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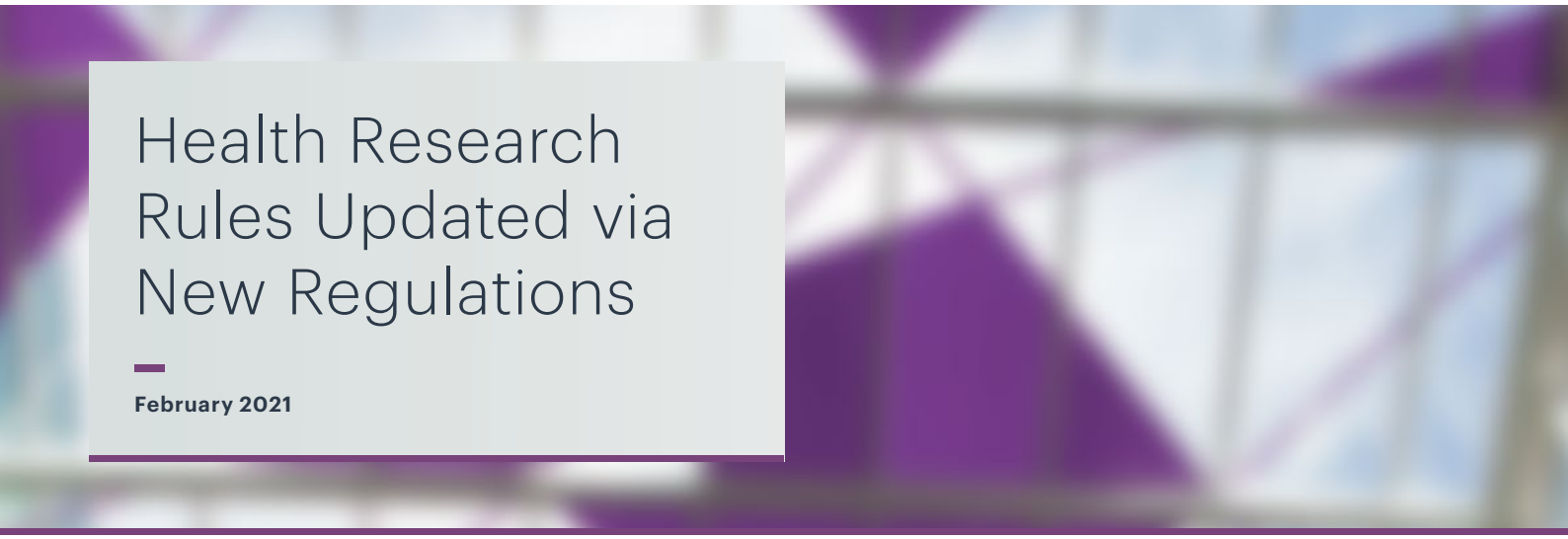
// TECHNOLOGY



Health Research Rules Updated via New Regulations

February 2021

The rules on the processing of personal data for health research purposes have been revised with the introduction of the new Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (the "**2021 Regulations**"). The 2021 Regulations update the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations (the "**2018 Regulations**").

The 2018 Regulations require that a controller who is processing personal data for health research purposes must ensure that *"suitable and specific measures are taken to safeguard the rights and freedoms of the data subject."* These measures include obtaining the explicit consent of a data subject to such processing, or else obtaining a declaration from the Health Research Consent Declaration Committee ("**HRCDC**") that explicit consent is not required, on the basis that the public interest in carrying out the research outweighs the public interest in obtaining explicit consent.

The Department of Health engaged with concerned stakeholders to identify challenges presented by the 2018 Regulations and any other issues which required review. These new 2021 Regulations seek to address these challenges and issues by:

1. reformulating the explicit consent requirement in a way more familiar to health researchers;
2. introducing new rules on pre-screening individuals for inclusion in health research;
3. exempting retrospective chart review studies from the explicit consent requirement;
4. deferring the requirement for consent where an individual is incapable of giving consent due to mental or physical incapacity;
5. providing an exemption to the explicit consent requirement where an individual has provided valid consent under the Data Protection Directive, which consent has not been withdrawn; and
6. making improvements to the appeals process.

The Department of Health, the HSE, the Health Research Board, the Secretariat to the HRCDC and the Data Protection Commission, have collaborated to publish guidance on the 2021 Regulations (the "**Guidance**").

1.

NEW BEST PRACTICE REQUIREMENTS FOR EXPLICIT CONSENT

Controllers processing personal data for health research purposes are still generally obliged to obtain either explicit consent or a HRCDC declaration that consent is not required on public interest grounds. However, the consent requirement has been reformulated. The new wording provides that prior to the commencement of the health research, explicit consent must be obtained, recorded and retained, and a copy provided to the data subject *"in accordance with international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight)"*.

The Guidance refers to international instruments on health research as evidencing that the requirement for informed consent in health research studies, and provision for its withdrawal, is an accepted core ethical principle of health research. The Guidance draws on these instruments in outlining the best practice trend in this area as being strongly in favour of informed consent that:

- identifies the scope of the specified research;
- provides information in a timely manner, in an intelligible and easily accessible form and using clear and plain language;
- gives choices to individuals about the areas of research that they want their information to be used in and third parties that they are willing to have their information shared or not shared with;
- allows for the withdrawal of consent in a convenient manner and explains the limits of withdrawal where that is required; and
- is documented in writing, electronically or in another format, with a copy of this record provided to the individual.

