

Collecting, storing and sharing demographic and equity, equality, diversity and inclusion (EEDI) data

Frequently asked questions (FAQs)

This FAQ document provides guidance to researchers for how to collect, store and share demographic and equity, equality, diversity and inclusion (EEDI) data in your project.

For clinical trials, we've included information to help you complete the relevant permissions and approvals forms through the IRAS (Integrated Research Application System).

Demographic data should be treated with the same level of care and sensitivity as other clinical data. This includes confidentiality and compliance with data protection regulations.

This document outlines our recommendations to help you collect, store and share demographic and EEDI data in an appropriate and sensitive manner. We understand this guidance may not be suitable for every trial or study.

We try to make sure the information in this guidance is kept up to date, but changes are possible. We encourage you to get in contact with us if you need further assistance or if there's anything not covered in this document. If you have any questions, you can email us at research@mssociety.org.uk or call us on 020 8438 0822.

Contents

1. General questions	3
1.1. Why is it important to collect and report demographic and EEDI data?	3
1.2. Which studies should collect demographic data?	3
2. Collection and storage of Data	4
2.1. How should I collect demographic data?.....	4
2.2. When should I collect demographic data?.....	4
2.3. What demographic and EEDI data should I collect (UK sites)?.....	4
2.4. What demographic and EEDI data should I collect (non-UK sites)?	5
2.5. Do I need to obtain consent for the collection and storage of demographic and EEDI data?	5
2.6. How do I handle and store data to maintain confidentiality?	6
3. Sharing and reporting of data.....	6
3.1. Why should I publicly share and report demographic and EEDI data?.....	6
3.2. How should I share demographic and EEDI data from my study?	7
3.3. Do I need to share my data with the MS Society?.....	7
3.4. Do I need to anonymise or aggregate demographic and EEDI data before sharing and reporting?	7
3.5. Can I share demographic and EEDI data with other researchers?.....	7
4. Your IRAS (Integrated Research Application System) application	8

4.1. What is an inclusivity and diversity plan?	8
4.2. IRAS Specific Questions	8

1. General questions

1.1. Why is it important to collect and report demographic and EEDI data?

Some groups of people are consistently under-represented in research. This includes:

- People living in rural areas
- People with higher levels of disability
- People with less education or money
- Older people
- People from minoritised ethnic groups
- Pregnant people
- Anyone who already experiences other health inequalities. For example, reduced access to healthcare professionals and services.

This under-representation can lead to biased results and healthcare solutions that may not be effective for everyone. It also prevents people from benefiting from study participation. For example, the benefits that come with increased clinical engagement.

To address this, we're committed to making the studies we fund more inclusive for people with MS. This includes a deliberate focus on recognising and addressing the sociocultural, psychological and biological differences that exist amongst people with MS.

Collecting and reporting demographic data is a key part of this process, it allows you to:

- Understand the diversity, or lack thereof, of participants in your study
- Identify gaps where certain people may be excluded or under-represented
- Understand the barriers to participation in your study
- Design targeted strategies, in and outside of the traditional routes, to recruit people from under-represented groups.
- Help develop healthcare solutions that're effective and appropriate for all people with MS
- Be accountable to make MS research more inclusive

1.2. Which studies should collect demographic data?

Any study involving more than 10 participants should collect and report demographic data. Below is a list of studies we expect to collect demographic data. This is not an exhaustive list.

- Interventional studies
 - Medicinal products
 - Medical devices
- Non-pharmacological and behavioural research
 - Symptom management trials
 - Behavioural or psychological studies
 - Early phase and exploratory studies

- Pilot studies
 - Feasibility studies for randomised controlled trials
 - Implementation studies
 - Observational studies
- Data registries
 - Tissue, blood or other biobanks

2. Collection and storage of Data

2.1. How should I collect demographic data?

Demographic and EEDI data can be collected in several different ways, including:

- Questionnaires or forms completed by participants
- Interviews or health visits conducted by researchers or health care professionals
- Electronic health records, if available and consent is obtained

However the data is collected, it's essential your method of data collection is clear, ethically approved and follows the GDPR principles of data collection and storage to ensure confidentiality.

2.2. When should I collect demographic data?

Some demographic data (i.e. sex and age) may be collected during a pre-screening phase. More detailed information (i.e. race and ethnicity, gender, socioeconomic background, sexual orientation and religious beliefs) is usually collected at study screening stage, to reduce the burden on study participants and study sites.

