Guidance for the participant information sheet

Here is a link to the template for producing a participant information sheet. The template has some standard text which you cannot change but also some text which you can amend and this text is in italics. This guidance helps you complete the sheet by offering further explanation of parts of the information sheet and things to ensure you have included.

The participant information sheet should be designed so that potential participants of your research project can give informed consent (link to informed consent page) to participate in the project.

It should:

- provide sufficient and appropriate information on which they can base an informed decision, including the risks and benefits
- be written in language that potential participants could reasonably be expected to understand.
- be free from coercive language and promises that cannot be kept or unjustified claims of benefits
- be provided for each data collection tool separately so if the research involves both interviews and focus groups, there must be a PIS for each activity.
- be provided for each group of participants so for example students one information sheet and staff a different one

The advantage of a written Information Sheet is that you and your participants have a record of all the relevant information about the study. In most cases this is supplementary to, rather than replacing, a discussion between the researcher and the potential participant. For some participants such as very young children, a written information sheet is not appropriate (although for children, their guardian should receive written information about the study). For other participants the information may be presented in a letter or email rather than as an 'Information Sheet'.

Checklist for writing a participant information sheet

The information sheet, covering letter or leaflet should be printed on City, University of London headed paper (where appropriate) with full contact details and should normally contain the following information:

Study title
The short title of the project exactly as it appears on your application form. The title should be simple and self-explanatory to a lay person.

Name of principal investigator
If you are a student then you need to include your supervisor’s details.

Invitation paragraph
This should explain that the individual is being asked to take part in a research study. The text for this is already set on the template.

What is the purpose of the study?
The background and the aim of the study should be given here. You should say how long the study will run and outline the overall design of the study. You should also indicate if this study is being undertaken as part of an educational programme.

Also include details of the legal basis of processing of personal data and sensitive personal data. This is a statutory requirement under General Data Protection Regulation (GDPR). Please note that City will not usually rely on consent as a lawful basis for processing of personal data for research purposes, only for special category data (previously known as sensitive data) unless the research is relates to health/social care. However, you may need to seek consent for collection of personal data for ethical or professional reasons. If you have any concerns about which lawful basis to use for your research, please contact the Information Compliance Team at dataprotection@city.ac.uk
Public task

City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (public task) as the processing of research participant data is necessary for learning and teaching purposes and all research with human participants by staff and students has to be scrutinised and approved by one of City's Research Ethics Committees.

Legitimate Interests

City, University of London considers the lawful basis for processing personal data to fall under Article 6(1)(e) of GDPR (legitimate interests) as the processing of research participant data is necessary for the purposes of City’s legitimate interests and having completed the legitimate interests assessment City believes that the research falls within its legitimate roles and is satisfied that City has considered the interests and fundamental rights and freedoms of the research participants as documented in our LIA below: [The text for the LIA needs to be completed on a case by case basis]

Special Category Data – Explicit Consent

In addition all research participants (and those with parental responsibility) will have been informed of the purposes behind the processing of the data and the participants themselves or the person with parental responsibility will have provided explicit consent to the collection of their personal and special category data. The data processing is therefore also lawful under Article 9(2)(a) of the GDPR as the provision of personal data will be completely voluntary.

Special Category Data – Substantial Public Interest

City considers the processing of special category personal data will fall under Article 9(2)(g) of the GDPR as the processing of special category data has to be for the public interest in order to receive research ethics approval and occurs on the basis of law that is, inter alia, proportionate to the aim pursued and protects the rights of data subjects.

Special Category Data – Provision of health or social care or treatment of health or social care systems

City considers the processing of special category personal data will fall under Article 9(2)(h) of the GDPR as the processing of special category data is purposes of the provision of health or social care or the treatment or management of health and social care systems and that the necessary safeguards are in place through City’s research ethics scrutiny.

Why have I been invited to participate?
You should explain how the individual was chosen to take part in the study and how many other people will be asked to participate.

Do I have to take part?
You should explain that taking part in the research is entirely voluntary. For example, you could say:

'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. If you decide to take part you are still free to withdraw at any time and without giving a reason.'

If your study involves the recruitment of students or pupils you must explain that by choosing to either take part or not take part in the study will have no impact on their marks, assessments or future studies.
You do also need to make clear that once the data has been anonymised if a participant wants to withdraw that is fine but they cannot withdraw their data at this point.

**What will happen to me if I take part?**
You should what the participants are expected to do. This means stating clearly how much time a participant will need to give to the project and for how long the project will last. You need to explain your methods of data collection so the participant knows if they will be meeting the researcher in an interview, focus group or through observation or if they will be completing a questionnaire. Ensure the explanation of data collection is brief and in lay terms but clear. You also need to say where the research is taking place for example interviews in a room and questionnaire online. *If the research involves automated decision making, machine learning or profiling using the research data, you are required to tell the participants about this and include information about how decisions are made, the significance of the decisions and consequences. Research exemptions under data protection legislation will not apply if any of the automated decision making will impact individual participants.* [Statutory requirement] Include details of any data transfers overseas to and from the UK and the safeguards in place to ensure that the data is processed to the same standards as within European Economic Area (EEA). [Statutory requirement]

**Expenses and Payments (if applicable)**
If there are any expenses you will pay for your participants such as travel you need to state this clearly. You also need to explain if any incentives are being offered how these will take place so for example a draw for a prize or vouchers for time given.

