National Research Ethics Committees (Ireland[1])

Guidance on the submission of a 'Statement of Compliance' for data protection compliance

1. Overview

The National Research Ethics Committees (NRECs) have a defined remit to ensure research studies submitted for assessment are conducted ethically to safeguard the well-being, safety and dignity of research participants. The ethical integrity of a research study must also be underpinned by compliance with all applicable legislation.

It is not the responsibility of the NRECs or National Office for Research Ethics Committees to regulate data protection law during the process of research ethics review, however, assurances must be provided that the legally compliant data protection measures are in place for a research study, to safeguard the interests of research participants.

The responsibility to ensure compliance with all applicable data protection legislation, including within the jurisdiction of Ireland, lies solely with the Sponsor.

This guidance[2] document sets out key considerations and requirements when submitting a Statement of Compliance for the purpose of ethical assessment of research studies to the NRECs.

For the purpose of this document, the 'Sponsor' of a study is assumed to be the Data Controller and these terms are used interchangeably throughout.

The National Office has developed a template Statement of Compliance for Sponsors to submit.

Template: Statement of Compliance

Appendix I sets out more general information regarding the importance of data protection compliance and how it interlinks with ethics, safeguarding of participants and ensuring their fundamental rights and freedoms can be exercised, lawfully and ethically.

Appendix II provides useful resources for Sponsor consideration and assistance with providing a Statement of Compliance

[1] Ireland means the Republic of Ireland

[2]This guidance does not contain any authoritative interpretation of EU or Irish data protection law and should not be construed as legal advice. The responsibility lies solely with the Sponsor/Data Controller regarding interpretation of, and compliance with all legislative data protection obligations.

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2. National Office requirements for ethical assessment of data processing and protection

The National Office has reviewed and revised the NREC procedures regarding Sponsor obligations to demonstrate compliance with applicable data protection legislation when processing participants personal data.

For the purposes of the National Research Ethics Committees (NRECs) ethical assessment, a '**Statement of Compliance**' regarding data protection compliance, is a mandatory component of the ethics application documentation for:

- clinical trials of medicinal products,
- clinical investigations of medical devices, and
- performance studies of *in vitro* diagnostic devices

NOTE: This procedural change for the requirement for a Statement of Compliance is not intended to be a substitute for conducting the necessary risks assessments and/or Data Protection Impact Assessment as required. The responsibility remains solely with the Sponsor/Data Controller to ensure compliance in accordance with GDPR and Irish data protection laws, as further outlined in Appendix I

3. Pre-submission considerations

In advance of submitting an application for ethics assessment by the NRECs, it is important that the Sponsor of the study:

☐ consults with its Data Protection Officer (DPO), or equivalent individual(s) who is a competent and recognised authority in data protection law and practices[3],

☐ carry out an assessment of the data protection risks associated with processing personal data for the purpose of the study and ensure all suitable safeguarding measures can be implemented to mitigate against any identified risks or harms to participants' rights,

☐ where possible, engage with the DPO of the lead study site / clinical investigation site / clinical trial site / performance study site in Ireland, to ensure the data processing processes, identified risks and associated mitigating safeguards have been discussed,

☐ implement all actionable feedback received from the Sponsor and study DPO(s),

☐ ensure all necessary data sharing/processing agreements are executed by all relevant parties,

☐ ensure full compliance with all applicable data protection laws, including the Health Research Regulations, 2018[4]

[3] https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-officrs/guidance-appropriate-qualifications
[4] https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

4. Statement of Compliance requirements

In providing a statement of compliance regarding suitable and specific data protection measures in place to ensure the fundamental rights and freedoms of the research participants, the Sponsor, or legally authorised representative for the study shall provide a comprehensive single statement to the NREC inclusive of the following points:

Legislative compliance

☐ all applicable personal (including de-identified/pseudonymous) data will be processed in accordance with the General Data Protection Regulation (EU) 2016/679 (GDPR)[5],

☐ 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[6], and as amended,

Risk assessment

☐ 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,

☐ 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 has been described,

☐ all suitable safeguarding measures for processing personal data will be implemented to mitigate against any identified risks or harms to participants rights, in accordance with all applicable data protection legislation,

