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# Legal Basis for Data Processing in Health Research

## **Introduction**

Processing of personal data for health research requires a legal basis under [Article 6 of the GDPR](https://gdpr-info.eu/art-6-gdpr/). Where there is processing of personal data which contains special category data, for example, data concerning health, for health research, such processing requires a legal basis under Article 6 and a condition for processing under [Article 9 of the GDPR](https://gdpr-info.eu/art-9-gdpr/)s.

It is important to note that the Controller for the processing of personal data for the purposes of the health research is responsible for determining the appropriate legal basis and condition for processing personal data. If your organisation is not the Controller, you must defer to the organisation that is the Controller.

The legal basis for processing of personal data in health research must be distinguished from consent required for ethical reasons or for Clinical Trial Regulations compliance or for compliance with the National Consent Policy. Researchers may be required to obtain consent to meet these requirements, but consent won’t necessarily be the legal basis for data processing.

### **Legal Basis and Condition for Processing**

The following legal basis is the most appropriate in non-commercial health research:

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| **Article 6(1)(e) of the GDPR** processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller; |

In the context of health research, the following condition for processing is the most commonly seen:

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| **Article 9(2)(j) of the GDPR** processing is necessary for archiving purposes in the public interest, **scientific or historical research** purposes or statistical purposes … and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. |

Article 6(1)(e) is relied on as a legal basis for data processing for health research by Health Research Data Protection Network (HRDPN) members as its members are:

* Public hospitals funded by the exchequer, who are empowered to commission or collaborate in research pursuant to its objects and functions under [Section 7 of the Health Act 2004](https://www.irishstatutebook.ie/eli/2004/act/42/section/7/enacted/en/html#sec7).
* Universities who are required to conduct research and scientific investigation pursuant to their objects and functions under [Section 12 and 13 of the Universities Act 1997](https://www.irishstatutebook.ie/eli/1997/act/24/section/12/enacted/en/html#partiii-chapi).
* Children’s Hospitals who are required to conduct research and scientific investigation pursuant to [Section 6 of the Children's Health Act 2018](https://www.irishstatutebook.ie/eli/2018/act/27/enacted/en/print#sec6).

Controllers relying upon this legal basis must ensure that the processing of the personal data ensures the data protection principles of necessity, proportionality and minimisation.

The above legal basis is not suitable in all instances. In particular, commercially funded research would not necessarily be in the “public interest” and may require an alternative legal basis. Commercial Sponsors are required to identify their legal basis for processing data when conducting research.

## **Health Research Regulations**

Under the Health Research Regulations any health research as defined in that legislation requires explicit consent as a suitable and specific safeguard.

This requirement is separate to the requirements under the GDPR. That is to say, that in addition to the above legal basis the parties will also require consent as a suitable and specific safeguard for any data processing for health research.

In any event, consent is needed for compliance with Clinical Trials Regulation, as an ethical requirement, and to comply with HSE Policies.

## Guidance on the Legal Basis for Data Processing in Regulated Studies for Universities and Public Hopsitals

If a study is a regulated study, such as those conducted under the Clinical Trials Regulation or the Medical Device Regulation, a different legal basis may be appropriate. The HRDPN commonly see the following legal basis for such processing:

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| **Article 6(1)(c) of the GDPR** processing is necessary for compliance with a legal obligation to which the controller is subject; |

The HRDPN commonly see the following condition for such processing:

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| **Article 9(2)(i) of the GDPR** processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices … which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy. |

This legal basis would be used in addition to the legal basis for the research study. For further information in relation to data processing for clinical trials, please see the European Data Protection Board [EDPB Opinion 3/2019](https://www.edpb.europa.eu/our-work-tools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers_en) concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR).

## Other Legal Basis

1. **Article 6(1)(a) of the GDPR** the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

**this consent must be fully revocable. Researchers will not be able to process the data once consent has been revoked.**  This is commonly used if there are any minors engaged in research as their parent or guardian must consent to them taking part if they are under the age of 18.

1. **Article 6(1)(b) of the GDPR** processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

tends not to be relevant

1. **Article 6(1)(c) of the GDPR** processing is necessary for compliance with a legal obligation to which the controller is subject;

*this legal basis might be relevant in a clinical trial where a researcher has legal obligations for reporting or regulatory requirements which require them to process data. Tends to be used in conjunction with another legal basis.*

1. **Article 6(1)(d) of the GDPR** processing is necessary in order to protect the vital interests of the data subject or of another natural person;

tends not to be relevant

1. **Article 6(1)(e) of the GDPR** processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

*most commonly seen legal basis in University and Hospital led health research*

1. **Article 6(1)(f) of the GDPR** processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child;

*not generally available to public bodies as a legal basis and requires the preparation of a legitimate interest assessment*.

We hope the above is helpful, however please note that this is high level guidance and if you have specific questions you should refer them to the University’s Data Protection Officer at dataprotection@mu.ie .

## Other Resources

Data Protection Commission, [Guidance on Legal Bases for Processing Personal Data](https://www.dataprotection.ie/sites/default/files/uploads/2020-04/Guidance%20on%20Legal%20Bases.pdf) (December 2019)