NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

NREC guidance on data protection for research purposes for applicants

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Preamble

This guidance has been prepared by the National Office for Research Ethics Committees to assist applicants conducting health research to comply with data protection legislation and best practice in research ethics in relation to considerations for safeguarding research participants' data.

The information contained herein is intended to be general guidance, provided in the spirit of fostering best practice in data protection for research that falls within the remits of the NRECs, which may be also relevant for other health research areas. It is not intended to be exhaustive nor necessarily prescriptive, and as such, should not be construed as legal advice.

The responsiblity for compliance with the GDPR, the Data Protection Acts, and the Health Research Regulations 2018 lies solely with the data controller or joint-data controllers.

It is always advisable to consult directly with your organisations' Data Protection Officer(s) on all data protection matters.

For definition of key terms used throughout this, please read the glossary of key terms[1] on the Data Protection Commission's website.

[1] Data Protection Commission: Definition of Key Terms. Retrieved from: https://www.dataprotection.ie/en/individuals/data-protection-basics/definition-key-terms

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1 Introduction

All research that involves the processing of any personal data must be able to demonstrate compliance with both legal requirements and ethical principles. In Ireland, an application to a National Research Ethics Committee (NREC) must demonstrate compliance with prevailing EU and Irish data protection legislation, including the EU General Data Protection Regulation[2] (GDPR) and the Health Research Regulations 2018[3] and as amended[4] [5].

When planning and conducting a research study, it is the responsibility of the Applicant[6] to identify the required legal provisions and ensure compliance. While it is not the responsibility of the NREC to verify compliance with data protection law, during the process of research ethics review, it will need to be assured that the legally compliant data protection measures are in place for a research study, to safeguard the interests of research participants.

As this document is for guidance only, applicants who are processing personal data for the purposes of health research should seek study-specific advice from their organisations' Data Protection Officer(s).

2 Irish legislation on data protection

The Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018) outline the suitable and specific measures for data processing. The Health Research Regulations 2018 also specify that all health research studies that encompass the processing of personal data must have research ethics approval.

Applicants intending to carry out research in Ireland should familiarise themselves with the Health Research Regulations 2018, which:

- outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research (Regulation 3(1))
- provide for explicit consent as a mandatory safeguard when processing personal data for health research (Regulation 3(1)(e))

[2] EU General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1. Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

[3] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 314 of 2018. Stationary Office. Retrieved from http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

[4] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 188 of 2021. Stationary Office. Retrieved from: http://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf

[5] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 18 of 2021. Stationary Office. Retrieved from: http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

[6] Applicant: The individual / entity that is responsible for the preparation, submission, conduct, and administration of a study for NREC review. Applicant is typically the Principal Investigator or sponsor.

- outline when explicit consent is not a mandatory safeguard when processing personal data for health research (Regulation 3, as amended)[7]
- provide a definition of health research for the purposes of the regulation (Regulation 3(2))
- provide for a process to apply for a consent declaration for new research (Regulation 5)
- provide for the requirement to engage with participants, patients and the public (Regulation 5(4)(d), as amended)
- provide for a Health Research Consent Declaration Committee to make decisions on applications for consent declarations (Regulation 7-13 and Schedule)
- provide for an appeals process (Regulation 11(2))
- include a number of miscellaneous provisions (Regulations 14-16).[8]

3 Consent

Most studies have to consider two aspects of consent in planning their research study: the first is explicit consent for data processing and the second is consent to participate in the research. Applicants should consider the circumstances of obtaining consent for both and be aware of the differences. For example, in individuals lacking capacity consent to participate in research by legal representative is permitted under SI 190/2004[9]. However no one can provide consent on behalf of another individual for data processing.

If explicit consent is not or cannot be obtained, anonymised data may be processed only, or the researcher must seek a consent declaration. This is a declaration made by the Health Research Consent Declaration Committee that it is satisfied that the public's interests in carrying out the health research significantly outweighs the requirement for explicit consent of the data subject.[10] For the purpose of this document, 'data subjects' are research participants whose personal data is processed for health research.

