HRCDC
Health Research Consent Declaration Committee

Seeking a Consent Declaration from the HRCDC

Dr. Emily Vereker - Programme Manager, Secretariat, HRCDC
Jonny Barrett - Project Officer, Secretariat, HRCDC

Transparency | Confidence | Trust

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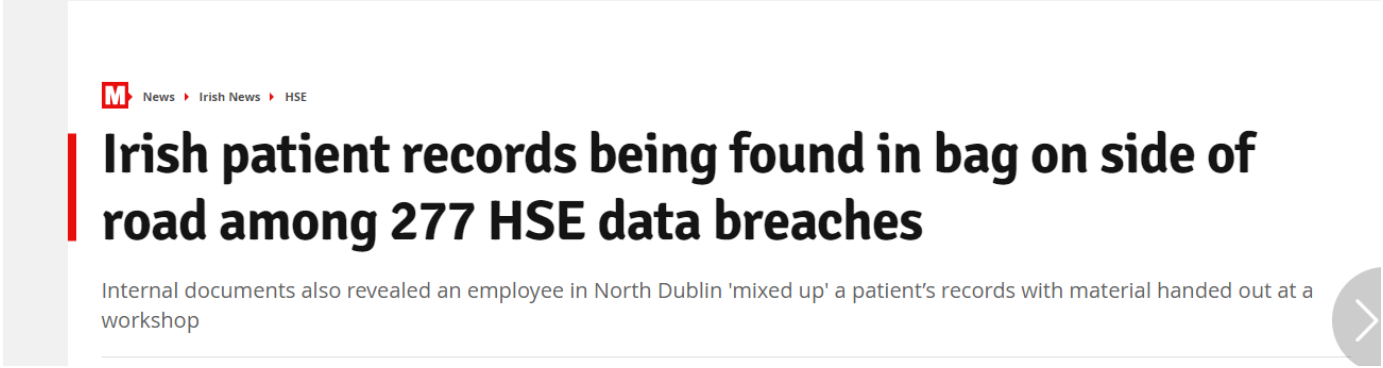
Data protection – fundamental rights & freedoms of individuals


News › Irish News › HSE

Irish patient records being found in bag on side of road among 277 HSE data breaches

Internal documents also revealed an employee in North Dublin 'mixed up' a patient's records with material handed out at a workshop


RTÉ News Sport Entertainment Business Lifestyle Culture Player TV Radio More

News > Leinster | Elections 2019 Ireland World Business Politics Nuacht Investigations Progra

Inquiry call after hospital patient notes found in Drogheda garden

Updated / Wednesday, 1 May 2019 **19:28**


The Telegraph

Home Video News World Sport Business Money Comment Culture Travel Life
Politics | Investigations | Obits | Education | Science | Earth | Weather | Health | Royal | Celebri

HOME » NEWS » UK NEWS

Alder Hey sold tissue from live children

By Nigel Bunyan
12:00AM GMT 27 Jan 2001

THE children's hospital **at the centre of a row over the stockpiling of babies' organs** sold body parts from living children to a pharmaceutical company for research, it emerged yesterday.

UK News
News »

EXTERNAL LINKS

Press releases -

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Health Research - engagement & transparency

- Health research has positive benefits for individuals, the health system and society in general
- Privacy and self-determination are very important legal and ethical rights and are particularly important where personal health information is involved
- Confidence and trust in health research can be achieved through transparency, consent and patient empowerment
  - Patient and Public involvement, HRCI, HRB
- Informed consent is important for researchers, participants and public trust
- Sometimes consent is not feasible

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GDPR and Health Research

- Scientific/historical research should be subject to Article 89(1); safeguards and accountability, derogations
- Appropriate safeguards must be in place for special categories of data; Article 9
- Research involving health, genetic or biometric data can be subject to further safeguards Article 9(4)

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EDPS

"Consent serves not only as a possible legal basis for the activity, it is also a safeguard - a means for giving individuals more control and choice and thereby for upholding society's trust in science.

There may be circumstances in which consent is not the most suitable legal basis for data processing, and other lawful grounds under both Articles 6 and 9 GDPR should be considered.

However, even where consent is not appropriate as a legal basis under GDPR, informed consent as a human research participant could still serve as an 'appropriate safeguard' of the rights of the data subject."

"*A Preliminary Opinion on data protection and scientific research*"
https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

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EU Commission

"Informed consent is the cornerstone of research ethics. It requires you to explain to research participants what your research is about, what their participation in your project will entail and any risks that may be involved. Only after you have conveyed this information to the participants – and they have fully understood it – can you seek and obtain their express permission to include them in your project (Articles 4(11) and 7 GDPR)."

