HRCDC

Health Research Consent Declaration Committee

Dr Emily Vereker

Programme Manager, HRCDC Secretariat

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Transparency | Confidence | Trust

HRCDC
Health Research Consent Declaration Committee

Consent declaration

Statutory mechanism that enables researchers to process, or further personal data for health research,

- where explicit consent can not feasibly be obtained, and
- where there is substantial public interest in the health research, and
- where suitable and specific measures are taken to safeguard the rights and freedoms of the research participant, and
- where all requirements with the Regulations are met

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HRCDC

- Ministerial appointed
- **17 Members**, 3 of which are patient, public & carer representatives
- Considers applications
  - makes a **consent declaration**
  - **requests further information**
  - **do not** make a consent declaration
- **revoke** a consent declaration
- consider **amendment** request to a consent declaration
- **consensus based** decision-making

Secretariat

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- **supports** the HRCDC in all aspects of its work
- responsible for the **application process**
- act as the central point of contact and **help desk** for the health research community
- manages **database** for all applications received
- draft, finalises, publishes **minutes**
- draft, finalises and sends **decision letters** to Applicants
- **monito**r declarations made
- coordinate training and professional development activities for the HRCDC
- manages FOIs, media queries

……consult with Chair and HRCDC on these activities where necessary

Application process

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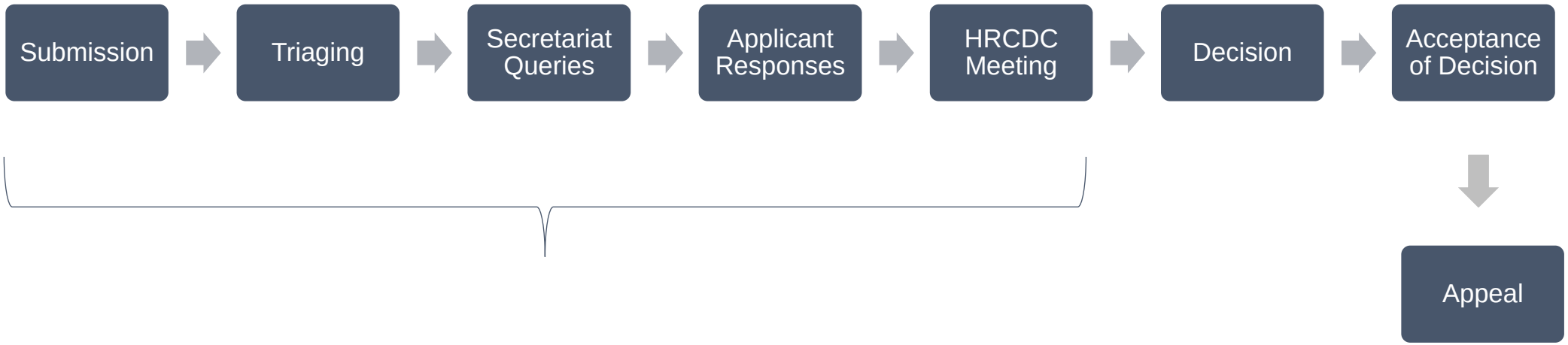

- Prioritisation of new research and COVID19 studies
- From submission to HRCDC consideration; ~ Decision within 5/6 weeks

