HRCDC
Health Research Consent Declaration Committee

The Health Research Regulations

Seeking a Consent Declaration

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Transparency | Confidence | Trust

History - Health Research Regulations

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Number 7 *of* 2018

Data Protection Act 2018

STATUTORY INSTRUMENTS.

S.I. No. 314 of 2018

Suitable and specific measures for processing

36. (1) Where a requirement that suitable and specific measures be taken to safeguard the fundamental rights and freedoms of data subjects in processing personal data of those subjects is imposed by this Act or regulations made under this Act, those measures may include in particular the following—

(a) explicit consent of the data subject for the processing of his or her personal data for one or more specified purposes,

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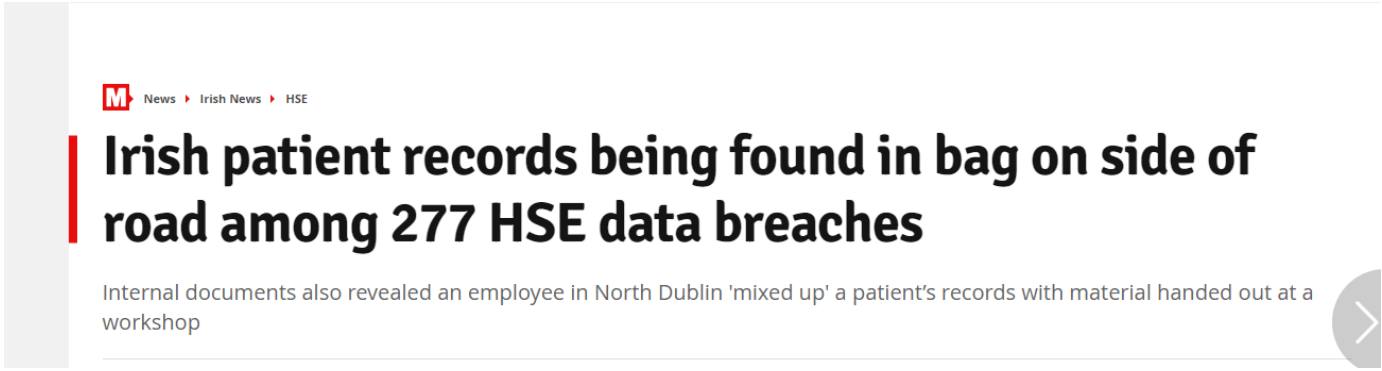
Privacy rights of individuals



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Consent is an essential consideration


THE IRISH TIMES

Tue, Apr 23, 2019

NEWS | SPORT | BUSINESS | OPINION | LIFE & STYLE | CULTURE

Brexit | Ireland | World | Politics | Crime & Law | Social Affairs | Health | Education

Consent on human tissue the key, says legal expert

Fri, Feb 11, 2000, 00:00

Kevin O'Sullivan

There is an urgent need to introduce legislation and guidelines embracing informed consent on the taking of organs and tissue from patients following post-mortems in Irish hospitals, according to an expert in medical and legal issues.

Prof Denis Cusack of UCD said the only legislation which touched on human tissue was the Anatomy Act dating from the 1830s, and it only related to whole corpses.


THE IRISH TIMES

Mon, Jun 24, 2019

NEWS | SPORT | BUSINESS | OPINION | LIFE & STYLE | CULTURE | MORE

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Gynaecologist performed 'exploratory work' without consent

Kilkenny hospital referred matter to Medical Council and sought suspension of doctor

about 14 hours ago

Paul Cullen Health Editor

Health Research Regulations

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- August 7th 2018
- 1 year transition period until August 7th, 2019, (July 7th)
- Reinforces Safeguards already set down in GDPR
- Safeguards;
  - Ethics approval
  - Controller(s) and Processor(s) identified
  - Details of sharing of data (who/purpose)
  - Training for researchers
  - DPIA and risk identification
  - Data minimisation & controls
  - Access limitation
  - Anonymisation, archiving, retention
  - Other technical /organisation measures eg contracts.
  - Transparency
- Introduces explicit '**Consent**' as a Safeguard;

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Explicit consent

EU **GDPR** Regulation "Consent should be given by a clear affirmative act establishing a freely given, specific, informed and *unambiguous* indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement."

