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

‘Statement of Compliance’

Data Protection Compliance Template

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.
* Where the NRECs determine that the Statement of Compliance is insufficient, such that there are ethical concerns, they reserve the right to request further information.
* 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)

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| 1. Trial/investigation and site identification | |
| EU Clinical Trial Number | Click or tap here to enter text. |
| Clinical investigation / Performance study number | Click or tap here to enter text. |
| Sponsor | Click or tap here to enter text. |
| Title of trial / investigation/ study | Click or tap here to enter text. |
| Date | Click or tap here to enter text. |
| Name of site(s) | 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 compliance with the General Data Protection Regulation (EU) 2016/679 (GDPR).[[2]](#footnote-2)  If not, please click here to comment |
|  | In the jurisdiction of Ireland, all applicable personal data (including de-identified/pseudonymous) will be processed in compliance with the Irish health research regulations (Data Protection Act 2018 (Section 36(2)(Health Research) Regulations 2018 [[3]](#footnote-3)), and as amended.  If not, please click here to comment |

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| 3. Risk assessment | |
| Tick all boxes that apply and include additional details, as applicable. | |
|  | An assessment of data protection risks associated with processing of personal data for the purpose of the study has been carried out in accordance with GDPR requirements, and any necessary mitigating actions have been implemented. [[4]](#footnote-4)  Please include additional details here |
|  | Due consideration has been given to the level of risk (i.e. high, medium, low) associated with processing personal data for the purpose of the study [[5]](#footnote-5) and has been determined (select one):  High  Medium  Low |
|  | Suitable safeguarding measures for processing personal data will be implemented to mitigate against any identified risks or harms to participants’ rights, in compliance with all applicable data protection legislations.  Please include additional details here |
|  | Due consideration has been given to any ethical implications that may arise due to the level of risk associated with processing of personal data. (Outline below as applicable).  Please include additional details here |

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| 4. Participants’ rights | |
| Tick the box if applicable or otherwise comment as to why the statement set out below is not applicable. | |
|  | The study participants are fully informed of their data protections rights and freedoms, through clear and unambiguous language within the Participant Information Leaflets and accompanying Informed Consent and/or Assent Forms, as applicable.  If not, please comment here |

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| **5. Data Protection Officer (DPO) Engagement** |
| Under the Health Research Regulations[[6]](#footnote-6) the Sponsor shall engage with the Sponsor DPO and/or the DPO of the lead study site/clinical investigation site/clinical trial site in Ireland and ensure that data processing operations, identified data protection risks and associated mitigating safeguards have been considered in relation to the personal data those sites are the Data Controller for, in accordance with all applicable data protection legislation.  Tick the box if applicable or otherwise comment as to why the statement set out below is not applicable. |
| Prior to the study starting the sponsor will obtain feedback from the relevant DPO.  If not, please comment here |

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