

**GUIDANCE ON THE ASSESSMENT OF EXPLICIT CONSENT FOR HEALTH RESEARCH**

**HOW TO USE THIS GUIDANCE NOTE**

This guidance note should be read and reviewed in conjunction with the guidance on Information Leaflets.

**Part 1** of this guidance note will provide you with guidance on the assessment of “existing” consents for health research that was **commenced prior to 8 August 2018** where a data controller **processes or further processes** personal data for the purposes of health research[[1]](#footnote-1) after 8 August 2018.

**Part 2** of this guidance note outlines the requirements of explicit consent and provides a sample consent form for research studies and guidance on how to prepare a consent form for a health research study that is in compliance with the General Data Protection Regulation (EU) 2016/679 (“**GDPR**”) and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (the “**Health Research Regulations**”).

**Please note that this guidance note may be amended from time to time and does not constitute legal advice.**

**Part 1**

**Guidance on assessment of consent for health research commenced prior to 8 August 2018 What has changed under the Health Research Regulations?**

Regulation 6 of the Health Research Regulations 2018 provides that a data controller who is carrying out health research that commenced prior to **8 August 2018** who **processes or further processes** personal data for the **purposes of that health research after 8 August 2018** shall, as soon as practicable and no later than [7 August 2019][[2]](#footnote-2), have **explicit consent** of the data subject (i.e. research participants) for the processing of his or her personal data for the purpose of specified health research, either:

* in relation to a particular area, or
* more generally in that area, or
* a related area of health research, or
* part thereof.

Please note that this guidance note does not cover the other requirements set out in Regulation 3(1)(a)-(e) of the Health Research Regulations, which specify the mandatory "suitable and specific measures" that must be taken when the processing of personal data is undertaken for the purposes of health research.

***What do I need to do as a researcher that has an ongoing health research study that was commenced prior to 8 August 2018?***

Please review your “existing consents” obtained for health research studies that are ongoing against the checklist contained in **Part 2** to determine if you have explicit consent in line with the Health Research Regulations and GDPR.

You should be able to respond “yes” to all of the questions set out in the checklist below.

If you are not able to respond “yes” to each, please contact the Data Protection Officer at dataprotection@tcd.ie with a copy of this completed checklist detailing the question or questions below that you are unable to respond “yes” to. The Data Protection Officer will assist you in determining whether you will need to re-consent data subjects or whether you will need to seek a consent declaration from the Health Research Consent Declaration Committee.

The Health Research Board (HRB) have developed a helpful decision making tree to determine if you need to re-consent data subjects or if your research study will need to apply to the Heath Research Consent Declaration Committee for a consent declaration, please see <https://hrcdc.ie/wp-content/uploads/2019/01/Decision_Tree_30072018.pdf>.

***When is the deadline for making an application to Health Research Consent Declaration Committee?***

Applications under Regulation 6 of the Health Research Regulations should be made **before 7 July 2019**.

The following key points should be noted:

1. After **7 August 2019** the requirement for explicit consent in relation to research falling under Regulation 6 will be fully in effect.
2. Applications submitted to the HRCDC on or before **7 July 2019**, will not be considered in breach of the requirement to have explicit consent in place, until such time as the Committee has made a decision on an application. **Accordingly, as a practical matter, all applications under Regulation 6 should be made before 7 July rather than after that date and before 7 August 2019.**
3. The Committee will not be able to consider applications purporting to be made under Regulation 6 if they are submitted after 7 August 2019, since any such application would be breach of the requirement to have explicit consent in place by that date.

**PART 2**

**What is required for “explicit consent”[[3]](#footnote-3)?**

Please note that the requirement for explicit consent is an additional safeguard which is required in order to be compliant with the Health Research Regulations. You will also need a lawful basis for the processing of personal data under Article 6 and Article 9 of the GDPR.

