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**GUIDELINES for PARTICIPANT INFORMATION SHEET**

A Participant Information Sheet, which clearly identifies the purpose of the study and what will be required of the participant, must accompany each Ethics Application. The following guidelines are a modified version of the guidelines provided by the Chief Scientist Office of the Scottish Executive. However, the principles and much of the content will be of use to researchers writing information sheets in their particular fields, for trials involving healthy volunteers. You will find it helpful to refer also to other guidelines produced for writing participant information sheets.

<http://www.hra-decisiontools.org.uk/consent/examples.html>

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. The information sheet should carry the University logo and clearly identify the Department or Institute where the research is being carried out.

**The text in italics under each heading is given as an example only and may be modified to suit the purposes of each individual study.**

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| --- |
| 1. **Study title**
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| Is the title self explanatory to a lay person? If not, a simplified title should be included. |
| 1. **Invitation paragraph**
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| This should explain that the potential participant is being asked to take part in a research study. For example: |
| * *You are being invited to take part in a research study. Before you decide, 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. If you decide to take part in this study, you will be given a copy of this Participant Information Sheet and the signed consent form to keep.*
 |
| 1. **What is the purpose of the study?**
 |
| The background and aim of the study should be given here. You should also mention the duration of the study. If the study is contributing towards an educational qualification, details of this should be included here. For example: |
| * *The purpose of this study is to test the <describe outcomes> of <describe vaccine> in people <with condition> who will take part in the study.*
* *This study aims to …..will compare < study vaccine> and < comparator vaccine>…..test…..where one group of people will receive < study vaccine> and the other group will receive < comparator vaccine>. The effects of the intervention < study vaccine> will be compared.*
* *The purpose of this study is to collect information about < disease> in <study population/area/special conditions>.*
* *The purpose of this study is to collect samples from < study population> to collect information/ better understand the….*
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| 1. **Why have I been invited to participate?**
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| You should explain how and why the potential participant was invited and how many other participants will be studied. |
| For example:* *You have been invited to take part in this study because you are…*
* *You have expressed interest in…*
* *You responded to an advertisement about the research*
* *Your health visitor suggested that you might be interested in taking part in the research*
* *You have a health / medical condition…*
* *Summarize the main inclusion and exclusion criteria in layman terms from the protocol but not verbatim (i.e. emphasize the key criteria for entry such as age, health, use of other medication etc.).*

*You can only be in this study if: (brief version of inclusion criteria can be inserted here)** *you are XX to XX years old*
* *you are healthy*
 |
| 1. **Do I have to take part?**
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| You should explain that taking part in the research is entirely voluntary.  For example: |
| * *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.*
 |
| If potential participants are students of the University or other institution, it is appropriate to state that a decision not to participate will not affect their grades in any way. |
| 1. **What will happen to me if I take part?**
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| You should state how long the participant will be involved in the research; how long the research will last (if this is different); whether and how often they will need to visit a clinic (if this is appropriate) and how long these visits will be; what exactly will happen, e.g. blood tests, exercise tolerance tests, psychometric tests, questionnaires, interviews, etc. Whenever possible, you should draw a simple flowchart or plan indicating what will happen at each visit. What are the participant's responsibilities? Set down clearly what you expect of the potential participants. If there will be any audio/video recording and/or photographs taken, potential participants should be informed of this here.You should say whether participants can choose to only complete some or all of the research activities (if appropriate). Explain how many participants are planned to take part in the study, how long they are expected to stay in the study and where the study will be conducted.  |
| For example:* *Explain that recruitment will stop once target enrolment has been achieved.*
* *Approximately < number> people / men / women / children will be invited to take part in this study. When we have enough people taking part in this study, we will not include or invite any more.*
* *or*

*Give examples of participating countries for multicentre studies.* * *The study will be done in Scotland, England…..<example of countries/part of the world, if known>.*
* *Each participant is expected to stay in the study for XX months….*

You should explain what type of study/intervention is planned and whether the participants will be randomised. You should also tell the potential participants what chance they have of getting the study treatment.For example: * *Explain the study design features (cross-over, placebo use, single- or double-blind). For randomised studies, describe how treatments (eg vaccine, comparator, placebo) are assigned (eg by chance). For blinded studies, explain that the subject/patient will not be told what treatment they receive until the end of the study, when the study blind is broken, except in a medical emergency.*
* *There will be XX number groups / visits in this study. If you agree to take part then you might be placed in either group. vaccine active inactive controlYou have an < one out of number> chance of being placed in < specify group>. This will be decided by chance, a computer will be used to put people into groups, much like the toss of a coin and you are not able to choose the group. This is called Randomisation.*