However, collecting at study screening stage means there's a paucity of data regarding people who don't fulfil pre-screening requirements. This means we may be missing groups of people who're facing barriers during the earliest phases of recruitment. For example, those with language or technology related barriers.

To address this gap, we recommend you consider adding a limited number of demographic questions to any pre-screening questionnaire. This would help identify under-representation and potential barriers experienced by specific groups of people at the earliest stages of recruitment.

2.3. What demographic and EEDI data should I collect (UK sites)?

The design of demographic and EEDI questions should align with any statutory reporting requirements. But should, wherever possible, allow people to describe themselves in ways that best reflect how they identify.

Our recommendations are based on the [Diversity and Inclusion Survey \(DAISY\) Question Guidance](#). These recommendations will be updated as and when guidance is reviewed.

Wherever possible, we encourage all the studies we fund to follow our recommended [survey template](#). This allows us to aggregate data for all our studies. However, we understand it

may not be practical, or relevant to your study to adopt all the questions or follow the exact same question structure.

For example, asking participants about their gender identity rather than their biological sex can provide a more accurate reflection of their lived experience. In some studies, collecting gender identity only may be sufficient, to minimise the amount of data collected. However, in other studies, it may be necessary to collect sex as well. You should choose the approach that's most appropriate for your study.

[Find the template survey and reporting guidance here.](#)

2.4. What demographic and EEDI data should I collect (non-UK sites)?

The approach to collecting demographic data differs between countries due to variations in population demographics, regulatory requirements and cultural sensitivities. These variations can create inconsistent data categories which make it difficult to collate data across UK and non-UK sites.

Regardless of location, we recommend that trials should collect core demographic information, including:

- Age
- Ethnicity
- Gender/sex
- Socioeconomic status

These factors may need to be adapted for local contexts. For example, you may need to include ethnicity categories that reflect local populations (e.g. aboriginal, hispanic, latino/a/x, and more).

If you're unsure how to approach demographic data collection for a specific country, you can get in touch with us at research@mssociety.org.uk

2.5. Do I need to obtain consent for the collection and storage of demographic and EEDI data?

Demographic data should always be regarded as sensitive data. And must be treated with the same level of care, confidentiality, and security as other sensitive and clinical data.

Some demographic questions will form special category data, which is particularly sensitive. This includes:

- Race and ethnicity
- Sexual orientation
- Religious and philosophical beliefs

You need explicit informed consent from participants to both collect and store sensitive data. And you must make sure you handle sensitive data in a manner that is lawful, fair, transparent and complies with the principles and requirements of the Data Protection Act 2018 and UK GDPR.

If you're already collecting sensitive data in your study

You may already be collecting sensitive data as part of your study. If so, you don't need a separate consent question for demographic data, provided these questions are included within the scope of your consent documentation.

If you're not otherwise collecting sensitive data in your study

If sensitive data is not otherwise being collected, you must obtain explicit consent for the collection of demographic data.

For all studies collecting demographic data

In all cases, your consent materials must:

- Tell people what demographic data you're collecting
- Provide a clear description of the purpose of collecting the demographic data
- Present demographic questions sensitively and inclusively, recognising that some people may find them personal or difficult to answer.
- Explain how the data will be stored and used
- Tell people how long the data will be kept
- Provide an option to opt-out of answering sensitive questions. Where not answering a question (for example sex or age) may result in exclusion from the study, this should be clearly communicated with the participant.
- Provide an explanation of participants' rights to withdraw consent at any time, and how this will be handled

2.6. How do I handle and store data to maintain confidentiality?

You should treat demographic data with the same level of care, confidentiality, and security as other sensitive or clinical data.

This means demographic data must be stored securely, accessed by authorised personnel only and handled in compliance with the requirements of the Data Protection Act 2018 and UK GDPR.

You should complete a Data Protection Impact Assessment (DPIA) or check your existing DPIA is up to date. A DPIA helps you to mitigate risks to participant privacy and ensure compliance with the Data Protection Act 2018 and UK GDPR.