**What do I have to do?**
You need to explain here linked to above point about what will happen to me if I take part what the participant needs to do. For example once they have agreed to participate will they be sent a link to an online questionnaire or will they need to agree a date for an interview? You also need to tell the participant if they need to make themselves available for more than one interview.

**What are the possible disadvantages and risks of taking part? (where appropriate)**
You should describe any disadvantages or 'costs' involved in taking part in the study, including the time involved. You must also make clear any risks even if potential and indicate possible severity and incidence.

**What are the possible benefits of taking part?**
You should outline any direct benefits for the individual and any other indirect benefits including furthering our understanding of the topic and potential benefits to the wider community.

**What will happen when the research study stops?**
If for any reason the research is stopped prior to completion the data will be kept anonymised but all personal details will be destroyed. On completion of the research and after the required period of time that data has to be kept all data will be destroyed using an appropriate method such as cross shredding for any paper records and permanent file deletion if held electronically.

**Will what I say in this study be kept confidential?**
You should explain that all information collected about the individual will be kept strictly confidential (subject to legal limitations) and describe how confidentiality, privacy and anonymity will be ensured in the collection, storage and publication of research material. You will also need to state clearly if any other people will have access to data such as co-researchers and supervisors.

Research data must be kept securely at all times, especially when collected in the field before being transferred back to City, University of London. Laptops and other devices should be encrypted; password protection alone is not adequate. Data generated by the study must be retained in accordance with the University's policy on Academic Integrity. You should include a statement that the data generated in the course of the research must be kept securely in paper or electronic form for a period of ten years after the completion of a research project. Informing research participants of the length of time records are retained is a statutory requirement under GDPR.
If it is a condition of your research funding that the research data must be shared and stored in a repository, you must explain how the data will be stored (for example with the [UK Data Service](https://www.ukdataservice.ac.uk) or the [UK Data Archive](https://www.data-archive.ac.uk)) and explain it will be anonymised.

Provide details of data sharing agreements and contracts with third parties ie partner organisations or external transcribing services. You should also include name and email address of their Data Protection Officers if they are a joint data controller with City. [Statutory requirement]

**Future use of personal information**  
[Note: consent is required for future use under data protection legislation. Provide as much detail as possible to participants at data collection and consider how consent may be revisited in future if data plans for data reuse change and re-consent is required]

**What should I do if I want to take part?**
Explain exactly how the participant should 'opt in' for the study.

**What will happen to the results of the research study?**
You should tell the individual what will happen to the results of the research. Will they be used in your dissertation or thesis? For what degree? Will they be published in a peer review journal or other article? How can they obtain a copy of the published research? Ensure that if you plan to use quotations from the data the participant knows this and that these will be anonymised.

You need to ensure that if you plan to re-use data that participants know this is only permitted where ethical approval has been given.

**What will happen if I do not want to carry on with the study?**
You must make clear that a participant is free to withdraw from the study without an explanation or penalty at any time.

**Who is organising and funding the research?**
You should explain that you are conducting the research as a member of staff or a student at City, University of London. Give your department name as well as the faculty. You should also state the organisation that is funding the research (e.g. Economic and Social Research Council, Nuffield Foundation, Tesco, etc.) if appropriate.

**Who has reviewed the study?**
You may state that the research has been approved by the appropriate Research Ethics Committee, City, University of London and add the title of the committee.

**Contact for Further Information**
You should give the individual a contact point for further information. This can be your name or that of your supervisor.

**What are my rights under the data protection legislation?**

[Suggested wording]

City, University of London is the data controller for the personal data collected for this research project. The rights you have under the data protection legislation are listed below, but not all of the rights will be apply to the personal data collected in each research project.

- right to be informed
- right of access
- right to rectification
- right to erasure
- right to restrict processing
- right to object to data processing
• right to data portability
• right to object
• rights in relation to automated decision making and profiling

For more information, please visit www.city.ac.uk/about/city-information/legal

What if I have concerns about how my personal data will be used after I have participated in the research?

In the first instance you should raise any concerns with the research team, but if you are dissatisfied with the response, you may contact the Information Compliance Team at dataprotection@city.ac.uk or phone 0207 040 4000, who will liaise with City’s Data Protection Officer Dr William Jordan to answer your query.

If you are dissatisfied with City’s response you may also complain to the Information Commissioner's Office at www.ico.org.uk.

What if there is a problem?
Projects taking place in countries where it is possible that the participants will not be able to go through the standard complaints procedure (e.g. if participants may feel inhibited or unable to complain to City, University of London, for reasons of cost, language, literacy and culture) a local contact needs to be identified. This should be someone who is not directly involved in the research. The name of this person should be provided to the research ethics committee approving the application. The local contact needs to be made aware that they have to pass all written and verbal complaints/issues on to the Secretary to Senate Research Ethics Committee soon as possible.

For all research undertaken in the UK if you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you can do this through City’s complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is: ................................................ .......................................................... .......................................................... ..........................................................

You could also write to the Secretary at:
Anna Ramberg
Research Governance & Integrity Manager, Research & Enterprise
City, University of London, Northampton Square, London, EC1 V0HB

You should add that if they have any concerns about the way in which the study has been conducted, they should contact the Vice-President (Research & Enterprise) at researchintegrity@city.ac.uk.

Thank you
Remember to thank the individual for taking time to read the information sheet.

Date
The information sheet should be dated and given a version.