2020 Snapshot

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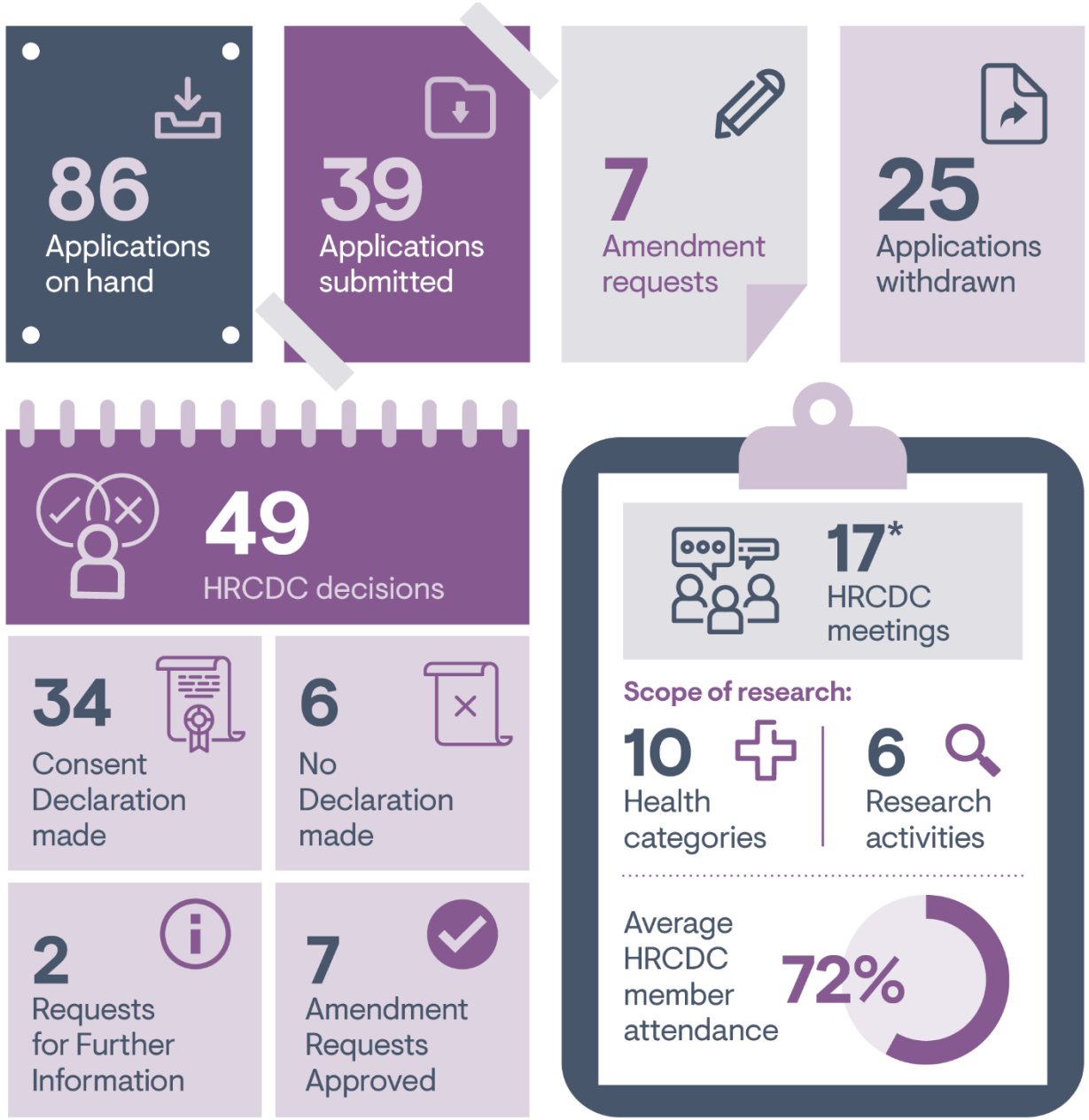

* One meeting had 6 members in attendance and was not quorate. No decisions were made at this meeting.

17
Annual Reviews Submitted

59
Live Consent Declarations

6 Meetings

11 Consent Declarations

7
FOI Requests

Scope of research

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Retrospective chart reviews

eg Irish National Adverse Events Study
eg Analysis of serious untoward incidents /mental health services /HSE South East

Retrospective observational studies

eg To estimate the Prevalence of Problem-Opiate Use in Ireland,
eg To evaluate the clinical effectiveness of treatment with zanamivir for Influenza

Clinical trials

eg Solidarity Trial: Treatments for COVID-19
eg REMAP-CAP: Evaluate multiple treatments simultaneously for community-acquired pneumonia

Scope of research

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Genomics & Genetics studies

eg The Genomic Basis of Alzheimers disease in Ireland
eg Irish Coronavirus Sequencing Consortium

Longitudinal studies

eg TILDA
eg IDS-TILDA

Biobanks (data only)

eg Colorectal cancer ‘COLOSSUS’ consortium
eg Rare Kidney Disease Biobank

Registries

eg Irish Prostate Cancer Outcomes Research (IPCOR) Registry,
eg Irish National AATD Registry (Apha-1 Foundation)
eg National Self Harm Registry Ireland