☐ any ethical implications that may arise due to the level of risk associated with processing of personal data,

Participant rights

☐ the research participants are fully informed of their data protections rights and freedoms, through clear and unambiguous language within the Participant Study Information Leaflets and accompanying consent and assent forms, as applicable,

DPO engagement

☐ the Sponsor's DPO statement regarding the data protection risks and mitigating safeguards being implemented in accordance with all applicable data protection legislation,

☐ where possible, engagement with the DPO of the lead study site /clinical investigation site / clinical trial site, performance study site in Ireland, 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.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN
[6] https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

Authorities

☐ declaration from the Sponsor, regarding the Statement of Compliance

Appendix 1 - General guidance

- **Data protection and ethics**

As part of the National Research Ethics Committee's (NREC) assessment process, the NRECs must consider the ethical aspects of data protection and processing of personal data for clinical trials of medicinal products, clinical investigations of medical devices and performance studies of *in vitro* diagnostic devices.

A fundamental ethical principal set out in the Declaration of Helsinki[7] states that:

> '*Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information'*.

It further states that ethics committees must:

> *'take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects'*

In accordance with Article 9(1)[8] of the General Data Protection Regulations (GDPR) and as described by the Data Protection Commission[9], health data is considered sensitive or a special category of personal data and therefore potentially raises higher ethical risks and must be subject to more stringent suitable and specific safeguarding measures.

In a document commissioned by the European Commission (DG Research & Innovation)[10], it is stated:

> *'Data protection is both a central issue for research ethics in Europe and a fundamental human right. It is intimately linked to autonomy and human dignity, and the principle that everyone should be valued and respected.'*

If research entails higher-risk data processing, it's imperative to consider any ethical issues that may arise as a result of planned data collection and processing operations. Furthermore, in the identification and analysis of potential ethics issues that may be arise, corresponding mitigating actions should be implemented to minimise data processing risks and harms to the research participants.

- **European and Irish legislative requirements**

[7] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
[8] https://gdpr-info.eu/art-9-gdpr/
[9] https://www.dataprotection.ie/en/organisations/know-your-obligations/lawful-processing/special-category-data (DPC - Irish supervisory authority for the GDPR)
[10] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-and-data-protection_he_en.pdf

In accordance with Article 7 of the Clinical Trial Regulations (CTR), the assessment of Part II[11] submissions to the NRECs involves the evaluation of the processing and safeguarding of personal data for the study being conducted within the jurisdiction of Ireland.

Regarding clinical investigation of medical devices, the NREC will consider any ethical issues in relation to the processing of personal data. In accordance with Article 72 (3)(4) and Annex XV of the Medical Device Regulation (MDR)[12], the Sponsor is obligated to ensure that all personal data and the confidentiality of records of the research participants remain protected in accordance with all applicable data protection laws on personal data.

Regarding performance studies of *in vitro* diagnostic medical devices as regulated under the In Vitro Diagnostics Regulations (IVDR)[13], equally the NREC will assess ethical aspects of data protection compliance and ensure the right to privacy for participants is safeguarded.

EU legislation transposed into Irish law further provides for the NRECs to have regard for

> '*the arrangements for the protection of research participants' privacy and confidentiality*[14];

- **Compliance with legislation**

All Sponsors must, if requested, be able to demonstrate compliance with both legal and ethical requirements. Such requests could come from research participants (or 'data subjects'), funding agencies or data protection supervisory authorities, such as the Data Protection Commission in Ireland.

Sponsors should implement adequate arrangements to ensure compliance with the applicable legislative requirements to safeguard the protection and confidentiality of personal data of research participants, in particular:

- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed,
- measures that will be implemented to ensure confidentiality of records and personal data of subjects, and
- measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects and harms to research participants.

[11] https://www.ema.europa.eu/en/documents/other/quick-guide-part-ii-how-evaluate-clinical-trial-application-assessment-decision-ctis-training_en.pdf
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[13] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746
[14] https://www.irishstatutebook.ie/eli/2022/si/257/made/en/pdf and https://www.irishstatutebook.ie/eli/2022/si/41/made/en/pdf

Where the lead study site /clinical investigation site / clinical trial site is deemed a 'data processor', or 'joint controller', all parties should be aware of their obligations as 'Controllers' and 'Processors'[15] under the GDPR and Health Research Regulations.