EU **Data Protection Directive**: "any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed"

An Roinn Sláinte
Department of Health

Guidance on Information Principles for informed consent for the processing of personal data for health research

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Do I need a Consent Declaration?

Keep your questions simple – the answers might be complicated.

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- Am I/We the Data Controller(s) (YES)
- Am I 'processing' personal data (YES)
- Is it anonymised? (NO)
- Can/should I anonymise the data (NO)
- Do I have permissions? (MAYBE)
- Do I have *explicit* consent? (NO)
- Can I get explicit consent? (NO)

https://www.dataprotection.ie/en/guidance-landing/anonymisation-and-pseudonymisation

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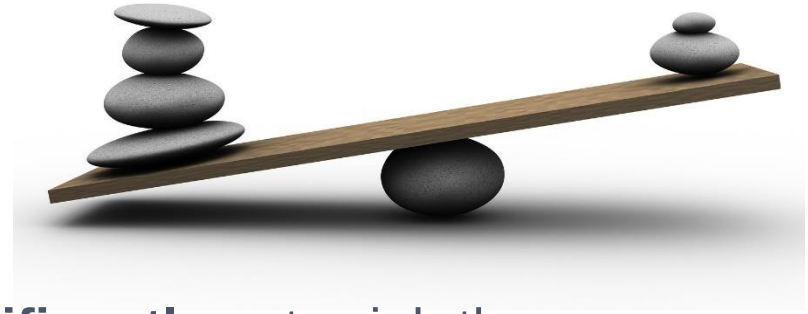
A Declaration…

- Is made solely to the Data Controller
- Covers the processing of data (collection, use, storage, retention, altering,
- Does not cover the transfer of data to other third party recipient data controllers
- Time limited
- May have conditions attached



- The public's interest in health research must **significantly** outweigh the requirement for explicit consent
- All other Safeguards must be in place

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How to Apply

- If in doubt……. DPO@DataControllerOrganisation.ie
- secretariat@hrcdc.ie , www.hrcdc.ie
- The application guideline notes are useful
- Take a different perspective,
- Step into the shoes of the data subject/patient/participant, whose data you are using
- The HRCDC is seeking assurances that in the absence of consent, the privacy rights of non consented individuals are met with GDPR level of Safeguards.

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Application Pitfalls

- Unclear who is the **Controller** - this determines who the declaration is made to

- Describe ALL the **data** being collected
  - Why the need to collect so much data?
  - The source of the data? Staff data? Patient data?
  - Can you minimise the data? Generalisation
  - eg Year of birth Vs date of birth Vs Age

- The **data flow** is unclear
  - A schematic/data flow map helps
  - Point of collection, to storage, to user

- **Exit Strategy** - this will aid defining the scope of the Declaration
  - eg how long is the declaration for?
  - eg when in the future can data be anonymised?
  - eg when will the ‘Master Key’ be destroyed?
  - eg when will the study be published and project completed?

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Application Pitfalls

- The **DPIA** is not consistent with the content of the application form
- The **DPO** must have provided feedback on the DPIA
- **REC** approval (or provisional) approval is required and must be in date
- Why **Consent** can not be obtained
  - Do not generalise
  - Resourcing is not an adequate reason on it's own.
  - Case by Case – cohort size, vulnerability, ethical considerations, etc
  - A strong evidenced based case should be presented.
  - Consider a pilot study
  - Talk to your REC
  - Talk to patient focus group, get perspectives

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Application Pitfalls

- **PPI Engagement**
  - eg consider liaising with focus groups,
  - eg consider have PPI been involved for the life time of the project
  - A basic letter endorsing the project may not be construed as PPI engagement from a group might

- **Transparency** is a Safeguard
  - This isn't about methodology, it's about the participant knowing what is happening with their data.
  - No surprises, update privacy notices, update websites

- **Technical** measures are Safeguards
  - eg controls, data access, storing, archiving, anonymising, retention periods

- Be **Consistent** and **Clear**
  - eg "the data will be irrevocably anonymised"....later on …."the pseudonymised data will"…
  - eg "the Research team"……later on…."the Hospital Staff"

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HRCDC key considerations

- Why (re)consent could not be sought?
- What is the public interest case?
- Higher the risk to privacy rights, the stronger the public interest and consent cases should be
- Has there been patient and/or public involvement
- All items are considered on balance with each other

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Summary

- Address all the Qs in the relevant sections
- Consider the perspective of the non-consented participant
- Build a strong ublic interest case
- The HRCDC are not an academic peer review group
- Jargon and complex language should be avoided so they can fully understand the project and need for a declaration.

