

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 or de-identified personal data

Yes



Or

I am Processing:

Irrevocably anonymised data, or pseudonymised data that is
anonymised in the hands of the Data Controller carrying out the
health research. Specifically, there is no means or no intention
to process the data in a manner that could identify the data
subject



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

HRCDC

Health Research Consent
Declaration Committee

*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