National Research Ethics Committees (Ireland[[1]](#footnote-2))

‘Statement of Compliance’ Template for data protection compliance

Instructions

* A ‘Statement of Compliance’ regarding data protection compliance is a mandatory component of the ethics application documentation for:
	+ clinical trials of medicinal products (Clinical Trials Regulation EU 536/2014),
	+ clinical investigations of medical devices (Medical Device Regulation EU 2017/745), and
	+ performance studies of *in vitro* diagnostic devices (*In Vitro* Diagnostic Regulation EU 2017/746)
* This template has been developed by the National Office in consultation with the National Research Ethics Committees (NRECs) to assist Sponsors with informing the respective NRECs of data protection compliance and associated ethical considerations.
* Please consult with the National Office ‘*guidance on the submission of a ‘*[*Statement of Compliance’ for Data Protection compliance*](https://www.nrecoffice.ie/wp-content/uploads/Guidance_Statement-of-Compliance.pdf)*’*

If using this template, please complete the following Sections to **i)** inform the NREC of the suitable and specific data protection measures in place to ensure the fundamental rights and freedoms of the research participants, **ii)** enable the NREC to consider any ethical aspects of data processing.

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| 1. Trial / Investigation and Site Identification  |
| Clinical trial number | Click or tap here to enter text. |
| Sponsor | Click or tap here to enter text. |
| Title of trial / investigation | Click or tap here to enter text. |
| Submission date | Click or tap here to enter text. |
| Name of site | Click or tap here to enter text. |

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| 2. Legislative compliance |
| Tick all boxes that apply or otherwise comment as to why the statements set out below are not applicable. |
| [ ]  all applicable personal (including de-identified/pseudonymous) data will be processed in accordance with the General Data Protection Regulation (EU) 2016/679 (GDPR).[[2]](#footnote-3)[ ]  in the jurisdiction of Ireland, all applicable personal data (including de-identified/pseudonymous) will be processed in accordance with the Irish Health Research Regulations 2018[[3]](#footnote-4), and as amended.Click or tap here to enter text. |

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| 3. Risk assessment |
| Tick all boxes that apply or otherwise comment as to why the statements set out below are not applicable. |
| [ ]  an assessment of the data protection risks associated with processing personal data for the purpose of the study has been carried out in accordance with GDPR requirements[[4]](#footnote-5),Click or tap here to enter text. |
| Describe the level of risk (ie high, medium, low) associated with processing personal data for the purpose of the study, that is being ethically assessed by the NREC.[[5]](#footnote-6) |
| Click or tap here to enter text. |
| Describe the suitable safeguarding measures for processing personal data which will be implemented to mitigate against any identified risks or harms to participants rights, in accordance with all applicable data protection legislation. |
| Click or tap here to enter text. |
| Describe any ethical implications that may arise due to the level of risk associated with processing of personal data. |
| Click or tap here to enter text. |

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| 4. Participant rights |
| Tick the box if applicable or otherwise comment as to why the statement set out below is not applicable. |
| [ ]  the research participants are fully informed of their data protections rights and freedoms, through clear and unambiguous language within the Participant Information Leaflets and accompanying consent and/or assent forms, as applicable.Click or tap here to enter text. |

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| 5. Data Protection Officer (DPO) engagement |
| Insert the Sponsor’s DPO statement regarding the data protection risks and mitigating safeguards being implemented in accordance with all applicable data protection legislation. |
| Click or tap here to enter text. |
| Describe any engagement with and feedback from the DPO of the lead study site /clinical investigation site / clinical trial site / performance study site in Ireland. Such engagement is strongly advised to ensure the data processing operations, identified risks and associated mitigating safeguards have been discussed in relation to the personal data those sites are the Data Controller for. |
| Click or tap here to enter text. |

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| 6. Declaration of Sponsor |
| On behalf of the Sponsor, and as a duly authorised representative, I declare that the information provided herein is accurate and all personal data being processed for the purpose of the study shall be in accordance with all applicable national and international data protection legislation and in accordance with best international ethical standards. |
| **Print Name**: Click or tap here to enter text.**Sponsor:** Click or tap here to enter text.**Role:** Click or tap here to enter text.**Date:** Click or tap to enter a date. (dd/month/yyyy)  |

1. Ireland means the Republic of Ireland [↑](#footnote-ref-2)
2. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN> [↑](#footnote-ref-3)
3. <https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf> [↑](#footnote-ref-4)
4. <https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments> [↑](#footnote-ref-5)
5. <https://www.dataprotection.ie/en/organisations/know-your-obligations/lawful-processing/special-category-data> [↑](#footnote-ref-6)