**Guidance on completing an Information Sheet**

An information sheet should provide sufficient information to enable potential participants to make an informed decision regarding whether or not to participate in a research project. It should state clearly and transparently that participants are free to choose whether or not to take part, and should provide information about how to request withdrawal from the study. This is both for ethical reasons and in order to comply with the General Data Protection Regulation (from May 2018) and UK data protection legislation.

The language used must be clear and plain, and prepared in consideration of the needs of the audience (this is particularly important when providing information to, for example, children or those for whom English is not their first language). Researchers should take the steps necessary to ensure that all participants in the research (a) understand the process in which they are to be engaged, including why their participation is necessary and what will happen to the data they provide, (b) understand the purpose of the research and how and to whom its research findings will be reported and (c) if applicable, understand that their data could be used for future research projects, if they agree to this.

**It is recommended that the content of an information sheet is:**

* relevant to the proposed research;
* accurate, concise, transparent, intelligible and easily accessible;
* presented on the headed paper of the institution carrying out the research;
* appropriate for the cultural and social context in which it is being given.

**It is recommended that the content of an information sheet does not include:**

* any abbreviations, jargon or technical terms, unless these are fully explained;
* bias or coercion or any inappropriate inducements;
* Language qualifiers such as “may”, “might”, “some”, “often” and “possible”.

**How long should an information sheet be?**

Information sheets should contain relevant information that a reasonable person would want to know (i.e. in order to decide whether or not to participate in a research project). However, certain information is also required legally where personal data is to be collected and used as part of the research (see section below). It is recommended that, where appropriate, an information sheet contains information in the order specified under the headings given on the following page.

The length and design of an information sheet should encourage a prospective participant to read it in full. A participant may take more care when reading a concise information sheet and, thereby, be better informed than if s/he has to read an information sheet that runs into several pages. However, with respect to projects that involve particularly vulnerable participants and/or which require access to sensitive ‘special category’ personal data, the information sheet may need to be relatively longer in order to provide more detailed information. A ‘layered’ approach to providing information may be appropriate (e.g. utilising webpages, leaflets, newsletters etc. in addition to an information sheet).

**Specific information that MUST be provided when processing personal data**

If you will be collecting and using personal data as part of the research, you must comply with the relevant data protection legislation. This includes certain requirements relating to the information you must provide to participants, such as; the legal basis on which you are relying for processing the data, details of who the Data Controller will be (i.e. the organisation which determines the purposes and means of processing the data), who to contact to complain about the use of personal data (ICO and The University Data Protection Officer, Luke Thompson – luke.thompson@sheffield.ac.uk ), information on when the data will be destroyed, where it will be stored and who will have access to the data. Further information on data protection legislation and the information that must be provided to data subjects/participants, as well as a glossary of key terms, is available here: <https://sites.google.com/a/sheffield.ac.uk/gdpr/>.

**Participant Information Sheet**

1. **Research Project Title:**

Is the title self-explanatory to a lay person? Use a simplified title if the original title is too technical.

1. **Invitation paragraph**

Explain that the prospective participant is being asked to take part in a research project.

Example paragraph:

*‘You are being invited to take part in a research project. Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.’*

1. **What is the project’s purpose?**

The background, aim and duration of the project should be given here in lay terms. Include whether this is for an educational qualification.

1. **Why have I been chosen?**

You should explain how the participant was chosen and how many other participants will be recruited.

1. **Do I have to take part?**

You should explain that taking part in the research is entirely voluntary and that if they do not wish to take part, there will be no negative consequences (this will depend on the context of the research – for example, if the participants will be your own students, they may need reassurance that refusal will not impact on their grades; similarly, if the participants will be patients, they may want to know that refusal to take part will not affect their care in any way). In addition, the information sheet should state that the participant may discontinue participation at any time and explain clearly how they should go about this.

Example paragraph:

*‘It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form) and you can still withdraw at any time\* without any negative consequences. You do not have to give a reason. If you wish to withdraw from the research, please contact…..”*

\*Please note that if there is a point at which it will not be possible for a participant’s data to be withdrawn from the research (e.g. once data have been anonymised and included within a large dataset), then it should be made clear that, whilst they can withdraw from any on-going or future data collection, their data cannot be removed from the study beyond this point. Ideally a date or time-frame should be provided for this.

1. **What will happen to me if I take part? What do I have to do?**

You should state how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to participate and for how long each time. You should explain if travel expenses are available. You should include the type of information that will be sought and why the collection of this information is relevant for achieving the research project’s objectives.

You should set out simply and clearly the research methods you will use and explain what exactly will happen in practical terms (e.g. blood tests, interviews etc.). Whenever possible you should draw a simple flowchart or plan indicating what will happen on each occasion they are to participate. You should explain the participant’s responsibilities, setting down clearly what you expect of them, and state if there are any lifestyle restrictions as a result of participating.

