**SPONSOR GUI 15 Participant Information Sheet Template Associated Guidance**

This document should be used in conjunction with:

* **SPONSOR TEMPLATE 3: Participant Information Sheet Template**
* **SPONSOR GUI 14: Preparation of Participant Information Sheets and Informed Consent Forms**
* The HRA have useful guidance on drafting Participant Information Sheets (PIS) available here: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/>.
* Be succinct. Ensure relevant information required to enable participants to make an informed decision to consent is included and described clearly.

**Study Title**

This might be the long title as stated in the study protocol or a simplified version understandable to a lay person. If the latter, this should be used as the short title in the IRAS form.

Long and short study titles must be consistent throughout the full documentation set.

**Invitation**

*Translations*: Study teams should decide whether a translation of the PIS is appropriate/feasible for the study. Translations should be produced using an approved translation service, and verified by back-translation. If the approved translation service does not also undertake the back-translation, this should be justified (e.g. in relation to the level of risk).

# What is the purpose of the study?

Briefly outline of the purpose of the study in lay language.

Do not cut and paste directly from the protocol.

# What will happen to me if I decide to take part?

Lay descriptions of blood volume:

* 5ml is equivalent to 1 teaspoon
* 15ml is equivalent to 1 tablespoon
* Biopsies can be compared to grains of rice

**Are there any possible disadvantages and risks of taking part?**

A table could be used to present information about known effects of study drugs:

|  |  |
| --- | --- |
| **Side Effect** | **Frequency** |
|  | Very common (in more than 1 in 10 participants) |
|  | Common (more than 1 in 100 but fewer than 1 in 10) |
|  | Uncommon (more than 1 in 1000 but fewer than 1 in 100) |

**Will my General Practitioner (GP) be informed of my participation?**

GPs should be notified if study participation could affect the clinical presentation or care of participants and provided with Letter and the Participant Information Sheet.

GPs may be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression.

# Will my taking part in the study be kept confidential?

This section concerns the common law obligations of confidentiality. **It is separate to the** *What will happen to my data?* section and the General Data Protection Regulations (GPDR) transparency statement; however, as this section refers to data processing and secure storage it may be useful to signpost to the *What will happen to my data* section.

**What will happen to my data?**

You can seek advice and check whether you need a DPIA by contacting your departmental Information Governance Office or the University Information Compliance Team (ICT). RGEA do not provide advice on whether a DPIA is required or the contents of a DPIA. Please refer to the ICT Data Protection by Design webpages for further information; these are available at: <https://compliance.admin.ox.ac.uk/data-protection-by-design> (DPIA Screening Tool) and <https://researchdata.ox.ac.uk/ethical-and-legal-issues#collapse1826871>. You can check if you require a Security for Third Party Security Assessment (TPSA) by referring to the above webpages and emailing: grc@infosec.ox.ac.uk.

Data management must be clearly set out in your study documents when submitting your project to RGEA for review. Advice on data management plans can be found here: <https://researchdata.ox.ac.uk/data-management-plans>

**GDPR transparency wording**

The HRA requires all sponsors to include GDPR transparency wording in Participant Information Sheets. HRA released revised GDPR on wording on 1 April 2025 to bring it in line with:

* [Participant Information Quality Standards](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-quality-standards/)
* the [four principles for meaningful involvement of patients and the public in health and social care research](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/#:~:text=Four%20principles%20for%20meaningful%20involvement%20of%20patients%20and,people%20enough%20Principle%204%3A%20Describe%20how%20it%20helps)
* patient and public feedback and engagement.

 The GDPR statement provides information about:

* the type of organisations that process and share participant information
* the categories of personal identifiable data being processed and shared
* the safeguards in place when data is shared outside of the UK

The University Information Compliance Team and Legal Services Office have agreed the GDPR statement to be used on all University of Oxford-sponsored studies.

**This has been registered and approved by the HRA as the University’s official statement** and must be included in participant information sheets used in studies that require NHS REC and HRA approval.

HRA approvals and NHS RECs review all Oxford University (OU) PISs against the approved version they have on file.

If the statement does not appear in its registered, approved format, NHS REC and HRA Approval cannot be issued.

