### Template 2

1. Title of Study

*Your study title must be the same on all related documents and should explain the study in simple English. If you have used a short title, make sure that you quote this as well as the full title on your ethics application form*.

2. Invitation Paragraph

*Invite the participant to take part in the study and take care to ensure that the reader would not feel they are being pressured or coerced. For example:*

You are being invited to participate in a research study. Before you decide whether 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 feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your family or friends if you wish. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to. Thank you for reading this.

3. Who I am?

*Explain who you are and why you are doing this study.*

3. What is the purpose of the study?

*In lay terms, with all technical terms and acronyms defined, you should explain why the study is being conducted: the background, aims and objectives.*

*In exceptional circumstances, researchers may decide not to disclose the purpose of the research at this stage; for example, if disclosure will affect the behaviour of participants in an observational study. Given the impact of non-disclosure on the informed consent process, this should not be undertaken lightly, and the reason for not informing participants of the purpose of the research must be fully explained in the protocol or research proposal that is submitted for further ethical scrutiny. Ethical approval will only be granted in the case of important issues or matters of social significance that cannot be uncovered in any other way. In such cases, participants must be fully debriefed at the end of the research and the debriefing form must be included with your application for research ethics review.*

4. Why have I been invited to take part?

*Briefly explain the reasons why and how you have chosen to invite participants, and also how many you are seeking to recruit*.

5. Do I have to take part?

*It should be made clear that participation is voluntary and that participants are free to withdraw their participation at any time, without explanation, and without incurring a disadvantage.*

6. What will happen if I take part?

*In language that can be understood by a lay reader, you should explain exactly what will be asked of the participant and what will happen during the research. For example, you should explain clearly:*

• *what the methods are*

*• who the researchers are*

*• who will be carrying out the study*

*• what the duration/frequency of the study is*

*• what the participant’s responsibilities are.*

*When writing this section, think about what you would want to know if you were to take part in a research study.*

*If the research involves any audio/visual recording, this should be made clear on both the information sheet and consent form.*

*If there is a possibility that the participant’s legal guardians (or another professional) may need to be contacted (depending on the type of study), this should also be made clear on the information sheet and consent form.*

7. How will my data be used?

*You must inform the participant of the lawful basis for processing their personal data and, if special category data or criminal offence data will be collected, you will need to outline how you will use this data, as well as the lawful basis for such use (please see the* [*GDPR for Researchers Guidance Document and Research Privacy Notice*](https://gdpr-info.eu/) *for further guidance on the lawful basis for processing).*

*If you are conducting a focus group then you should add that it will be impossible to guarantee the confidentiality of what is said. You may also add the ground rules, e.g. ‘*We ask all participants not to repeat what was said by other people after we have finished the focus group*’*.

Further information on how your data will be used can be found in the table below.

| How will my data be collected? | *Outline the data collection methods used in the study.* |
| --- | --- |
| How will my data be stored? | *Explain the storage arrangements for the data including whether any data will be stored on external systems and databases.* |
| How long will my data be stored? | *Outline the retention period for the type of data collected.* |
| What measures are in place to protect the security and confidentiality of my data? | *Outline methods such as encryption and, if necessary, how data will be secured during transfer between field collection/storage/ researchers.* |
| Will my data be anonymised? | *Explain whether the data will be anonymised and include the details of any anonymisation/​pseudonymisation, including when in the research lifecycle this will take place, and (in the case of pseudonymisation) who will have access to the original dataset.* |
| How will my data be used? | *Include details on:*   * *The types of data collected and what will be done with it* * *Why is the data is used in this way – e.g. why it is necessary for the research outcomes.* |
| Who will have access to my data? | *Explain who will have access to the data including the research team. It should also be explained in this section which other organisations you intend to share personal data with (if applicable) – e.g. research partners, ‘data processors’, any other third-party organisations.*  *(A ‘data processor’ is an organisation or individual who holds or processes data on the research team’s behalf.)* |
| Will my data be archived for use in other research projects in the future? | *If the data from this project is intended to be open access or stored in your organisation’s data bank for future use in accordance with the relevant data management policy, please provide details here.* |
| How will my data be destroyed? | *Provide details of when and how the data will be destroyed.* |

[Transferring data outside the EU](https://www.itgovernance.co.uk/blog/transferring-personal-data-under-the-gdpr)

If personal data will be transferred outside the European Union, you must explain how this will be conducted, why it is necessary and outline the safeguards in place to protect the data.