3.1 Consent for data processing

Important factors in obtaining valid, lawful consent for data processing is ensuring that the consent to processing is freely given, specific and informed and recorded.

[7] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 314 of 2018. Stationary Office. Retrieved from http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

[8] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 314 of 2018. Stationary Office. Retrieved from http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

[9] European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 - S.I. No. 190/2004. Stationary Office. Retrieved from: http://www.irishstatutebook.ie/eli/2004/si/190/made/en/print

[10] Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018, S.I. No. 314 of 2018. Stationary Office. Retrieved from http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

The GDPR specifies that consent for participation in health research and associated data processing must be [1112]:

- Unbundled: ie, separate from other terms and conditions;
- Granular: ie, options to differentially consent to distinct types of processing if relevant to the study;
- Named: ie, organisations and third parties relying on consent must be individually named;
- Recorded: ie, consent is appropriately recorded to ensure it is explicit;
- Easy to withdraw: ie, must be clear to research participants that they have the right to withdraw consent at any time, and how to do this.

Furthermore, Regulation 3(1)(e) of the Health Research Regulations 2018 requires that the explicit consent of the individual has been obtained prior to the commencement of the research for the processing of his or her personal data for the purpose of the research. Regulation 3(1)(e) has been amended further to provide for a derogation from obtaining explicit consent in certain areas of research such as retrospective chart review, pre-screening, or research in the 'vital' interests, subject for certain provisions being met.

Applicants should be particularly mindful in how they present both the study information and the options and choices available to research participants (including the options to not participate in the study and to withdraw at a later stage) so that they can be assured that research participants understand exactly the nature and extent of their consent to participate in health research. This includes information on any intended follow up contact with the participants as part of the current or future research.

Whilst study consent should cover all processing activities carried out as a part of the study, at times it is not possible to fully identify the specific purpose of data collection at the time of collection. Therefore, Applicants should consider whether they want to seek consent for future uses of data from participants. In line with GDPR, Applicants need to seek consent from participants to the use of their data depending on the area of scientific research, extent allowed by the intended purpose, while keeping with recognised ethical standards for scientific research. This means, participants should be asked a) whether they allow storage and processing of their data for possible future research, once approved by a relevant research ethics committee, that is b) with or without further consent in the future; c) related or unrelated to current study; and d) commercial or non-commercial purpose.

In addition to the Health Research Regulations, the National Office recommends that Applicants familiarise themselves with the 'Guidance on information principles for informed consent for the processing of personal data for health research'[13] prepared by the

[11] EU General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

[12] Davis R. What do Health Research Regulations 2018 mean for health researchers? 19/10/18. Retrieved from https://www.hrb.ie/fileadmin/1._Non-plugin_related_files/RSF_files/GDPR_guidance_for_researchers/What_do_Health_Research_Regulations_2018_mean_for_health_researchers_-_Ruth_Davies.pdf

[13] Department of Health: Guidance on Information Principles for informed consent for the

Department of Health. This document offers guidance on the information researchers should consider providing to research participants to ensure consent is informed and appropriately recorded. Applicants should consult the information principles outlined in this guidance when designing research participant documentation for their study.

3.2 Consent for research participation

The consent to participate in research is separate aspect of consent to that for data processing, and is a requirement by Irish and international law, in addition to ethical obligations (such as Declaration of Helsinki).

The requirement of informed consent for the conduct of research is set out in the HSE National Consent Policy 2019[14]. The policy highlights that the goal of consent is to ensure that research participants have sufficient information to be able to make informed decisions about their participation, which are compatible with their individual interests and values, thereby demonstrating the principle of respect for persons. The policy also notes that special consideration must be given to the timing of the consent process to allow potential participants enough time to fully consider their participation and to ask questions.

4 Data Protection Impact Assessment

A Data Protection Impact Assessment (DPIA) is used to identify and mitigate against data protection-related risks arising from the conduct of a proposed research study. As the nature and operational implications for data privacy of a study may not be apparent at an early stage in the planning, the DPIA may need to be an ongoing process, and Applicants need to review or repeat the DPIA throughout the lifetime of the study[15].