2.

PRE-SCREENING FOR INCLUSION IN HEALTH RESEARCH

The 2021 Regulations clarify that pre-screening, i.e. processing personal data in order to establish whether an individual may be suitable or eligible for inclusion in health research, is in itself health research. While the 2021 Regulations do not detail what pre-screening actions may consist of, the Guidance provides that the following actions are all envisaged:

1. reviewing personal data of a data subject to assess suitability or eligibility for inclusion in a health research study;
2. analysing pre-screening data and documenting findings;
3. sharing findings (in a non-identifiable manner) with others involved in the research team;
4. approaching individuals found to be eligible or suitable to determine their interest in participating in a study; and
5. sharing the identity of individuals with the research team on a confidential basis where the individuals have consented to being contacted by the research team.

New measures have been introduced to better facilitate controllers who already hold such personal data in conducting such processing. A controller shall not require explicit consent or ethical approval by a Research Ethics Committee ("**REC**") to perform pre-screening, provided that such processing is undertaken by:

- a health practitioner employed by the controller or a person studying to be a health practitioner under the direction and control of the controller;
- an employee of the controller, such as a medical records clerk, who would ordinarily, in the course of his or her duties, have access to the personal data of such individuals held by the controller; or
- an authorised person (i.e. an employee of a higher education institution, a health practitioner or a charity), who is under the direction and control of a health practitioner who is an employee of the controller.

The controller must also have in place a binding agreement with the authorised person's employer. This agreement must provide that any processing of personal data without explicit consent which is not for pre-screening purposes shall be a breach of that authorised person's employment contract carrying sanctions. There are also transparency requirements: the controller must promote the fact that an authorised person may use individuals' personal data for pre-screening purposes without their explicit consent via notices in its public areas (for example, notices for the attention of patients in the public areas of a hospital).

3.

EXPLICIT CONSENT EXEMPTION FOR RETROSPECTIVE CHART REVIEW STUDIES

Retrospective chart review studies are a type of research in which a controller, often a hospital, refers to pre-recorded patient personal data it has already collected to answer research questions. The 2021 Regulations provide that a controller shall not be obliged to obtain the explicit consent of data subjects in order to perform a retrospective chart review study in certain circumstances. The controller must have assessed the data protection risks of such research as being low, and an REC must have approved this finding. Only certain persons may perform such a review: employees of the controller who are health practitioners or whose duties ordinarily involve access to the personal data concerned for the purpose of providing health care to those individuals, or persons studying to be a health practitioner. Similar transparency requirements as those noted above in relation to pre-screening will also apply.

4.

DEFERRING THE CONSENT REQUIREMENT IN CASES OF INCAPACITY

The 2021 Regulations provide that in exceptional circumstances where an individual is incapable of giving consent due to physical or mental incapacity, that individual's personal data may be processed for a health research purpose with the requirement for consent deferred until the individual is capable of giving their consent. This is limited to circumstances where the principal purpose of the processing of the individual's personal data by the controller is necessary for the provision of health care to that individual and to protect their vital interests. The health research purpose must be related to this principal purpose and approved by an REC.

Explicit consent must be obtained from the individual as soon as is practicable upon their regaining decision-making capacity. If the individual does not give their consent, then the processing must cease and any personal data already processed for the health research purpose must be erased, except where to do so would be likely to render impossible or seriously impair the achievement of the objectives of that processing.

5.

VALID DATA PROTECTION DIRECTIVE-ERA CONSENT EXEMPTION

Under the 2018 Regulations, as amended in 2019, a controller conducting health research that commenced prior to the 8 August 2018 (the date the 2018 Regulations came into effect) was obliged to obtain the explicit consent of the data subjects concerned to the processing of their personal data. This obligation presented significant practical difficulties. Alternatively, a controller in this position could apply to the HRCDC for a declaration that explicit consent was not required either on public interest grounds, or because they had obtained valid consent to the processing under the law applicable at the time (namely the EU Data Protection Directive and the Data Protection Acts 1988 and 2003).

The 2021 Regulations revise this obligation. A controller shall not be required to obtain explicit consent (nor the alternative HRCDC declaration) provided:

- the controller obtained valid consent under the Data Protection Directive regime;
- this consent has not been withdrawn; and
- the controller has a valid legal basis for such processing under Article 6 of the GDPR and meets one of the conditions in Article 9 of the GDPR.

The Guidance encourages controllers who have an application for a declaration awaiting consideration by the HRCDC to consider the amendment and to contact the Secretariat of the HRCDC to determine whether the application is still necessary.

6.

IMPROVEMENTS TO THE APPEALS PROCESS

Lastly, the appeals process for decisions of the HRCDC has been revised. The size of the appeal panel has been increased from three to between five and seven. An appellant has 30 working days from the date the appeal panel is established to provide any written information relevant to the appeal. The appeal panel shall also stand for a further 30 working days after having made a decision in order to provide formal clarification on any matters arising from the decision. The appeal panel is also now empowered to request the HRCDC to forward its observations to it and to invite submissions from anyone that it considers appropriate.

CONCLUSION

The 2021 Regulations reflect the efforts of the Department of Health to identify and address the practical challenges the 2018 Regulations posed for health research in Ireland. Hopefully the amendments will serve to remove those impediments faced by stakeholders in conducting health research while ensuring that the public can continue to have confidence in how such personal data is used.

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