Ethics and Data Protection, November 2018

https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf

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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

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

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

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,

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)
  - Data Protection 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;

Explicit consent

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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"

***

While explicit consent is not defined, it must be informed consent that is properly captured and recorded

Consent - Information Principles

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"Guidance on information principles for informed consent for the processing of personal data for health research"

- GDPR sets out several elements for consent to be valid
- The GDPR is clear that consent should not be bundled up as a condition of service
- The GDPR is also clear that individuals must be able to refuse and withdraw consent without being penalized

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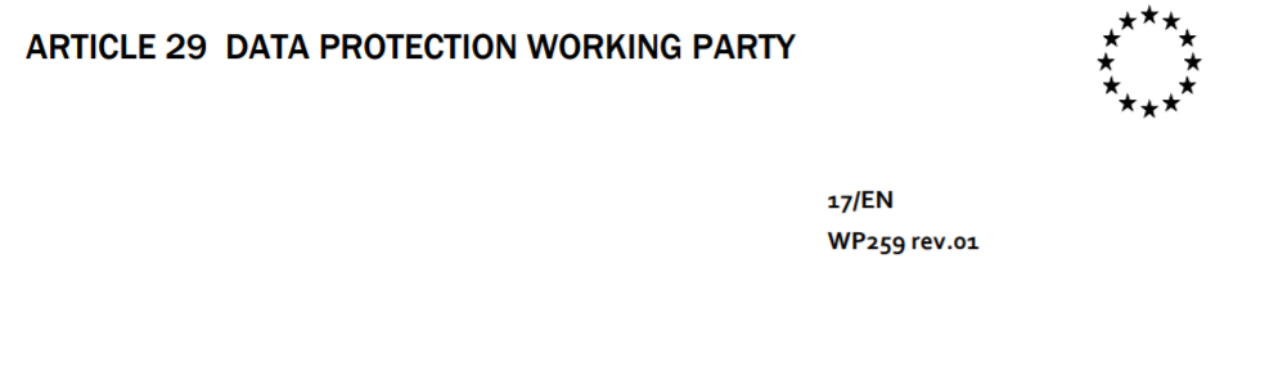
Useful guides

- Article 7: Conditions for informed consent
- Recital 33: specification and granularity of consent allowed in the context of scientific research
- Article 29 Working Group/European Data Protection Board (EDPB)



ARTICLE 29 DATA PROTECTION WORKING PARTY

17/EN
WP259 rev.01

Article 29 Working Party
Guidelines on consent under Regulation 2016/679

Adopted on 28 November 2017
As last Revised and Adopted on 10 April 2018

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Do I need a Consent Declaration?

Keep your questions simple - the answers might be complicated

- Am I/We the Data Controller(s)
- Am I ‘processing’ personal data
- Is it anonymised?
- Can/should I anonymise the data
- Do I have REC approval?
- Do I have *explicit* consent?
- Can I get explicit consent?

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

IF NOT →

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Q1. Has health research commenced after August 8th, 2018?*

Yes ↓ | No → Consult with your DPO

Q2. Am I the Data Controller? **

Yes ↓ | No → Consult with your Data Controller

Q3. Am I processing personal data for health research?

My Processing activity is: eg
Collecting, Retaining/Storing, Analysing, Deleting, Anonymising, Transferring/sharing

↓

Personal data is: eg
Bio-samples, Archival tissue, Clinical data, Demographic data, Health administrative data, other health categories

↓

Personal data is:
Pseudonymised personal data

Yes ↓

Or

I am Processing:

Irrevocably anonymised data,

↓

You do not need to apply for a consent declaration for processing anonymised data as it falls outside the scope of GDPR and the Health Research Regulations

Q4. Do you have '*explicit consent*' for the purpose of processing the data for health research?

No ↓

Yes → You do not need to apply for a consent declaration. All other elements of GDPR and Health Research Regulations 2018 must be observed

Q5. Is it the view of the Data Controller, that the public's interest in carrying out the Health Research significantly outweighs the public interest in seeking explicit consent?