The completion of a DPIA is a mandatory requirement under GDPR and the Health Research Regulations 2018 for studies that are deemed ‘high risk’ for the processing of personal data. In assessing whether data processing is likely to result in a ‘high risk’, Applicants are asked to consider following criteria:

1. Evaluation or scoring - especially to do with someone's work performance or health eg a biotechnology firm offering genetic testing to customers in order to predict disease / health risks;
2. Automated-decision making with legal or similar effect - the processing may lead to discrimination or exclusion;
3. Systematic monitoring eg CCTV in a public space;

processing of personal data for health research. Retrieved from https://www.hrb.ie/fileadmin/1._Non-plugin_related_files/RSF_files/GDPR_guidance_for_researchers/Health_Research_Information_Principles.pdf

[14] HSE National Quality Improvement Team. National Consent Policy HSE V.1.3. Retrieved from https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf

[15] Data Protection Commission: Data Protection Impact Assessments. Retrieved from: https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments

4. Sensitive data eg health data, genetic data and all Article 9[16] special categories of data;
5. Data processing on a large scale;
6. Datasets that have been matched or combined;
7. Data concerning vulnerable research participants - power imbalance between the researchers / clinical team and participants eg patients, children, the elderly, employees, persons with disabilities;
8. Innovative use or applying technological or organisational solutions - eg fingerprint or facial recognition;
9. Data transfer outside the EU;
10. Where the processing itself prevents a data subject from accessing a service - eg credit screening by banks to decide whether to give someone a loan.

In terms of health research, criteria 4 & 7 frequently apply, and criteria 1,5 & 9 can sometimes apply.17 This will likely be applicable to many clinical trials and clinical investigations where sensitive information related to a person's health is routinely processed.

The NRECs require that DPIAs are submitted with an application for research ethics review. Alternatively, Applicants have the option to submit a statement outlining why a DPIA is not required.

For the purposes of NREC review, the DPIA will need to be completed by the Data Controller of the research study and reviewed by its Data Protection Officer (DPO). The advice of the DPO must be documented as part of the DPIA process18. The Participant Information Leaflet should include the names and contact details of Data Controller(s), Data Processors and the DPO associated with the research study. Where there are Joint-Data Controllers, the advice of the DPOs from all Data Controllers is required.

Where the Data Controller is based in a non-EU country, the National Office will accept DPIAs reviewed by a person with the equivalent role and responsibilities to a DPO.

Additionally, where the Data Controller is situated outside of Ireland, the National Office strongly advises that the DPO of the lead Irish-based institution should be given the opportunity to review and provide comment on the DPIA to ensure the data protections rights of Irish research participants are safeguarded.

Applicants who require further information on the completion of a DPIA, are advised to review resources available on the Data Protection Commission website and to consult with their institutional DPO.

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[16] EU General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1. Retrieved from http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

[17] Beaumont Hospital and Ms Mary Kirwan: Research Ethics Committee Standard Application Form (RECSAF) 5.6 (adapted version, copyright Beaumont Hospital)(last updated 8 June 2021)) for the ethical review of health-related research studies, which are not subject to National Research Ethics Committee Review. Retrieved from: https://www.beaumontethics.ie/docs/application/standard_applicationform5.6_8.6.21.doc

[18] Data Protection Commission: Data Protection Impact Assessments. Retrieved from: https://www.dataprotection.ie/en/organisations/know-your-obligations/data-protection-impact-assessments

5 Transfers of personal data to third countries or international organisations

Transfers to third countries or international organisations should be done in full compliance with Chapter V of the GDPR19. If the research study proposed is likely to encompass transfer of participants' data to non-EU countries, the NREC application must clarify the legal basis for any such transfer. The Applicants should seek the advice of their host institution's DPO or a suitably qualified expert, and include their opinion in the application20. Transfers of personal data to third countries or international organisations should be clearly communicated to research participants and should be included in the Participant Information Leaflet.

