Health Research – An Update*

Decision flowchart

Key documents: The Inclusive Research Methods (IRM) Team has developed two documents to support your inclusive research steps. The first is called '*Differences in prevalence of health conditions being identified in Primary Care across areas of Greater Manchester, Blackpool and Preston: hot and cold spot analysis*' which demonstrates the disparities in the prevalence of various health conditions (see table 1) across Greater Manchester, Blackpool, and Preston with a focus on highly deprived areas using a technique called "hot and cold spot" analysis. The second is *'A report on indicators of inclusivity in health research- An update'*. This report provides an analysis of indicators in health research, including the protected characteristics, and lists 17 indicators and their sub-indicators to ensure data collection for both monitoring and research purposes. Inclusive Research Oversight Board (IROB) recommends using the NIHR workforce questions for anonymised non-linked monitoring (this will need to be justified in both ethics applications and data management plans).

Existing databases / disease registers: These are different sources of data depending on the end-user of this audit template. NHS Trust researchers can collect data from the Electronic Patient Records (EPR) or a similar system. For CRF researchers, it can be a CRF database, NIHR databases, or patient recruitment records. Researchers from the HDRC and HRC need to think about access they have to databases of their population of interest. When these data are unlikely to be found in one place, researchers need to consider strategies to examine dedicated research databases and electronic patient records or other relevant sources of data together. See instruction number 8.

An Audit of Socio-demographic and Economic Indicators Collection in [add database] for People with [add disease / condition / attribute] in [add place]:

Name of the NHS Trust(s) (if applicable)	
Name of the NIHR infrastructure (BRC/CRF/HDRC/ HRC)	
Name of the investigator	
Name of the relevant IRM team member	
Disease/Topic	
Title	An Audit of socio-demographic and economic indicators in [add database] for People with [add disease / condition / attribute] in [add place]
Background	Recording demographic characteristics for anonymised non-linked monitoring is key to ensuring inclusivity and diversity in effective patient care and health research (Washington et al., 2023). [Please see '*A report on indicators of inclusivity in health research- An update'* for more information]. The Equality Act (2010)[3] recognises 9 protected characteristics: age, disability, gender [reassignment], marriage and civil partnership, pregnancy and maternity, race[4] [ethnicity included], religion or belief, sex, and sexual orientation. In order to monitor these protected characteristics, the National Institute for Health and Care Research (NIHR) define the indicators to be collected as age, disability, national identity, ethnicity, religion, sex, gender, sexual orientation, marriage or civil partnership, parental leave, caring responsibilities, and socio-economic background.[5]

[3] The definitions for each protected characteristic can be found in the Equality Act 2010 here: https://www.legislation.gov.uk/ukpga/2010/15/contents (Last accessed 26/03/2025).
[4] Ethnicity is defined under race in the Equality Act.
[5] Socio-economic status is not part of protected characteristics but is recommended by the NIHR.

	[Contact IRM team for the standard recommended NIHR wording for collection of indicators] The recommended key indicators to be audited are: age, ethnicity, religion, sex, gender, sexual orientation, and marriage or civil partnership. Optional indicators include: disability, national identity, parental leave, caring responsibilities, and socio-economic background. By understanding the available data—or acknowledging the lack of recorded or collected data related to these indicators, stakeholders can plan and implement steps towards improving inclusivity. This includes creating a baseline dataset of target populations at Host Trusts, Higher Education Institutions, and their collaborating organisations in Greater Manchester. By comparison and repeated analysis of the consolidated dataset over time, researchers can measure changes in diversity in participation as needed in their area of interest/research/services/activities. [The person who leads the audit should decide the number of indicators to be included in the design].
Aim & objectives	The aim of this audit is to determine how many people with [add disease / condition / attribute] have their protected characteristics recorded in [database] in [add place]. The objectives are: 1. To identify any missing data in the recording of protected characteristics of people with [add disease / condition / attribute] in [add place] 2. To identify the number of people with [add disease / condition / attribute] who declined to share their data
Standards & criteria	1. Every person with [add disease / condition / attribute] should include their socio-demographic and economic indicators recorded in the [database] in [add place]. All people should have received a confirmed [add disease] diagnosis [change this to [attribute or equivalent] if not a clinical audit on a disease population]. 2. All people should have given consent for their socio-demographic and economic indicators data to be used for anonymised non-linked monitoring purposes.[6]

[6] Please confirm the consent requirements for audits with the clinical audit department at the hospital or the university.

<table>
<tr><td>Method</td><td>Sample selection:

Inclusion criteria[7]

1. All people who have a confirmed diagnosis of [add disease]. [change and adapt this to [attribute or equivalent] if not a clinical audit on a disease population].
2. All people who consented for their socio-demographic and economic indicators data to be used for anonymised non-linked monitoring purposes.

Either use a retrospective audit design and run reports on patient lists and measure the proportion of patients with each characteristic recorded during a XX month period OR prospectively investigate a sequential 100 (or equivalent) patients attending out-patient clinics [or adapt this according to the non-clinical audit purpose].

Data to be collected on proforma (see below).</td></tr>
<tr><td>Results</td><td>The results of this audit show the following compliance with the standards.