Yes - **Apply** ↓

No → Unless you are processing anonymised data, steps should be taken to ensure compliance with GDPR and the Health Research Regulations

- Provide a letter of approval from relevant REC(s)
- Provide a Data Protection Impact Assessment (DPIA) with DPO feedback
- Outline why obtaining explicit consent, in line with GDPR was not demonstrably feasible.
- Outline the reasons why the public's interest in carrying out the health research significantly outweighs the requirement to seek consent

*Commencement of research is deemed to be the date REC approval has been granted. Regulation 4(1)

**It is essential to establish correct Data Controller and Data Processor designation. These terms have the meaning ascribed to them in GDPR

Please consult https://hrcdc.ie/ for additional guidance and clarifications.

For further queries, please contact: Secretariat@hrcdc.ie

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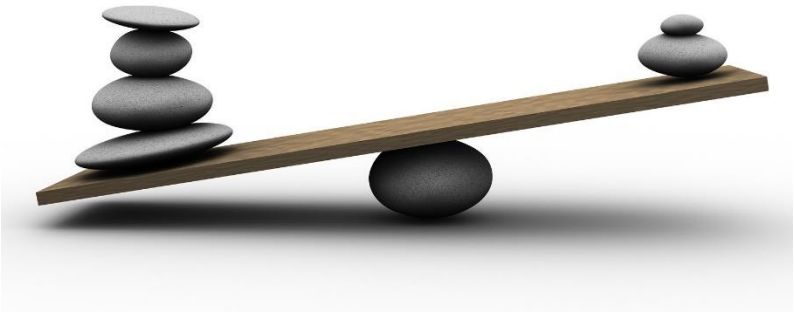
A Declaration…

- Is made solely to the Data Controller
- Covers the processing of data (collection, use, storage, retention, altering etc)
- 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……. Contact your Data Protection Officer
- 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 data protection rights and freedoms of non consented individuals are met with GDPR level of Safeguards.

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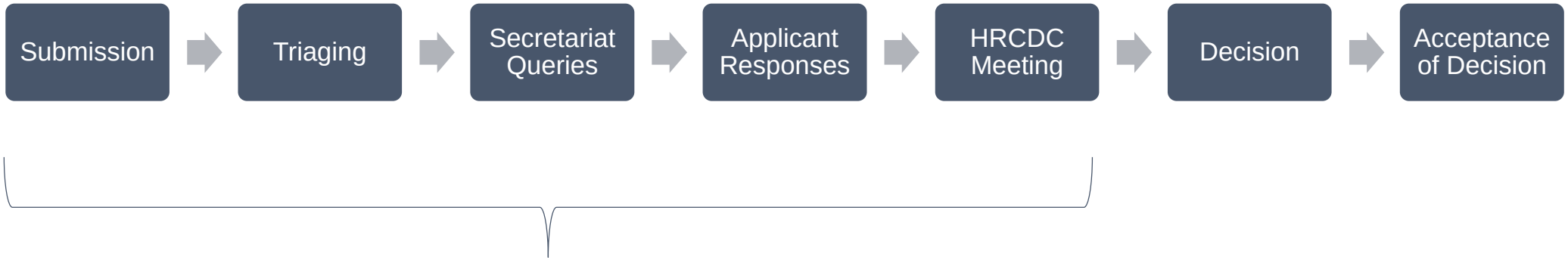
HRCDC application process



- Prioritisation of new research studies
- From submission to HRCDC consideration; ~Decision within 6 weeks

HRCDC Meetings and Decisions

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9 x HRCDC Meetings

March 2019 - December 2019

3 x Declarations

17 x Conditional Declarations

1 x Request for Information

1x Appeal Upheld

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Common ‘Pitfalls’ & Points to Consider

1. Who is the Data Controller ?

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- Data Controller Vs Joint Data Controllers Vs Data Processor
- A Declaration can only be made to a Data Controller
- Roles and responsibilities must be clear
  - Article 4 of GDPR
  - https://www.dataprotection.ie/en/organisations/know-your-obligations/controller-and-processor-relationships
- It is *not determined by opinion* but is a '*matter of fact*'
- Context is key

Case Study

Researcher from a **University** wants to process personal data for a study. The personal data they want to use is held by a **Hospital** (e.g. biobank/registry).

The **Hospital** is the **Data Controller** of the personal data they store.

In their HRCDC submission the Researcher describes the hospital and their own institution as Joint Controllers on the study.

However, by referring back to the GDPR definition and discussing with the DPOs this was deemed not to be the case.

The Hospital is only providing the Researcher with access to the personal data; however the **Hospital is not determining how the personal data will be used** research.

Based on definition above it has been determined by the parties that the Hospital is not a Joint Controller in the research study.

