KEY:

Yellow highlight: For the researcher to edit.

Red text: Suggested text.

*Italic: Boilerplate text for statements on GDPR and Open Data, etc.*

**PARTICIPANT INFORMATION SHEET GUIDANCE FOR RESEARCHERS**

The purpose of the participant information sheet is to provide clear, accessible and sufficient information to a prospective research volunteer so that they can make an informed decision whether to take part in your research. The information sheet should include a range of information to enable informed decision making, including (but not limited to):[[1]](#footnote-1)

* details of what the study is about, who is undertaking the study and why it is being conducted;
* the name of the data controller for the study (normally Northumbria University) and contact details of the Records and Information Manager;
* participation is voluntary; people are free to withdraw at any time without giving a reason and with no negative consequences (e.g. without loss of current services/care);
* eligibility criteria;
* clear details of what participation would involve- i.e. what they would be asked to do, where, for how long etc.;
* the advantages/disadvantages of taking part;
* how confidentiality and anonymity will be addressed within the study;
* the data subject’s rights, including the right to lodge a complaint with the Information Commissioner’s Office (ICO);
* the categories of personal data collected;
* the legal basis of the data processing you are undertaking (normally task in the public interest for university research), and additional legal basis if you are collecting ‘special category’ data (see below);
* the recipients or categories of recipients of the personal data (if any);
* the source from which the personal data originate, if applicable, for example whether it came from publicly accessible sources (e.g. online, social media);
* what will happen to the data you collect- how it will be stored, for how long and with whom / how it will be shared, including whether any automated decision-making will apply, as well as the significance and the envisaged consequences of such processing for the participant;
* what safeguards are in place in relation to personal data transferred out of Europe;
* who has reviewed the study;
* the researcher’s contact details;
* another named person, besides the researcher, whom people can contact (e.g. with any questions / complaints);

It is important that the information is accessible and given in the most appropriate format for the intended sample group. It is your responsibility as the researcher to understand your potential participants’ information needs, and to ensure you are providing information that is accessible and appropriate for the needs and abilities of (the different groups in) your sample. For example, this may mean that an information leaflet will be accompanied with a DVD or audio/visual information. If there are different sample groups within your study it is likely you will need to develop different information leaflets, for example, for children of different ages, or teachers and parents who are being asked to take part in different data collection activities. Creating information leaflets specific to a sample group can mean shorter, clearer and more accessible information leaflets. It may be appropriate to “layer” the information above, so that some of it appears on a single page information sheet given to the participant and other parts are on a project website or in a booklet.

It is important that the potential participant can spend time considering the information without being pressured by the investigator. Potential participants need to be able to discuss the information about the study and their involvement with whomever they wish and be able to ask you questions, have them answered and have plenty of time to decide whether they wish to take part.[[2]](#footnote-2)

For studies submitted through the IRAS process, and where the University is sponsoring the study, you should also include information on the responsibilities of sponsorship, including the sponsors representative, and the complaints procedure:

For example:

The Sponsor (Northumbria University) is ultimately responsible for the safe conduct of the study and the well-being of participants. Any unforeseen circumstances will be reported to the Sponsor’s representative (Research Policy Manager, Research and Innovation Services) and dealt with appropriately.

You should inform participants how complaints will be handled and what redress may be available.

For example:

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this by contacting [insert details]. Details can be obtained from [insert name]. As study Sponsor, Northumbria University has insurance to cover this research study, which includes compensation cover in the event that any claims arise from participation in the study.

**PARTICIPANT INFORMATION SHEET TEMPLATE**

**[Study Title]**

**Participant Information Sheet**

You are being invited to take part in this research study. Before you decide if you would like to take part, it is important that you read this document so you understand why the study is being carried out and what it will involve.

Reading this document, discussing it with others, or asking any questions you might have will help you decide whether you would like to take part.

**What is the Purpose of the Study?**

There should be sufficient information here, some researchers might keep this section short and vague so as not to give away the true purpose of their research and generate expectancy bias. Other researchers might give a lot more information here.

Example: The aim of this study is to examine how different people perform on a commonly used test of problem-solving/reasoning called the Mental Rotation Task.

Example: I have developed a new parent education group to give information to parents about sensory processing, sensory behaviours and intervention strategies in Autism Spectrum Disorder. It is important to find out parents’ views and opinions of the group and whether it helps them with understanding and managing their child’s sensory processing needs. The study will deliver the new education group to a number of parents and then gather their views and experiences of the group. I am conducting this study as part of my MA in [insert course title] at Northumbria University.