If appropriate, you should tell the potential participants about the type of study design in a lay fashion. For example: * ***Randomised Trial:***

*Sometimes because we do not know which way of treating participants is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer i.e., by chance. Participants in each group then have a different treatment, and these are compared.** ***Blind/Masked trial:***

*In a blind trial, you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor the researcher will know which treatment group you are in.** ***Cross-over trial:***

*In a cross-over trial, the groups each have the different treatments in turn.** ***Placebo:***

*A placebo is a dummy treatment such as a pill which looks like the real thing but is not. It contains no active ingredient.*You should explain details of participant involvement, procedures to be followed, where it will happen including all invasive procedures (e.g. urine, blood collection, measurements….)For example:* *Taking part involves attending, visiting, taking part in ……… If you decide to take part you will be invited to………….*
* *Taking part in the research involves completing questionnaires at several time points. The study team will arrange to meet you to complete the questionnaires for the first time…... This will take 20-30 minutes. After this meeting, you will be told whether you will ………*

If blood samples are to be taken, the risks should be stated.For example:* *Bruising may occur at the site of the needle.*
* *Some people may feel faint, etc.*

You should explain if some measurement or procedure might cause discomfort and indicate presence of researcher to deal with the discomfort. You should also explain, if relevant, that the process of disclosing personal, private or distressing information to the research team might be upsetting and outline the steps that will be taken to minimise and cope with resultant distress.You should explain details related to sample management, what will be collected, what amount and in what frequency. Whether the samples will be tested in a laboratory, transported for testing elsewhere (within the UK or Europe) and how and where they will be stored and for how long. For example:* *Include a brief description of the tissue samples to be collected in the study. Tissue in this context includes blood, and samples of organ, skin, bone, muscle, and connective tissue but are not limited to these examples.*

*Mention any planned research uses of the samples (include purpose, what will be achieved and if samples will be kept in the short term to monitor the subject’s/ patient’s condition during the study or to evaluate a study data point). For example, blood is collected to establish the subject’s eligibility. For ICFs dealing only with screening procedures, type 1 testing will relate to the screening tests.**If the intention is to retain tissue samples collected during the study for potential secondary research uses that are outside the scope of the current study (i.e. not related to the investigational vaccine or disease condition under current investigation), consent must be obtained. (Potential secondary research uses can be described generally, in terms of research into a specific disease, a class of disease or a field of research).* *Explain that collected samples may be transferred to GSK or other researchers working with GSK.* *Delete this entire section if no samples are taken or if samples are taken according to routine clinical practice and are not tested by GSK Vaccines’.* *This section is aligned and should be used in conjunction with the protocol version 14.1 and CRF version 14.1.** *As part of the study, you will be asked to give samples of …….(list all types of samples). If blood samples are to be taken, the amount should be stated in ml and also in the equivalent lay term, teaspoons (5 ml = 1 teaspoon).*
* *Your samples will be given a code so that it does not directly identify you. Your …….(list all types of samples) samples will be tested in the selected laboratory working with the university. The samples will be transferred to the collaborating laboratory where they will be stored until testing.*
* *Your samples will be kept for a maximum of XX years from the end of the study. Any sample remaining at that time will be destroyed/transferred…...*
* *If you agree, your sample(s) may also be used for future research. For example, research related to the study to improve scientific understanding. Should this occur, you won’t be contacted.*
* *We will always ask for approval for this research from an independent ethics committee or independent review board. You can choose not to allow these optional tests and still be in this study.*

Tables can be inserted, if suitable, explaining what will happen during each visit including details of participant involvement.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time point/duration of the visit** | **Month 0/(visit 1) 1-2 hours** | **Month 6/(visit 2)** **1 hour** | **Month 12/ (visit 3) 30 mins** | **Month 18/(visit 4) 45 mins** |
| **What will happen at this visit** |  |  |  |  |
| Consent process | • |  |  |  |
| Measurement – Weight, Height | • |  | • | • |
| Urine/saliva/blood collection | • |  | • | • |
| Questionnaires completed-X-Y-Z | ••• | ••• | ••• | ••• |