It is likely to be one Data Controller to Data Controller transfer.

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2. What is a Consent Declaration for?

- For processing personal data without explicit consent;

> accessing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction

- It should be clear what data processing activities are being carried out within the research study, for the which the Declaration is being sought.
- Consider a data flow diagram/illustration to map out the data journey

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Case Study

A Researcher wishes to **access and collect personal data** from a number of data sources including patient charts and other reports.

Once they have collected the personal data it is subsequently anonymised before any further processing takes place (i.e. the researcher can no longer identify the patient)

A **Declaration** is only sought for **accessing, collecting and anonymising the personal data** - once the personal data has been anonymised it does not fall under the remit of the Regulations

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3. Exit Strategy – Duration of a Declaration

A Declaration, is typically *time limited* i.e. given until the personal data has been destroyed, anonymised, returned or until consent has been obtained from the participant

Common pitfall is lack of clarity when a declaration is no longer required

12. Describe your exit strategy whereby the research study will no longer require a consent declaration. *eg Please consider at what stage during the research study personal data will be rendered irrevocably anonymised to the Data Controller(s), returned or destroyed, or when future consent maybe obtained etc. Where relevant, consider at what point the master list/key that codifies the personal data, will be destroyed. If you require a consent declaration over several years, or indefinitely, please set out the reasons why.*

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Case Study

A Researcher conducting a **new study** wishes to draw down **personal data from a Biobank**.

Participants have consented for **the use their personal data in future studies** - however the Researcher reviews the consent form and determines that the **New Study** is **not within the scope** of the original consent obtained by the Biobank.

The Researcher seeks a Declaration for all additional processing activities until the point at which they will **destroy or irrevocably anonymise** the personal data, **3 years after the study ends**.

The declaration will need to cover these 3 years as Storage/Archiving is a form of data processing.

4. Why is it not possible to seek Consent

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- Strong evidence based rationale is essential
- Context is important
- A number of factors maybe important;
  - » Number of participants,
  - » Vulnerability of study cohort
  - » Type of study
  - » Ethical aspect to reconsenting
  - » If there is follow-up care and engagement with participants
  - » Retrospective Vs Prospective participants etc.
  - » Compromising the integrity of the study
- Citing insufficient resources alone may not be convincing;
- Was consent discussed with a REC, subject matter experts, collaborators, patient representative, advocacy groups etc. ?
- Pilot Study to attempt to consent?

Case Study

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A Data Controller wishes to **access personal data and biosamples** that were collected from a **small number of patients** who were treated in a hospital several years ago (retrospective participants). The Data Controller also wants to access personal data and samples of future patients who meet the study criteria (prospective participants).

A Declaration is sought to process the personal data of both of these groups where consent has not been sought.

Based on the information provided by the HRCDC requested the Applicant to further elaborate on **why no attempt was made to seek the consent of the retrospective participants.**

In addition the HRCDC was of the view that **it would be possible to obtain explicit consent** from the prospective participants.

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4. Seeking a Declaration - lack of decision-making capacity of the participant;

4. i) Briefly outline how the decision-making capacity of a research participant(s) is determined.
☐ Not Applicable Brief Outline of Protocol:
ii) Where proxy assent is being used as a suitable safeguard, briefly outline what measures are in place to ensure that the identified proxy is the most appropriate individual who can communicate on behalf of the participant and understands the participant's will and preferences. *NOTE: proxy (next-of-kin relative, friend, as appropriate) assent for data processing on behalf of an individual that lacks decision making capacity has no lawful basis. However, proxy assent should be used as a suitable safeguard, in additional to seeking a consent declaration.* ***Please provide Study Information Leaflets and Assent Form and other relevant documentation***
☐ Not Applicable Brief statement:

5. Will consent from the participant(s) be sought at any stage during the research study? *eg If deferred consent is being obtained, please expand further. This answer will tie in with Part B, Section 11, exit strategy. Please also explain what will happen to the personal data if the research participant does not regain capacity and deferred consent is not obtained.* ***Please provide proposed Patient Information Leaflets and Assent Form and other relevant documentation***

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5. Transparency - Safeguard

Where it not possible to obtain explicit consent it is important to ensure data is processed in a transparent manner

. Specify the transparency arrangements that are/will be in place to ensure that personal data are processed in a transparent manner *(Ref Art 5(1)(a)/GDPR)* *eg public notices, publicity campaigns, information leaflets, websites etc.*

….the **participants** of the research study **should not be surprise**d as to has their data is being used.

