GUIDANCE

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

The 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.

For example, the Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index. Rationale for collecting CHI numbers should be discussed/agreed with the Sponsor/R&D and Caldicott Guardian if required. If collecting CHI numbers this should be described in the PIS. The CHI number should remain within the NHS wherever possible.

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.

The Health Research Authority (HRA) provides guidance on what should be covered in a participant information sheet and consent form. This also provides useful information of the following:

* Adults with incapacity in Scotland, Wales, Northern Ireland and England covering both CTIMPS and non-CTIMPs.
* Children and Young people both CTIMPS and non CTIMPs
* Emergency research
* Those who are deceased
* Tissue samples
* Research databases and tissue banks
* Genetic research
* Ionising radiation

It is recommended that you read through this guidance before developing your participant information sheets

The link to the guidance can be found [here](http://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance.pdf).

**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.**

|  |
| --- |
| **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.].ORYou 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.
* Number of visits involved and duration. For example, these will be conducted at your standard clinic appointments but will require you to stay xx minutes longer or you will be asked to attend xx extra visits.
* 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.
* Distinguish what will be standard clinical care and what will be research-specific.
* Describe any randomisation procedures (and explain what randomisation is, in lay language).
* Blinding (again, explain in lay language).
* Describe any drugs/interventions involved with the study.
* 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)).
* Any anticipated inconvenience.
* If participants are providing blood/tissue samples – specify exactly how much will be taken (in lay terms e.g. tea/tablespoons and equivalent mls).
* If you intend to use samples for DNA, this must be detailed here – with explicit consent sought for (i) DNA analysis and/or for (ii) genome wide analysis – suggest you provide a basic lay friendly explanation of this.
* If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform the participant of this.
* Exposure to ionising radiation.
* Research Databases and Tissue Banks.
* Impacts on possible pregnancy/breast feeding and the need to take pregnancy test if applicable.
* Will there be any expenses paid (e.g. travel expenses).
* What will happen if new information becomes available?
 |
| **Is there anything I need to do or avoid?** |
| Consider:* Are there any special precautions / requirements for participants – e.g. fasting, medications to be stopped, avoiding alcohol etc.
 |
| **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.”]If there is any possibility that findings from the study may be used towards the development of a commercial product, test or treatment, a statement must be added to inform participants that they will not benefit financially due to their involvement in the study. For example:[“The results of this study may be used for the future commercial development of a new medicinal product, treatment or test. Your participation in this study will not entitle you to benefit financially from the commercial development of the product, treatment or test.”] |
| **What are the possible disadvantages of taking part?** |
| Consider:* Reiterating how much time, how many visits etc. will be required in the study.
* Mention if there is a possibility of incidental findings and the procedure of how these will be dealt with. Participant should be informed that their GP/healthcare professional will be made aware of any incidental findings.
 |
| **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 and this is due to someone’s negligence then you may have grounds for a legal action for compensation against NHS **[XXXX]** but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). |
| **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 clinics or taking any further active part in the research?
* Could participants withdraw their samples from further analysis?
* If your study includes medium to long term follow up, how can participants withdraw from this element? For example, if you intend to access registry data over time, how could participants withdraw from this?
* Could withdrawal post intervention pose a safety issue? If so, how would you manage this (e.g. with an exit check-up)? Participants should be able to ask that any information collected at an exit check-up be included or excluded from the study.
* Can participants withdraw both data and tissue samples from subsequent tissue or data banking?
 |
| **What happens when the study is finished?** |
| Consider:* What will happen to data and tissue (retained or destroyed)?
* How long will it be retained (specify years or indefinitely)?
* Where will samples/data be retained (name the organisation and country where tissue/data will be retained)?
* Will samples or data be sent to any third parties (if yes and it is known where the samples/data will be sent, the organisation(s)/location should be named and needs to be clear what is being shared. If not known, consider if this should be an opt-out consent point. Any consent for sharing samples/data should be specific e.g. sharing with commercial companies and what will be shared (identifiable or anonymised)?
* Will any treatment be continued beyond the end of study?
* If you plan to use data/tissue for future ethically approved studies, please detail this here (explicit consent required for this)
 |
| **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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| **How will we use information about you?** |
| We will need to use information from [you] [from your medical records] [your GP] [**OTHER**] for this research project.**OPTION where applicable (and justified)**: We will collect your Community Health Index (CHI) number or NHS number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number or NHS number is being collected to allow us to [**rationale for collection of CHI to be added here**].Other personal identifiable information collected will include your [**delete as appropriate**: initials/ name / date of birth / ethnicity / address / post code/ telephone number / e-mail address / IP address [**provide a bullet list of identifiers held by site and/or sponsor for the research**]. People will use this information to do the research or to check your records to make sure that the research is being done properly.**OPTION where applicable:** People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number assigned instead.**OPTION if not already stated: [insert name of Sponsor]** is the Sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:* **In bullet points, concisely list some of the steps you will take to keep information secure.**