**Why have I been invited?**

Make sure that you explain clearly who can or cannot take part, and justify this – i.e. explain why there may be age limits, why you are only seeking to recruit females, etc.

Example: It is important that we assess as many people as possible and you have indicated that you are interested in taking part in this study, and that you are an adult aged between the ages of 18-40.

Example: Because you are a parent who has a child with a diagnosis of Autism who has been referred into the Occupational Therapy Service for an assessment of their sensory processing.

**Do I have to take part?**

Example: No. It is up to you whether you would like to take part in the study. I am giving you this information sheet to help you make that decision. If you do decide to take part, remember that you can stop being involved in the study whenever you choose, without telling me why. You are completely free to decide whether to take part, or to take part and then leave the study before completion. You are welcome to take part in the parent education group and choose not to take part in the research. Deciding not to take part, or leaving the study, will not affect your right to come to the parent education group. (Or: your role, your care etc.).

**What will happen if I take part?**

This must give the prospective participant all the information they need to make an informed choice – i.e. where and when the research takes place, what will be required, how long it is expected to take, etc.

If your study has any special requirements - e.g. to avoid eating or drinking on the morning of the testing - then you must make such requirements very clear beforehand.

If you are testing people individually, or in groups, then you should also state this as well.

Example: You will be asked to attend a testing session held in [room] in [building] at Northumbria University on [date]. After signing a consent form, the investigator will ask you to [insert activity here]. After you have completed the study, the investigator may give you a debrief sheet explaining the nature of the research, how you can find out about the results, and how you can withdraw your data if you wish. It is estimated that the total time to complete this study will be [time].

Example: You will be asked complete a short survey/questionnaire anonymously prior to the education group then you will attend the parent education group with 5 other parents, which will last half a day. Four weeks after the parent education group you will be contacted and asked to complete a repeat of the questionnaire you completed prior to the group and then be asked to participate in a short interview with me, for approx. 45 minutes - 1 hour. This interview will be informal and will be arranged for a day and time that suits you **best and** will take place at the OT service or in your own home, whatever you prefer. With your permission I would audio-record this interview, to make sure I remember everything you talk about.

**What are the possible disadvantages of taking part?**

Think about the person and what might inconvenience them – e.g. time taken, they might experience some embarrassment, they might experience some emotional discomfort etc.

Reassure them that you have thought about such issues and perhaps refer to a Risk Assessment, reassure them about confidentiality, anonymity, and the fact that they can withdraw at any point. If the research relates to sensitive topics or with vulnerable individuals, then describe what support and guidance will be provided during and after their participation.

If the research involves any ‘automated decision making’ then you will need to communicate this to the participants. This is where a system will make decisions about a person automatically without human intervention. You should notify the participant that they have a right to seek human intervention by contacting the lead researcher, referring to the name and contact details at the end of the document.

**What are the possible benefits of taking part?**

Example: By taking part in the study, you will be participating in the parent education group which will hopefully provide you with information regarding sensory processing and strategies which you may be able to use with your child. Also, by taking part and telling us your views of the parent education group you will be helping to develop effective services based on parents’ views.

**Will my taking part in this study be kept confidential and anonymous?**

Example: Yes. Your name will not be written on any of the data we collect; the written information you provide will have an ID number, not your name. Your name will not be written on the recorded interviews, or on the typed up versions of your discussions from the interview, and your name will not appear in any reports or documents resulting from this study. The consent form you have signed will be stored separately from your other data. The data collected from you in this study will be confidential. The only exception to this confidentiality is if the researcher feels that you or others may be harmed if information is not shared.

**How will my data be stored, and how long will it be stored for?**

You should inform participants how long personally identifiable data will be stored for. This should be as little as possible, as per the principles of ‘data minimisation’. The University has retention schedules for different categories of data, and you should follow these as a basis, unless the funder stipulates a different period of retention. Though a funder may expect data to be retained for a longer period, and in many cases made accessible on a data repository, this will almost always be anonymised data rather than personally identifiable data.

**Example:** All paper data **-** including the questionnaires, the **typed-up** transcripts from your interview**,** and your consent forms **-** will be kept in locked storage. All electronic data**,** including the recordings from your interview, will be stored on the University One**D**rive, which is password protected. All data will be stored in accordance with **Northumbria University** guidelines and the Data Protection Act (2018).

**What categories of personal data will be collected and processed in this study?**

Under the EU’s General Data Protection Regulation, if you are collecting personal data indirectly, then you will need to be transparent about what categories of personal data you will collect and process in the study. For example, this might be contact details, financial information, biometric or health data, depending on the nature of the research.

