In order to demonstrate Sponsor compliance with the regulatory requirements of GDPR and the DPA (2018), the table below provides suggested wording for use within the Participant Information Sheet (PIS) that meet requirements as set out by the regulator, the Information Commissioner’s Office (ICO).
The wording (italicised and in quotes) is suggested as a starting point, but there may be good reason to amend expression based on the nature of activity proposed or participant population. This will be agreed with the Sponsor’s office as part of Sponsorship review; provision of Sponsorship should be understood as assurance from the Sponsor and data controller that the requirements of the ICO are met.

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| --- | --- |
| **ICO Checklist item[[1]](#footnote-1)** | **RGEA template PIS section and/or suggested wording[[2]](#footnote-2)** |
| The name and contact details of our organisation. | Sections: *What if there is a problem?* ;  *Further information and contact details;* PIS header |
| The name and contact details of our representative (if applicable). | * RGEA are sponsor representative; researcher’s contact details included as above.
* Research teams are delegated some sponsor duties and their contact details are included, as above.
 |
| The contact details of our data protection officer (if applicable). | Sections: *What if there is a problem? ;* *What will happen to my data?* * RGEA /research team act as first point of contact and provide these details as required, in keeping with layered approach to provision of information.
* Website link included in PIS includes data protection officer contact details

 (<https://compliance.web.ox.ac.uk/individual-rights>). |
| The purposes of the processing. | Section: *What will happen to my data?** “*We will be using information from [source: e.g. you, your medical records*, *NHS England and other central NHS registries] in order to undertake this study”*
* *“The [local NHS Trust or local study team] will use your [list details, e.g. name, NHS number, home address, and contact details], to [give reason: e.g. contact you about the research study, and to oversee the quality of the study]”.*
* Details about any third party processors such as apps, cloud servers, mailing services and transcriptionists, will be provided, including their specific role, retention periods of data, and relevant security measures. Where relevant, there will have been referral to the University’s Information Security for Third Party Security Assessment (TPSA): grc@infosec.ox.ac.uk
 |
| The lawful basis for the processing. | Section: *What will happen to my data?** “*Data protection regulation requires that we the state the legal basis for processing information about you. In the case of research, this is ‘a task in the public interest.’”*
 |
| The legitimate interests for the processing (if applicable). | N/A - processing is necessary for the performance of a task carried out in the public interest. |
| The categories of personal data obtained (if the personal data is not obtained from the individual it relates to). | Section: *What will happen to my data?* * “*We will be using information from [source: e.g. you, your medical records, NHS England and other central NHS registries] in order to undertake this study”.*

Section*: What will happen to the samples I give?** Where DNA analysis is to be undertaken*: “To help keep your information confidential, your DNA and blood sample will be ‘anonymised ’ and assigned a study code. However, your DNA is unique to you so it can never be completely anonymous.”*
 |
| **ICO Checklist item[[3]](#footnote-3)** | **RGEA template PIS section and/or suggested wording[[4]](#footnote-4)** |
| The recipients or categories of recipients of the personal data. | Section: *What will happen to my data?* * Bespoke wording included where local study team/NHS Trust, central research team, and/or third parties will be processing :
* *“[central team] will be using information from [source: e.g. you, your medical records, NHS England and other central NHS registries] in order to undertake this study”.*
* *“The [local NHS Trust or local study team] will use your [list details, e.g. name, NHS number, home address, and contact details]”*
* Details of any third parties involved will also be specified. See ‘Purposes of Processing’, above.
 |
| The details of transfers of the personal data to any third countries or international organisations (if applicable). | Section: *What will happen to my data?* * Bespoke. PIS template guidance notes state: “If personal data will be shared with others outside the EU, you should make potential participants aware that such countries might not offer the same level of protection of privacy as that demanded by law in the UK. Inform potential participants of the steps you will take to ensure that any such transfer of information abroad will not compromise confidentiality, and obtain explicit consent for the transfer of personal data”.
 |
| The retention periods for the personal data. | Sections: *What will happen to my data?*  *Participation in future research*; *What will happen to the samples I give?* * *“We will keep identifiable information about you for [time as per IRAS A43/Combined Review B15] after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for [time as per IRAS A44/Combined Review B16] after the end of the study.*
* Where contact details are held for future research: *“If you agree to your details being held to be contacted regarding future research, we will hold a copy of your consent form until such time as your details are removed from our database.”*
* Where samples are retained for future use: *“If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.”*
* Where consent forms are held in medical notes, these will be held in keeping with the Trust’s policy on retention of medical records.
 |
| The rights available to individuals in respect of the processing. | Sections: *What will happen to my data?* *What will happen if I don't want to carry on with the study* *“Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at* <https://compliance.web.ox.ac.uk/individual-rights>*”.** Bespoke specification of limits with regard withdrawal of data/samples, as appropriate for each study.
* PIS template guidance notes state: “Limits on anonymity should be made clear to participants. Since complete anonymity is difficult to achieve, it is more in keeping with data protection regulation to refer to data as ‘anonymised’.”
 |
| The right to withdraw consent (if applicable). | Sections: *Do I have to take part? ;* *What will happen if I don't want to carry on with the study?* |
| The right to lodge a complaint with a supervisory authority. | Sections: *What if there is a problem?* ; *What will happen to my data?** Link to ICO via: <https://compliance.web.ox.ac.uk/individual-rights>
 |
| The source of the personal data (if the personal data is not obtained from the individual it relates to). | * “*We will be using information from [source: e.g. you, your medical records, NHS England and other central NHS registries] in order to undertake this study.”*
* PIS template guidance notes: “If you are receiving information from another source (e.g. NHS England) please indicate what you will be collecting”; “Outline any plans for long-term monitoring/follow-up, including ‘passive’ follow up through medical notes or data gained from central NHS registries (such as NHS England / NHS Central Register).”
 |
| The details of whether individuals are under a statutory or contractual obligation to provide the personal data. | Section: *Do I have to take part?** There is no obligation to participate in research.
 |
| The details of the existence of automated decision-making, including profiling (if applicable). | Usually N/A – bespoke wording to be included where research database or other automation using personal data is included.  |

1. <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-be-informed/> [↑](#footnote-ref-1)
2. Further guidance is given in the PIS template, available at https://researchsupport.admin.ox.ac.uk/clinical-trials-research-governance/resources#expand-2 [↑](#footnote-ref-2)
3. <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-be-informed/> [↑](#footnote-ref-3)
4. Further guidance is given in the PIS template, available at https://researchsupport.admin.ox.ac.uk/clinical-trials-research-governance/resources#expand-2 [↑](#footnote-ref-4)