**GUIDANCE**

When designing the Participant Information Sheet and consent form consideration should be taken as to what is appropriate for the type of study and participants who will be involved.

The Participant Information Sheet and Consent Form Template below provides general and suggested consent items, **you may not need to include all items**. Remember one size does not fit all, only include what is appropriate for your study. This is intended for use for qualitative research studies which are single Sponsored by University of Edinburgh and require no NHS approvals.

For some studies it may be appropriate to provide itemised consent covering specific issues. Only offer potential participants options if you are confident that you can deliver all combinations of accepted or rejected options.

**Participant Information Sheet**

**Add in Study Title**

**You are invited to take part in a research study. To help you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact 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.**

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| **What is the purpose of the study?** |
| Add the purpose of the study here – this should be written in lay language and should include:   * Background to the rationale for the study * Why is the study being conducted? * What you are trying to achieve * How many people will be involved? |
| **Why have I been invited to take part?** |
| You have been asked to take part as you have been [diagnosed with xxx / attended xxx clinic / received an xxx / etc.].  OR  You are a healthy volunteer for a study investigating [xxx]. |
| **Do I have to take part?** |
| No, 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. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. |
| **What will happen if I take part?** |
| Explain what will happen from the participant’s point of view in lay language – this should include:   * How long participants will have to decide to take part. * Who will take consent and provide an explanation of the consent process (including if this is to be done electronically). * Number of study visits involved and duration. For example how long would the interviews take to complete. * Screening and inclusion procedures. * Other procedures involved (i.e. what procedures the participant is expected to do). * Where procedures will take place. * Simple flowcharts or tables outlining the study are useful to include here. * Describe if participants will be required to use portable media (iPads, mobile phones, wearable devices) or if they (or the research team) will be required to enter personal information into an online portal or questionnaire, and where the data generated will be stored (e.g. organisation, country, cloud-based storage). Participants should be reminded that if they are using their own personal device to complete study questionnaires, they are responsible for the security of their own devices and should be provided with some basic best practice advice ([National Cyber Security Centre](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncsc.gov.uk%2Fcollection%2Fsmall-business-guide%2Fkeeping-your-smartphones-and-tablets-safe&data=05%7C02%7CGavin.Robertson%40nhs.scot%7C3df88741a85e4e5a950e08dc68266537%7C10efe0bda0304bca809cb5e6745e499a%7C0%7C0%7C638499761310260413%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=ThmSTVrSO%2F6MYlhyHSqNPzRjDHz09K3YJ6C4uHPXQes%3D&reserved=0)). * What electronic platforms will be used for surveys/remote interviews/online focus groups * Will there be any audio/visual recordings of the study visits, if so how will this be achieved. Will encrypted recorders be used? * Will there be any transcription of data? If so who will do this * Will there be any expenses paid (e.g. travel expenses). |
| **Is there anything I need to do or avoid?** |
| Consider:   * Are there any special precautions / requirements for participants |
| **What are the possible benefits of taking part?** |
| You may/may not get a benefit from taking part in this study.  If no direct benefit suggest:  [“There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.”] |
| **What are the possible disadvantages of taking part?** |
| Consider:   * Reiterating how much time, how many visits etc. will be required in the study. * If there is a risk that a participant could find discussions/topics distressing consider adding in: It is possible that taking part in these discussions could be upsetting or cause you distress.  You can ask to stop at any time, pause, bring a support person. Also provide contact details for follow up support relevant to the type of research, for example a relevant carer's support group, support groups for particular medical conditions etc. possibly suggest they contact their GP. |
| **What if there are any problems?** |
| If you have a concern about any aspect of this study please contact <insert name and contact details here> who will do their best to answer your questions.  In the unlikely event that something goes wrong, and you are harmed during the research, then you may have grounds for a legal action for compensation against The University of Edinburgh, but you may have to pay your legal costs |
| **What will happen if I don’t want to carry on with the study?** |
| You should make it clear at the outset what the participant should expect if they were to withdraw their consent. Some of the issues that may need to be addressed include:   * Does withdrawal simply mean that participants will no longer be attending further research appointments or taking any further active part in the research? * Could participants withdraw their data from further analysis for example once transcriptions has taken place? * If your study includes medium to long-term follow up, how can participants withdraw from this element? * Can participants withdraw from data subsequent data banking? |
| **What happens when the study is finished?** |
| Consider:   * What will happen to data (retained or destroyed)? * How long will data be retained (specify years or indefinitely)? * Where will data be retained (name the organisation and country where data will be retained)? * Will data be sent to any third parties (if yes and it is known where the data will be sent, the organisation(s)/location should be named and needs to be clear what is being shared (this includes any transcription that is to be used). Any consent for sharing data should be specific e.g. sharing with commercial companies and what will be shared (identifiable or anonymised)? * If you plan to use data for future ethically approved studies, please detail this here (explicit consent required for this) * Will you keep details for contacting participants about future studies, if so this should be an optional consent point on the consent form. |
| **Will my taking part be kept confidential?** |
| All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. |