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6. Legal agreements/arrangements

Regulation 5(4)(b)

5. Joint Data-Controller(s): Please outline what arrangements are in place between the Joint Data-Controllers to reflect the roles and responsibilities *(Ref Art 26/GDPR)*
Example arrangements maybe data transfer agreements, inter-institutional agreements, contractual arrangements etc

☐ Not Applicable
Details:

7. Controller-Processors: Please outline what legal agreements or legal acts are in place between the Controller and Processor *(Ref Art 28/GDPR)*

☐ Not Applicable

☐ Copy of Contract attached
Other Details:

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Other pitfalls

- The **DPIA** is not consistent with the content of the application form
- The **DPO(s)** hasn't provided feedback on the DPIA
- **REC** approval (or provisional) approval is required and must be in date
- **Patient & Public Involvement/Engagement is lacking or not considered**
  - 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
- **Technical measures** as 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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Conditions Attached

Contractual Arrangements

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The HRCDC has requested that all appropriate **contractual arrangements (legal agreements)** must be in place with the relevant institutions, regarding the transfer of personal data for the purpose of the research study. This is a safeguard that the HRCDC has requested and therefore confirmation that these agreements must be provided to the HRCDC. Until this confirmation is received the Declaration will not cover the processing activity of transferring data.

It is noted from the information provided to the HRCDC, that data sharing agreements are currently being established between the HSE and the five participating hospitals. As the HSE, St. James and Tallaght University Hospital have now been confirmed as Joint-Data Controllers, an appropriate **Joint Data Controller arrangement also should be in place between these parties**. It is advisable to discuss this with your Institution's legal office and Data Protection Office, as necessary

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REC Approval

Confirmation of Research Ethics approval from the Hospital site must be provide to the HRCDC, once granted. No data processing can commence at this site until such written confirmation is provided to the HRCDC.

….(THIS CONDITION HAS BEEN MET)

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Capacity – Confirmation of assent

The HRCDC has requested that, where a **patient continues to lack capacity for a prolonged period of time** and where the next-of-kin assent remains in place, the following action should be taken as an additional safeguard: The r**esearcher should seek confirmation from the next-of-kin (or individuals) who provided assent, that they wish for the study participant's personal data to continue to be processed as part of this research study.** Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned.

Transparency

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#1 The Appeal Panel has requested **a publicity campaign** to be carried out by the Appellant, drawing attention to the health research project and affording patients the opportunity to withdraw their brain tumour samples and personal data from the health research project.

#2 In line with the advice of the Data Controller's Data Protection Officer, the HRCDC has requested that data protection **transparency measures implemented within the Hospital setting to ensure patients and their relatives, or those accompanying patients, are aware of the study and the use of clinical data and biological samples, and role of both Data Controllers.** For example, transparency measures should ensure patients are made aware of how to exercise their data protection rights.

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Consent

The HRCDC has requested that the Applicant make best reasonable efforts to obtain **retrospective consent from individuals whose data and biological material has been collected to date**. This condition is a reporting obligation that must be fulfilled and reflected in the Annual Report.

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Exit Strategy - Confirmation

The HRCDC require written confirmation once the Master list (hard and soft copies) have been destroyed.

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Summary

- Address all the Qs in the relevant sections
- Consider the perspective of the non-consented participant
- Build a strong evidence based public 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.

Qs

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- How long does it take? **DEPENDS, ~6-8 WEEKS FOR NEW APPLICATIONS**
- What is involved in making an application? How much work, documentation? **DEPENDS ON COMPLEXITY OF THE STUDY**
- Could a consultant doctor PI do it on his own or would he need an assistant to help? **TYPICALLY, YES, THE IS CASE BY CASE**
- What services/guidance is available to assist with making an application? **CONSULT WITH DPO & WWW.HRCDC.IE**
- Is there an office that can assist? **CONSULT WITH DPO & WWW.HRCDC.IE**
- Company applications - public interest test. Given the commercial interests of a company is it in a position to make a case that a project is in the public interest? **YES, RESEARCH MUST BE IN THE PUBLIC INTEREST IN ORDER TO GET A DECLARATION**
- Have any companies made applications? **YES, SEE APPLICATION LOG (WWW.HRCDC.IE)**
- Is there a trend of companies asking universities to front the applications to satisfy the public interest? **NO. APPLICATION MUST BE COMPLETED AS A MATTER OF FACT.**

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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 data protection 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

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Thank you

Secretariat@hrcdc.ie

www.hrcdc.ie