Where a participant is to be interviewed, an outline of the topics that will be covered in the questions should be provided, and the questioning style should be explained (e.g. clarify if questions will enable open as well as closed answers to be given in relation to a particular topic; e.g. clarify which aspects of the topic participants should be able to discuss in-depth and which not in-depth).

1. **What are the possible disadvantages and risks of taking part?**

Any reasonably foreseeable discomforts, disadvantages and risks need to be stated. Researchers should make known to the participants any predictable detriment arising from the proposed research process. Any unexpected discomforts, disadvantages and risks to participants which may arise during the research, should be brought immediately to their attention.

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

Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be stated clearly. It is important not to exaggerate the possible benefits to the particular participant during the course of the project. This could be seen as coercive. Example opening sentence:

*‘Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will …’*

1. **Will my taking part in this project be kept confidential?**

Researchers should consult the University’s Research Ethics Policy Note no.2 ‘Principles of Transparency and Consent’ for detailed advice on what information to provide to prospective participants:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/further-guidance/homepage>

You should provide assurances to your participants about the extent to which their identity will be protected, and how this will be achieved. Example paragraph:

*‘All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. You will not be able to be identified in any reports or publications unless you have given your explicit consent for this. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this’.*

Where, due to the nature of the research, it may not be possible to safeguard the confidentiality of the data then the reasons for this should be stated here (for example, if there is a possibility that a participant may disclose information about criminal activity or risks to public safety, which the researcher may be obliged to report to the relevant authorities). Furthermore, the consequences to the participant from data not remaining confidential should be provided here. If the participant specifically wishes to be named in publications or reports on the research findings, then specific consent for this should be obtained as part of the informed consent process.

1. **What is the legal basis for processing my personal data?**

If you will be collecting any personal data (i.e. data which may identify someone), your participants should be informed of the legal basis for processing (i.e. collecting and using) their personal data (including an additional condition if you are going to collect ‘Special Category’ (i.e., sensitive) personal data). In most cases, under the General Data Protection Regulation (applicable in the UK and EU from 25 May 2018) the appropriate legal basis for research purposes will be ‘a task in the public interest’. Example paragraph:

*‘According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that ‘processing is necessary for the performance of a task carried out in the public interest’ (Article 6(1)(e)). Further information can be found in the University’s Privacy Notice* [*https://www.sheffield.ac.uk/govern/data-protection/privacy/general*](https://www.sheffield.ac.uk/govern/data-protection/privacy/general)*.’*

Additional text if using sensitive ‘special category’ data:

*‘As we will be collecting some data that is defined in the legislation as more sensitive (information about …), we also need to let you know that we are applying the following condition in law: that the use of your data is ‘necessary for scientific or historical research purposes’.*

For more guidance on legal bases, including the additional conditions that apply to ‘Special Category’ personal data, refer to the University’s Research Ethics Policy Note, and Specialist Research Ethics Guidance paper, on ‘Anonymity, Confidentiality and Data Protection’: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/further-guidance/homepage>.

1. **What will happen to the data collected, and the results of the research project?**

You should inform the participants of what will happen to the data collected, who will have access to it (e.g. any collaborators, translation, transcription or anonymization services, etc. – known as ‘Data Processors’) and in what form (i.e. identifiable, pseudonymised, anonymised), what will happen to the results of the research (i.e. when the results are likely to be published, where they can obtain a copy of the published results, whether they be told which arm of the project they were involved in) and whether or not they will be identified in any report or publication. If personal data are to be transferred outside the European Economic Area (EEA), the participants should be informed of this, and additional safeguards are required for the management of the transfer of data; please refer to the Specialist Research Ethics Guidance Paper on ‘Anonymity, Confidentiality and Data Protection’ for further guidance.

Participants should also be informed how long the data they provide will be stored for, in what form (i.e. identifiable, pseudonymised, anonymised) and when it will be destroyed. Identifiable personal data (such as the key which links an individual to the data they provided) should be destroyed as soon as possible once it is clear that this will not affect the research purpose. If it is not possible to provide a specific timeframe for destruction of the personal data, then details of the criteria that will be used to determine this date should be provided.

It is good practice to consider possible future uses of the data, including opportunities to share data more widely in line with the open access agenda (and this may also be a requirement of the research funder), so it is recommended that you include a statement indicating how the data collected during the course of the project might be shared, and/or used for additional or subsequent research (this should also be explicit on the participant consent form).

A suggested statement is as follows:

‘*Due to the nature of this research it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way*.’

1. **Who is organising and funding the research?**

You should state the organisation and/or company that is funding the research.

1. **Who is the Data Controller?**

You should explicitly state who the ‘Data Controller’ is for the personal data that will be collected and used as part of the research. The Data Controller is the ‘organisation which determines the purposes and means of processing personal data’; usually, for University research projects, this will be the University of Sheffield; however, if working in collaboration with other organisations, an alternative Data Controller, or joint Data Controllers, may be appropriate, and care should be taken to ensure that this responsibility is clearly agreed, documented in a collaboration agreement, and that the details are provided to participants.