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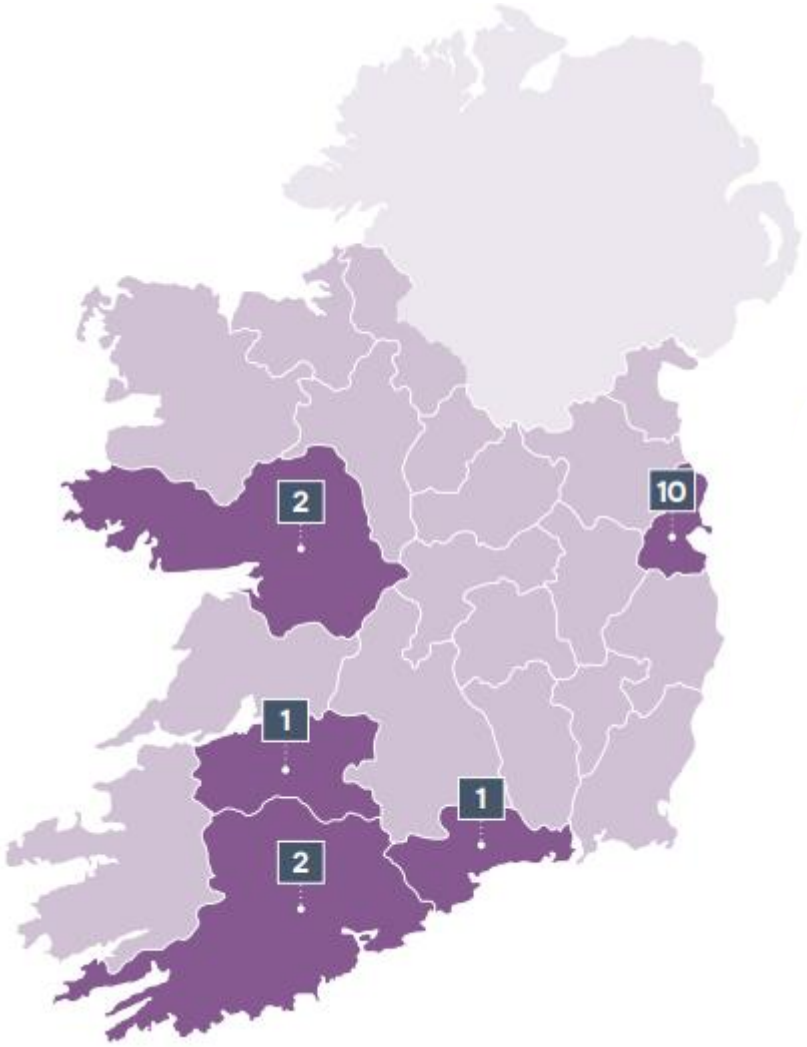
Data controllers



The implementation of a consent declaration, made to an international data controller who is seeking to obtain the personal data of Irish participants for health research purposes **is enforceable** in Ireland.

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Considerations
-
Consent Declarations

When to apply for a consent declaration

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- Strong evidence based, substantiated rationale is essential
- A number of factors maybe important as to why consent can not be sought;
  - » number of participants,
  - » Multi-site, international study
  - » vulnerability of participant groups
  - » type of study, nature and volume of data being processed
  - » ethical aspect to reconsenting
  - » retrospective Vs prospective participants taking part in the study
  - » compromising the integrity of the study, by decreasing the quality of the data
  - » infection control measures mitigate the ability to obtain consent at a point in time
  - » decision making capacity of the participants, short term, permanent

HRCDC Considerations

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- why (re)consent could not be obtained?
- was consent discussed with a REC?
- are there opportunities to seek consent eg follow-up care and engagement with participants,
- has there been patient and public involvement,
- the higher the data protection risks, the stronger the public interest and consent case should be made.
- will the study be sufficiently impactful to justify no consent, on balance with the safeguards in place to ensure the fundamental rights and freedoms of participants?
- is the study substantially in the **public interest**?
- **All points put forward by Applicant are considered on balance with each other**

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The public interest in the study,
must significantly outweigh
the public interest in requiring explicit consent
from the individual whose data is being processed

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Consent Declaration

- Is made solely to the Data Controller/Joint Controllers of a study
- Covers **the processing of personal data** (collection, use, storage, sharing, pseudonymisation, seeking access to pseudonymised data, retention, altering etc)
- Is not transferrable to other third parties
- Time limited, generally
- Has a **defined scope**
- May have conditions attached, and recommendations made
- Monitored through submission of the Annual Review
- All other safeguards, as per the Regulations, must be in place

Scope of a Declaration

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A conditional consent declaration is made only for the **processing of retrospectively collected personal data associated with clinical and community-tested bio-samples**, which are already obtained and tested (in the early stages of the pandemic).

The **data processing activities** include the collection, storage, pseudonymisation and subsequent transfer of data from the sites that hold the data, to the data controller of this study. When sequenced, the viral genome and the associated pseudonymised/de-identified data will also be uploaded to publicly accessible databases for analysis by researchers.