**What is the legal basis for processing personal data?**

GDPR requires researchers to be transparent about the legal basis for undertaking research which will collect and process personal data. GDPR provides **several** legal bases to choose from, but in most cases the legal basis for university research projects will in most cases be Article 6(1) (e) “processing is necessary for the performance of a task carried out in the public interest”.

If the research is collecting special categories of personal data (this is mostly what used to be referred to as ‘sensitive’ personal data, e.g. racial or ethnic origin, political opinions, religious beliefs, sexual orientation) then an additional legal basis is **required,** and this must be communicated to the data subject. Again, in most cases researchers should rely on Article 9 (2)(j) “processing is necessary for scientific and historical research purposes”. Researchers will need additional safeguards in place when processing special categories of personal data**.**

**Who are the recipients or categories of recipients of personal data, if any?**

Who is going to be using, analysing or otherwise processing the personal data, apart from the research team at Northumbria? For example, will the research involve transferring personally identifiable data to third parties for further processing? This may be research teams in other universities, or it may be the funder or partners or other agencies.

If you are intending to transfer personal data of EU citizens outside of the EU, then you will need to ensure appropriate safeguards are in place and communicate what these are to the data subjects in your study. For example, this could involve contacting IT Services to set up a SharePoint site which only the research teams involved in the research can access, which is password protected, with hierarchies of access if appropriate, and with clear onboarding and offboarding procedures to detail how researchers gain access to the system, who approves that access, and how long that access persists (e.g. until the end of the project, or just for part of the project).

**What will happen to the results of the study, and could personal data collected be used in future research?**

Where there is a likelihood that data collected in this study may be used for future research, then you should also let the participants know, either than anonymized data could be used, or that personally identifiable data could be used and the safeguards in place for ensuring it is kept secure. As this often applies to health-related research, we recommend you consult the [suggested transparency wording for participant information sheets](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/) provided by the NHS Health Research Authority.

**Example:** The general findings might be reported in a scientific journal or presented at a research conference, however the data will be anonymized and you or the data you have provided will not be personally identifiable, unless we have asked for your specific consent for this beforehand. The findings may also be shared with other organizations/institutions that have been involved with the study. We can provide you with a summary of the findings from the study if you email the researcher at the address listed below.

**Who is organising and funding the study?**

State the organizer (normally Northumbria University, unless the research is being led by another University) and any other organizations/institutions that have been involved with the research, or the funding.

**Who has reviewed this study?**

The research project, submission reference [insert project ID number] has been approved in Northumbria University’s Ethics Online system. It has been reviewed to safeguard your interests and have granted approval to conduct the study.

Example: Before this study could begin, permissions were obtained from [insert here] NHS Trust and Northumbria University.

**What are my rights as a participant in this study?**

A statement outlining the [individual’s rights under GDPR](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/data-protection-principles/a-guide-to-the-data-protection-principles/) should be included, including the following: a right of access to a copy of the information comprised in their personal data (to do so individuals should submit a [Subject Access Request](https://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---rights-of-the-individual/right-to-subject-access/)); a right in certain circumstances to have inaccurate personal data rectified; and a right to object to decisions being taken by automated means. Participants should also be informed that if they are dissatisfied with the University’s processing of personal data, they have the right to complain to the Information Commissioner’s Office. For more information see [the ICO website](http://www.ico.org.uk/).

**Contacts for further information**

Researcher email: [insert here]

Supervisor email (if applicable): [insert here]

Name another person who can provide independent information or advice about the project.

Name and contact details of the Records and Information Officer at Northumbria University, Duncan James (dp.officer@northumbria.ac.uk).

You can find out more about how we use your information at our [GDPR webpage](https://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/), or by contacting a member of the research team.

1. This guidance should be read in conjunction with section on Data Protection of the [Research Ethics and Governance Handbook](https://www.northumbria.ac.uk/research/ethics-and-governance/). This participant information sheet guide and the Handbook have been updated considering the requirements under the European Union’s General Data Protection Regulation (GDPR) which applies to all organisations collecting personal data for any purpose and come into force on 25th May 2018. [↑](#footnote-ref-1)
2. Researchers undertaking biomedical, clinical, health and/or social care research may wish to use the NHS Health Research Authority recommended wording for Participant Information Sheets to cover transparency requirements under GDPR: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/> This should be read in conjunction with their existing guidance on Participant Information Sheets: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/> [↑](#footnote-ref-2)