8. Are there any risks in taking part?

*Explain whether there are any perceived disadvantages or risks involved. Emphasise that, if the participant should experience any discomfort (mental, emotional or physical) or disadvantage as a result of taking part in the research, this should be made known to the researcher(s) immediately.*

*Certain types of research may lead to the identification of serious risks to the participant or others, for example, related to the identification of financial concerns (e.g. severe debt) or legal concerns. If you believe your research could identify such risks, you must have a policy in place for handling the information. Details of the procedure to be followed (for example, will you inform the participant?) must be provided on the information sheet, together with sources of advice and other relevant resources.*

*For example:*

1. *If you are studying consumer behaviour/spending behaviour, you may include a section in the information sheet giving the details of the Citizens Advice Bureau so that participants may contact them for further advice on dealing with debt.*
2. *Consideration should also be given to signposting participants to any local or national support services or helplines that could assist with any other risks to the participant identified during the research.*

9. Are there any benefits from taking part?

*It is important to remember that participation in research is typically altruistic; it is on the basis of informed consent (rather than benefit) that we are able to include participants. Of course, we may hope for benefits for participants but, in most cases, we cannot claim that there will be benefits. Unless benefits for participants have been built into the design and can be guaranteed (such as via benefit-sharing agreements), care needs to be taken when describing benefits. Where there is no intended/likely benefit to the participant, this should be made clear.*

10. Expenses and/or payments

*Detail any expenses that participants may incur (e.g. travel) and any reimbursement for which they may be eligible. Reimbursement may make participation in your research accessible to more people but should not be so generous as to provide an incentive to take part.*

11. What will happen to the results of the study?

*Detail how the results will be made available to the participants. If the results are to be published, state this clearly and describe how and where they will be available. Tell participants that they will not be identifiable from the results unless they have consented to be so.*

12. What will happen if I want to stop taking part?

*It is important to remember that informed consent is an ongoing process, not just something that occurs at the start of a study. Consequently, participants must be free to withdraw their participation at any time, and details of how they can do this should be clear on the information sheet. Make it clear that participants do not need to offer any reasons or explanation for why they wish to withdraw from the study.*

*If it is decided that participants will not be given the option to withdraw previously collected data, they should be informed in this section that results or data collected up to the point of withdrawal may be used, but no further data will be collected following the participant’s withdrawal.*

*If, after considering the ethical implications of the study, it is decided that participants should be offered the option to withdraw previously collected data, it is still recommended that participants are advised that data collected up to the period of withdrawal may be used if they are happy for this to be done. Otherwise, participants may request that their data be destroyed, and no further use is made of it. If data is anonymised, you should make it clear that it can only be withdrawn before anonymisation; afterwards, it will not be possible to tell which data belongs to which person. Additionally, once data has been collated and/or reported, it may not be possible to isolate and extract. In such circumstances, you should provide a period after which it will not be possible to extract the data.*

*You should provide details of how participants can withdraw their information, explain who should be contacted and highlight any limitations on the withdrawal of information (for example, if the data has been fully anonymised, collated and/or reported).*

13. What if I am unhappy or if there is a problem?

*A complaints procedure must be made clear in the PIS. All complaints will normally go through a relevant ethical scrutiny unit in your organisation. You should use something similar to the following wording to explain how complaints will be handled:*

If you are unhappy, or if there is a problem, please feel free to let us know by contacting [main researcher’s name and number] and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with, then please contact […].

*Sometimes it may be necessary to put alternative/additional processes in place for dealing with complaints. For example, when conducting research in another country or with individuals who may struggle to use email, an email contact on the information sheet may not suffice. Complaints processes and procedures must be truly accessible for all, and this may require a tailored approach to individual circumstances. Whatever process is put in place for complaints, it must be clearly specified in the information and approved by the research ethics committee.*

14. Whom can I contact if I have further questions?

*You should give the name, address and contact telephone number of the main researcher.*

15. Contact details of investigatory team.

**Notes: Optional sections (choose as appropriate)**

**Disclosure Barring Service check (DBS)**

If the research involves vulnerable people (such as children, the elderly or those with learning disabilities), you will usually need to obtain a DBS check. You may therefore want to make a short statement to explain that the researchers involved have obtained a DBS check and that research participants may request evidence of the DBS from the Principal Investigator.

**Discussing sensitive or distressing topics**

If the research involves the potential disclosure of personal or sensitive information, you should explain the potential risk of emotional distress and emphasise that participants can abstain from answering any questions they may be uncomfortable with.

You should explain the procedures in place to manage a situation where participant distress occurs (for example, pausing the interview to provide time for participants to consider whether to continue or withdraw from the study). You should also state the sources of support that you can provide/refer participants to (e.g. counselling or local/national support services).

**Disclosure of criminal activity and other confidentiality issues**

If you are carrying out research where you may collect information with the potential for disclosure of a criminal activity (e.g. research with young offenders/prisoners), or where there is the potential for other areas of concern to be raised (e.g. concerns about the safety or welfare of the participant or others, for example, in research around domestic abuse) you should inform participants that confidentiality may not always be assured. For research involving young offenders or prisoners, please also ensure that you have discussed with the Prison or Young Offender Institution an appropriate reporting procedure to follow if such information is disclosed.