DEADLINES: For Health Research that commenced prior to August 8th, 2018

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JULY 7TH

- application pending, under the HRCDC make a decision

July7th – Aug 7th

- applications will be considered, but maybe in breach of the Regs

AUG 7TH

- applications can not be considered

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Q & A

- DISCLAIMER – The Secretariat can not provide legal advice. Guidance and feedback is for information purposes only and should not be construed as legal advice. Only the Data Controller can predetermine whether a consent declaration is necessary.

- All GDPR queries should be directed to the DPO

- All consent queries should be discussed with appropriate authorities eg patient focus groups, RECs. https://hrcdc.ie/guidance/

- Anonymisation and Pseudonymisation – https://www.dataprotection.ie/en/guidance-landing/anonymisation-and-pseudonymisation

Questions - From UCC

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Q1.

- If researchers are working towards re-consenting all participants in a study to a GDPR-complaint consent form, but know that they will be unable to re-consent everyone by the 7th August 2019 (e.g. due to logistical reasons), what would you recommend they do?

- Can they suspend recruitment to the study until all re-consents have been obtained? Or do they need to apply to the HRCDC, even though they are aware they can obtain consent from all recruited participants in the next few months?

A.

- Researchers may be in breach if the study is continued without explicit consent, after Aug 7th

-Consider whether ‘halting’ the ‘processing’ of the current data will jeopardise the study, until explicit consent can be obtained;

-Consider what activity is being carried out that falls outside the current consent;

Recruitment may not need to be suspended - if the recruitment is seeking ‘explicit’ consent’ of new recruits

Questions - From UCC

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Q2.

A recap on the distinction between the data controller and the data processor(s) would be useful. Some researchers in UCC have collaborations with other groups in terms of data sharing, processing and storing samples etc., (in this instance, data/samples would be pseudonoymised before being shared); they aren't sure whether these other groups are joint data controllers or data processors.

A.

- Consult with DPO

- Data Controllers…. 'determines the purposes and means of the processing of personal data' (Art 4(7))

NOTE: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf
NOTE: https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_opinionctrq_a_final_en.pdf

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Questions - From UCC

Q3

a

If you do not submit to the HRCDC by the 7th July, and are not in compliance with the HRR 2018/GDPR, but you have a legal obligation to store the data as per the Clinical Trials Directive 2001, what should you do with the data?

a.

- 'Clinical Trials' (as defined in CTD 2001) falls outside the scope of the Health Research Regulations.
  - -Consider what was covered in the consent/information leaflets;
  - - Consider whether secondary use of Clinical Data was consented for;
- A Declaration maybe required, if consent was not and can not be obtained for health research
- See '**Notes**' above
- Context important

b.

Where the HRR might conflict with other data retention policies (e.g. UCC policies), does HRR take precedence?

b.

- The HRR does not prescribe specific data retention practices
- The HRR require Safeguards including GDPR standards of retention of data
- UCC Policies should be in line with GDPR data retention requirements
- No conflict should arise
- Consult with DPO

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Questions - From UCC Q4.

How specific does consent for storing samples/data for future research have to be?

A.

- Participants should be informed about the storage and retention of their data/samples,
- Data Controllers should taking into account GDPR data retention compliance
- There is no right or wrong answer so long as the information is ‘unambiguous’ and ‘needs must’ approach
- Broad consent is acceptable i.e. A Broad scope of use is acceptable, provided it is clear and unambiguous
- Future proofing is good

Questions - From UCC

Q5.

We have had a lot of queries around the requirement of explicit consent for retrospective chart reviews, can you please discuss this and provide information on when an update on this can be expected?

A.

Requirement for explicit consent has been deferred for Retrospective chart reviews carried out by a data controller's

i) health practitioner; and
ii) employee; and
iii) affiliated students

https://hrcdc.ie/retrospective-chart-reviews/

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Thank you

Secretariat@hrcdc.ie

www.hrcdc.ie