# Lawful Basis - Ordinary Personal Data

If processing ‘Ordinary’ personal data[[4]](#footnote-4) then you must satisfy at least one of the lawful bases as set out under [Article 6 GDPR](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#d1e1797-1-1)

# Lawful Basis - Special Category Data (Sensitive Personal Data)

# If processing sensitive personal data[[5]](#footnote-5) then, in addition to the Article 6 lawful basis, you must also satisfy one of the conditions as set out under [Article 9 GDPR](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679#d1e1797-1-1)

# Health Research Regulations - Explicit Consent required for Health Research

In addition to satisfying Articles 6 & 9 GDPR requirements you must also obtain explicit consent for processing personal data for health research purposes. This mandatory requirement is set out under Regulation 3(1)(e) of the [2018 Health Research Regulations](http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf).

# Explicit consent is informed consent which is recorded/documented

In order for consent to be valid, it must be:

* Freely given;
* Specific;
* Informed;
* Unambiguous; and
* Such consent must be recorded by a statement or by a clear affirmative action.

Please see table below for guidance on each of these aspects of informed consent.

**Checklist to determine whether consent in is line with the GDPR and Health Research Regulations**

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| --- | --- |
| **GDPR Explicit Consent Requirements – Processing of Personal Data** | **Yes/No** |
| 1. **Has the consent been freely given? Have you informed the data subject that they have the option to withdraw their consent at any time if they so wish?**
* The element “free” implies real choice and control for data subjects.
* If the data subject has no real choice, feels compelled or coerced to consent in any way or if the data subject feels that if they do not consent their medical care or treatment may be affected in some way, then their consent will not be valid.
* We understand that given the relationship between a data subject and the medical/research team, this can be a difficult balance. If your data subject is fully informed (see item 3), it will be easier to assess whether their consent is freely given.
* The data subject must be informed that they can withdraw their consent at any time without detriment. This should be highlighted from the outset so that the data subject does not feel under any obligation to continue against their wishes.
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| 1. **Is the consent specific?**
* The data subject should not be surprised by any use of their personal data, health data or any other sensitive data by the research team.
* Have all of the data controllers been clearly identified?
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| 1. **Is the consent informed?**
* In order to be informed, the data subject should have enough information to be able to make their decision to consent or not.
* Have you clearly stated what (type of) personal data will be collected and used? (e.g. names, addresses, blood type, medical condition, etc.).
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| 1. **The consent must be unambiguous**
* Consent requires a statement from the data subject or a clear affirmative act, which means that the data subject must have taken a deliberate action to specifically consent to the particular processing of the personal data. Is it obvious that the data subject has consented to the particular processing?
* You must demonstrate that consent has been given to a particular processing activity. Have you maintained a written record of the consent?
* The consent form should be signed by the data subject in order to remove all possible doubt.
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| 1. **Automated decision-making**
* *If applicable*  Have you included information about the use of the data for automated decision-making in accordance with [Article 22 (2)(c) GDPR](https://gdpr-info.eu/art-22-gdpr/)? Processing is ‘automated’ where it is carried out without human intervention, and where it produces legal effects or significantly affects a data subject. Automated processing includes profiling.
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| 1. **International data transfers**
* *If applicable* Have you included information on the possible risks of data transfers outside the EEA due to absence of an adequacy decision and of appropriate safeguards as described in Article 46? See: <https://gdpr-info.eu/art-46-gdpr/>
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1. A definition of Health Research can be found here <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/what-is-research/>. [↑](#footnote-ref-1)
2. Please note that an extension of the transitional period deadline to the 7th August 2019 has been agreed by the Department of Health (the “**DOH**”), the DOH and the Data Protection Commission . For further information please see <https://hrcdc.ie/update-amendment-to-regulation-6-april-30th-deadline-for-explicit-consent/>. [↑](#footnote-ref-2)
3. Article 4 (11) of GDPR and in accordance with guidelines on consent issued by the Article 29 Working Party – include link. [↑](#footnote-ref-3)
4. Please see Article 4(1) for a definition of Personal Data: <https://gdpr-info.eu/art-4-gdpr/> [↑](#footnote-ref-4)
5. Please see Article 9(1) of GDPR for a definition of special categories of personal data/sensitive personal data. <https://gdpr-info.eu/art-9-gdpr/> [↑](#footnote-ref-5)