International Transfers[**OPTION:** **If no transfers out of the UK will occur**] Your data will not be shared outside the UK.**OR**[**OPTION: If transfers out of the UK will occur, or if it remains a possibility in the future, including the sharing of de-identified information with other researchers, include this text and delete the text above**]We may share data about you outside the UK for research related purposes to:* **In bullet points, concisely list the reasons why you will send data out of the UK**

If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following types of organisations:* [insert list e.g. our partners who analyse your data, companies to pay your expenses, organisations who store your data]

We will make sure your data is protected. Anyone who accesses your data outside the UK must follow our instructions so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following [**delete as applicable**]:* Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
* We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner’s Office (ICO) website](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/).
* We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
* We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
* We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the ICO website](https://ico.org.uk/for-organisations/report-a-breach).
* [OTHER]

Once the study is finished, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.**DELETE one option in square brackets:** We will keep your study data for the minimum period of time required by [**state the conditions that will be used to determine this time period**] **OR** [we will keep your study data for a maximum of **XX** years]. The study data will then be fully anonymised and securely archived or destroyed. |
| **What are your choices about how your information is used?** |
| You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.**OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop.You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.**OPTION if data will be used for future research:** If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [**Insert details of any specific bank / repository**]**OPTION if contact details will be used to invite the participant to take part in future ethically approved research:** If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.  |

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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, including the specific mechanism used by us when transferring your personal data out of the UK.* our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to [**email**], or
* by ringing us on [**phone number**].

**NOTE: At least one of these sources must be able to point people directly to the Sponsor’s Data Protection Officer(s).** |
| **What will happen to the results of the study?** |
| This study will be written up as **xxxxxx** (publication, conference presentation).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 e.g., ISRCTN). 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 **xxxxxxxx.**The study is being funded by **xxxxx.**Participants should be told if a doctor is being paid for their role in the study. |
| **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 in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from **<insert REC name>**. NHS Management Approval has also been given. |
| **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:**<insert contact details>** to be adapted depending on research site.Find below the example for NHS LothianPatient Experience Team – NHS LothianMainpoint102 WestportEdinburghEH3 9DN By telephone0131 536 3370 (open Mon-Fri, 9am to 2pm)By emailLOTH.Feedback@nhs.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/tissue 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.
 | c |
| **\*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.
 | c |
| 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.
 | c |
| 1. **(If appropriate or delete)** I give permission for the research team to access my medical records for the purposes of this research study.
 | c |
| 1. **(If appropriate or delete)** I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.
 | c |
| 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 NHS servers / passed to the University of Edinburgh / Trials Unit Centre [NAME] for administration of the study.
 | c |
| 1. **(If appropriate or delete options that are not applicable)** I give permission for my Community Health Index (CHI) number or hospital number to be collected and retained on NHS servers / passed to the University of Edinburgh and/or Trials Unit Centre [NAME]
 | c |
| 1. **(If appropriate)** I agree to my General Practitioner being informed of my participation in the study.
 | c |
| 1. I understand that data collected about me during the study may be converted to anonymised data.
 | c |
| 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.
 | c |
| 1. **(If appropriate or delete)** I agree to give a blood sample which will be used for genetic DNA analysis.
 | Yes c No c |
| 1. **(If appropriate or delete)** I give permission for whole genome/exome analysis to be conducted on my samples.
 | Yes c No c |
| 1. **(If appropriate or delete)** I agree to my anonymised data being used for future ethically approved studies.
 | Yes c No c |
| 1. **(If appropriate or delete)** I agree to my anonymised tissue being used for future ethically approved studies.
 | Yes c No c |
| 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 c No c |
| 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 c No c |
| 1. **(If appropriate or delete)** I agree to my audio/video recorded interview being transcribed by a third party contractor.
 | Yes c No c |
| 1. **(If appropriate or delete)** I agree to my tissue being used in procedures involving animals.
 | Yes c No c |
| 1. **(If appropriate or delete)** I agree to my tissue being used to create stem cells.
 | Yes c No c |
| 1. **(If appropriate or delete)** I understand that the data generated and tissue collected during this study may be used for future commercial development of products/tests/treatments/biomarkers and I will not benefit financially from this.
 | c |
| 1. I agree to take part in the above study.
 | c |

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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; 1x copy – into medical record