 A suggested statement is as follows:

*The [University of Sheffield/other] will act as the Data Controller for this study. This means that [the University] is responsible for looking after your information and using it properly.*

1. **Who has ethically reviewed the project?**

You should state the name of the academic department that managed the ethics review process – i.e. *‘this project has been ethically approved via the University of Sheffield’s Ethics Review Procedure, as administered by ‘x’ department’* (every academic department either administers the University’s Ethics Review Procedure itself, internally within the department, or accesses the University’s Ethics Review Procedure via a cognate, partner department). If you work in the Professional Services, you should state that the project has been reviewed via *‘the University of Sheffield’s Ethics Review Procedure, as administered by the Professional Services’*. The University’s Research Ethics Committee monitors the application and delivery of the University’s Ethics Review Procedure across the University.

1. **What if something goes wrong and I wish to complain about the research?**

You should inform participants how complaints will be handled and what redress may be available (i.e. what the process is). You need to distinguish between handling complaints from participants regarding their treatment by researchers and something serious occurring during or following their participation in the project (e.g. a reportable serious adverse event).

In the first instance you should inform the participants which member of the research project they should contact should they wish to raise a complaint (this is most likely to be the Principal Investigator or Supervisor). However, the participants should also be informed that should they feel their complaint has not been handled to their satisfaction (e.g. by the Principal Investigator or Supervisor) that they can contact the Head of Department, who will then escalate the complaint through the appropriate channels. You should also mention that, if the complaint relates to how the participants’ personal data has been handled, they can contact The University of Sheffield Data Protection Officer, Luke Thompson – luke.thompson@sheffield.ac.uk . Further information about how to raise a complaint can be found in the University’s Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>. If the participants feel their complaint has not been handled to their satisfaction, they can contact the Information Commissioner’s Office.

1. **Contact for further information**

You should give the participants contact details for at least two individuals, in case they wish to obtain further information about the project. This would usually be the name, address and telephone number of the lead researcher, and at least one alternative contact should the lead researcher be unavailable; this could be another researcher involved the project, or the Supervisor of a supervised-student project.

**Finally …**

the information sheet should state that the participant will be given a copy of the information sheet and, if appropriate, a signed consent form to keep.

**Remember to thank the participants for taking part in the project.**

**Question to insert into an information sheet if the research**

**involves producing recorded media:**

**Will I be recorded, and how will the recorded media be used?**

You need to obtain the participants’ permission to record their activities on audio or video media. You must ensure that there is a clear and transparent understanding as to how these recorded media will be used. For instance, if you record a music or theatre performance, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performers’ permission. Storage (and eventual disposal) of interview recordings which contain sensitive material can also be an issue to address.

Example paragraph:

*‘The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.’*

If you plan to use the recording in a publication or broadcast or deposit it in an archive, it will usually be best to prepare and sign a separate release form for each item used.

**Questions to insert into an information sheet if the research project is a clinical trial:**

**Please note the University does not act as research governance sponsor for CTIMPs (Clinical Trial of Investigational Medicinal Products).**

**If you are testing a medical device, software or application you will need to register with the MHRA.**

**What is the drug or procedure that is being tested?**

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Participants entered into drug trials should be given a card (similar to a credit card) with details of the trial they are in. They should be asked to carry it at all times.

**What are the alternatives for diagnosis or treatment?**

For therapeutic research the participant should be told what other treatments are available.

**What are the side effects of any treatment received when taking part?**

For any new drug or procedure, you should explain to the participants the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given. The known side effects should be listed in terms the participant will clearly understand (e.g. ‘damage to the heart’ rather than ‘cardiotoxicity’; ‘abnormalities of liver tests’ rather than ‘raised liver enzymes’). For any relatively new drug it should be explained that there may be unknown side effects.

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

For projects where there could be harm to an unborn child if the participant were pregnant or became pregnant during the project, the following (or similar) should be said -

*‘It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this project, neither should women who plan to become pregnant during the project. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this project. Any woman who finds that she has become pregnant while taking part in the project should immediately tell her research doctor.’*

Use the above statement carefully. In some circumstances (e.g. terminal illness) it may potentially be inappropriate and insensitive to bring up pregnancy. There should be appropriate warning and advice for men if the treatment could damage sperm that might therefore lead to a risk of a damaged foetus.

If future insurance status (e.g. for life insurance or private medical insurance) could be affected by taking part this should be stated (if e.g. high blood pressure is detected.) If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the patient was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

**What if new information becomes available?**

If additional information becomes available during the course of the research you will need to tell the participant about this. You could use the following:

*‘Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.*

*Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.’*

**Further guidance on the development of information sheets and consent forms within a health research context can be found on the Health Research Authority’s website:** [**https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/**](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/)