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| **Where can you find out more about how your information is used?** |
| You can find out more about how we use your information   * by asking one of the research team * by sending an email to [**email**], or * by ringing us on [**phone number**]. * For further information about how the University of Edinburgh will use your personal data please see [www.ed.ac.uk/data-protection/privacy-notice-research](http://www.ed.ac.uk/data-protection/privacy-notice-research) |
| **What will happen to the results of the study?** |
| This study will be written up as **xxxxxx** (publication, conference presentation, dissertation).  You will not be identifiable from any published results.  If the results of the study are to be made available to the participants, they should be informed, and advised in what format the results will be provided (newsletter, e-mail, website, publicly accessible research registry). If using a website, please insert URL. Detail how they will access this. |
| **Who is organising and funding the research?** |
| This study has been organised by **xxxx** and Sponsored by University of Edinburgh**.**  The study is being funded by **xxxxx.**  Participants should be told if a researcher is being paid for their role in the study.  If applicable:  This study forms part of an educational qualification (specify what the qualification is) |
| **Who has reviewed the study?** |
| The study proposal has been reviewed by **xxxx.**  Have patients and the public been involved in the development of this study, if so, how?  All research is looked at by an independent group of people called an Ethics Committee. A favourable ethical opinion has been obtained from **<insert ethics committee name>**. |
| **Researcher Contact Details** |
| If you have any further questions about the study please contact <insert name> on <insert phone number> or email on: **<insert email address>**. |
| **Independent Contact Details** |
| If you would like to discuss this study with someone independent of the study please contact **<insert contact details>**. |
| **Complaints** |
| If you wish to make a complaint about the study please contact:  **<resgov@accord.scot>**. |

**The Chief Investigator/research team is responsible for adapting the following Consent Form template for the purposes of a specific study. There may be consent points that are not applicable and can be removed or it may be preferable to change opt-out consent points to be compulsory if consenting to take part.**

**Things to consider:**

* **If opt-in/out options are removed and consent points are made compulsory, this may reduce the pool of potential participants willing to consent e.g. potential participants may not wish their data to be used in future ethically approved research.**
* **If a participant declines to be part of the anonymised dataset, this will preclude you from including their data in individual participant datasets for future ethically approved research. This must be made clear when sharing anonymised datasets with other researchers.**

**It is up to the research team to decide how participant's choices are tracked for their study e.g. in the study database or in a study specific document/file at site and/or centrally**

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| **Participant ID:** |  | | **Centre ID (if applicable)** |  | |

**CONSENT FORM**

**Study Title**

|  | Please **initial** box |
| --- | --- |
| 1. I confirm that I have read and understand the information sheet for the above study.  |  |  | | --- | --- | | **\*Date (DD MMM YYYY)** | **\*Version Number** | |  |  |   \**complete during consent process*   1. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. | ⬜  ⬜ |
| 1. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. | ⬜ |
| 1. (**If appropriate or delete**) I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh), from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. | ⬜ |
| 1. (**If appropriate or delete all or non-relevant information**) I give permission for my personal information (including initials, name, date of birth, ethnicity, address, postcode, telephone number, email address, IP address, and consent form) to be retained on University of Edinburgh servers for administration of the study. | ⬜ |
| 1. (If appropriate) I agree to my General Practitioner being informed of my participation in the study. | ⬜ |
| 1. I understand that data collected about me during the study may be converted to anonymised data. | ⬜ |
| 1. (**if appropriate or delete**) I understand that data generated during the study will be sent outside of the UK / European Economic Area where laws protecting my personal information may be different to my own country. | ⬜ |
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| 1. (**If appropriate or delete**) I agree to my anonymised data being used for future ethically approved studies. | Yes ⬜ No ⬜ |
| 1. (**If appropriate or delete**) I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies. | Yes ⬜ No ⬜ |
| 1. (**If appropriate or delete**) I agree to my interview being audio/video recorded and the use of anonymised quotes in research reports and publications. | Yes ⬜ No ⬜ |
| 1. (**If appropriate or delete**) I agree to my audio/video recorded interview being transcribed by a third party contractor. | Yes ⬜ No ⬜ |
| 1. (**If appropriate or delete**) I understand that the data generated during this study may be used for future commercial development of products/tests/treatments/biomarkers and I will not benefit financially from this. | ⬜ |
| 1. I agree to take part in the above study. | ⬜ |

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|  |  |  |  |  |
| Name of Person Giving Consent |  | Date |  | Signature |
|  |  |  |  |  |
| Name of Person Receiving Consent |  | Date |  | Signature |

1x original – into Site File; 1x copy – to Participant;