NOTE: For the avoidance of doubt, the conditional declaration **does not cover** the processing of personal data of **prospective participants** who **will be** tested for **COVID19** in a community setting, as part of standard detection testing for the virus, as proposed in the application.

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Conditions Attached
-
Safeguards

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Patient & Public Involvement

Public and patient involvement (PPI) is considered an important activity by the HRCDC and is viewed as a **key data protection safeguard** in situations where the participant lacks decision-making capacity to provide consent. PPI helps to create a more **patient-centred approach** by ensuring that the **perspective of patients and their families are taken into account** when designing and conducting the study and determining the most appropriate method of obtaining consent/assent. Furthermore, PPI also provides a valuable way of enhancing the level of transparency, which itself is an important data protection principle.

eg The Applicant must commence PPI activities within 3 months of the date of this declaration

Transparency

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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.

Study Information Leaflets & Assent/Consent Forms

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To ensure clarity, transparency and consistency of information for participants and/or those providing assent, the study information leaflet and assent/consent forms should be reviewed and revised as necessary:

eg Study information leaflets to be **quite technical** in parts and should be **readable from the perspective of the participant** and those providing assent.

eg relative/next-of-kin 'consent' for data processing should be replaced with '**assent**', when referring to a **proxy individual** providing assent on behalf of the research participant. '**Consent' should only be used when engaging directly with the research participant**. Assent is an important data protection safeguard but has no lawful basis for data processing.

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Full Research Ethics Approval

Confirmation of full REC approval, when obtained, must be provided to the HRCDC as soon as possible. The conditional declaration shall not be in effect until this condition is met.

The consent declaration only **covers data processing** at the research sites that have been granted **full REC approval**.

Data minimisation

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The HRCDC request that the Applicant **implement further data minimisation** measures where at all possible. Specifically, **consider if age, date of birth, full address and contact number, medical record number** are all required in addition to the Patient Study Number.

Contractual arrangements

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This declaration is **not effective until** confirmation has been received by the HRCDC that the required **data transfer agreements are in place** between [the data controller of the study] and the providers of the personal data.

The agreements in place should include appropriate terms and conditions setting out obligations of confidentiality for researchers with direct access to the data on-site, where relevant.

For the avoidance of doubt, **no transfer of personal data** and/or direct access to personal data can occur until the appropriate **agreements are concluded**.

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No Declaration

Influencing factors

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- **Poor rationale for no consent**
  - lack of resources
  - citing distress
  - citing biased results
- **Opportunities to seek consent** are evident
- Inadequate transparency measures on balance with data being processed
- Lack of clarity on data flow and transfer,
- High data protection risks coupled with volume of data being processed.
- **Sensitivity of data** eg genetic data, sexual health data
- Poorly designed research study to the extent that its impact would not be in the public interest, on balance with the protecting the rights of the individual
- No/poor patient, public and carer involvement

Communication to Applicant

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When weighing up the aforementioned points of discussion, in particular the rationale for why it was not possible to obtain consent, the **lack of data protection safeguards** such as of **transparency measures and PPI and the overall sensitive and extensive nature of the personal data being sought,** the HRCDC was of the opinion that **the public benefit and interest** in the research study **did not significantly outweigh the public interest** in the requirement to obtain explicit consent of the participant.

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Open engagement

- Secretariat engages directly with Applicants on behalf of HRCDC
- The refusal by the HRCDC to make a declaration, **does not preclude** an Applicant Data Controller **from submitting a new application** in the future for this study, where significant and material changes have been made to the application seeking a consent declaration.
- For new submissions, any issues raised in the previous application are expected to be addressed.
- Where best endeavourers have been made to seek consent from participants and where no response was provided, a consent declaration may be applied for in this scenario.

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The role of the HRCDC post Amendments?

The HRCDC still continues to consider applications for research studies seeking a consent declaration, where consent can not be obtained:

- the COVID-19 Data Research Hub
- where participants lack decision-making capacity due to intellectual disability,
- medium/high/risk retrospective chart reviews,
- research involving processing of personal data and analysis of associated biological samples
- any processing of data that does not fall under the amendments

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secretariat@hrcdc.ie

Please get in touch if you wish for the Secretariat to provide a seminar on the consent declaration application process and understand more about the HRCDC and its role.

https://hrcdc.ie/wp-content/uploads/2021/04/HRCDC-Activities-Report-2020_Single-FINAL-WebVersion.pdf

www.hrcdc.ie