Retrospective / Prospective audit design

Audit period:

Total number of people included in the audit:

<table>
<tr><td rowspan="2">Indicator</td><td colspan="2">Number (and %) of people for whom the indicator has been entered</td><td colspan="2">Number (and %) of people recorded to have explicitly declined to provide data</td><td colspan="2">Number (and %) of people for whom there was no data entry for the indicator</td></tr>
<tr><td>Number</td><td>%</td><td>Number</td><td>%</td><td>Number</td><td>%</td></tr>
<tr><td>1 Age (Year of birth):</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2 Ethnicity:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>3 Religion:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>4 Sex:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>5 Gender:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

[7] The inclusion criteria should be adapted to be applicable to patients under 18 or where individuals cannot consent for themselves. The project team need to contextualise the audit in relation to the site (e.g. university, national referral centre, disease specific hospital etc), specific patient list and / or its format as well as rare diseases types.

	6 Sexual orientation:						
	7 Marriage or civil partnership:						
	Optional indicators						
	1. Disability:[8]						
	2. National identity:						
	3. Parental leave:						
	4. Caring responsibilities:						
	5. Socio-economic background:						

Summary of data completeness	**Number**	**Percentage**
Total people with [add disease / condition / attribute]		
People with all core indicators recorded		
People with partial core indicators recorded		
People who declined to share data		
People for whom there was no data entry for socio-demographic and economic Indicators		

Conclusion	[to be developed based on findings]
Recommend-ations	[The results will be used to make recommendations for the best method to improve reporting of protected characteristics in [add place]]

[8] Learning disability is explicitly listed in some trusts' databases but no other disabilities. Please consider this while designing the audit in the setting.

Action plan	[to be developed based on findings and recommendations]
Re-audit date	
Reference	Washington, V., et al. (2023). 'Diversity, equity, and inclusion in clinical research: A path toward precision health for everyone' *Clin Pharmacol Ther*, 113 (3), pp. 575-584. DOI: 10.1002/cpt.2804.

Acknowledgements
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Useful resources

- Standard recommended wording for collection of indicators (NIHR Questionnaire – Qualtrics & paper versions) can be obtained from the IRM team using the contact form here: (https://www.qualtrics.manchester.ac.uk/jfe/form/SV_80vMg3UT0bvLBu6).
- *Differences in prevalence of health conditions being identified in Primary Care across areas of Greater Manchester, Blackpool and Preston: hot and cold spot analysis*; https://www.manchesterbrc.nihr.ac.uk/wp-content/uploads/2025/03/Hot-and-Cold-Spot-Analysis-Report-July-2024.pdf
- *NIHR's Inclusive Research Plans (New NIHR Conditions, Oct '24)*, https://www.manchesterbrc.nihr.ac.uk/wp-content/uploads/2025/03/NIHR-Inclusive-Research-new-conditions-of-funding-report.pdf. For the UREC recommended standardised paragraphs for monitoring data in ethics application (patient information sheet / consent / online application / data management protocol). See pages 5-6 under the 'Collecting EDI characteristics of research sample for monitoring inclusivity' section
- *A Report on Indicators of Inclusivity in Health Research – An Update*, https://www.manchesterbrc.nihr.ac.uk/wp-content/uploads/2025/03/indicator-report_final_28.01.25.pdf
- Inclusivity website (resources/links for IRM EDI PPIE): https://www.manchesterbrc.nihr.ac.uk/brc-staff-information/research-inclusion-resources/
- Monthly drop-in sessions for Inclusive research methods support - second Tuesday of the month at 2-3pm using MS Teams https://tinyurl.com/5e5wj9ux You can book with team beforehand (email - IROB@manchester.ac.uk) to guarantee a slot or just turn up on the day.
- The IRM Team is here to help as part of work scoped under the four named Manchester NIHR infrastructures. Whether you have questions, feedback, are interested in advice for a specific project, bid or Fellowship or longer-term project support / collaboration (The IRM team can be costed in as part of the research team if appropriate). Please get in touch by completing the contact form below: https://www.qualtrics.manchester.ac.uk/jfe/form/SV_80vMg3UT0bvLBu6

Data collection proforma

Individual information

Record ID:

Hospital / Trust / team name:

Consent information

Consent for data use: Yes / No / Prefer not to say
Date of consent: DD / MM / YYYY

Individual information

Date of Appointment / consultation: DD / MM / YYYY [please delete as needed]
Hospital /Trust / team:

Record ID	Indicator	Recorded (Yes / No)	Not recorded (refused to share data)	Not recorded (no data entry)
	1 Age (Year of birth):			
	2 Ethnicity:			
	3 Religion:			
	4 Sex:			
	5 Gender:			
	6 Sexual orientation:			
	7 Marriage or civil partnership:			
	Optional indicators			
	1. Disability:			
	2. National identity:			
	3. Parental leave:			
	4. Caring responsibilities:			
	5. Socio-economic background:			

Retrospective / Prospective audit design

Total number of people included in the audit:

Indicator	Number (and %) of people for whom the indicator has been entered		Number (and %) of people recorded to have explicitly declined to provide data		Number (and %) of people for whom there was no data entry for the indicator	
	Number	Percentage	Number	Percentage	Number	Percentage
1 Age (Year of birth):						
2 Ethnicity:						
3 Religion:						
4 Sex:						
5 Gender:						
6 Sexual orientation:						
7 Marriage or civil partnership:						
Optional indicators						
1. Disability:						
2. National identity:						
3. Parental leave:						
4. Caring responsibilities:						
5. Socio-economic background:						

Summary of data completeness	Number	Percentage
Total people with [add disease / condition / attribute]		
People with all core indicators recorded		
People with partial core indicators recorded		
People who declined to share data		
People for whom there was no data entry for socio-demographic and economic Indicators		