- **DPIA obligations**

A Data Protection Impact Assessment (DPIA)[16] is a documented process to facilitate the Sponsor to systematically analyse, identify, and minimise the data protection risks of a project. It is an integral part of the Sponsor's accountability obligations under Article 35[17] of GDPR, and when done adequately helps to assess and demonstrate how the Sponsor will comply with data protection obligations.

The completion of a DPIA is a mandatory requirement under GDPR and the Health Research Regulations 2018[18] for studies that are deemed 'high risk' for the processing of personal data. Health data is considered a 'special category of data' that is 'likely to result in high risks' to the rights and freedoms of research participants.[19] [20]

The completion of a DPIA (if required) for the processing of personal data for a given research purpose is the sole responsibility of the controller of the data being used for that research purpose.

- **Data Protection Officer role**

Article 37(1)[21] of GDPR states that a Data Controller and Processor shall designate a Data Protection Officer (DPO)) in any case where:

> *the processing is carried out by a public authority or body, except for courts acting in their judicial capacity;*
>
> *the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or*
>
> *the core activities of the controller or the processor consist of processing on a large scale of special categories of data pursuant to Article 9 or personal data relating to criminal convictions and offences referred to in Article 10.*

[15] https://www.dataprotection.ie/en/organisations/know-your-obligations/controller-and-processor-relationships
[16] https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments
[17] https://gdpr-info.eu/art-35-gdpr/
[18] https://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf
[19] https://www.dataprotection.ie/en/organisations/know-your-obligations/lawful-processing/special-category-data
[20] https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments
[21] https://gdpr-info.eu/art-37-gdpr/

DPO feedback on the data protection risks and mitigating actions associated is an integral component of the Statement of Compliance. This is especially important where the Sponsor is situated outside of Ireland.

The National Office strongly advises that the DPO of the lead study site /clinical investigation site / clinical trial site / performance study site in Ireland, should be given the opportunity to review and provide comment on the DPIA to ensure the data protection rights of Irish research participants are safeguarded.

Sponsors and Principal Investigators of a study who require further information on the completion of a DPIA, are advised to review resources available on the Data Protection Commission web and to consult with their respective DPOs.

- **Health Research Regulations (Ireland)**

In the jurisdiction of Ireland, the Health Research Regulations 2018, transpose into Irish law, suitable and specific mandatory safeguards that must be implemented when conducting health research.

Regarding data protection compliance, suitable and specific safeguards and the requirement for a DPIA, the Health Research Regulations align with the requirements set out in GDPR and state:

> *Regulation 3. (1) A controller who is processing or further processing personal data for the purposes of health research shall ensure that the following suitable and specific measures are taken to safeguard the fundamental rights and freedoms of the data subject…..*
>
> *(c) the following processes and procedures relating to the management and conduct of the health research are in place:*
>
> > *(i) the carrying out of an assessment of the data protection implications of the health research;*
> >
> > *(ii) where the assessment carried out under clause (i) indicates a high risk to the rights and freedoms of individuals, the carrying out of a data protection impact assessment;*

It is essential that all Sponsors (and study sites as applicable) are in compliance with the Health Research Regulations when conducting health research in the jurisdiction of Ireland, including the collection and use of personal data of research participants.

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Appendix 2 - Resources

- National Office 'Guidance on data protection and health information' https://www.nrecoffice.ie/committees/policies-and-procedures/guidance-on-data-protection-and-health-information/
- Health Research Data Protection Network (HRDPN): PRACTICAL GUIDE ON DATA PROTECTION FOR HEALTH RESEARCHERS https://ncto.ie/wp-content/uploads/2022/10/HRDPN-Data-Protection-Guide-Document-for-Health-Researchers.July-2022.v1.pdf
- European Commission: Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation', developed by the European Commission https://health.ec.europa.eu/system/files/2019-04/qa_clinicaltrials_gdpr_en_0.pdf