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| 1. **What do I have to do?**
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| Are there any lifestyle restrictions? You should tell a participant if there are any dietary restrictions. For example:* *Can the participant drive, drink or take part in sport?*
* *Can the participant continue to take their regular medication?*
* *Should the participant refrain from giving blood?*
* *What happens if the participant becomes pregnant?*
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| 1. **What are the possible disadvantages and risks of taking part?**
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| You should identify here any possible disadvantages or time burdens of taking part. You should avoid generic statements such as “there are no potential disadvantages or harms in taking part in the study”. |
| 1. **What are the possible benefits of taking part?**
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| Where there is no intended benefit to the participant from taking part in the trial this should be stated clearly. Participation and advantages therein should not be overestimated. |
| For example:* *You will receive no direct benefit from taking part in this study. The information that is collected during this study will give us a better understanding of…….*
 |
| 1. **Will my taking part in this study be kept confidential?**
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| You should always bear in mind that you, as the researcher, are responsible for ensuring that you are not contravening the legal or regulatory requirements in any part of the UK, when collecting or using data. This is not the responsibility of the University Ethics Committee.If the potential participant’s GP, or any other professional, will be notified of their participation, this should be specified here. |
| For example:* *All information which is collected about you, or responses that you provide, during the course of the research will be kept strictly confidential. You will be identified by an ID number, and any information about you will have your name and address removed so that you cannot be recognised from it. Please note that assurances on confidentiality will be strictly adhered to unless evidence of serious harm, or risk of serious harm, is uncovered. In such cases, the University may be obliged to contact relevant statutory bodies/agencies.*
* *Any data in paper form will be stored in locked cabinets in rooms with restricted access at the University of Glasgow. All data in electronic format will be stored on secure password–protected computers. No one outside of the research team or appropriate governance staff will be able to find out your name, or any other information which could identify you.*
 |
| 1. **What will happen to my data?**
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| **You should ALWAYS include a statement on compliance with the General Data Protection Regulation (2018) if the study involves identifiable or pseudo anonymised data. You may also need to complete a Data Protection Impact Assessment (DPIA). If your study involves personal data, you should also give participants a Privacy Notice. Links to these documents are on the front page of the application form.****There may be some duplication between the privacy notice and this section. In this section, you should give specifics of how all data will be stored, what will the retention period be and whether there is an intention to share data in the future. You should also provide details of what will happen to any of their data that have already been collected if the participants decide to withdraw from the project.**For example:* *We may be collecting and storing identifiable information from you in order to undertake this study. This means that the University is responsible for looking after your information and using it properly. We may keep identifiable information about you [for x years after the study has finished/ until x] and will not pass this information to a third party without your express permission.*
* *Your rights to access, change or move the information we store may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information from [Principal Investigator contact details].*
* *Researchers from the University of Glasgow collect, store and process all personal information in accordance with the General Data Protection Regulation (2018).*
* *All study data will be held in accordance with The General Data Protection Regulation (2018)*
* *The data will be stored in archiving facilities in line with the University of Glasgow retention policy of up to 10 years. After this period, further retention may be agreed or your data will be securely destroyed in accordance with the relevant standard procedures.*
* *Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data will form part of the study result that will be published in expert journals, presentations, student dissertations/theses (if applicable) and on the internet for other researchers to use. Your name will not appear in any publication.*
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| 1. **What will happen to the results of the research study?**
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| You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? If direct quotes will be used in any resulting publications or reports, this should be specified here, even if they are anonymised. |
| 1. **Who is organising and funding the research?**
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| The answer should include the organisation or company sponsoring or funding the research (e.g., Medical Research Council, pharmaceutical company, charity or academic institution). |
| 1. **Who has reviewed the study?**
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| You may wish to add that the project has been reviewed by the College of Medical, Veterinary & Life Sciences Ethics Committee. |
| 1. **Contact for Further Information**
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| You should give the participant a contact point for further information. This can be your name or that of your supervisor involved in the study. You should use professional phone numbers and email addresses only, and are advised to use generic mailboxes where possible. |
| **Remember to thank the potential participants for reading the Information Sheet** |
| **The Participant Information Sheet and Consent Form should be dated and given a version number in the footer of the document**. |

**WHEN IS A CONSENT FORM NOT NEEDED?**

Under certain survey conditions a Signed Consent Form may not be needed. For instance, when participants are mailed a questionnaire, return of the questionnaire can be considered to indicate consent. Similarly, when survey participants are recruited as they enter or exit a particular venue (e.g., exit poll survey), agreement to complete the questionnaire or participate in the interview can be considered to indicate consent.

However, in both cases, the researcher must provide proof that participants will be adequately informed of the purpose of the study, the extent of the participant's involvement and how the data will be handled with respect to confidentiality. In the case of an exit poll, survey participants should be given an abbreviated information sheet or card which describes the purpose of the survey, along with the researcher's school/institute/affiliation and contact details should the participant wish to contact the research team. In the case of a postal survey, a copy of an abbreviated information sheet or a cover letter detailing the above information should be submitted with the application.