6 Data protection-related elements of review

When planning and conducting a research study, Applicants must consider and demonstrate compliance with legal requirements and ethical principles of processing of personal data. These typically include but are not limited to the following[21]:

a) provision of training in data protection law and practice to anyone involved in carrying out the research

b) the method of processing personal data to establish suitability or eligibility of potential participants for inclusion in health research (pre-screening)[22]

c) the process for obtaining consent for data processing from participants

d) a description of the persons who will have access to personal data of the participants including medical records and biological samples

e) a description of provisions to ensure the confidentiality and security of personal information concerning participants/volunteers

f) the extent to which the data will be anonymised

g) how data will be obtained, and the purposes for which they will be used

h) how long data will be kept

[19] Data Protection Commission: Transfers of Personal Data to Third Countries or International Organisations. Retrieved from: https://www.dataprotection.ie/en/organisations/international-transfers/transfers-personal-data-third-countries-or-international-organisations

[20] European Commission: Ethics and data protection. 2018. Retrieved from https://ec.europa.eu/info/sites/info/files/5._h2020_ethics_and_data_protection_0.pdf

[21] Adapted from Irish Council for Bioethics. Guidance on Operational Procedures for Research Ethics Committees. Irish Council for Bioethics, Dublin, 2004. Retrieved from https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2015/11/Operational_Procedures-ffor-Research-Ethics-Committees-Guidance-2004.pdf

[22] Department of Health. Guidance on Pre-screening Amendment to the Health Research Regulations January 2021. Retrieved from: https://assets.gov.ie/120265/830650eb-0a83-49a9-9e4f-65741fa13c12.pdf

i) who will have access to the data and for what purpose

j) to which countries (if any) the data will be sent

k) the extent to which the study involves the processing of personal data of living persons

l) whether it is possible for this study to be undertaken using anonymised data

m) identification and evaluation of data protection risks and the risk mitigation outlined in the DPIA

n) the security measures that will be in place during processing

o) other measures are in place to ensure the protection of participant's personal data

p) arrangements to anonymise, archive or destroy data once the research has been completed.

7 Useful resources

All European Academies. International Transfer of Health Data for Research | (allea.org) Retrieved from: https://allea.org/international-transfer-of-health-data-for-research/

Beaumont Hospital and Kirwan M. Research Ethics Committee Standard Application Form (RECSAF) 5.6 (adapted version, copyright Beaumont Hospital)(last updated 8 June 2021)) for the ethical review of health-related research studies, which are not subject to National Research Ethics Committee Review. Retrieved from: https://www.beaumontethics.ie/docs/application/standard_applicationform5.6_8.6.21.doc

Data Protection Commission: https://www.dataprotection.ie/

Davis R. What do Health Research Regulations 2018 mean for health researchers? 19/10/18. Retrieved from https://www.hrb.ie/fileadmin/1._Non-plugin_related_files/RSF_files/GDPR_guidance_for_researchers/What_do_Health_Research_Regulations_2018_mean_for_health_researchers_-_Ruth_Davies.pdf

Department of Health. Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018). Stationary Office. Retrieved from http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

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Department of Health. Guidance on Pre-screening Amendment to the Health Research Regulations, January 2021. https://assets.gov.ie/120265/830650eb-0a83-49a9-9e4f-65741fa13c12.pdf

European Commission. Ethics and data protection. 2018. Retrieved from https://ec.europa.eu/info/sites/info/files/5._h2020_ethics_and_data_protection_0.pdf

European Data Protection Board. EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, February 2021. Retrieved from https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

European University Institute. Good Data Protection Practice in Research, 2019. Retrieved from: https://www.eui.eu/documents/servicesadmin/deanofstudies/researchethics/guide-data-protection-research.pdf

Health Research Consent Declaration Committee (HRCDC) https://hrcdc.ie/

HSE National Quality Improvement Team. National Consent Policy HSE V.1.3. Retrieved from https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf

Irish Council for Bioethics. Guidance on Operational Procedures for Research Ethics Committees. Irish Council for Bioethics, Dublin, 2004. Retrieved from https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2015/11/Operational_Procedures-ffor-Research-Ethics-Committees-Guidance-2004.pdf

Official Journal of the European Union. Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council. Retrieved from https://eur-lex.europa.eu/eli/dec_impl/2021/914/oj?uri=CELEX:32021D0914&locale=en

Official Journal of the European Union. EU General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1. Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679