It is essential that the statement is not amended or altered in any way with the exception of:

* Items in [blue text between square brackets] which each study team should amend in line with their specific circumstances
* References to ‘you’ can be substituted for ‘your child’ in PISs intended for parents being asked to provide consent on behalf of their child.

Guidance on completing information required in [blue text between square brackets] is below:

|  |  |
| --- | --- |
| **GDPR wording** | **Examples/ Explanations** |
| Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a ‘task in the public interest’. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.  | Meets GPDR transparency by: * Identifying the sponsor by the legal name
* States the lawful basis for processing
* Names the sponsor as responsible for safeguarding data (i.e. is the Data Controller)
 |
| We will need to use information from you **[**from your medical records/your GP/your hospital records etc.**]** for this research project. We will share your information related to this research project with the following types of organisations **[**insert organisation types**].**  | Organisation types could include: * research collaborators and partners
* NHS organisations
* universities
* commercial organisations
* third parties providing services (cloud and web services, translators, transcribers etc), government departments).

Only organisations **relevant to the study** should be included in the list. Please populate this information from the information specific to your study and contained in your protocol and study documentation. This will be checked during sponsor review.  |
| This information will include your **[**initials/ NHS number/ name/ contact details/ provide a bullet list of identifiers held 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 instead.**OPTION if not already stated:** We will keep all information about you safe and secure by: **[**include a bullet list of some steps you will take to keep information secure**]**.  | Complete this section using information from your study protocol and supporting documentation. Keeping information secure may include:* data stored in a secure environment with relevant governance frameworks in place
* access limited to essential personnel only
* data stored in an ISO-accredited or other Secure Data Environment
* data has been deidentified as soon as possible
* methods appropriate to secure linked datasets
* paper-based data is stored in locked filing cabinets/storage with access restricted to authorised personnel

**Only include arrangements that apply to your study.**  |
| ***International Transfers***Please choose the option that applies to your study.  |
| **OPTION 1** **NO transfers out of the UK** - please use the wording below:Your personal data will not be shared outside the UK.  | Check whether any third-party service providers involved in the study are based outside of the UK. If Option 1 is selected, new consent would be required to make any such transfers in the future (including to service providers). |
| **OPTION 1 NO transfers out of the UK** – please use the wording below: Your personal data will not be shared outside the UK.  |  |
| **OPTION 2 If transfers out of the UK** **WILL OCCUR –** including if this remains a possibility in the future **AND if this includes sharing data in de-identified form** with other researchers **–** please use the following wording: 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 can’t 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 sorts of organisations: **[**insert list**]**.We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them 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:* (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 <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 <https://ico.org.uk/for-organisations/report-a-breach>.
 | Reasons why you might share outside the UK may include:* a data processor or third party based outside of the UK is required to process the data according to the instructions set out by the sponsor (i.e. the purposes set out in the protocol and related agreements)
* a collaborator / third party involved in the study is based outside of the UK
* you are sharing data in de-identified form with others outside of the UK.

**Only include the circumstances relevant to your stud**y.  The types of organisations may include:Cloud service providersInternational collaboratorsCommercial organisationsUniversity organisationsOrganisations analysing the dataOrganisations providing a service (IT, translation etc.) **Only include organisations applicable to your study.** This section covers the various safeguards the University has in place to manage international transfers safely. This text should not be amended.  |
| Once we have finished the study, 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.We will keep your study data for the minimum period of time required by **[**refer to University Policy on Management of Data for minimum periods**]**.  | Refer to the policy or regulation which determines the minimum retention period. These may include: Clinical Trials RegulationsOther regulations and Directives as applicableUniversity Policy on Management of Data |
| You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. 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. | This statement informs participants that whilst they might request removal, amendment or deletion of data, there may be circumstances where this is not possible. The PIS should set out the conditions for withdrawal of data clearly in the *What if I don’t want to carry on with the study* section  |
| **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. | Choose as applicable to your study |
| **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**]** | Choose as applicable to your study |
| 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 by:* asking one of the research team **[**include CI or study team email**]**
* sending an email to **[**relevant email contact**]**
* calling us on **[**study team number**]**
* contacting the University’s Data Protection Officer data.protection@admin.ox.ac.uk
* looking at the University’s privacy notice available at: <https://compliance.admin.ox.ac.uk/research-data>.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>.  |  |