3. Sharing and reporting of data

3.1. Why should I publicly share and report demographic and EEDI data?

Sharing and reporting of EEDI data is important because it:

- **Increases transparency** - Ensures accountability in our efforts to make clinical trials more inclusive and representative
- **Builds trust** - Demonstrates efforts to include marginalised groups, which fosters trust and encourages participation in future studies
- **Promotes awareness** - Highlights disparities in trial participation, encouraging the MS research community to address inequities

- **Enhances scientific validity** - Ensures that study findings are relevant for all people with MS, improving the appropriateness and effectiveness of clinical interventions
- **Informs future research** - Provides insights into barriers to participation and helps design more inclusive trials in the future
- **Drives continuous improvement** - Tracks progress over time and identifies areas where additional efforts are needed.

3.2. How should I share demographic and EEDI data from my study?

We encourage demographic and EEDI data to be shared through:

- Peer reviewed scientific publications
- Presentations and posters at conferences
- Lay reports aimed at people with MS

You should consider how you'll appropriately share your findings with marginalised groups to build trust and transparency in the clinical research process.

3.3. Do I need to share my data with the MS Society?

Yes, we're asking all our funded clinical research studies and trials to report anonymised demographic data of their participants on an annual basis.

You can find guidance for how your data should be shared with us in our [demographic and EEDI survey template document](#).

3.4. Do I need to anonymise or aggregate demographic and EEDI data before sharing and reporting?

Yes, you'll need to anonymise demographic or EEDI data before sharing and reporting. Anonymisation is essential to protect participant's confidentiality and ensure compliance with the informed consent agreement, and with GDPR and the Data Protection Act 2018.

You may need to aggregate your data if you have a small sample size for specific sub-groups that could potentially reveal individual identities.

You can find further information on the recommended aggregate categories within our recommended [survey template document](#).

3.5. Can I share demographic and EEDI data with other researchers?

Sharing anonymised individual data requires explicit consent from participants. If you plan to share anonymised data with other researchers or organisations, this must be clearly stated in the consent form. If the data is to be shared with external organisations or for secondary research purposes, participants should be informed of this possibility and given the option to agree or decline.

4. Your IRAS (Integrated Research Application System) application

4.1. What is an inclusivity and diversity plan?

The purpose of an inclusivity and diversity plan is to help you consider who'll be impacted by your research findings. And who may be at risk of being excluded. Your plan will help you consider how you'll address barriers to participation at the trial design stage.

There may be instances in which excluding people may be necessary. The reasons for this exclusion should be detailed within your plan.

You can submit a plan for review as part of your IRAS application. It's not mandatory to submit a plan but is encouraged by the HRA and MHRA. The Research Ethics Committee will use the information in your plan to inform the review of your application.

- You can find more information about the requirements of an inclusivity and diversity plan within the [HRA and MHRA inclusion and diversity guidance](#)
- We recommend you use the guidance from the [NIHR - INCLUDE project](#) to help you design your plan.

4.2. IRAS Specific Questions

When completing the IRAS you should list any demographic and/or EEDI questionnaire as part of the set of non-clinical interventions under the Research procedures, Risks and Benefits section. You should describe the demographic and EEDI data you'll collect, how you'll collect it and the purpose of collecting it.

For transparency, we encourage public reporting of all collected EEDI data. If you're planning to disseminate your EEDI data, you'll need to describe how you intend to report and disseminate the data under the publication and dissemination section of the form. This should include details of how you'll anonymise or aggregate data before dissemination.

Once listed under Section B, any demographic or EEDI questionnaire can be considered under the umbrella of all personal data in the following parts of your application (this may not be an exhaustive list and may vary from trial to trial).

Research procedures, risks and benefits

- The potential risks and burdens for research participants and how will you minimise them?
- Will interviews/questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting?

Confidentiality

- The physical security arrangements for storage of personal data during the study
- How will you ensure the confidentiality of personal data?
- Who will have access to participants' personal data during the study?
- How long will personal data be stored or accessed after the study has ended?
- Give details of the long-term arrangements for storage of research data after the study has ended.

- If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Recruitment and informed consent

- Will identification of potential participants involve access to identifiable information? If yes, describe what measures will be in place to confirm that access to this information will be lawful
- How, when and where will informed consent be obtained?

We're the MS Society.

Our community is here for you through the highs, lows and everything in between. We understand what life's like with MS.

Together, we are strong enough to stop MS.

mssociety.org.uk

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